2014

PROTOCOL
on
ANTIMICROBIAL STEWARDSHIP
PROGRAM
In Healthcare Facilities

FOREWORD

Antimicrobial resistance is an alarming global public health threat which refers to resistance of a microorganism to an antimicrobial drug that was originally effective for treatment of infections caused by it due to the injudicious and irresponsible use of these drugs. Without prompt and coordinated action, the world might be heading back towards the pre- antibiotics era in where there are no longer effective drugs for the common infections which can lead to death. Furthermore, the pipeline of antibiotic development is nearly dry and antibiotics research cites high cost with no promising returns.

As a healthcare provider, we play an important role in tackling this issue. Efforts in battling this issue include immunization, infection control, protecting the food supply, antibiotic stewardship, accurate treatment and education. As a response to these challenges, Antimicrobial Stewardship Program was developed to optimize antimicrobial use thus obtaining the best clinical outcomes, limiting selective pressures that drive the emergence of resistance and reducing excessive costs due to suboptimal antimicrobial use. Recognizing the importance of Antimicrobial Stewardship, the Ministry of Health has taken initiatives to produce the "Protocol on Antimicrobial Stewardship Program" in healthcare facilities. It serves as a practical guide for the health professionals in the proper usage of antimicrobials. This will hopefully benefit the clinicians and pharmacist in achieving a good antimicrobial prescribing practice thus improving the quality of patients care.

I would like to congratulate the Committee, Medical Care Quality Section of Medical Development Division, Pharmaceutical Service Division and Family Health Development Division for their commendable efforts in developing this protocol. I hope this protocol will be implemented effectively at the healthcare facilities thus halting the antimicrobial resistance issue.

Thank you.

DATUK DR NOOR HISHAM ABDULLAH
Director General of Health Malaysia

<div align="center">MESSAGE</div>

Bismillahirrahmanirrahim,

Alhamdulillah, thanks to Allah SWT, whom at His willingness allows the secretariat and the contributors the opportunity to complete and publish this **Protocol on Antimicrobial Stewardship Program in Healthcare Facilities**.

WHO's 2014 report on global surveillance of antimicrobial resistance reveals that antibiotic resistance is no longer a prediction for the future; it is happening right now, across the world, and is putting at risk the ability to treat common infections in the community and hospitals. Without urgent, coordinated action, the world is heading towards a post-antibiotic era, in which common infections and minor injuries, which have been treatable for decades, can once again kill. Thus, this protocol was prepared to improve the quality of antibiotic utilisation and thereby improve patient clinical outcomes.

I believe that pharmacists have the responsibility to play prominent roles in antimicrobial stewardship program and participate in infection prevention and control programs of health systems. This responsibility arises, in part, from pharmacists' understanding of and influence over antimicrobial use within health systems. Furthermore, I believe the pharmacists' ability to effectively participate in antimicrobial stewardship and infection prevention and control efforts can be realized through clinical endeavours focused on proper antimicrobial utilisation and membership on multidisciplinary work groups and committees within the health system. These efforts should contribute to the appropriate use of antimicrobials, ultimately resulting in successful therapeutic outcomes for patients with infectious diseases and reduce the risk of infections for other patients and health care professionals. In other words, it is an essential part of patient safety and deserves careful oversight and guidance. With this protocol, I hope it can give guidance to all healthcare professionals especially the pharmacists in implementing antimicrobial stewardship program in health systems.

Once again, I would like to thank the secretariat and contributors for their hard work in developing this protocol and making it a reality.

DATO' EISAH A. RAHMAN
Senior Director Pharmaceutical Services

MESSAGE

This is the first protocol on Antimicrobial Stewardship developed by the committee members from the National Infection and Antibiotic Control Committee together with Medical Care Quality Section, Pharmaceutical Division and the Family Health Development Division.

Much of the medical treatment advancement has been made possible through access to safe and effective antibiotics and although it remains as the treatment of most infections, these antibiotics are often used inappropriately for dubious indications leading it to the emergence of antimicrobial resistance. Efforts at curbing antimicrobial resistance at our health care facilities remain ongoing and this call for an urgent need of antimicrobial stewardship which is an effective approach to improve antimicrobial use in our health care facilities thus preserving it for our future generation.

This protocol is developed as a guideline to all health care professionals in delivering an appropriate antimicrobial management involving a systematic approach on details of the structure, function and activities on the implementation of antimicrobial stewardship program. This program aims to curb antimicrobial resistance by reducing inappropriate antimicrobial use thus minimizing patient's harm and healthcare cost.

Finally, I would like to thank all contributors from the multidisciplinary group of health professional together with Medical Care Quality Section, Pharmaceutical Service Division and Family Health Development Division for their valuable time and experiences in developing this protocol. I would also like to thank all individuals who have contributed directly or indirectly towards the completion of this protocol. I hope implementers from various levels will use this protocol as a guide in prescribing and dispensing antimicrobials effectively.

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1. Formulation of AMS team in each hospital. (Core Strategy)
2. Surveillance and feedback mechanism on specific antibiotic consumption. (Core Strategy)
3. Implementation of prospective audit and feedback according to local needs. (Core Strategy)
4. Formalize regular rounds by AMS team especially in State and Specialist Hospital. (Core Strategy)
5. Establishment of formulary restriction and pre-authorization/approval system. (Core Strategy)
6. Establishment of antimicrobial order tools for restricted antimicrobials.
7. Streamlining the antimicrobial usage
8. Antimicrobial selection and dose optimization of antimicrobials.
9. Initiation of intravenous (IV) to oral (PO) switch program
10. Educational on AMS program via continuous medical education (CME) and antibiotic awareness campaign

SECTION A : ANTIMICROBIAL STEWARDSHIP PROGRAM IN HOSPITALS

1. Governance
2. General Role Of Antimicrobial Stewardship Team
3. Antimicrobial Stewardship Team Members
    i.   Head of AMS team
    ii. Infectious Disease (ID) Physician or Physician
    iii. Antimicrobial Pharmacist or Clinical Pharmacist
    iv. Clinical Microbiologist or Microbiologist
    v.   Information Technology Officer (optional)
    vi. Infectious Control Nurse Practitioner (optional)

1. Encourage formulation of local guidelines & clinical pathways
2. Surveillance and feedback
3. Prospective audit and feedback
4. Formulary restriction and pre-authorization
5. Antimicrobial order tools
6. Antimicrobial Streamlining

INTRODUCTION

The introduction of antimicrobial agents has contributed to the reduction of infectious diseases as the major cause of premature death. Treatment with antimicrobial agents seems so effective and safe that they are sometimes prescribed for dubious indications and for longer than necessary, with little concern for adverse effects and the development of resistance.

In the last 40 years, the prevalence of multidrug-resistant microorganisms (eg. extended spectrum Beta-lactamase inhibitor *enterobacteriaceae*) have risen alarmingly. Antimicrobial resistance (AMR) occurs when microorganisms change in ways that render the medications used to cure the infections they cause ineffective. There is evidence that overall rates of antimicrobial resistance correlate with the use of antimicrobials. Certain antimicrobials like quinolones promote the emergence of resistance more than others. Quinolone usage has been linked to an increase in *Methicillin-ResistantStaphylococcus aureus* and with increased quinolones resistance in gram negative *bacilli*.

The emergence of AMR can cause the resistance to first-line medicines and leads to the use of second or third-line drugs which is less effective, more toxic and more costly. The pace of antimicrobial development has slowed markedly in the past 20 years. As more resistance is acquired, we are eventually left without any effective drug therapies. Thus AMR cangive a negative impact on patient outcomes, poses a major threat for patient safety, increases health expenditure and results in loss of treatment options for common infections.

Antimicrobial management or stewardship program have been developed as a response to these issues. Antimicrobial Stewardship (AMS) is thus a coordinated systematic approach to improve the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial drug regimen; right choice of antimicrobial, right route of administration, right dose, right time, right duration and minimize harm to the patient and future patients.

The development of antimicrobial resistance strains in hospitals is intensified because of high level of antimicrobial use and concentration of patients with multiple pathogens. Ongoing monitoring and prospective audits have been shown to improve patient care, decrease unnecessary antimicrobial use and microbial resistance and reduce pharmacy expenditures. Antimicrobial Stewardship (AMS) have demonstrated 22% - 36% decrease in antimicrobial use.

OBJECTIVES

1. To improve patient outcomes (e.g. reduce morbidity and mortality from infection)
2. To optimize antimicrobial therapy, by promoting judicious use of antimicrobials, optimizing antimicrobial selection, dosing, route and duration of therapy in order to maximize clinical cure or prevent infections.
3. Tolimitthe unintended consequences such as the emergence of antimicrobial resistance and adverse drug events.
4. To reduce healthcare cost without adversely impacting quality of care.

ANTIMICROBIAL STEWARDSHIP POLICY

Every healthcare facility shall develop and document its local antimicrobial policy. The policy should be endorsed by the Drugs and Therapeutics Committee (JKUT) and ultimately the hospital director / District Health Officer/Medical Officer in Charge and publicized to the whole health care facility. The policy shall include as below:

- Indications for antimicrobials are to be explicitly spelt out at the time of prescribing to assist with audit efforts.
- Appropriate Microbiology investigations (culture or serology) prior to antimicrobial commencement.
- Clinicians to prescribe antimicrobials guided by the National Antibiotic Guidelines or local antibiotic guideline where applicable.
- A list of restricted antimicrobials and the procedures for obtaining approval.
- To limit the use of broad spectrum antibiotics unless necessary.
- Toreview patient's antimicrobial therapy on a regular basis based on microbiology result and the patients progress.

1. **Formulation of AMS team in each hospital, Health District Office and Health Clinics (Core Strategy)***

   The core members of AMS team should be multidisciplinary and appointed by Hospital Director/ District Health Officer/Medical Officer In-Charge.

2. **Surveillance and feedback mechanism on specific antimicrobial consumption.(Core Strategy)***

   Surveillance and feedback on antibiotic utilization should be conducted regularly or at least twice a year (every 6 monthly). Report of this surveillance and feedback must be submitted to state and national level. Necessary action should be taken based on surveillance finding and local resistance pattern.

3. **Implementation of prospective audit and feedback according to local needs. (Core Strategy)***

   Prospective Audit and Feedback such as antibiotic point prevalence survey should be conducted in response to incidences:e.g.
   - when the quarterly usage of a specific antibiotic increases by more than 50% from the previous baseline
   - of a particular antibiotic if the facility is an outlier for usage of a particular antibiotic in the state, region or nation

4. **Formalize regular antimicrobial rounds by AMS team especially in State and Specialist Hospital (Core Strategy)**

   Identify and suggest streamlining of antimicrobial (e.g.choice of antimicrobial; de-escalation; dose optimization; IV to oral switch) during the rounds. Impact on antibiotic utilization data and acceptance rate should be documented.

5. **Establishment of formulary restriction and pre-authorization/approval system (Core Strategy)***

All prescribers should comply with both local and national formulary restriction.

6. **Establishment of antimicrobial order tools for restricted antimicrobials**

Antimicrobial order tools should be completely filled by prescribers before sending it to pharmacy department especially for intravenous (IV) antimicrobial with broad spectrum activity.

7. **Streamlining the antibiotic usage**

- Appropriate selection of antimicrobial when there is a need to prescribe two or more intravenous antimicrobial simultaneously to prevent overlapping in the spectrum of antimicrobial coverage.
- Antimicrobial prescribing must be reviewed no later than the 72 hours after it has been initiated and de-escalated to narrow spectrum agents promptly when appropriate or based on microbiology results.
- Relevant data such as stop or review date, indication etc should be documented in the medical notes or on the drug chart.

8. **Antimicrobial selection and dose optimization of the antimicrobial***

Antimicrobial selection and dose optimization should be based on clinical indication of individual patient and current clinical guidelines.

9. **Initiation of intravenous (IV) to oral (PO) switch program.**

Intravenous antimicrobial therapy must be reviewed and switched to oral alternatives when clinically appropriate and available.

10. **Education on AMS program via continuous medical education (CME) and antibiotic awareness campaign.***

Provide regular updates on antimicrobial prescribing, practice and usage for healthcare professionals.

Note: **(*)** also applicable to primary care

SECTION A:

ANTIMICROBIAL STEWARDSHIP PROGRAM IN HOSPITALS

ANTIMICROBIAL STEWARDSHIP PROGRAM IN HOSPITAL

PREAMBLE

The judicious use of antibiotics is an important strategy to preserving efficacy of antimicrobial agentsin the treatment of infectious diseases. Thus this protocol was developed to provide practical recommendations to healthcare professionals in the hospitals in implementing antimicrobial stewardship program to improve the quality of antibiotic usage and prescribing as well as improve patient clinical outcomes. The recommendations in this protocol are based on reviews of several published guidelines such as IDSA Guidelines, CDC – Core Elements Antimicrobial Stewardship in Hospitals, WHO Practical Guide to Antimicrobial Stewardship in Hospital and other guidelines from other countries whenever possible.

A.1 ANTIMICROBIAL STEWARDSHIP TEAM

1. Governance

The Antimicrobial Stewardship Program in hospitals is under the purview of the Hospital Infection Control and Antibiotic Committee and is supported by the:
   a. Hospital Director
   b. Head of various clinical departments
   c. Head of Pharmacy Department
   d. Head of Medical Microbiology

Implementing and maintaining an effective AMS requires a dedicated multidisciplinary team and involves ongoing communication and collaboration among multiple disciplines and departments. The AMS team should be appointed by the Hospital Director.

> The role of the Hospital Director is critical in ensuring the success of the Antimicrobial Stewardship Program initiatives by:
> - ensuring AMS becomes strategic goal of the organisation
> - communicating on why change is needed to staff and other leaders of Departments
> - allocating adequate resources in terms of manpower and time for dedicated AMS team activities
> - reviewing progress by the team, identifying barriers and providing advice
> - assigning high-performing staff to the team and resourcing them adequately
> - endorsing theAMS team and the activities.

2. General Role of Antimicrobial Stewardship Team:

1. Strengthens formulary restriction and approval systems.
2. Regularly reviews antimicrobial prescribing with intervention and direct feedback to the prescribers.
3. Educates prescribers, pharmacists and nurses about good antimicrobial prescribing practice and antimicrobial resistance.

4. Evaluates compliance to clinical guidelines and reports on process measures, outcomes measures (e.g. clinical and financial) and antimicrobial resistance patterns to Hospital Infection and Antibiotic Control Committee (HIACC) and Hospital Director.

3. Antimicrobial Stewardship Team Members

3.1 AMS team member in Hospital includes:

- Head of AMS team
- Infectious Disease(ID) Physician Or Physician (if available)
- Antimicrobial Pharmacist or Clinical Pharmacists
- Clinical microbiologist or microbiologist
- Other members may consist of:
  - Information Technology Officer
  - Infection Control Nurse
  - Hospital Epidemiologist
  - Ward Pharmacists
  - Interested Clinicians

3.2 Role and Responsibilities

i. Head of AMS team

- Is either an Infectious Disease Physician/Pediatrician, senior physician or clinician deemed to be suitable by the Hospital Director.
- Represents the AMS team in the hospital infection control committee and gives feedback on AMS program.
- Co-opted into the Drugs and Therapeutics Committee (JKUT) when considering changes of antimicrobials in the hospital formulary
- Prepares surveillance and audit reports for submission to state and national level
- Proposes annual AMS activities with the hospital Director and various departments

ii. Infectious Disease Physician Or Pediatrician (if available)

- Leads the technical component of Antimicrobial Stewardship team.
- Consults and advises on specific stewardship related cases and issues

iii. Antimicrobial Pharmacist or Clinical Pharmacists

- Is preferably a dedicated full-time Pharmacist trained in AMS
- Clinical role in conjunction with other members of the AMS Team
  - Gives technical know how on finer aspects of antimicrobials and newer agents.
  - Works with and educates ward pharmacists to identify potential patients for stewardship interventions (e.g. de-escalation etc)

- Ensures dose optimization is carried out especially for complex antimicrobials and complex clinical scenarios.
- Enforces the approval system of restricted antimicrobials
- Ensures safe and effective use of medication to reduce risk for errors and adverse events
- Surveillance of antimicrobial use
    - Collection and analysis of local consumption and expenditure
    - Provision of data to regional /national surveillance programs
    - Carries out and analyses point prevalence studies on antimicrobial usage
- Audit and feedback
    - Leads and conducts appropriate antimicrobial audits
    - Provides timely feedback for future improvement

iv. Clinical microbiologist

- Provision of guidance on appropriate diagnostic tests in microbiology.
- Provision of timely and accurate reporting of culture and antimicrobial susceptibility data.
- Ensures selective reporting of antimicrobial susceptibilities and interpretative reporting of microbiology results.
- Provision of antimicrobial resistance patterns data in individual hospital on yearly basis.
- Ensure the appropriateness of microbiology request, sample collection (types, time, date taken and documentation) and sample quality.
- Work closely with the attending clinician, infectious diseases specialist and antimicrobial pharmacist in the management of patients with infections

v. Information Technology Officer

- Hospitals with existing IT systems may consider including an IT personnel into the AMS team to assist with :
    - Creating localized electronic decision making systems that can be available through the hospital network system.
    - Providing AMS team access to microbiological data and antibiotic utilisation data.
    - Producing automated antimicrobial utilisation data and other programmed clinical data.

vi. Infection Control Nurse

- AMS teams frequently chance upon opportunities to tighten infection control practices during their course of the work. Having an Infection Control Nurse Practitioner within the team complements the efforts of the AMS team in bringing down resistance rates.

A.2 ANTIMICROBIAL STEWARDSHIP ACTIVITIES

1.   Encourage Formulation of Local Guidelines & Clinical

Local antibiotics guidelines & clinical pathways should be formulated based on the national antibiotic guideline, evidence in the literature and local microbiology and resistance patterns. Clinical pathways such as common infections can be produced to bring about uniformity in prescribersapproaches in local setting.

Examples of common clinical pathways:Refer to APPENDIX 1

Treatment of:
- Urinary Tract Infections
- Lower Respiratory Tract Infections
- Soft Tissue Infections
- Sepsis

Prophylaxis Use For:
- Prevention of bacterial endocarditis
- Endoscopic procedures
- Surgical procedures
- Splenectomised patients

2.   Surveillance and Feedback

Surveillance of antimicrobial use can show us how and why antimicrobial are being used and misused by patients and healthcare providers. Monitoring antimicrobial prescription and consumption behavior provides insights and tools needed to inform therapy decisions, to assess the public health consequences of antimicrobial misuse, and to evaluate the impact resistance containment interventions. Access to information on antimicrobial consumption can be an important source for healthcare professionals and policy makers to monitor progress towards a more prudent use of antimicrobials.

- Collection and analysis of local antimicrobial consumption and expenditure
  - Data collection and analysis of antimicrobial use and expenditure should be undertaken regularly (at least every 6 months).
  - The results of antimicrobial use and expenditure should be fed back to prescribing clinician and discuss the results in relevant meeting.

- Indicators for reporting antibiotic consumption:
  - Daily Defined Dose (DDD) per 100 patient admission and DDD per 1000 Patient Days are used to determine the antibiotic consumption.

- Provision of data to regional /national surveillance programs

- The data should be reported and presented at local and state level. It also has to be submitted to Pharmaceutical Services Division for National Surveillance on Antibiotic Utilisation.

3. Prospective Audit and Feedback

A prospective audit and feedback system involves a multidisciplinary team who regularly reviews patients. However occasionally there may be further directive from national or state level if local usage is not in keeping with national or state usage trend.

How to Perform an Audit - Refer to APPENDIX 2

Process of prospective audit

Audit is achieved by conducting a systematic review of care set against pre-determined criteria; suitable changes implemented and the effect of those changes re-evaluated. It comprises:

- Prior to initiation of audit, selected antibiotics will be chosen either based on any increment of usage from the previous years or data on susceptibility of organisms against selected antimicrobials.
- A predetermined criterion has to be set and agreed which includes approved indications and utilisation patterns.
- Any deviations based on agreed predetermined criteria has to be communicated and discussed with the doctors and other health care team members who are involved with the patients.
- Any reasons for deviations from the predetermined criteria have to be documented.

Elements of audit

1. Guideline / Protocol

   For any selected antimicrobial to be audited, an established antimicrobial guideline or protocol either from local hospitals or national guidelines should be available and practiced by prescribers.

2. Predetermined audit criteria

   Any predetermined audit criteria will be discussed its suitability and practicality prior to implementation. It consists of:

   i. Approved indications based on available guidelines/protocol. The antimicrobial audit may be conducted for:

      a. Surgical prophylaxis
      b. Empirical therapy where patient's clinical conditions, supported by laboratory findings are executed
      c. Definitive therapy, whereby antimicrobial is prescribed following the availability of microbiological results

   ii. Utilisation patterns derived from process indicators which measures one or all the following:

a) Time and date of administration of antimicrobials
b) Appropriate dose or frequency based on existing renal function
c) Available cultures and their antimicrobial susceptibilities
d) Duration of antimicrobial treatment

iii. Outcome of the therapy

Audit on antimicrobial should be extended until it is stopped or switched. The reasons for changes in therapy shall be documented.

All data must be documented and reviewed periodically. Any deviations from agreed criteria has to be communicated, discussed and documented.

Feedback

In order to ensure the success of the program, two-way system or communications has to be established within the institution. Feedback may occur through direct interaction with the prescribing clinician or through notes or stickers left in the chart or electronic medical records.

Mode of feedback:

a) Email/letter to heads of units/individual prescribers
b) Newsletter or bulletins
c) Presentation at ward or unit meetings
d) Presentation at Drug Committee And Therapeutic Meeting or HIACC

4. Formulary Restriction and Pre-authorization

Formulary restriction is one of the pillars of AMS Program. A list of restricted antimicrobials would need to be included in the antimicrobial policy which will be reviewed on regular basis.

Restriction can be implemented through a number of ways:
- pre-approval (can only be started after getting a specific approval)
- temporary approval (can be started but would need approval for continued usage and this can be done via antimicrobial order tools**)

Methods to acquire approval:
- antimicrobial order tools
- telephone

Example of Formulary Restriction – Refer to APPENDIX 3

5. Antimicrobial Order Tools

The order tools are designed to encourage the clinician to review basic clinical and laboratory information and to categorize antimicrobial use as prophylactic, empirical and therapeutic. An antimicrobial order tools may improve the quality of prescriptions by increasing the awareness of clinicians of desired antimicrobial spectrum. By filling in the antimicrobial order tools, the prescribers also provide themselves the data for drug utilisation surveillance. Antimicrobial order tools can be an

effective measure to decrease antimicrobial consumption by implementing automatic stop orders and/or requiring clinicians to justify antimicrobial use.

Example of Antibiotic Order Form - Refer to APPENDIX 4

6.   Antimicrobial Streamlining

Spectrum of Antimicrobial Coverage

Occasionally patients are started on two or more intravenous antimicrobials simultaneously. There can be overlapping in the spectrum of antimicrobial coverage leading to unnecessary cost and adverse events.

De-Escalation

The use of empirical broad-spectrum antimicrobial treatment may increase the risk of antimicrobial resistance.

The de-escalation strategy has the potential to improve patient outcomes without compromising patient safety. Studies show that de-escalation was associated with reduced mortality, shorter length of stay and lower costs in intensive care unit patients with pneumonia.

Streamlining can be typically conducted in several ways:

a) Antimicrobials streamlined to narrow-spectrum agents once cultures and sensitivities are available.
b) If the dosage was initially high, it can be de-escalated to a standard dosage for a susceptible organism.
c) Discontinuing empiric therapy if testing subsequently fails to demonstrate evidence of infection.
d) Discontinuing dual antimicrobial therapy if there is overlapping in the spectrum of activity
e) Advising on the optimal choice of antimicrobials for the specific clinical setting

How to carry out de-escalation:

1. Target broad spectrum antimicrobials that are used empirically
2. Review at :
    i.   72 hours after antimicrobial initiation or;
    ii.   Once a week review of a specific ward, unit, hospital
3. Identify de-escalation opportunities
    i.   Were appropriate cultures taken initially?
    ii.   Has there been any growth from the cultures?
    iii. If there is no growth, can the antimicrobial be stopped?
    iv.   If there is growth, can the antimicrobial be de-escalated

Example of 72 hour Antimicrobial stop/review Order - Refer to APPENDIX 5

7. Antimicrobial Selection and Dose Optimization

Antimicrobial selection and dose optimization will tailor therapy to the patient's characteristics, causative organism, site of infection, and pharmacokinetic and pharmacodynamic characteristics of the antimicrobial agent.

Strategies that may be considered for dose optimization include:
- extended or continuous infusion of beta-lactams
- once-daily dosing of aminoglycosides
- appropriate dosing of antimicrobials (e.g.; vancomycin, polymyxins, cefepime)
- weight-based dosing of certain antimicrobials
- dose adjustments for patients with renal dysfunction

8. Intravenous (IV) to Oral (PO) Antibiotics Conversion

This describes the practice of converting intravenous antimicrobials therapy to an effective alternative oral formulation. Several clinical trials have been conducted that demonstrate the efficacy and safety of IV to PO antimicrobials conversion, and several studies have also addressed the economic impact of this conversion.

Cost savings are achieved through lowering direct acquisition costs, eliminating the need for ancillary supplies, reducing pharmacy and nursing time, and shortening the length of hospital stay. IV to oral antimicrobials conversion also benefits the patient by eliminating adverse events associated with IV therapy, increasing patient comfort and mobility and increasing the possibility of earlier discharge.

Conversion to oral therapy also reduces the risk of adverse effects associated with intravascular lines like catheter-related blood stream infection (CRBSI) and thrombophlebitis.

Example of Antimicrobials That Can Be Included in IV to PO Therapy Conversion and Bioavailability of Selected Antimicrobials Available in Both IV and PO Formulations- Refer to APPENDIX 6

Criteria used to determine Patients for IV to PO Therapy Conversion:Refer to APPENDIX 7

(A) Intact and functioning gastrointestinal (GI) tract

Criteria Indicating Absorption of Oral Medications May Be Compromised

- Nil by mouth (NBM) status (and no medications are being administered orally)
- Nasogastric (NG) tube with continuous suction
- Severe/persistent nausea or vomiting
- Gastrointestinal transit time too short for absorption such as malabsorption syndromes, partial or total removal of the stomach, short bowel syndrome
- Active upper gastrointestinal bleeding
- High doses of vasopressor medications (typically in persistent hypotension despite high dose of vasopressor)
- Difficulty swallowing or loss of consciousness and no NG access available
- Documented ileus or gastrointestinal obstruction
- Continuous tube feedings that cannot be interrupted and patient requires a medication known to bind to enteral nutrition formulas

(B) Improving clinical status

The patient should be clinically stable and deterioration should not be expected.

- Should be afebrile or have had a maximum temperature of less than 38°C in the previous 24 hours.
- White blood cell (WBC) count should be trending downward. It is important to examine the patient's medication therapy for other medications that can cause an increase or sustained high WBC count such as steroids.
- Patients who are neutropenicare typically excluded from IV to PO therapy conversion.
- It is also important to review the cultured pathogen (bacteria, fungus, etc.) and ensure that it is susceptible to the oral medication.

Does not meet any of the following exclusion criteria
- endocarditis
- central nervous system infections (e.g.; meningitis, brain abscess, etc.)
- orbital cellulitis
- osteomyelitis
- endophthalmitis
- melioidosis (at least 10 to 14 days of IV therapy)
- abscesses

9. Education

Antimicrobial Stewardship team would prepare a program of ongoing education for pharmacists, doctors and nurses to influence prescribing behavior and to provide knowledge that will enhance and increase the acceptance of Antimicrobial Stewardship strategies. This program should ideally be included in the induction training for all newly reporting medical, nursing and pharmacy staff.

Educational Key Points- Refer to APPENDIX 8

Recommended Educational Programs

1. Continuous Nurse Education (CNE) / Continuous Medical Education.

2. Antimicrobial newsletter/including a sub-topic on antimicrobials in any hospital publications

3. Prescribing aids
   - Educational aids to guide prescribers at the point of prescribing. These may include clinical algorithms for the diagnosis of infection, or methods to standardize documentation of treatment decisions, such as infection stamps or stickers to be included in the clinical notes.
   - Where possible, information technology support for prudent antimicrobial use should be introduced.
   - This includes electronic patient records, computerized prescribing and clinical decision support software.

A.3 ANTIMICROBIAL STEWARDSHIP PROGRAM MEASUREMENT

Successful antimicrobial stewardship program include all the elements of successful quality improvement programs and measuring the effectiveness of program activities is a key component. Monitoring and analysis of antimicrobial usage is critical to measure the effects of stewardship interventions. Process and outcome measures should be incorporated into the AMS plan.

A.   Process Measures

- Rate of clinician acceptance of AMS recommendations.

- Rate of adherence to documentation policy at time of antimicrobial initiation (dose, duration and indication explicitly written)

- Rate of review of Carbapenem and Polymyx inprescriptions by primary team at 72 hours

- Rate of appropriate empirical prescription according to antimicrobial guideline

B.   Outcome Indicators

- Specific antibiotic DDDs over every 6 months

- Cost differences

  - For intervention results in the antimicrobial being stopped or switched to a cheaper alternative or to oral dosage form.
  - Formula of cost saving and days calculation - Refer to APPENDIX 9

C.   Other Suggested Indicators (Where applicable)

- Readmission within 30 days

  - Percentage of patient with AMS recommendation accepted being readmitted within 30 days.

- Mortality within 30 days

  - Rates of mortality within 30 days in patient with AMS intervention.

SECTION B:

ANTIMICROBIAL STEWARDSHIP PROGRAM IN PRIMARY CARE

ANTIMICROBIAL STEWARDSHIP PROGRAM IN PRIMARY CARE

PREAMBLE

Inappropriate use of antimicrobial, primarily involving therapeutic agent use to treat infection in humans, is considered one of the world's most pressing public health problems. In addition of diminishing the therapeutic benefit of essential medications, inappropriate use of antimicrobial also facilitate the development and spread of multidrug resistant organism.

Data from 2011 have shown an increase of 84.8% in primary care MOH antibiotic expenditure and it accounts for 10% of the total drug primary care MOH expenditure. Judicious use of antibiotic not only can prevent antimicrobial resistance but can also reduce health economic burden.

The initiative to introduce ASP in primary care setting was decided by The National Infection Control and Antibiotic Committee as a strategy in combatting antimicrobial resistance. Successful implementation of this protocol requires continuous commitment from all level of management in MOH primary healthcare settings, hence it should be incorporated in existing meetings such as Drug Committee Meeting, Infection Control Committee Meeting and Management Meeting at all levels.

B.1 ANTIMICROBIAL STEWARDSHIP TEAM

1. **Governance**

The Antimicrobial Stewardship Program (ASP) in Primary Care should be formulated at both District and Health Clinic level and is under the purview of the District Infection Control and Antibiotic Committee.

Implementing and maintaining an effective ASP requires a dedicated multidisciplinary team and involves ongoing communication and collaboration among team members. The ASP team at the District level should be appointed by the District Health Officer.

Advanced type of Health Clinic should have an ASP team at the clinic level. Members of ASP team at clinic level must be appointed by Family Medicine Specialist/Medical Officer In-Charge.
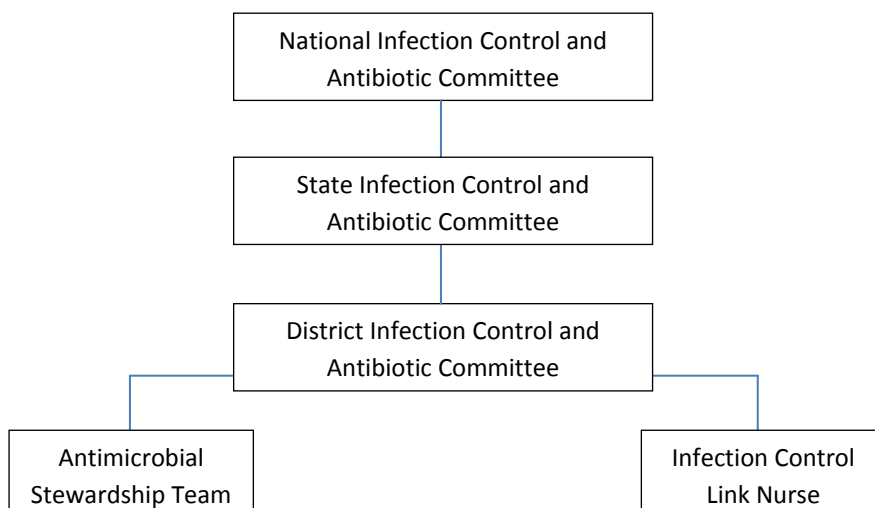
The role of the District Health Officer in ensuring the success of the Antimicrobial Stewardship Program initiative is critical. Among his/her roles, the District Health Officer can assist in

- ensuring ASP becomes strategic goal of the organisation
- communicating on why change is needed to staff and head of units
- allocating adequate resources in terms of manpower and time for dedicated ASP team activities
- reviewing progress by the team, identifying barriers and providing advice
- assigning high-performing staff to the team and resourcing them adequately
- most importantly, endorsing the ASP team and the activities.

2. General Role of Antimicrobial Stewardship Program

1   Ensure implementation of ASP strategies and activities.
2   Establishes formulary restriction and approval systems especially for broad-spectrum antimicrobials.
3   Ensure implementation of *National Antibiotic Guideline*, treatment guidelines and clinical pathways for common infections.
4   Ensure necessary action is taken based on surveillance findings.
5   Educates public and private prescribers, pharmacists and paramedics about good antimicrobial prescribing practice and antimicrobial resistance.
6   Evaluates and reports the surveillance and clinical audit findings.

3. Antimicrobial Stewardship Team Members

3.1. ASP team member in Primary Care includes:

a) District level
   a. Appointed Family Medicine Specialist
   b. Family Medicine Specialist/Medical Officer In-Charge from each KK
   c. Pharmacist In Charge of District (Secretariat)
   d. Pharmacist from each KK
   e. Senior Assistant Medical Officer
   f. MLT In Charge of District
   g. Link Nurse (Optional)
   h. Information Technology Officer (Optional)

b) Health Clinic Level
   a. Family Medicine Specialist/Medical Officer In-Charge
   b. Pharmacist (Secretariat)
   c. MLT
   d. Link Nurse (Optional)
   e. Information Technology Officer (Optional)

3.2 Roles and responsibilities

No.	Member	Roles and Responsibilities	
		District Level	Health Clinic Level
1	**Head of ASP Team (an appointed FMS)**	Represents the AMS team in the district infection control and antibiotic meeting and gives feedback on ASP program.	Represents the AMS Health Clinic team in the district AMS meeting and gives feedback on ASP program.
		Collaborates with the District Drugs and Therapeutics Committee (JKUT) to determine available antimicrobials on the district and KK formulary.	Collaborates with the Clinic Drugs and Therapeutics Committee (JKUT) to determine available antimicrobials on the KK formulary.
		Prepares surveillance and audit reports for submission to state and national level	Prepares surveillance and audit reports for submission to district level
		Proposes annual ASP activities.	
2	**Family Medicine Specialist/ Medical Officer In-Charge**	Leads the technical component of Antimicrobial Stewardship team.	
		Consults and advises on specific stewardship related cases and issues	
		Surveillance – point prevalence survey	
		♣ Audit and feedback ♣ Conduct appropriate antimicrobial audits ♣ Provides timely feedback for future improvement	
3	**Pharmacist**	Ensure pharmacist role at KK level in support of ASP.	
		Clinical role in conjunction with other members of the Antimicrobial Stewardship Team. ♣ Gives technical advice on finer aspects of antimicrobials and newer agents. ♣ Ensure dose optimization for antibiotics is carried out. ♣ Enforces the approval system of restricted antimicrobials	
		♣ Ensures safe and effective use of medication to reduce risk for errors and adverse events	
		♣ Surveillance of antimicrobial use	♣ Surveillance of antimicrobial use - Collection and analysis of clinic

		- Collection and analysis of district consumption and expenditure - Provision of data to state /national surveillance programs	consumption and expenditure - Provision of data to district surveillance programs
		⊕ Audit and feedback ▪ Assist in conducting appropriate antimicrobial audits ▪ Provides timely feedback for future improvement	
4	**Medical Lab Technician**		⊕ Gives technical advice on correct sample collection and management
			⊕ Ensure timely result of culture and antimicrobial sensitivity test
			⊕ Documenting antimicrobial sensitivity test results.
5	**Information Technology Officer (optional)**		⊕ Health clinics with existing IT systems may consider including an IT personnel into the ASP team to assist with ▪ Creating localized electronic decision making systems that can be available through the health clinic network system. ▪ Providing ASP team access for microbiological data and antibiotic utilisation data ▪ Producing automated antibiotic utilisation data and other programmed clinical data.
6	**Senior Assistant Medical Officer**	⊕ Senior Assistant Medical Officer will help in ensuring implementation of ASP activities among Assistant Medical Officers.	
7	**Infection Control Link Nurse (optional)**	⊕ ASP teams frequently chance upon opportunities to tighten infection control practices during their course of the work. Having a Link Nurse within the team complements the efforts of the ASP team in bringing down resistance rates.	

1.   Implementation of Treatment Guidelines and Clinical

ASP team should ensure the implementation of treatment guidelines and clinical pathways when they are available. In the primary care setting inappropriate antimicrobial use are most common in the areas of upper respiratory infections and diarrhea. Clinical pathways should be developed for these two common conditions. If successful, it can make a significant impact on decreasing antimicrobial use in primary care.The example of clinical pathway for UTI is shown in APPENDIX 1.

2.   Surveillance and Feedback

Surveillance and feedback on antimicrobial utilization should be conducted continuously in clinics with IT system. Where else, for Advanced Clinics without IT system, antimicrobial point prevalence survey should be conducted yearly.Report of this surveillance and feedback must be submitted to state and national level. Clinical audit should be carried out to ensure adherence to treatment guidelines and clinical pathway. Necessary action should be taken based on both findings.

Surveillance of antimicrobial use can show us how and why antimicrobials are being used and misused by patients and healthcare providers. Monitoring antimicrobial prescription and consumption behavior provides insights and tools needed to inform therapy decisions, to assess the public health consequences of antimicrobial misuse. Access to information on antimicrobial consumption can be an important source for healthcare professionals and policy makers to monitor progress towards a more prudent use of antibiotics.

The European Surveillance of Antimicrobial Consumption program (ESAC) has demonstrated that monitoring antimicrobial use patterns and costs can prove the crucial factor driving political commitment to successful campaigns to contain resistance, especially when surveillance of use is enhanced by surveillance of resistance.

- Collection and analysis of local antimicrobial consumption and expenditure

    - Data collection and analysis of antimicrobial use and expenditure should be undertaken regularly.
    - The results of antimicrobial use and expenditure should fed back to prescribing clinician and discuss the results in relevant meeting.

- **Indicators for reporting antimicrobial usage pattern**

    - Proportion of total expenditure on antimicrobial relative to all medications.
    - Daily Defined Dose (DDD) per 1000 patient attendances is used to determine the antimicrobial consumption.
    - Antibiotic Prescriber Profiling which include antibiotic prescribing rate per prescriber for specific diseases (for example URTI).

- Provision of data to regional /national surveillance programs

    - The data should be reported and presented at local and state level. It also has to be submitted to BPKK and Pharmaceutical Services Division for National Surveillance on Antibiotic Utilization.

3.   Audit and Feedback

The scope of clinical audit is to include appropriateness of antimicrobial prescription. Annual report of the clinical audit should be presented in ASP District Meeting.

Modified Clinical Audit Guideline- Refer to APPENDIX 10

In order to ensure the success of the program, two-way system or communication has to be established within the institution. Any feedback may be disseminated via:

- e) Email/letter to heads of units
- f) Email/letters to individual prescribers
- g) Newsletter or bulletins
- h) Presentation at unit or district meetings
- i) Presentation at Drug Committee And Therapeutic Meeting

4.   Formulary Restriction

Formulary restriction is one of the pillars of AMS Program. MOH formulary already has restrictions based on category of prescribers, however these restrictions may not be adequate to guide the local prescribers about judicious use of antibiotic. Thus each district is required to formulate their own district's formulary with consideration of specific MOH program such as Integrated Management of Childhood Illnesses and Modified Systemic Approach. All prescribers should comply with formulary restriction either from local or national formulary.

Restriction can be implemented through a number of ways such as pre-approval (can only be started after getting a specific approval) through forms or verbally.

5.   Antibiotic Selection and Dose Optimization

Antimicrobial selection and dose optimization should be tailored to the patient's characteristics, causative organism, site of infection, and pharmacokinetic and pharmacodynamic characteristics of the antimicrobial agent. Concomitant drug use should be considered to prevent interaction.

Strategies that may be considered include:

- weight-based dosing of certain antimicrobials for paediatric.
- dose adjustments for patients with renal dysfunction

6.   Education

Antimicrobial Stewardship team should prepare a program of continuous education for doctors, pharmacists and paramedics to influence prescribing behavior and to provide knowledge that will enhance and increase the acceptance of Antimicrobial Stewardship strategies. This program should be included in the induction training for all newly reporting medical, paramedic and pharmacy staff. Educational Key Points (Refer APPENDIX 8)must be highlighted during these session to instill appropriate use of antimicrobial.

Recommended Educational Programs

1. Continuous Medical Education (CME)
2. Newsletter/including a sub-topic on antibiotics in any publications
3. Prescribing aids
   - Educational aids to guide prescribers at the point of prescribing. These may include clinical algorithms for the diagnosis of infection, or methods to standardize documentation of treatment decisions, such as infection stamps or stickers to be included in the clinical notes.
   - Where possible, information technology support for prudent antimicrobial use should be introduced.
   - This includes electronic patient records, computerized prescribing and clinical decision support software.

B.3   ANTIMICROBIAL STEWARDSHIP PROGRAM MEASUREMENT

Successful antimicrobial stewardship program include all the elements of successful quality improvement programs and measuring the effectiveness of program activities is a key component. Monitoring and analysis of antimicrobial usage is critical to measure the effects of stewardship interventions. Process and outcome measures should be incorporated into the ASP plan.

A.   Process measures

- Number of clinical audits including antibiotic
- Annual report of antibiotic Prescriber Profiling for Electronically enabled clinic annually

B.   Outcome indicators

- Annual report of total antimicrobial expenditure
- Specific antibiotic DDDs annually
- Reduction of URTI patient prescribed with antibiotic for Electronically enabled clinic annually
- Increase in appropriate antibiotic prescription.

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APPENDICES AND ANNEXES

APPENDIX 1: Clinical Pathway for Urinary Tract Infection UTI (Example)

QUICK REFERRENCE GUIDE FOR UTI

GENERAL PRINCIPLES

1. ASSESS RISK FACTORS- Sexually active, recurrent UTI, Spermicide Use, Structural defects
2. Do not treat Asymptomatic bacteriuria in young men and women and patients with indwelling catheter
3. Treat asymptomatic bacteriuria in 2 conditions: patients going for urological procedures /transurethral resection of prostate and in pregnant women.
4. Asymptomatic Bacteriuria is common in diabetic patients; men: 0.7-11% and women 10-16%
5. In sexually active young men and women, with symptoms suggestive of UTI consider Chlamydiae Trachomatis

UTI IN THE OLDER ADULT >65 YRS OF AGE

1. Asymptomatic bacteriuria is common in elderly: men 3.6-19%, women: 10-16%
2. Asymptomatic bacteriuria is common in elderly from Nursing home: women: 25-54%, MEN : 15-30%
3. +ve LE or Nitrite in the dipstick does not rule in UTI
4. Atypical Presentation: New / worsening urgency, frequency , dysuria and hematuria, Hypothermic or low grade fever, worsening incontinence , worsening of mental function/ functional status/ agitation and lethargy , falls **PLUS** UC&S>10^5 CFU/ml with no more than 2 organism OR Pyurea ≥ 10 WBC/field
5. In infected elderly patients: urine cultures may have lower colony counts 10^2-10^3.

Catheter Related UTI

1. Asymptomatic bacteriuria is common: short term catheter 9-23%, Long term catheter 100%
2. Rx if symptoms suggestive of UTI (fever/ suprapubic pain, loin tenderness, altered mental state, SIRS and shock), without any identifiable source and CFU ≥ 10^3-10^5 (higher CFU better PPV)
3. Pyurea (wcc>10) does not equal UTI
4. Urine odour does not predict UTI
5. Absence of WBC in urine--- good NPV→ look for another source.

SPECIMEN COLLECTION

1. Cleaning with soap and water and special antiseptics are not necessary.
2. Send fresh specimen / refrigerate specimen to prevent overgrowth in case of delay
3. In men and women get MSU specimen.
4. In catheterised patient—clamp CBD bag, drain a few mls of urine then clean the sampling port with alcohol wipes→ let dry 1min. Then insert a sterile syringe and take 5cc of urine sampling.
5. Alternatively, reinsert a new catheter and take the mid stream urine.

DIPSTICK URINALYSIS—WHAT DOES IT ALL MEAN

1. Urine specific gravity—correlates with urine osmolality and dehydration.
2. Nitrites- normally not found
   a. +ve means enterobactericiae, (CDC—can be staph saprophyticus as well).
   b. Specific but not sensitive--- if Negative does not rule out UTI
   c. High Positive Predictive value
   d. Keep bottle closed at all times : exposed strip can give false negative result
3. Leucocyte esterase
   a. Read according to insert advice(takes 30sec- 2 mins)
   b. Indicates enzymes produced by neutrophils
   c. Higher the pyurea ,better predictive value)
   d. Not specific, WCC can be from anywhere may be positive in TB/ Chlamydiae, presence of foreign bodies, steroid use and stones.

How to interpret the culture result

1. Single organism with ≥ 10^5 CFU
2. Or Escherichia coli or Staphylococcus saprophyticus ≥ 10^3 CFU/mL
3. Other conditions when CFU 103-105 is significant due to
   a. Organism other than E.coli/ Proteus
   b. Already on Ab
   c. In men

MANAGEMENT of UTI in men and women < 65 years old

Severe Symptoms of UTI

- Dysuria   - Polyurea
- Urgency   - Worsening urinary incontinence
- Frequency   - Haematuria
- Loin pain/suprapubic pain

Not for urine culture.
Treat empirically
1. Bactrim 2 tabs (80/160) bd for 3 days OR
2. Trimethoprim 200mg bd for 3 days OR
3. Nitrofurantoin 100mg bd for 3 days

Men: treatment for 7 days

Women
No vaginal discharge / irritation
Severe symptoms of UTI (≥3) - no need urine culture pre treatment

MEN
Send for urine culture before treatment
If mild symptoms use –ve leuc on urinalysis TRO UTI

+ve Nitrite & LE/Blood→ 92% PPV Or +ve Nitrite alone	-ve Nitrite +ve LE	-ve Nitrite -ve LE 76% NPV
↓	↓	↓
Probable UTI	-repeat and RX empirically if severe - send urine c/s and RX	Consider alternative diagnosis
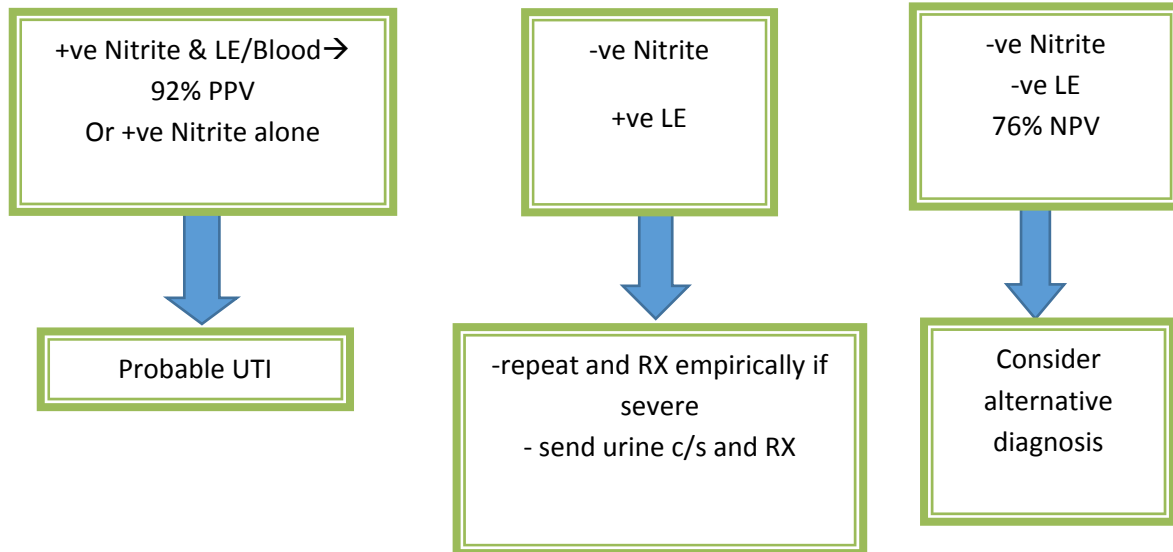
1. Risk factors for complicated cystitis/ pyelonephritis
- Diabetes
- Pregnancy
- Symptoms ≥ 7 days
- Hospital acquired infection
- Renal failure
- Urinary obstruction
- Recent catheter use
- Recent urinary tract manipulation
- Structural defect
- Renal transplant
- Immunosuppression

Clinical Features

1. Cystitis symptoms may be absent
2. Fever >38 & chills
3. Flank pain
4. Costovertebral angle tenderness
5. Nausea/ vomiting
6. May mimic Pelvic inflammatory disease
7. Septicaemic shock and multiorgan dysfunction

Suspect when clinical symptoms have not resolved after 48 to 72 hrs of starting treatment

APPENDIX 2:How to Perform an Audit

WORK PROCESS OF PROSPECTIVE AUDIT & FEEDBACK

| Area of Problem Identified | → | Specified agreed criteria to be determined |

No

Intervention

Source of data

1. Antibiotic consumption (DDD)
2. Antibiotic prescription
3. Culture & Susceptibility data
4. Patient progress note
5. Other relevant data

Yes

Feedback

All feedback has to communicated and documented through:

1. Direct interactions
2. Note or stickers in the chart or Electronic Medical Records

Published Audit Findings

1. Email/letter to heads of units
2. Email/letters to individual prescribers
3. Newsletter or bulletins
4. Presentation at ward or unit meetings
5. Presentation at Drug Committee And Therapeutic Meeting

APPENDIX 3: Formulary Restriction (Example)

Antimicrobials are divided into 3 categories – the first being antibiotics that require preauthorization before it can be prescribed. Authorization is issued by the relevant consultant of the department and in accordance with preapproved indications. The second category involves antimicrobials that can be prescribed only for specific indications which will auto-generate a referral to the stewardship team who will review the patient within 3 working days. Justification of its continued usage will be needed before it can be continued. Lastly are antimicrobials that do not require approvals.

PREAUTHORIZATION	CONDITIONAL	AVAILABLE
Linezolid Tigecycline Caspofungin Variconazole Anidulafungin Pentamidine Gancyclovir	Carbapenems Vancomycin 3rd & 4th GC Antipseudomonal BL/BLI Fluconazole Aminoglycoside Fluoroquinolos Colistin	Other antibiotics

APPENDIX 4: Antibiotic Order Form (Example)

Patient name:	
RN:	Ward:
Antibiotic requested:	
Dosage & Frequency	
Indication	[ ] **Nosocomial ≥48 hrs of hospitalization** *colonization should not be treated* [ ] **Community**
Diagnosis	
Culture sent prior to antibiotic initiation (Please Underline)	Samples: Blood/Sputum / BAL / Urine / Tissue /Pus/ CSF/ Body Fluid (Specify):_____
Culture result (Please attach the sensitivity results if available)	1. 2. 3. 4.
Authorized Specialist's signature	Date

* Please attach this form together with prescription/advice slip before sending to pharmacy.

----

72 HOURS ANTIBIOTIC REVIEW FORM

Patient name:	
RN:	Ward:
Antibiotic requested:	
Dosage & Frequency	
Justification for continuation	
Culture result (if available)	
Authorized Specialist's signature	Date

* Please attach this form together with prescription/advice slip before sending to pharmacy.

APPENDIX 5: Example of 72hours Antibiotic Stop/Review Order

CARBAPENEM STOP/REVIEW ORDER FORM

Name: [_____]

SB No.: [____]

[1]Discipline: [_____]

Ward Admission:　　　Day : [____]　Month : [____]　Year : [____]

Specialist Name:　　　[_____]

[2]Indication/Diagnosis:　　[_____]

Types of Carbapenem (please √):
	Imipenem	[____]	Date Start: [____]
	Meropenem	[____]	Date Start: [____]
	Ertapenem	[____]	Date Start: [____]

Reason for initiating Carbapenem Group (please √) :

1. Empirical Therapy [____]
2. Based on preliminary result of susceptible pathogen to Carbapenem [____]
3. Definitive Therapy [____]
3. Empirical & Can't be deescalated because (please state reason) : [____]

_____

APPENDIX 6: Example of Antibiotics That Can Be Included in IV to PO Therapy Conversion

IV to PO Switch	
SEQUENTIAL/SWITCH THERAPY	**STEP-DOWN THERAPY (ORAL EQUIVALENT)**
Azithromycin, cefuroxime, ciprofloxacin, clindamycin, doxycycline, levofloxacin, linezolid, metronidazole, moxifloxacin, sulfamethoxazole/ trimethoprim	Ampicillin (amoxicillin), ampicillin/ sulbactam (amoxicillin/clavulanate), piperacillin/tazobactam (multiple options), ticarcillin/clavulanic acid (multiple options), aztreonam (ciprofloxacin or levofloxacin), cefazolin (cephalexin), cefotaxime or ceftriaxone (cefpodoxime or cefuroxime axetil), ceftazidime or cefepime (ciprofloxacin or levofloxacin)

Bioavailability of Selected Antibiotics Available in Both IV and PO Formulations
80% to 100%
Ciprofloxacin
Clindamycin
Doxycycline
Fluconazole
Linezolid
Metronidazole
Moxifloxacin
Sulfamethoxaxole/trimethoprim
Azithromycin (<50%: Although azithromycin has a low bioavailability, it is well-distributed into tissues)

APPENDIX 7: Criteria Used to Determine Patients for IV to PO Therapy Conversion

IV-Oral Antibiotic Switch Therapy Protocol

Patient receiving an IV antibiotic?

↓

Oral route compromised (vomiting, nil by mouth, severe diarrhoea, swallowing disorder, unconscious)

Or

Continuing sepsis (i.e. 2 or more of the following: T > 38°C or <36°C, HR > 90bpm, RR> 20/min, WCC > 12 or < 4)/ deteriorating clinical condition

Or

Special indication [endocarditis, central nervous system infections (e.g.; meningitis, brain abscess, etc.), orbital cellulitis, osteomyelitis, endophthalmitis, melioidosis (at least 10 to 14 days of IV therapy), deep abscesses]

Or

No oral formulation of the drug available

Yes → **Continue to review the need for IV therapy**

No ↓

Switch to oral therapy

APPENDIX 8:Educational Key Points

The educational programs should include the interventions points as below:-
[adapted from recommendations produced by the UK Specialist Advisory Committee on Antimicrobial Resistance (SACAR)]

- Antimicrobials should be used after a treatable infection has been recognized or there is a high degree of suspicion of infection. In general, colonization or contamination should not be treated. Antimicrobials should be used for the prevention of infection where research has demonstrated that the potential benefits outweigh the risks. Long-term prophylaxis should be avoided unless there is a clear clinical indication (for example, rheumatic fever and post-splenectomy).

- The choice of antimicrobial should be determined by the sensitivity of the identified causative organism when this is known. Empiric therapy, for the likely causative organism (s) should be governed by local guidelines that have been informed by recent information about trends in antimicrobial sensitivities.

- Targeted therapy should be used in preference to broad-spectrum antimicrobials unless there is a clear clinical reason (for example, mixed infections or life-threatening sepsis). The prescription of broad spectrum antimicrobials should be reviewed as soon as possible and promptly switched to narrow spectrum agents when sensitivity results become available. Mechanisms should be in place to control the prescribing of all new broad-spectrum antimicrobials.

- The timing, regimen, dose, route of administration and duration of antimicrobial therapy should be optimized and documented. The indication for which the patient is being prescribed the antimicrobials should be documented in the drug chart and case notes by the prescriber.

- Wherever possible, antimicrobials should be given orally rather than intravenously. Clear criteria should be defined for when intravenous therapy is appropriate. As soon as possible the prescription should be switched to an oral equivalent. The intravenous prescription should be reviewed after 48 hours as a minimum.

- Antimicrobial treatment should be stopped as soon as possible. A stop date or review date should be recorded by the prescriber on the drug chart. In general, antimicrobial courses should be reviewed within five days.

- To ensure rapid treatment and infection control, mechanisms should be in place to ensure that patients receive antimicrobial drugs in a timely manner.

APPENDIX 9: Cost Savings Formula & Days Calculation

> If antibiotic stopped:
>
> **Cost savings = cost of the stopped antibiotic x cost saving days (see below)**
>
> If antibiotic was switched to cheaper alternative or to oral:
>
> **Cost savings = (cost of previous antibiotic x cost saving days) – (cost of new antibiotic x cost saving days)**

AMS Intervention	Number of cost saving days
Discontinue / stopped antibiotic	No. of days to primary team's initial planned stop date OR If team's intended stop date is not known; No. of days to the nearest multiple of 7 (e.g. D7, D14, D21)
Switch antibiotic	No. of days of the recommended antibiotics*
IV to PO switch	No. of days of the recommended PO antibiotics*

* Should also include duration of discharged antibiotics if patient is discharged during the course.

Example on Switched Antibiotic Calculation:

Meropenem 1g tds has been deescalated to oral Amoxycillin/Clavulanate 625mg tds on day 3 of therapy for pneumonia which is planned to complete on day 7.

Cost Savings:

= (cost of previous antibiotic x cost saving days) – (cost of new antibiotic x cost saving days)

= [RM 16 (price of Meropenem) x 3 (frequency of Meropenem) x 5 (remaining days of Meropenem) – (RM 0.70 (Price of oral Amoxycillin/Clavulanate) x 3 (frequency of Amoxycillin/Clavulanate) x 5 (planned duration of oral Amoxycillin/Clavulanate)

APPENDIX 10: Modified Clinical Audit Guidelines for Medical Officers in Health Clinic

INTRODUCTION

Patients have their right to have good and quality health care. Clinical audit is an important tool in assessing the quality of patients' health care and management delivered in any health care facilities. It can be done by various ways including assessment of patients' record or through direct observation of consultation. This will also serve as a fortification for health care providers especially pertaining to medico-legal issues.

Through this process, the weaknesses and strength of patients' management whether documented or observed can be identified. It is not a fault finding process, rather as an avenue to provide improvement of clinical knowledge for the health care providers hence improving the quality of the patients care at long term.

OBJECTIVES

General Objectives:

To improve the quality of service at Primary Care Level

Specific Objectives:

1. To ensure competency among the Medical Officers in Health clinics
2. To ensure patient's safety is being practiced
3. To identify weaknesses in patient's management and plan rectification measures.
4. To ensure presence of continuous and comprehensiveness care.

CLINICAL AUDIT METHOD

Types of Clinical Audit:

There are 2 types of audits that can be carried out in Primary care level:
1. Auditing patients' records
2. Direct observation of the consultation and procedures

A. PATIENT RECORD AUDIT

Methodology

Auditor:
FMS

Auditee:
Medical Officers in Health Clinics. All MO under supervision of FMS to be audited at least 2x a year
Audit Tool: Clinical audit chart (ANNEX I)

Samples and sampling method:
Patients' records are selected from patients with walk in cases, chronic illness and/or from antenatal records through systematic random sampling. Minimum of 10 patients' records per medical officer will be audited.

Audit process:

1. Brief the auditees regarding the clinical audit process
2. Audit the most recent consultation or together with the previous consultation if necessary.
3. One clinical audit chart is used for ten patient's record.
4. Audit findings and remedial measures:
5. All audits should be completed with percentage of performance of the auditee, weakness and strength identified and remedial measures taken or planned for.
6. Eighty percent of the audited cards of more than 80% marks indicate good overall performance.
7. This can be used as an adjunct for the annual clinical appraisal of medical officers, (Laporan Penilaian Prestasi Tahunan).
8. Each state FMS representatives will monitor the progress and implementation of clinical audit performance in each state and be reported during the FMS Technical meeting.

B. OBSERVATION / INTERVIEW AUDIT

This is done as an option to supplement findings of the clinical audit cards. i.e. where the performance of clinical card audit was either too good or too poor as shown in work process. (ANNEXII)

Process

Observation is done directly during any patients' consultation and procedures. This can be carried out more than one patient per medical officer using clinical audit observation chart (ANNEXIII).

Clinical Audit Review Panel

Dr Maimunah Mahmud	Dr Ruziaton Hasim
Dr Sri Wahyu Taher	Dr. Yunus Sharif
Dr Nik Azhan Nik Mohamad	Dr Adlina Bakar
Dr Zil Falillah Mohd Said	Dr. Jaidon Ramli
Dr Rosini Zakaria	Dr. Suhaimi Md Isa
Dr Mohd Sukarno Saud	Dr Salmiah Md Sharif
Dr Mohd Suzuki	Dr Nor Asmah Hasan
Dr Husni Husin	Dr Sukumar A/L Rajaretnam

CLINICAL AUDIT FOR MEDICAL OFFICER

A.	Auditee:
B.	Auditor:
C.	Date and time:
D.	Place:
E.	Total no of cases seen on audited day:

F. Case	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10			
Condition/ Program	ASP	ASP	Acute	Acute	DM	DM	CVD	CVD	Resp	Mental			
Diagnosis													
Encounter number													
Name of Medical Officer Audited:	DONE=1, NOT DONE=0, NOT APPLICABLE=(empty)										TOTAL SCORE PER AUDIT CRITERIA	Denominator	% PERFPORMANCE PER AUDIT CRITERIA
1 Patients RN											0	0	
2 Date / time of consultation											0	0	
3 Reason for coming to the clinic/ history taking											0	0	
4 Problem listing											0	0	
5 Physical examination : Vital sign											0	0	
6 Relevant examination											0	0	
7 Diagnosis											0	0	
8 Registered with relevant registry; e.g. Diabetic, HITRAX, Asthma, Mental Registry											0	0	

Case	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	TOTAL SCORE PER AUDIT CRITERIA	Denominator	% PERFPORMANCE PER AUDIT CRITERIA
Condition/ Program	ASP	ASP	Acute	Acute	DM	DM	CVD	CVD	Resp	Mental			
Encounter number													
Name of Medical Officer Audited:	DONE=1, NOT DONE=0, NOT APPLICABLE=(empty)												
9 Relevant investigations and interpretation of results											0	0	
10 Appropriate management : eg Treatment/Antibiotic											0	0	
11 Appropriate Referral											0	0	
12 Appropriate follow up / plan, (prevention)											0	0	
13 Notification											0	0	
14 Identification of practitioner: Name/ Chop											0	0	
TOTAL SCORE PER CASE	0	0	0	0	0	0	0	0	0	0			
Denominator	0	0	0	0	0	0	0	0	0	0			
% PERFPORMANCE PER CASE													
% OVERALL PERFORMANCE													

INDICATOR FOR PERCENTAGE OF OVERALL PERFORMANCE

Good Clinical Practice   ≥ 80 %

Reasonable Clinical Practice :   51 – 79 %

Poor Clinical Practice   ≤ 50 %

Comment :

1.) Overall Performance:

2.) Strength

3.) Weakness

4.) Recommendation

Name and signature of auditee:	Name and signature of Auditor:

Description of the items in clinical audit chart

Item	Description
Time of consultation	Applicable for medico-legal cases and emergency cases
Reason for coming to the clinic	
Problem listing	
Physical examination • Vital signs • Relevant examination	
Diagnosis	
Registered with relevant registry; e.g. Diabetic, HITRAX, Asthma, Mental Registry Relevant investigations ordered	If relevant registry available in the clinic
Appropriate interpretation of results	
Appropriate management • Treatment • Referral	Patients requiring referral but not referred – score 0
Appropriate follow up / plan , (prevention)	
Notification	Applicable to notifiable infectious diseases
Identification of practitioner (MO) • Name / Chop	

ANNEX II

WORK PROCESS OF CLINICAL AUDIT

```
                    ┌─────────────────────────┐
                    │   Selection of auditee   │
                    └─────────────────────────┘
                               │
                               ▼
                    ┌─────────────────────────┐
                    │ Selection of patient     │
                    │ records                  │
                    └─────────────────────────┘
                               │
                               ▼
                    ┌─────────────────────────┐
                    │   Perform the card audit │
                    └─────────────────────────┘
                               │
                               ▼
                    ┌─────────────────────────┐
                    │   Overall Performance    │
                    └─────────────────────────┘
                               │
             ┌─────────────────┼─────────────────┐
             ▼                 ▼                 ▼
      ┌────────────┐    ┌────────────┐    ┌────────────┐
      │ Marks > 80%│    │  50 - 80%  │    │   < 50%    │
      └────────────┘    └────────────┘    └────────────┘
              ╲                                 ╱
       Optional ╲                             ╱
                 ▼                           ▼
              ┌─────────────────────────────────┐
              │    Perform Observation Audit     │
              └─────────────────────────────────┘
```
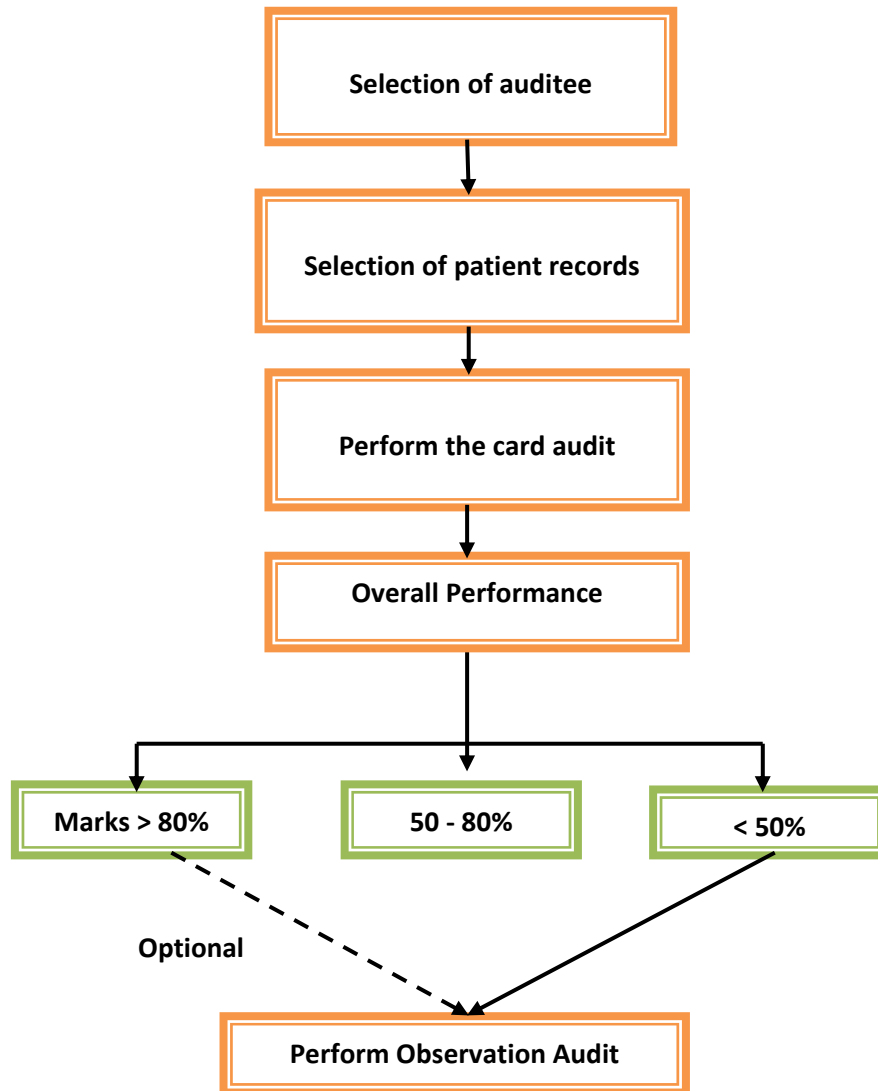
EXAMPLE OF INTERPRETATION OF CLINICAL AUDIT FOR THE CLINIC

Dr/ score	No of cards with ≤ 50 (%)	No of cards with 51-79 (%)	No of cards with ≥ 80 (%)	Overall performance
Dr A	0	2	8	good
Dr B	0	3	7	fair
Dr C	6	4	0	poor

Score for all doctors will be divided into three categories;

1. **Good performance**

    Score 80% and above in≥8 cards

2. **Poor performance**

    Score 50% or less in ≥ 5 cards

3. **Fair performance**

    Those whose marks fall in between good and badperformance

Final report for the clinic

1. Total number of doctors in the clinic

2. Number of doctors with good performance

3. Number of doctors with fair performance

4. Number of doctors with poor performance

5. Percentage of doctors with good performance

ANNEX III

CLINICAL AUDIT OBSERVATION CHART					
A.	**Auditee:**				
B.	**Auditor:**				
C.	**Date and time:**				
D.	**Place:**				
		Good	Average	Poor	Not Done
1.	Rapport				
2.	Communication **:**				
	• verbal/non verbal				
	• medical jargon				
	• closed / open ended questions				
3.	Adequate/ appropriate history taking				
4.	Appropriate physical examination				
5.	Proper physical examination (without causing discomfort)				
	• Summary of findings				
	• Explanation of management				
	• Patient needs met				
	• Address patient concerns				
6.	Confidentiality maintained				
7.	Ending consultation				
8.	Overall attitude				
9.	Appearance				
10.	Discussion of case with MO; History, physical findings, diagnosis, impressions, prevention				

Comment :					
5.) Overall Performance:					
6.) Strength					
7.) Weakness					
8.) Recommendation					
Name and signature of auditee:			**Name and signature of Auditor:**		

MINISTRY OF HEALTH MALAYSIA

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1ST EDITION