How to Investigate Antimicrobial Use in Hospitals:

Selected Indicators

November 2012

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CONTENTS

ACRONYMS

ABC	method of ranking and analyzing to determine highest- and lowest-consumption products
ADR	adverse drug reaction
AMR	antimicrobial resistance
BAN	British Approved Name
CH	clinical history
DTC	Drug and Therapeutics Committee
EML	Essential Medicines List
EUR	euro
FL	formulary list
HIV	human immunodeficiency virus
INN	international nonproprietary name
MDR-TB	multidrug-resistant tuberculosis
PI	principal investigator
PROM	premature rupture of membranes
STG	standard treatment guideline
TB	tuberculosis
USAN	US Adopted Name
USD	US dollar
VEN	vital, essential, nonessential
WHO	World Health Organization
WHO/DAP	WHO Action Programme on Essential Drugs
XDR-TB	extensively drug-resistant tuberculosis
ZAR	South African rand

INTRODUCTION

The *World Medicines Situation Report* of 2011 concludes that inappropriate antibiotic use, including overuse and misuse, is a serious global problem. Established and newly emerging infectious diseases are increasingly threatening the health of populations. Harmful consequences of irrational use include unnecessary adverse medicines events and rapidly increasing antimicrobial resistance (AMR) due to overuse of antibiotics. The World Health Organization (WHO) states that it is essential to have reliable data on how medicines are used in order to assess the accessibility, quality, and cost-effectiveness of care and to identify problematic areas to develop targeted intervention strategies (WHO 2011b).

The 1985 WHO conference on rational medicine use marked the beginning of efforts to improve the use of medicines, especially in developing countries (WHO 1987). In 1993, the WHO Action Programme on Essential Drugs (WHO/DAP) published the manual *How to Investigate Drug Use in Health Facilities* in response to the increased awareness of the problems impeding the rational use of medicines (WHO 1993). This manual presented 12 indicators for assessing medicine use in outpatient health facilities and has been instrumental in standardizing medicine use studies.

The manual has been used to assess medicine use in hospitals, even though the medicine use indicators for outpatient settings do not address a number of the factors and situations that affect medicine use in hospitals, such as the duration of stay or the different diseases treated. For example, an indicator such as "the time to dispense a prescription" to an ambulatory patient is meaningless in an inpatient setting. Similarly, the type and severity of illness that cause patients to be hospitalized often necessitate the use of intravenous medicines. Therefore, the indicator "percentage of injectables prescribed" would be higher in hospitals than in outpatient facilities, and thus less meaningful for inpatient medicine use. Another indicator, "average number of medicines per encounter," would not be very useful in a hospital setting because a temporary increase in the number medicines administered usually occurs while patients are hospitalized.

The First International Conference on Improving Use of Medicines, held in Thailand in 1997, identified the need for a set of indicators and appropriate methodology to assess the use of medicines in hospitals, particularly antimicrobials (EDM 1997). The detection of problems with use of antimicrobial medicines in hospitals is the first step in evaluating the underlying causes and taking remedial action. The Second International Conference on Improving Use of Medicines confirmed the need for medicine use indicators to measure trends in pharmaceutical management, prescribing, and dispensing in the public and private sectors (ICIUM 2004). The International Conference for Improving Use of Medicines held in Antalya, Turkey in November 2011 (ICIUM 2011) also renewed the call for closely monitoring and measuring medicine use and identifying medicine use problems. The development and implementation of the indicators in this manual was presented at this conference (Green et al. 2011).

The management and use of antimicrobials have clinical, economic, and environmental implications. In many countries, antimicrobials are the most frequently prescribed therapeutic agents, accounting for 30 to 50 percent of prescriptions for medicines. From a clinical standpoint, four principal concerns surround the use and management of antimicrobials—

1. They are necessary for treatment of most bacterial infections. If they are not available in hospital pharmacies, lives may be jeopardized.

2. They may be prescribed inappropriately by physicians and drug sellers, and used inappropriately, especially by the general public through self-prescribing in places where antimicrobial medicines are sold over the counter. Inappropriate prescribing includes use of antimicrobials without proof of infection or to treat viral infections or noninfectious diarrhea. The wrong medicine may be prescribed or taken for a particular infection or, if the correct medicine is used, it may be prescribed or taken at the wrong dosage or by an inappropriate route of administration. Perhaps the greatest misuse of antimicrobials is failing to follow the indicated full course of therapy.

3. Adverse drug reactions (ADRs) constitute the third critical area of antimicrobial use. Such reactions include nephrotoxicity and allergic reactions as well as antibiotic-associated diarrhea. It is estimated that 25 percent of ADRs are caused by antimicrobial medicines (Beringer et al. 1998). ADRs constitute a serious risk to health and will substantially increase morbidity and mortality if not managed in a comprehensive manner.

4. The overuse and misuse of antimicrobials are the key drivers of AMR. The epidemic of AMR is changing the way antimicrobials are used, increasing mortality and morbidity, and greatly increasing the cost of health care.

Antimicrobial Resistance

The inappropriate use of antimicrobials and the emerging problem of AMR require worldwide attention and urgent and intense actions. The use of antimicrobial medicines has greatly contributed to the decline in morbidity and mortality caused by infectious diseases, but these advances in treatment are being undermined by the rapidly increasing problems of AMR. Common infectious diseases, such as tuberculosis (TB), sexually transmitted infections, acute respiratory infections, malaria, dysentery, and HIV/AIDS, are becoming increasingly difficult and expensive to treat, and the burden is greatest in developing countries where resources are limited and infection rates are high. With antimicrobial options becoming limited, physicians in developing countries may have to use older antimicrobials that have become increasingly ineffective (Howard and Scott 2005).

In affluent nations, infections acquired in settings such as hospitals and nursing homes are a major cause of illness and death. Each year in the United States alone, some 14,000 people die from resistant infections acquired in hospitals (APUA 2005).

Global Situation of Antimicrobial Resistance

Drug resistance has emerged across the spectrum of microbes: viruses, fungi, parasites, and bacteria. Major pathogens that have become resistant to antimicrobials include—

- Bacteria causing diverse infections, such as *Staphylococci* (including methicillin-resistant strains), *Enterococci*, and *E. coli*

- Gram-negative bacilli that produce beta-lactamase enzymes and cause serious hospital infections

- Agents that cause respiratory infections, such as *Streptococcus pneumoniae,* TB, and influenza. *Mycobacterium tuberculosis* has developed resistance to single, multiple, and, in some cases, almost all the available antimicrobials (extensively drug-resistant organisms)

- Food-borne pathogens, such as *Salmonella* and *Campylobacter*

- Sexually transmitted organisms, such as *Neisseria gonorrhea*

- *Candida* and other fungal infections

- Parasites, such as *Plasmodium falciparum* that cause malaria; in addition to becoming resistant to traditional antimalarials, resistance is also developing to artemisinin-based combination therapy

- The human immunodeficiency virus (HIV) that can lead to AIDS; resistance has been developed to first-line treatments and some second-line antiretrovirals

MRSA continues to be a serious problem in the US, a prominent cause of *S. aureus* infections in both the health care and community settings. These resistant organisms are primarily due to transmission of relatively few ancestral clones rather than de novo development of resistance among susceptible strains (Hidron 2008). This illustrates the need to contain the *development* of resistance, but also *reducing the transmission* of these resistant organisms in hospitals and the community. Of 8,987 observed cases of invasive methicillin-resistant *Staphylococcus aureus* (MRSA) reported in a study between July 2004 and December 2005, 58 percent were health care associated and 27 percent were hospital-onset associated (Klevens et al. 2007). The increasing incidence of this resistant organism in both hospitals and the community is indicative of the emerging AMR crisis. Contributing to the accelerating surge of drug resistance are multidrug-resistant tuberculosis (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB). When resistance develops to two or more antimicrobials, the result is multidrug resistance. In early 2006, an XDR-TB strain killed 52 of 53 individuals with identified cases in South Africa. XDR-TB has since been identified in all regions of the world (U.S. CDC 2006 and Singh et al. 2007). About 440,000 new cases of MDR-TB emerge annually, causing at least 150,000 deaths; XDR-TB has been reported in 64 countries to date (WHO 2011a).

Following are more examples that illustrate the increasingly global AMR problem (Okeke et al. 2005):

- Multidrug-resistant *S. enterica* serotype paratyphi (*S. paratyphi*) infections have been associated with an increase in the reported severity of disease and emerged as a major public health problem in Asia.

- Resistance of *Shigella* to ampicillin, tetracycline, co-trimoxazole, and chloramphenicol is widespread in Africa, even though these medicines are still used for first-line chemotherapy for dysentery in many parts of the continent. The introduction of nalidixic acid has been followed by emergence of *Shigella* resistance.

- The emergence and spread of *S. dysenteriae* type I resistant to co-trimoxazole, ampicillin, tetracycline, chloramphenicol, and increasingly nalidixic acid in the past two decades means that these inexpensive and widely available antimicrobials can no longer be used empirically.

- Penicillin and erythromycin resistance is an emerging problem in community-acquired *S. pneumoniae* in Asia, Mexico, Argentina, and Brazil as well as in parts of Kenya and Uganda.

- Widespread resistance of *N. gonorrhea* has necessitated the replacement of penicillin and tetracycline with more expensive first-line medicines, to which resistance quickly emerged. In the Caribbean and South America, azithromycin resistance was found in 16 to 72 percent of isolates in different locations, resulting in the recommendation that this medicine in turn be replaced by ceftriaxone, spectinomycin, or the quinolones. The high cost of other options, however, such as third-generation cephalosporins makes their use prohibitive in many developing countries.

- AMR is becoming increasingly common in cholera infections in developing countries. Up to 90 percent of *Vibrio cholerae* isolates are resistant to at least one antimicrobial.

Economics of Antimicrobial Misuse and AMR

In economic terms, expenditures on antimicrobials are increasing yearly. Antimicrobials constitute about 20 to 40 percent of a hospital's medicine budget and can lead to significant, unnecessary health care costs if not carefully managed. Thus, antimicrobial medicines are a large and growing component of pharmaceutical expenditures in developing countries and must be managed effectively in the face of limited financial resources.

The annual additional cost of treating hospital-acquired infections from just six species of antibiotic-resistant bacteria was estimated to be at least USD 1.3 billion in 1992 dollars (USD 1.87 billion in 2006 dollars) (Laxminarayan and Malani 2007). Costs associated with AMR among outpatients in the United States have been estimated to lie between USD 400 million and USD 18.6 billion, and corresponding inpatient costs are likely to be several times higher (Okeke et al. 2005). WHO estimates that AMR in Europe costs EUR 9 billion annually (WHO 2011b). Little published evidence exists on the economic burden of resistance in developing countries. A single resistant organism, MDR-TB, serves to illustrate the enormity of the problem in resource-constrained countries. The cost of a full course of drug treatment for MDR-TB in the northwest province of South Africa is in South African rands (ZAR) 26,354 (roughly USD 4,300) compared with ZAR 215 for drug-susceptible TB (roughly USD 35). Data from Peru support the hypothesis that MDR-TB is much more expensive to treat than susceptible tuberculosis strains that are resistant to only one or two medicines—costs were estimated at USD 8,000 and USD

267, respectively (Okeke et al. 2005). The high cost of treating drug-resistant infections may exceed the financial capacity of many patients and hospitals in developing countries. Thus, managers must monitor and minimize antibacterial resistance in their hospitals.

In conclusion, hospitals must ensure availability of antimicrobials while at the same time controlling and improving prescribing practices of physicians and minimizing untoward side effects and AMR. Lack of control of antimicrobial use will enevitably lead to overuse, poor outcomes, and higher heath care costs. There is every reason to carefully manage the use of these important commodities.

PURPOSE

The purpose of this manual is to define a limited number of indicators that will objectively describe the management and use of antimicrobials in hospitals and to provide tools and step-by-step instructions for designing and carrying out an assessment of antibiotic use and management in hospitals. The indicators in this manual will complement the existing WHO (1993) indicators of outpatient antimicrobial use suggested in *How to Investigate Drug Use in Health Facilities* (including percentage of encounters in which an antibiotic was prescribed and percentage of medicine costs spent on antibiotics) and will address the need for antimicrobial indicators for inpatient conditions. The manual will follow the pattern of previous Rational Pharmaceutical Management Plus Program assessment guides and the WHO publication by presenting a limited number of indicators useful for screening, monitoring, and assessing impact. Because these indicators do not need adaptation and can be used in any indicator-based antimicrobial use study, they provide a simple tool for quickly and reliably evaluating critical aspects of antimicrobial use in hospitals. A supplemental indicator of the use of sensitivity testing is also presented, but it may have limited application because of limitations in laboratory services.

This manual is intended as a rapid assessment tool that can be used by hospital administrators, drug and therapeutics committees (DTCs), researchers, and program managers in developing countries to identify problems with antimicrobial use in their hospitals. It will allow basic comparisons of antimicrobial use both in one hospital over time and between hospitals. This set of indicators can be used at the district, regional, or referral hospital level. Ideally, all of the indicators would be used in a study, but some hospitals may find that they would use only selected indicators that apply to their particular circumstances. For example, a small hospital that has no surgical services would not need to use the two indicators on surgical prophylaxis. Hospitals that do not have adequate laboratory services would not actually calculate the supplementary indicator on culture and sensitivity testing.

After problems have been detected, investigators will need to interpret the meaning of the results in the context of the hospital (size, type of patient, level of complexity) and probe more deeply to uncover possible underlying causes. For example, the hospital indicator "expenditure on antimicrobial medicines as percentage of total hospital medicine costs" may show that antimicrobial medicines account for 80 percent of a hospital's budget. This level may seem excessive, but circumstances at the hospital may warrant such a high percentage. The cost of antimicrobial medicines in a pulmonary hospital with many TB cases would be high, whereas in a maternity hospital**,** it would probably be low. If the cost of antimicrobials is inappropriately high, it may be caused by several factors, including physicians using expensive, brand-name antimicrobials instead of generic products on the formulary list (FL); physicians treating the majority of patients with multiple antimicrobials when this treatment is not indicated; antimicrobials being procured at high cost because of poor procurement practices; or a combination of all these factors. Further analysis will therefore be needed to determine the root cause of the problem**.**

OBJECTIVES OF A HOSPITAL ANTIMICROBIAL USE STUDY

Hospital administrators, researchers, and DTCs will want to study antimicrobial use to—

- Describe antimicrobial prescribing practices
- Compare performance among hospitals or prescribers
- Monitor performance and orient supervision
- Assess changes resulting from interventions

After problems have been detected, investigators will decide whether further study is warranted to explore causes of the problems detected in the first round. These additional studies will explore areas such as—

- Antimicrobial selection procedures and criteria
- Antimicrobial use in specific wards or specialties or by individual prescribers
- Purchasing and financing of medicines and antimicrobials
- Comparison of antimicrobial use among hospitals

Investigators should clearly state why the study is needed and what is expected as the outcome. For example, hospital management may want to use the following wording: "Undertake a rapid, hospital-wide review of antimicrobial use and management to detect problem areas and assign responsibility for correction to the respective departments."

BACKGROUND OF MEDICINE USE INDICATORS

Medicine use indicators are standardized measurements of various aspects of hospital operations related to pharmaceutical management and use that can be compared to normative ranges to establish adequacy of performance or other diagnostic conditions. They may be quantitative or qualitative. To be useful, indicators should be—

Relevant—An indicator should reflect progress toward stated national or program goals, objectives, or standards.

Important—Each indicator must reflect an important dimension of performance. Even though data may be readily and consistently available, they may not say anything important about the system performance.

Measurable—Each indicator must be measurable within existing constraints of time and variable quality and availability of source data. Measuring antimicrobial prescribing practices retrospectively might be desirable, but if prescriptions are not written completely in clinical records, the indicator is not measurable.

Reliable—Each indicator must give consistent results over time and with different observers. If one observer reports a certain result from a set of data, it is expected that a second observer will report the same result.

Valid—Each indicator must allow a consistent and clear interpretation and have a similar meaning across different environments.

Action oriented—The data needed for an indicator should be useful for those doing the recording, whether they are physicians, pharmacists, nurses, or other staff; the data must lead to necessary action to improve use of medicines.

The indicators described in this manual are not all-inclusive—they do not measure every aspect of antimicrobial use in hospitals. Also, they are best understood as proposed, standardized measures of normative ranges because defined "cut-off points" between acceptable and unacceptable performance have not been established.

FORMAT OF THE MANUAL AND INDICATORS

The manual is divided into three main sections. The first describes the indicators for antimicrobial use and management according to a standard format. The second suggests procedures to apply the indicators in a hospital study. The third section consists of two annexes that provide all the necessary forms to conduct an indicator study. Annex A contains the forms with detailed instructions and examples of data collection, and Annex B provides all of the necessary blank forms for conducting a study.

The indicators developed for this manual follow the format summarized below.

Indicator Name: The complete name of the indicator.

Rationale: The reason this indicator is important.

Definition: The meaning of the indicator and the terms used to describe it.

Data Collection: The most likely source(s) of information are summarized in a table indicating *where* the data are to be collected, *whom* to ask for assistance, and *what* documents and records to review.

Brief discussions of methods and issues related to data collection.

Citations of the data collection forms to be used, if any. Data for 10 of the indicators are collected using five different forms. (See the discussion of how to develop the required forms in "How to Conduct an Antimicrobial Use Study" and examples in Annex A.)

Calculation: Calculations, if any, that are needed to derive the indicator.

Instrument: The specific data collection instrument and location of the data necessary to calculate the indicator.

Example: Example of the use or results of the indicator.

Notes: Suggestions for additional information or discussion required to put the indicator in proper context or to provide more detail.

ANTIMICROBIAL USE INDICATORS

Sixteen indicators related to antimicrobial use in hospitals are described in this section: 5 are hospital related, 9 are prescribing indicators, and 2 relate to patient care. A 17th supplemental indicator is related to drug sensitivity testing.

Hospital Indicators

Indicator 1. Existence of standard treatment guidelines (STGs) for infectious diseases

Indicator 2. Existence of an approved hospital formulary list or essential medicines list (EML)

Indicator 3. Availability of a set of key antimicrobials in the hospital stores on the day of the study

Indicator 4. Average number of days that a set of key antimicrobials is out of stock

Indicator 5. Expenditure on antimicrobials as a percentage of total hospital medicine costs

Prescribing Indicators

Indicator 6. Percentage of hospitalizations with one or more antimicrobials prescribed

Indicator 7. Average number of antimicrobials prescribed per hospitalization in which antimicrobials were prescribed

Indicator 8. Percentage of antimicrobials prescribed consistent with the hospital formulary list[*]

Indicator 9. Average cost of antimicrobials prescribed per hospitalization in which antimicrobials were prescribed

Indicator 10. Average duration of prescribed antimicrobial treatment

Indicator 11. Percentage of patients who receive surgical antimicrobial prophylaxis for cesarean section in accordance with hospital guideline

Indicator 12. Average number of doses of surgical antimicrobial prophylaxis prescribed for cesarean section procedures

Indicator 13. Percentage of patients with pneumonia who are prescribed antimicrobials in accordance with standard treatment guidelines

Indicator 14. Percentage of antimicrobials prescribed by generic name

[*] This may or may not be a part of the national essential medicines list or formulary list.

Patient Care Indicators

Indicator 15. Percentage of doses of prescribed antimicrobials actually administered

Indicator 16. Average duration of hospital stay of patients who receive antimicrobials

Supplemental Indicator

Indicator 17. Number of antimicrobial drug sensitivity tests reported per hospital admission with curative antimicrobials prescribed

Description of Hospital Indicators

Indicator 1. Existence of standard treatment guidelines for infectious diseases

Rationale

The existence of an STG for infectious diseases approved for use in the hospital is a measure of the hospital's commitment to standards of patient care and rational medicine use. This STG can be specifically for infectious diseases or part of a comprehensive STG provided by the hospital or adopted from provincial, regional, or national-level guidelines.

Definition

For purposes of this indicator, the STG must be intended as a clinical reference for prescribers and contain treatment protocols for the most frequent infectious diseases seen in the hospital. The latest revision must be no more than three years old.

Data Collection

Where to look	Whom to ask	What to get
Hospital director's office DTC Pharmacy	Hospital director Service chiefs DTC chair Pharmacist	Copy of STG

The STG must officially exist for this indicator to be meaningful. Obtain the most recent copy of the document evaluate whether they have been revised within three years and sanctioned by the hospital administration and/or the DTC.

Calculation

Record the existence of the STG and when it was last revised.

Instrument

The information for this indicator can be found on Instrument 1, questions 8, 9, and 10 (Annex A).

Example

Hospital Y has does not have STGs for infectious diseases. Physicians are free to prescribe antimicrobials based on their best judgment. Consequently, the hospital does not have a standard for physicians to follow and has difficulty in determining whether antimicrobials are being prescribed appropriately

Indicator 2. Existence of an approved hospital formulary list or EML

Rationale

The existence of a list of essential (antimicrobial) medicines selected using unbiased and evidence-based information in the hospital is a measure of the hospital's commitment to high-quality patient care and rational medicine use. The formulary list or EML ensures that only authorized antimicrobial medicines will be procured.

Definition

The formulary list or EML must be approved by hospital administration and/or the DTC and must be derived from the STG (if one exists) and be no more than two years old.

Data Collection

Where to look	Whom to ask	What to get
Hospital director's office DTC Pharmacy	Hospital director Service chiefs DTC chair Pharmacist	Copy of formulary list

The formulary list must officially exist for this indicator to be meaningful. Obtain the most recent copy and evaluate whether it has been revised within the past two years and sanctioned by the hospital administration and/or the DTC.

Calculation

Record the existence of the formulary list and when it was last revised and the number of generic antimicrobials on the formulary list (not counting formulations).

Instrument

The information for this indicator can be found on Instrument 1, questions 3, 4, 5, 6, and 7 (Annex A).

Example

Hospital Y has a formulary list approved by hospital administration that was revised within the last two years and is intended for use by physicians, nurses, and the pharmacy.

Indicator 3. Availability of a set of key antimicrobials in the hospital stores on the day of the study

Rationale

Rational prescribing is based on the availability of needed medicines. If key antimicrobial medicines are not present in hospital stores, patients may not receive the drug of choice for their infections or may receive no treatment at all, with risk of increased morbidity and mortality.

Definition

Indicator 3 measures the availability of key antimicrobials in the hospital and the management of hospital pharmacy medicine supply. The hospital must have a formulary list of key antimicrobial medicines authorized for use (see Indicator 2). If key antimicrobials are not defined by the hospital, they will need to be determined before using this indicator.

Data Collection

Where to look	Whom to ask	What to get
Hospital medical stores Hospital pharmacy	Manager Chief pharmacist	Hospital formulary list Generic and brand names of antimicrobial medicines on the formulary list Inventory records for study period

Calculation

Percentage, calculated by dividing the number of key antimicrobials actually in stock on that day by the number of key antimicrobials that should be available, multiplied by 100.

$$\frac{\text{Number of key antimicrobials actually in stock}}{\text{Number of key antimicrobials that should be available}} \times 100$$

Instrument

The necessary information is found on Instrument 7 (Annex A) and is calculated by adding the total numbers of entries in column 2 (current stock) that are more than 0 and then dividing by the total number of products in column 1.

Example

At hospital Z, only 75 percent of a set of key antimicrobials was available on the day of the study. The pharmacist indicated that because the drug budget was so low the hospital had decided to suspend purchase of the most expensive medicines, including five antimicrobials. The DTC conducted an ABC analysis and a VEN (vital, essential, and nonessential) analysis of all medicines and found that the hospital was purchasing quantities of intravenous solutions and analgesics (nonessential) because of their low cost and was not purchasing several vital medicines (including the expensive antimicrobials). The situation was explained to the hospital director and the suggestion was made that hospital purchasing policy consider the therapeutic importance of the medicines as well as their cost.

Indicator 4. Average number of days that a set of key antimicrobials is out of stock

Rationale

The average numbers of days that key antimicrobials are out of stock for the 12 months prior to the study is a measure of the availability of antimicrobial medicines. Other study periods can be used, but 12 months is recommended.

Definition

Indicator 4 measures the probability that any of the key antimicrobials were out of stock during the past year. The average number of days that antimicrobials are out of stock assesses a hospital's capacity to procure and distribute medicines and maintain a constant supply.

Data Collection

Where to look	Whom to ask	What to get
Hospital medical stores Hospital pharmacy	Manager Chief pharmacist	Inventory records for study period

Calculation

The average is calculated by dividing the sum of the number of days that each key antimicrobial is out of stock over a 12-month period (or for the defined study period) by the total number of key antimicrobials.

$$\frac{\text{Number of days that each key antimicrobial is out of stock}}{\text{Number of key antimicrobials in the review}}$$

Instrument

The information is found on Instrument 7 (Annex A) and is calculated by adding the total days out of stock in column 15, then dividing by the number of products in column 1.

Example

In hospital I, key antimicrobials were out of stock for an average of 66 days over the past 12 months. The acting manager of the hospital medical stores indicated that the purchasing department was ordering medicines only when inventory was completely depleted. When a permanent manager was hired, she applied good procurement practices, and percentage of time out of stock decreased to 28 days.

Note: This indicator measures an average of a "set" of key antimicrobials for the hospital. Individual hospitals may want to calculate, analyze, and present findings on individual antimicrobials (or other medicines) if they have sufficient time and staff to accomplish this task.

Indicator 5. Expenditure on antimicrobials as a percentage of total hospital medicine costs

Rationale

Medicine costs generally represent a major expense for hospitals and, as such, should be closely monitored. This indicator documents the cost of antimicrobials relative to other hospital medicine costs. High percentages may indicate prescribing of multiple antimicrobials, unjustified use of antimicrobials, or use of expensive, branded antimicrobials.

Ideally, medicine cost should be obtained from computerized records. If computerized records do not exist, a manual system can be used (review of purchase orders and procurement records using data collection forms provided in this manual), but it does involve a significant amount of labor to collect all of the necessary information. If cost data are not readily available, hospitals should consider deleting this indicator from the study.

Definition

Indicator 5 measures the relative expenditure on antimicrobials as a portion of all medicine costs.

Data Collection

Where to look	Whom to ask	What to get
Hospital pharmacy	Pharmacist	Records of all units of medicines received or purchased
Hospital medical stores	Manager	Price list Purchase orders

Calculation

Percentage is calculated by dividing the total cost of all antimicrobials purchased by the total cost of all medicines purchased and multiplying by 100.

$$\frac{\text{Total cost of all antimicrobials purchased}}{\text{Total cost of all medicines purchased}} \times 100$$

Instrument

The information is found on Instruments 4 and 6 (Annex A) and is calculated by adding the total costs of antimicrobials in column 2 on Instrument 6, dividing by the total purchase cost of all medicines from column 4 on Instrument 4, and multiplying by 100.

Example

In hospital M, antimicrobials account for 45 percent of all medicine costs. An investigation by the chief pharmacist showed that 25 percent of expenditures were for antimicrobials used in surgical prophylaxis. The DTC assisted prescribers in preparing STGs for surgical prophylaxis. After implementation of the STGs, the percentage of hospital medicine costs spent on antimicrobials fell by 10 percent.

Description of Prescribing Indicators

Indicator 6. Percentage of hospitalizations with one or more antimicrobials prescribed

Rationale

Antimicrobials used in hospitals for treating infections or for surgical prophylaxis are often used inappropriately. Such inappropriate use may result in prolonged morbidity, increased duration of therapy, and development of AMR.

Definition

Indicator 6 measures the extent of antimicrobial use in hospitals. When used over time, it allows observation of changes in trends. When combined with information collected for work on

Indicator 5, it will provide information on antimicrobial cost per hospitalization. It will give information on cost-effectiveness (e.g., if antimicrobial medicine cost per hospitalization goes down but antimicrobial prescribing remains constant, then cost of therapy has been reduced). The interpretation of the indicator will depend on the type of hospital and patients seen (e.g., psychiatric versus maternity versus infectious disease hospitals and patients). The indicator may provide valuable information on prescribing behavior by ward, specialty, or diagnosis.

Data Collection

Where to look	Whom to ask	What to get
Medical records department	Manager or clerk	Inpatient records (treatment charts, nurses' notes, doctors' notes)

Calculation

Percentage is calculated by dividing the number of patient hospitalizations during which one or more antimicrobials are prescribed by the total number of hospitalizations studied and multiplying by 100.

$$\frac{\text{Number of patient hospitalizations with one or more antimicrobials prescribed}}{\text{Total number of hospitalizations studied}} \times 100$$

Instrument

The information is found on Instrument 2 (Annex A) and is calculated by adding the total of *Y*s in column 3, dividing by the total number of patients in column 1, and multiplying by 100.

Example

In hospital B, one or more antimicrobials were prescribed in 47 percent of all hospitalizations. This was neither extremely high nor extremely low, so no further investigation was done.

Indicator 7. Average number of antimicrobials prescribed per hospitalization in which antimicrobials were prescribed

Rationale

Hospital patients may receive more than one antimicrobial during a hospitalization. This prescribing may be justified on clinical grounds but also may be the result of unnecessary combination antimicrobial therapy; duplication of medicines; or frequent, unjustified changes of therapeutic regimen. The purpose of this indicator is to determine the extent of antimicrobial use in hospitals for those patients prescribed antimicrobials.

Definition

Indicator 7 measures the average number of antimicrobials prescribed per hospitalization.

Data Collection

Where to look	Whom to ask	What to get
Medical records department	Manager or clerk	Inpatient records (treatment charts, nurses' notes, doctors' notes)

Calculation

The average is calculated by dividing the total number of antimicrobials prescribed for all hospitalizations by the total number of hospitalizations studied in which antimicrobials were prescribed. Different formulations of the same antimicrobial should be counted as one.

$$\frac{\text{Number of antimicrobials prescribed for all hospitalizations}}{\text{Total number of hospitalizations with antimicrobials prescribed}}$$

Instrument

The information is found on Instrument 2 (Annex A) and is calculated by dividing the total of column 11 by the total *Y*s of column 3.

Example

In hospital A, patients who are prescribed antimicrobials are prescribed an average of 2.3 antimicrobials per hospitalization. This rate is acceptable in most situations.

Indicator 8. Percentage of antimicrobials prescribed consistent with the hospital formulary list

Rationale

Formulary lists represent the medicines of choice for a hospital, as defined by the competent medical authority, and represent one way to optimize the use of medicines. Nonadherence to such hospital policy may be caused by prescribers not being aware of or in agreement with the list, listed antimicrobials not being available at the hospital, or prescriptions being listed with brand names while medicines are stocked and dispensed under generic names.

Definition

Indicator 8 measures the degree of prescriber adherence to the hospital formulary list. The formulary list is defined as the medicines approved by the DTC for purchase and prescribing in the hospital. If such a list does not exist, it will be necessary to refer to an EML provided by the ministry of health.

Data Collection

Where to look	Whom to ask	What to get
Hospital pharmacy	Chief pharmacist DTC secretary	Hospital formulary list
Medical records department	Manager or clerk	Inpatient records (treatment charts, nurses' notes, doctors' notes)

Calculation

Percentage is calculated by dividing the number of antimicrobials prescribed that are on the hospital formulary list by the total number of antimicrobials prescribed and multiplying by 100.

$$\frac{\text{Number of antimicrobials prescribed that are on the formulary list}}{\text{Number of antimicrobials prescribed}} \times 100$$

Instrument

The information is found on Instrument 2 (Annex A) and is calculated by adding the number of *Y*s in column 8, dividing by the total of column 6, and multiplying by 100.

Example

In hospital C, only 54 percent of antimicrobials prescribed were on the hospital formulary list. To the hospital DTC this percentage appeared to be low, and an assessment was done to examine the cause of non-adherence. The DTC found that prescribers were not in agreement with the list and preferred to use many nonformulary medicines in their prescriptions. The DTC undertook a program to develop treatment protocols in each service and ward, insisting that prescribers achieve a consensus on therapies and preferred medicines. The formulary list was revised, and prescribing adherence was monitored on a monthly basis with results prominently displayed. This program resulted in increased use of antimicrobials that were approved and on the formulary list.

Indicator 9. Average cost of antimicrobials prescribed per hospitalization in which antimicrobials were prescribed

Rationale

Antimicrobials typically account for 20 to 40 percent of hospital expenditures on medicines. Inappropriate treatment, such as prescribing more antimicrobials than recommended, prescribing higher doses or longer treatments than required, and prescribing brand-name instead of generic antimicrobials may increase costs. Determining the cost of antimicrobials used during a hospitalization may lead to interventions that decrease hospital expenditures on antimicrobials.

Definition

Indicator 9 measures the cost of antimicrobial therapeutic practices in the hospital. If the only antimicrobials administered in the hospital are those supplied by the hospital pharmacy, then the cost is defined as the most recent purchase price for the medicine. However, if the patient's family purchases antimicrobials on the street or if inflation creates large price movements, then the cost should be defined as the published prices to the public on the day of data collection. If the indicator is to be measured over time, prices must be standardized by an inflation factor.

Data Collection

Where to look	Whom to ask	What to get
Inpatient records (treatment charts, nurses' notes, doctors' notes) Hospital pharmacy	Chief pharmacist DTC secretary	Hospital formulary list Generic and brand names of medicines on the list
Medical records department	Manager or clerk	

Calculation

To find the average cost, divide the total cost of all antimicrobials prescribed by the number of hospitalizations in which at least one antimicrobial was prescribed.

$$\frac{\text{Cost of all antimicrobials prescribed}}{\text{Number of hospitalizations in which at least one antimicrobial was prescribed}}$$

Instrument

The information is found on Instrument 2 (Annex A) and is calculated by dividing the total cost in column 16 by the total *Y*s of column 3.

Example

A study of hospital L found that the average cost of antimicrobials prescribed per hospitalization was USD 123.00. Two years before, this indicator was calculated at USD 84.50. Investigation revealed that the hospital was using more costly sources of supply than in the past. Appropriate changes in supply sources were subsequently made to lower the average cost.

Indicator 10. Average duration of prescribed antimicrobial treatment

Rationale

The optimal duration of therapy for many bacterial infections has not been determined, but the current recommendation is usually 7–10 days of treatment. Longer treatment courses are recommended for some diseases, for example, meningitis for 14 days and osteomyelitis for up to six weeks. Too short a course of treatment may prolong patient morbidity and promote

emergence of drug-resistant organisms. Too long a course of therapy increases patient exposure to antimicrobials, increasing the risk of ADRs, of the incidence of AMR, and of unnecessary expenditure on antimicrobials. Frequent, unnecessary changes in antimicrobial therapy contribute to AMR, high costs, and increased patient morbidity.

Definition

Indicator 10 measures the intensity of patient exposure to antimicrobials during a hospitalization. It also assesses the length of time antimicrobials are prescribed. The number of days on antimicrobial treatment includes the number of days of all antimicrobials prescribed for a patient during the hospitalization and does not distinguish routes of administration or changes in dosage. This indicator measures the number of days of acute antimicrobial treatment for each generic antibiotic and does not include antimicrobials for prophylaxis. Hospitals may want to calculate a secondary indicator that includes the duration of antimicrobials prescribed for inpatients and the duration prescribed at discharge. This combined prescribing will provide the total duration of antimicrobial treatment.

Data Collection

Where to look	Whom to ask	What to get
Medical records department	Manager or clerk	Inpatient records (treatment charts, nurses' notes, doctors' notes)

Calculation

The average duration is calculated by dividing the total number of days of antimicrobial treatment by the total number of patients prescribed an antimicrobial.

$$\frac{\text{Total number of days on antimicrobial treatment}}{\text{Total number of patients prescribed an antimicrobial}}$$

Instrument

The information is found on Instrument 2 (Annex A) and is calculated by dividing the total number of days in column 10 by the total number of patients who were prescribed an antimicrobial in column 3.

Example

In hospital L, the average duration of prescribed antimicrobial treatment was 16.7 days. Because this duration of therapy is generally long for most antimicrobials according to recommendations, a more detailed analysis of medical records was undertaken. It was found that many patients were continued on antimicrobials for several days past standard recommendations and past the time that they were clinically cured. Discontinuing their antimicrobials may have been overlooked. The DTC was able to provide education to clinicians on treatment standards, including duration of treatment.

Indicator 11. Percentage of patients who receive surgical antimicrobial prophylaxis for cesarean section in accordance with hospital guideline

Rationale

Antimicrobial prophylaxis is recommended before certain surgical procedures and can decrease the incidence of infection, particularly surgical site infection. Studies have shown that surgical prophylaxis is often administered when there is no recognized indication for its use and frequently given with inappropriate antimicrobials for varying lengths of time. Unnecessary prophylaxis increases patient exposure to antimicrobials, likelihood of ADRs, and expenditure on antimicrobials, and it promotes the emergence of resistant organisms.

Definition

Indicator 11 measures whether the quality of patient care for surgical patients who require antimicrobial prophylaxis meets guidelines. If the hospital does not have a treatment guideline for surgical prophylaxis, then one can use provincial, regional, or national guidelines. If no other guidelines are available, then a reputable international guideline can be used. Examples include:

- Scottish Intercollegiate Guidelines Network (SIGN) (http://www.sign.ac.uk/guidelines/fulltext/104/index.html)

- National Institute for Clinical Excellence (NICE) (http://www.nice.org.uk/nicemedia/pdf/CG013fullguideline.pdf).

Patients with preexisting infections as indicated in the admission notes or diagnosis and patients with a high potential for infection, e.g., premature rupture of membranes (PROM) 6-12 hours (or more) before onset of labor, should be excluded from this indicator. These patients may require therapeutic treatment and not antimicrobial prophylaxis.

Data Collection

Where to look	Whom to ask	What to get
Operating theater	Nurse in charge	Records of surgical procedures performed on inpatients
Medical records department	Manager or clerk	Inpatient records (treatment charts, nurses' notes, doctors' notes)

Calculation

The percentage is the number of patients who receive surgical antimicrobial prophylaxis for cesarean section in accordance with hospital guidelines divided by the total number of patients who have cesarean section procedures, multiplied by 100.

$$\frac{\text{Number of patients receiving surgical antimicrobial prophylaxis for cesarean section in accordance with hospital guidelines}}{\text{Total number of patients with cesarean section procedures}} \times 100$$

Instrument

The information is found on Instrument 3 (Annex A) and is calculated by adding the total *Y*s of column 4, dividing by the total number of cesarean section procedures listed in column 2, and multiplying by 100.

Example

In hospital L, 12 percent of all patients who had a cesarean section surgery received antimicrobial prophylaxis in accordance with hospital guidelines. Many patients received multiple medicines and received multiple doses, and these were not administered at the appropriate time. The DTC investigated further and found that other surgical procedures were not following guidelines, or there were no guidelines to follow. The DTC revised the guidelines, and education was provided to the physicians. Three months later, the percentage of surgical patients receiving antimicrobial prophylaxis for cesarean section in accordance with guidelines had increased to 80 percent.

Note: Investigators are encouraged to review all surgical prophylaxis procedures to obtain more in-depth information on the use antimicrobials in surgical prophylaxis.

Indicator 12. Average number of doses of surgical antimicrobial prophylaxis prescribed for cesarean section procedures

Rationale

Antimicrobial prophylaxis is recommended before certain surgical procedures including cesarean section. For these procedures, the recommended regimen is generally one dose administered within one hour before the procedure. Some exceptions include adding doses to cover long procedures (Smaill and Hofmeyr 2002). However, studies have shown that surgical prophylaxis is often administered in many doses over several days. Excessive duration of prophylaxis increases patient exposure to antimicrobials, the likelihood of ADRs, and expenditure on antimicrobial medicines, and it promotes the emergence of resistant organisms.

Patients with preexisting infections as indicated in the admission notes or diagnosis and patients with a high potential for infection, e.g., PROM of 6–12 hours (or more) before onset of labor,

should be excluded from this indicator. These patients may require therapeutic treatment and not prophylaxis.

Definition

Indicator 12 measures the average number of doses of surgical antimicrobial prophylaxis given to patients who have a cesarean section procedure.

Data Collection

Where to look	Whom to ask	What to get
Operating theater	Nurse in charge	Records of cesarean section procedures performed on inpatients
Medical records department	Manager or clerk	Inpatient records (treatment charts, nurses' notes, doctors' notes)

Calculation

The average is the number of doses of cesarean section prophylaxis divided by the total number of patients who have a cesarean section procedure.

$$\frac{\text{Number of doses of surgical antimicrobial prophylaxis for cesarean section}}{\text{Total number of cesarean section procedures}}$$

Instrument

The information is found on Instrument 3 (Annex A) and is calculated by adding the total number of doses of column 5, then dividing by the total number of *Y*s for prophylaxis in column 3.

Example

In hospital L, the average number of doses given for surgical antimicrobial prophylaxis for cesarean section was 9.3. Guidelines usually recommend one dose; therefore, hospital L shows a high level of unnecessary medicine use and expenditure. In conducting a drug use review, the DTC found that antimicrobial prophylaxis was being given excessively. An algorithm to guide decisions on prophylaxis dosage was designed and implemented. Three months later, the average number of doses given for surgical patients receiving antimicrobial prophylaxis had decreased to 1.6.

Indicator 13. Percentage of patients with pneumonia who are prescribed antimicrobials in accordance with STGs

Rationale

Indicator 13 measures whether the quality of patient care for a common infectious disease meets treatment guidelines.

Definition

The compliance of prescribers with hospital treatment standards is defined by (a) use of *only* antimicrobials of choice as defined in the STG, and (b) observance of dosing indications for the same antimicrobials. The indicator can be evaluated only if STGs for infectious diseases exist in the hospital (see Indicator 1).

Data Collection

Where to look	Whom to ask	What to get
Medical records	Records manager or clerk	Inpatient records (treatment charts, nurses' notes, doctors' notes)
DTC office and/or hospital director's office	DTC chair; also service chiefs and/or hospital director	STG

Calculation

1. The percentage for (a) is calculated by dividing the number of patients with pneumonia treated only with antimicrobials contained in the hospital's STG by the total number of patients with pneumonia and multiplying by 100.

$$\frac{\text{Number of pneumonia patients treated only with antimicrobials per STG}}{\text{Total number of patients with pneumonia}} \times 100$$

2. The percentage for (b) is calculated by dividing the number of patients with pneumonia who were prescribed the correct dosage of the antimicrobial recommended in the STG by the total number of patients with pneumonia receiving the recommended antimicrobial according to the hospital's STG and multiplying by 100.

$$\frac{\text{Number of pneumonia patients prescribed correct dose of correct antimicrobial per STG}}{\text{Number of pneumonia patients who received the recommended antimicrobial per STG}} \times 100$$

Instrument

The information is found on Instrument 2 (Annex A) and is calculated by looking at each treatment for pneumonia shown by a *Y* in column 2 and comparing it with the STG. Percentages can then be calculated using the formulas under Calculations.

Example

In hospital H, 54 percent of pneumonia cases were treated only with the recommended antimicrobial according to the hospital's STG. Of these, 95 percent were prescribed the correct dose, according to the STG. The first percentage suggests that some prescribers either are not aware of the STG or are in willful noncompliance. However, of those prescribers who prescribe the recommended antimicrobial medicines, nearly all use the appropriate dose.

Indicator 14. Percentage of antimicrobials prescribed by generic name

Rationale

If health care providers prescribe by generic names instead of brand names, confusion is avoided about multiple names for the same product. This practice simplifies procurement and dispensing, thus facilitating generic substitution and improving hospital efficiency.

Definition

Indicator 14 measures the percentage of antimicrobials that are prescribed using their internationally recognized generic names, as identified in the WHO list of international nonproprietary names (INN) (WHO 2008). The availability of generically named medicines in the market and the information available to prescribers will influence the pattern observed. Although the INN is used as the "official" generic name for this indicator, in some countries, generic medicines may be available under both INN and other variations, such as U.S. Adopted Name (USAN) or British Approved Name (BAN). For example, the antihistamine chlorphenamine (INN) may be marketed as chlorpheniramine (USAN). In other countries, only the USAN or BAN generic product may be marketed. In such situations, any of the common generic names may be counted for purposes of this indicator.

Data Collection

Where to look	Whom to ask	What to get
Medical records department	Manager or clerk	Inpatient records (treatment charts, nurses' notes, doctors' notes)

Study organizers must develop a list of (or an explicit way of defining) the specific product names to be included as generic medicines. Usually, the generic names of medicines are identified on the national or hospital drug formulary list or the EML. Data collectors must be able to observe the actual names used to describe the medicines prescribed, as opposed to having

access only to the names of the products dispensed. Thus, the dispensing ledger (if there is one) may not be an accurate source for this indicator.

Calculation

The indicator is recorded as a percentage, computed by dividing the number of antimicrobials prescribed by generic name by the total number of antimicrobials prescribed, and multiplying this quotient by 100.

$$\frac{\text{Total number of antimicrobials prescribed by generic name}}{\text{Total number of antimicrobials prescribed}} \times 100$$

Instrument

The information is found on Instrument 2 (Annex A). The percentage is calculated by dividing the total *Y*s of column 7 by the total of column 6 and multiplying by 100.

Example

Hospital K completed an indicator study and found that 68 percent of medications were prescribed by their generic names. Many medicines were prescribed as a specific brand name when generic products were available. This practice resulted in a very high cost for the procurement of these branded products. The DTC counseled all clinicians to prescribe by generic name whenever possible, and a subsequent study showed that 91 percent of medicines were prescribed by their generic names. A substantial savings was realized in overall medicine costs.

Description of Patient Care Indicators

Indicator 15. Percentage of doses of prescribed antimicrobials actually administered

Rationale

To be effective, the doses of antimicrobials that are prescribed must be administered. Reasons medicines are not administered may include unavailability, dispensing errors, or nursing errors.

Definition

Indicator 15 measures the extent to which prescribed antimicrobials *actually* reach the patient in the dosages prescribed. The basic assumption is that administration of the medicine, no matter what its source (hospital pharmacy, patient's family), is recorded on the patient's treatment record or in nurses' notes. If this assumption is not true, the indicator cannot be calculated.

Data Collected

Where to look	Whom to ask	What to get
Medical records department	Manager or clerk	Inpatient records (treatment charts, nurses' notes, doctors' notes)

Calculation

The percentage is calculated by dividing the number of doses of antimicrobials administered by the total number of doses of antimicrobials prescribed and multiplying by 100.

$$\frac{\text{Number of doses of antimicrobials administered}}{\text{Total number of doses of antimicrobials prescribed}} \times 100$$

Instrument

The information is found on Instrument 2 (Annex A) and is calculated by dividing the total doses administered of column 14 by the total doses prescribed of column 13 and multiplying by 100.

Example

In hospital D, 80 percent of doses of prescribed antimicrobials were actually administered in the hospital. Investigation by the DTC revealed that doses were not given because nurses were often busy with other duties at the time the medication would have been administered. Some of the nurses' duties were reassigned to nurses' aides, and a study six months later showed that 90 percent of prescribed doses of antimicrobials were being administered.

Indicator 16. Average duration of hospital stay of patients who receive antimicrobials

Rationale

The length of treatment with antimicrobials should not exceed the recommended duration. If patients who receive antimicrobials do not improve within the recommended time, it is possible that the treatment is not appropriate or the diagnosis is incorrect. Prolonged hospital stay is costly, increases the risk to the patient of nosocomial infections, and promotes the emergence of organisms resistant to antimicrobials. If the hospital stay is too short, antimicrobial treatment may be ineffective because of subtherapeutic treatments, relapses, promotion of AMR, and finally, increased costs.

Definition

Indicator 16 measures the duration of hospital stay as an index of treatment effectiveness.

Data Collection

Where to look	Whom to ask	What to get
Medical records department	Manager or clerk	Inpatient records (treatment charts, nurses' notes, doctors' notes)

Calculation

The average is calculated by dividing the total number of days for all hospitalizations for patients treated with antimicrobial medicines by the number of patients treated with antimicrobials.

$$\frac{\text{Total number of days of hospitalization for patients receiving antimicrobials}}{\text{Number of patients receiving antimicrobials}}$$

Instrument

The information is found on Instrument 2 (Annex A) and is calculated by finding the total days in hospital of column 4 and dividing by the total *Y*s in column 3 (remembering that if no antimicrobial were given to a patient, this column should be blank).

Example

In hospital F, the average duration of stay for patients treated with antimicrobials was 7 days. According to recommendations, this duration was acceptable. However, further examination revealed that 10 percent of patients treated with antimicrobials stayed more than 30 days. These patients had numerous, unwarranted changes in antimicrobial therapy.

Description of Supplemental Indicator

Indicator 17 measures the degree of compliance with STGs (where these exist) and the use of antimicrobial drug sensitivity information (antibiograms or culture and sensitivity testing) for establishing appropriate treatments. Because not all hospitals have STGs or conduct sensitivity tests, this indicator is optional and may be used to supplement the information derived from the core indicators at hospitals where the necessary data are available.

Indicator 17. Number of antimicrobial drug sensitivity tests reported per hospital admission with curative antimicrobials prescribed

Rationale

The use of effective antimicrobial therapy depends on knowing the sensitivity of infectious microorganisms to possible therapeutic agents. The frequency of sensitivity tests performed is a measure of the hospital's ability to provide rational antimicrobial therapy.

Definition

Indicator 17 measures the availability of antimicrobial drug sensitivity information to determine optimal treatment of infections.

Prerequisites

A microbiology laboratory capable of cultivating specimens and testing for antimicrobial drug sensitivity is required. Reports from the laboratory indicating the results of sensitivity tests must be available in the patient's clinical history (CH) in order to calculate this indicator.

Where to look	Whom to ask	What to get
CH or laboratory	Manager or clerk Laboratory chief or technician	Reports of antimicrobial drug sensitivity tests performed

Calculation

Percentage is calculated by dividing the total number of sensitivity tests performed by the number of patients with antimicrobials prescribed.

$$\frac{\text{Number of patients with a sensitivity test performed}}{\text{Number of patients with curative antimicrobials prescribed}} \times 100$$

Patients receiving antimicrobials for prophylaxis must be excluded from this calculation.

Instrument

The information is found on Instrument 2 (Annex A) and is calculated by dividing the total *Y*s in column 5 by the total *Y*s of column 3 (that are curative and not prophylactic treatments) and multiplying by 100.

Example

In hospital J, one antimicrobial drug sensitivity test was performed for every 5.3 hospital admissions treated with curative antimicrobial medicines, or about 19 percent. After an intervention to improve bacteriology laboratory services, this indicator improved to 76 percent.

HOW TO CONDUCT AN ANTIMICROBIAL USE STUDY

Purpose and Design of the Study

Antimicrobial use studies serve one of the following four purposes—

1. A facility assessment to screen antimicrobial management and use in a hospital will assess facility-wide aspects of supply and distribution as well as overall cost of antimicrobials. Results may be disaggregated by ward or service. Multiple facilities may be compared.

2. Comparisons between groups or prescribers are generally cross-sectional surveys to compare prescribing and patient care between selected groups (wards, patients with specific diagnoses, etc.).

3. To monitor performance and orient supervision with regard to a norm or goal, selected indicators will be measured periodically in prospective, cross-sectional surveys to observe changes at facility, ward, or patient levels.

4. Assessments of changes resulting from interventions in control and intervention groups are similar to item 3 above but usually follow a before-after design.

An antimicrobial use study may be proposed by hospital management, the DTC, or individual investigators. Multifacility studies may be undertaken by ministries of health, nongovernmental organizations, or international organizations.

The agency sponsoring the study must determine the purpose of the study and assign a person or committee to develop an appropriate study design according to the objectives of the study, type of record-keeping system, availability of resources, and depth of information required, as suggested in Table 1.

Table 1. Basic Parameters of Different Types of Antimicrobial Use Studies

	Types of Antimicrobial Use Studies			
Parameters	**Facility Assessment**	**Service/ Prescriber Comparison**	**Monitoring and Supervision**	**Assess Intervention Impact**
Study objective	Screen for antimicrobial use/management problems	Detect antimicrobial over/underuse	Continuous observation of key problems	Determine whether an intervention achieved its objective
Number of prescribing encounters	100	100	Apply lot quality assurance system according to instruction in WHO 1993, Annex 4	100
Type of prescribing data	Retrospective, if possible, otherwise prospective	Retrospective or prospective	Prospective	Retrospective
Time frame for prescribing data (retrospective)	One year	One year	Days, weeks, or months	At least 4–6 months after intervention
Type of patient care data	Retrospective, if possible, otherwise prospective	Prospective	Prospective	Retrospective
Time frame for patient care data	One year	One year	Days or weeks	1–2 months after intervention
Type of hospital data	Retrospective purchasing and stocking data	Not applicable	Prospective purchasing and stocking data	Prospective purchasing and stocking data
Time frame for hospital data	One year	Not applicable	Weeks or months	At least 4–6 months after intervention

Source: Adapted from Table 4 in WHO 1993.

Design Criteria

1. *Hospital type and groups to study.* Antimicrobial use will vary depending on the size/type (general, teaching, number of beds) and location (urban, rural) of the hospital. Specialty hospitals (e.g., pediatric, cancer) also have expected patterns of antimicrobial use. Within a hospital, wards or services may be studied if disaggregation is necessary and, within these, patients with specific diagnoses, if warranted.

   In an initial antimicrobial use study, the whole hospital will likely be studied to determine whether problems exist, how significant they are, and where they appear to be located. In this

case, the sampling unit will be the hospital, and approximately 100 "usable" patient records will be studied, as suggested in Table 1.

2. *Retrospective versus prospective clinic records.* Generally, collecting retrospective data from a sample of patient records will be the quickest way to conduct a study. The principal concern in deciding for or against retrospective data collection is the availability and accessibility of medical records. Before actually undertaking the study, a preliminary review of patient records should be conducted to ensure that it is possible to extract the required information efficiently. The following questions should be answered during this review—

    - Is there a chronological list of patients from which the sample can be drawn?
    - Are the CHs reasonably complete with regard to diagnoses, medicine prescriptions, and medicine administration?
    - Are patient records available for study for the period of the investigation?
    - If prescribing information is kept in the pharmacy, can this information be linked with patient records?

    With this information, investigators can make an informed decision about the accessibility and usability of patient records and whether to adopt a retrospective or prospective design. If too many records must be discarded as unusable (30 percent or more), a prospective study may have to be conducted.

    Prospective data collection is also appropriate for measuring short-term changes in performance following an intervention. However, because prescribers and dispensers will be aware of the data collection, their behavior is likely to be influenced by the study, introducing bias.

3. *Data sources.* Two sources for collecting data are patient charts and hospital pharmacy and financial records.

    - *Patient charts*. A thorough understanding of the sections of the patient record (medical orders/prescribing page, physician notes, nurses' notes, treatment records, etc.) will be necessary because data may need to be collected from various sections of the patient chart.
    - *Hospital pharmacy and financial records.* These records can be explored both retrospectively and prospectively, and stocks can be examined at various points in the distribution chain.

    If the facility-wide antimicrobial use study reveals problems, these areas should be studied intensively, in which case the sampling unit may be the ward or service or a group of patients with the same diagnosis.

4. *Period of study.* A long study period will minimize biases caused by interruption of the medicine supply or seasonal outbreaks of febrile illnesses that may cause more antimicrobials to be prescribed than usual. In general, antimicrobial assessments should cover 12 consecutive months to ensure that any seasonal variations are taken into consideration. All data collectors should use the same 12-month period. Other study periods can be used, including 3 or 6 months. This largely depends on the record-keeping system available and the objectives of the study. If the study is prospective, the study period will probably be shorter, in the range of 1 to 3 months.

5. *Exclusions of antimicrobial classes.* The following drug classes are excluded from these indicator studies:

   - *Antituberculosis:* This group of antimicrobials is frequently used in high numbers and at high cost for long periods of time and frequently at separate, specialized hospitals. Including these antimicrobials would significantly affect the results of most indicators, making them difficult to analyze and impeding the ability to make decisions based on the results. Being consistent with this exclusion makes comparison with other hospitals more reliable. Not using this class of medicines is consistent with the WHO manual *How to Investigate Drug Use in Health Facilities*. Individual hospitals can make the decision to include these medicines if compelling reasons to do so exist and the objectives of the study are to analyze this class of medicines more closely. Ideally, they should be studied separately using the same indicators that are described in this manual.

   - *Antiretroviral drugs used for HIV:* This group of medicines should not be included for the same reasons described above for TB medicines. As with antituberculosis medicines, individual hospitals may make the decision to include this class of medicines in an indicator study if compelling reasons exist and the objectives of the study are to analyze these medicines more closely. Ideally, they should be studied separately.

6. *Studies in hospitals where there is a high incidence of malaria*. Medicines used to treat malaria are included in this indicator study. In some hospitals a high burden of malaria cases would affect the results of most indicators. In those hospitals, evaluators are encouraged to disaggregate the indicators and to describe results from antimalaria medicines and other antimicrobials separately.

Planning and Field Methods

1. *Preparation.* The first step is to inform hospital management of the study and obtain concurrence. Management will want to know why the study should be carried out, what the likely outcomes are, how long it will take, how much staff effort will be required, how much it will cost and where financing will come from, and finally, whether the study will interfere with usual operations. Investigators should ask for a meeting with the hospital director(s) and chiefs of services to explain these points and resolve questions.

When hospital management has authorized the study, investigators will have to decide the following details of the investigation.

- **Who**: The typical team would consist of a principal investigator (PI) and one or two data collectors who can be doctors, pharmacists, nurses, or students. The critical considerations for data collectors are (a) experience with the clinical record system, (b) knowledge of diseases and diagnoses, and (c) ability to interpret medicine names and dosages. At least one data collector should be familiar with pharmaceutical purchasing procedures and be responsible for this aspect of data collection.

- **How**: The data collection instruments are the basic tools for the study. They must be revised to reflect the technical and administrative conditions of the hospital and then reproduced in sufficient quantity. Also, a list should be prepared of antimicrobials available in the market, with generic and trade names and prices. The PI or data collectors can usually process the data manually with a calculator or, if a computer is available, with an electronic spreadsheet.

- **Where**: Define data collection sites—wards, statistics department, pharmacy, administration, and finance. It is also a good idea for the study to have an office or work space with desks and chairs.

- **When**: Develop a calendar of activities—training, data collection, critique, tabulation, and analysis. Allow about two days for training and a pilot trial, one week for data collection, three days for critique and tabulation of data, and two to three days for analysis and report writing.

- **What**: Inform hospital staff of the study and what will be required of them. Usually, the heaviest loads are on statistics and finance or accounting departments and on the pharmacy. Staff members will generally make records available to the data collectors, and the actual time needed to complete this task will depend on how well these departments are organized.

2. *Define a key set of antimicrobials.* This set may already have been defined by the formulary list, VEN analysis, or by other mechanisms. It should include antimicrobials that are considered essential and ones that have high use within the hospital.

3. *Draw the sample according to the following instructions*.

If the hospital cases are listed chronologically (the usual situation):

1. Select a 12-month period and count or sum how many patients were hospitalized during that period (e.g., 4,235).
2. Assume that you will randomly and systematically sample 100 cases. Divide the total number of cases in the 12-month period by 100. In the example, the result is 42.35. After rounding down to 42, the result will be the "sampling interval." That is to say, every 42nd clinical history (CH) will be examined for the study.
3. To start the sample, you need a random "entry number." For example, take the first digit of the serial number on a bill of currency. Say it is 8. Find the 8th CH for the selected 12-month period.
4. Now count CHs starting with the 8th, and select the 42nd as the first sampled CH. Count another 42 CHs and select that one. Continue counting and selecting until you have 100 CHs to be sampled.
5. Examine each selected case, and record the data on Instrument 2 for sampled cases.

If the cases are not listed chronologically and CHs are shelved in numerical order:

1. Locate the CHs having the same date as yesterday's, one year earlier.
2. Subtract the number of the first CH of that day a year ago from the last CH of yesterday (e.g., yesterday was November 4, 2007, and the last CH opened yesterday was number 12397). One year ago, the first CH on November 4 was number 10946. Subtracting this number from the former, the result is 1,451 CHs opened in one year.
3. Assume that 100 CHs from the last year are to be randomly and systematically sampled. Divide the 1,451 CHs from last year by 100; the result is 14.51. Round this number to the lower unit (i.e., 14). This gives the "sampling interval," which means that every 14th CH will be selected for examination.
4. To begin the sample selection, a random "index number" is needed. Take the first digit of the serial number on a bill of currency (e.g., 9). Now, add this number to the first CH from a year ago (10946) to produce the "entry number" (i.e., 9 + 10946 = 10955). Find the CH with this number. This will be the first CH in the sample.
5. To select the next case, add the interval number to the last case (i.e., 14 + 10955 = 10969). Examine this case and collect the appropriate data.
6. Repeat step 5 until all of the 100 cases have been sampled through yesterday's date.
7. Examine each selected case, and record the data on Instrument 2 for sampled cases.

If the cases are shelved in alphabetical order:

1. For each letter, pull all the cases opened with a date in the last 12 months (e.g., A = 47 cases). Compile and count all CHs pulled (e.g., 2,481).
2. Count all the CHs and divide by 100 to determine the "sampling interval" (e.g., 24.81).
3. Select a random "index number" as in step 4, above.
4. Beginning with the first CH pulled from letter "A," add the index number and select the CH of the patient. For example, if the index is 4, take the 4th case.
5. Count through the remaining CHs up to the "sampling interval" to select the next CH.
6. Repeat step 5 until all of the CHs pulled from last year have been sampled.
7. Examine each case, and record the data on Instrument 2 for sampled cases.

4. *Train data collectors*. Two days of training and practice are recommended, according to the following training schedule. Staff from statistics, accounting, and nursing departments should explain how their respective information systems record data, where the data are found, and how to interpret them.

Illustrative Training Plan

Day	Training Activities	Time
1 (a.m.)	Opening – introductions – approval and support of hospital management	1 hr
	Purpose of the study – sponsors Objectives of the training – master data collection instruments and data sources	
	Where to collect data – clinical records, pharmacy, accounting/finance	2 hr
	What to do if cases are incomplete or unusable, data are missing, etc.	1 hr
	Calendar of activities – data collection, critique, analysis, reporting	
(p.m.)	Overview of data collection forms	1 hr
	How to interpret and record diagnoses, drug names, dosages, and treatment regimens	
	Practice filling in the forms and conduct exercises with records containing missing or uninterruptable data	2 hr
2 (a.m.)	Conduct a pilot trial – sample 10 records from a different period (e.g., 2 years before) and collect per methodology and instruction	4 hr
(p.m.)	Debrief on pilot trial – critique and troubleshoot problems	2 hr
	Organize the data collection by distributing tasks among the team members	1 hr
	Hand out data collection instruments	

5. *Disseminate instructions for data collection instruments*. See Annex A for detailed instructions and filled-in sample data collection forms (Instruments 1–7) and Annex B for blank forms that may be copied.

   - Instrument 1: Basic Information
   - Instrument 2: Form to Record Antimicrobial Treatments
   - Instrument 3: Form to Record Surgical Prophylaxis
   - Instrument 4: Form to Record Medicine Purchases
   - Instrument 5: Antimicrobials Purchased
   - Instrument 6: Cumulative Purchase of Antimicrobials
   - Instrument 7: Availability of a Set of Key Indicator Antimicrobials and Time Out of Stock

   Annex A includes detailed instructions and examples for using each instrument. Each form has a note at the foot of the page that identifies the indicator(s) for which the data are

collected, as well as instructions to data collectors about how to record the data and process the information.

6. *Collect data*.

    a. Locate the data to be collected in the clinical records or accounting documents.

    b. Fill in forms. Trained data collectors will need to review available drug use data and complete data collection instruments 1–7. After data have been transcribed from sources, additional information (e.g., prices, generic names) will have to be entered to complete the forms.

    c. Supervise collection. The study supervisor or PI should observe data collectors periodically to ensure consistent interpretation and recording. This step is especially important during the first day of data collection.

7. *Critique data*. Distribute the forms among the team so that each person has the forms of another team member. Read through the recorded data to ensure completeness and coherency. A physician, nurse, or pharmacists with good clinical skills should review the forms for diagnostic and treatment data.

8. *Tabulate and process information.* The team will process the data following the instructions on each form and in Annex A. The initial procedures are primarily counts and sums with some rank ordering.

9. *Calculate and analyze indicators*. Each indicator is calculated according to the instructions given in the section of this guide titled "Antimicrobial Use Indicators." Most indicators are percentages or rates. Initial analysis of the indicators will be primarily subjective, since standards do not exist. Each DTC or hospital management will have to interpret the results in light of its own treatment and administrative norms and objectives.

10. *Prepare a report of results.* A brief written report is necessary to present the result to hospital administrators and the DTC. It will generally consist of a simple table or list. If comparative results are presented (e.g., between facilities or in a facility at different times), these should be displayed graphically using bar charts. The report may be presented for publication in house journals.

11. *Report to the hospital or service.* Call a meeting of hospital (or service) staff to present the study results. Time should be allowed for participants to understand the implications of the results for their work and discuss possible actions to improve antimicrobial medicine management. Discuss the results in a nonjudgmental way and ask participants for suggestions to explain unexpected results. Record the suggestions for the report to management and the hospital DTC.

12. *Prepare to report to the administrative level.* Invite all officials involved in drug use issues, including prescribers, nurses, pharmacy staff, and senior management, to meet and discuss

the study. Before the meeting, prepare and circulate the summary report with tables and graphs. Hospital management should receive the written report of results as well as the recommendations of hospital staff for remedial actions.

13. *Review with the administrative group the purpose of the study and present overall results*. If similar studies have been conducted elsewhere in the country or outside, compare results and conduct a discussion of similarities and differences. Explore the possibility of making the study an ongoing monitoring activity of the hospital within routine supervision activities. Record conclusions and decisions and define follow-up actions.

HOW MUCH TIME IS REQUIRED AND WHAT IS THE COST OF AN ANTIMICROBIAL INDICATOR STUDY?

The time to complete an antimicrobial indicator study will vary widely in hospitals and health care systems. The number of indicators chosen for the assessment, the state of the hospital information system, and availability and skill level of data collectors all need to be considered. A trial test of this antimicrobial indicator manual using all of the indicators listed required 1.5 person-months of effort. Typically, three people can collect data over three days, and an additional five days is required to review, analyze, validate, and make a detailed report on the findings.

The cost of a typical antimicrobial indicator assessment is primarily determined by staff time, as discussed above. The only other inputs are the photocopying of forms and reports, which costs less than USD 10.

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ANNEX A. DETAILED INSTRUCTIONS AND SAMPLE DATA FORMS

Instructions for Completing Instrument 1: Basic Information

This form is used for the following indicators:

Indicator 1. Existence of standard treatment guidelines (STGs) for infectious diseases

Indicator 2. Existence of an approved hospital formulary list or essential medicines list (EML)

Data collection summary:

Information for this form is collected from hospital management (e.g., director, chairman of DTC, finance manager) during interviews at the beginning of the study.

Instructions:

1. **Name of Unit:** Record the name of hospital and/or service.

2. **Data collector:** Record the name of the person collecting the data.

3. **Date:** Record the date on which the data are collected.

4. **Numbered Questions 1–16:** Answer each question with either *Y* (yes) or *N* (no) or the specific information requested. For question 2, the date of the last meeting of the DTC **must** be taken from the minutes of the meeting. If there are no minutes, there was no meeting. Be sure to ask for and collect copies of the formulary list and STGs or treatment protocol for pneumonia, if these exist.

Note: *All* spaces should be filled in on this data collection form. Enter *N/A* if data for a particular item is not available.

Instrument 1—SAMPLE

Basic Information

Name of unit: *General Hospital* Data collector: *John Thomas* Date: *March 2, 2008*

1. Does the hospital have a Drug and Therapeutics Committee? *yes*
2. If affirmative, when was the last meeting? *no minutes* [Review minutes, if any.]
3. Does the hospital have a formulary list or EML authorized for acquisition of medicines by the hospital? *yes*
4. Date of last revision of the formulary list or EML? *October 20, 2006*
5. If yes, how many antimicrobials are on the formulary list or EML? *18* [Request a copy of the list.]
6. Are all of the medicines on the formulary list or EML identified by generic name (INN)? *no*
7. Are the formulary or EML medicines based on those recommended in the STG? *No*
8. Does the hospital have standard treatment guidelines for infectious diseases for the most prevalent conditions? *no* For pneumonia? *yes* [Request a copy of the list.]
9. Date of last revision for STGs for infectious diseases: *January 2005*
10. How many infectious disease treatments are listed in the STGs? *4*
11. Does the hospital laboratory routinely perform antimicrobial drug sensitivity tests (antibiograms, cultures)? *no*
12. How many discharges did the hospital have during the last calendar year? *1,745*
13. How many surgical interventions were performed during the last calendar year? *239*
14. Does the hospital have protocols or norms for surgical prophylaxis with antimicrobials? *no*
15. How much did the hospital spend on medicines last year? *$110,000*
16. How much was budgeted or allotted for medicines by the hospital or Ministry of Health last year? *$19,200*

[Instrument 1 is used to collect information for Indicators 1 and 2.]

Instructions for Completing Instrument 2: Form to Record Antimicrobial Treatments

This form is used for the following indicators:

Indicator 6. Percentage of hospitalizations with one or more antimicrobials prescribed

Indicator 7. Average number of antimicrobials prescribed per hospitalization in which antimicrobials were prescribed

Indicator 8. Percentage of antimicrobials prescribed consistent with the hospital formulary list

Indicator 9. Average cost of antimicrobials prescribed per hospitalization in which antimicrobials were prescribed

Indicator 10. Average duration of prescribed antimicrobial treatment

Indicator 13. Percentage of patients with pneumonia who are prescribed antimicrobials in accordance with standard treatment guidelines

Indicator 14. Percentage of antimicrobials prescribed by generic name

Indicator 15. Percentage of doses of prescribed antimicrobials actually administered

Indicator 16. Average duration of hospital stay of patients who receive antimicrobials

Indicator 17. Number of antimicrobial drug sensitivity tests reported per hospital admission with curative antimicrobials prescribed

Data collection summary:

Information for this form is collected from the hospital clinical histories (CH) sampled. Each CH number is entered in column 1, and the CH is examined to determine whether an antimicrobial was prescribed. If not, enter *N* in column 3. If affirmative, enter the name of the antimicrobial in column 6, exactly as written in the prescription on the CH. If more than one antimicrobial was prescribed during the hospital stay, enter each one on a new line of the form. Then, for each antimicrobial prescribed, enter the remaining prescription information.

If an antimicrobial is prescribed for a patient (*Y* in column 3), then all remaining cells in the row should be filled in. If no antimicrobial was prescribed, leave columns 4–17 blank.

If the patient has tuberculosis and is being prescribed antituberculosis medicines, enter column 1 and 6 and put an asterisk (*) in the rest of the columns for all antituberculosis medicines.

If the patient has HIV and is being treated with antiretrovirals, enter column 1 and 6 and put an asterisk (*) in the rest of the columns for all antiretroviral medicines

Do not use this instrument for recording antimicrobial surgical prophylaxis, use Instrument 3.

Instructions:

1. **Name of unit:** Record the name of hospital and/or service.

2. **Data collector:** Record the name of the person collecting the data.

3. **Date:** Record the date on which the data are collected.

4. **Numbered columns:**

Column 1 Enter the serial number of the CH.
At the bottom of the column, total the number of clinical records entered.

Column 2 Was the patient diagnosed with pneumonia? Enter *Y* (yes) or *N* (no).
At the bottom of the column, total the number of *Y*s.

Column 3 Was an antimicrobial prescribed? Enter *Y* or *N*. At the bottom of the column, total the number of *Y*s.

Column 4 Enter the number of days spent in hospital between entry and discharge.
At the bottom of the column, total the number of days spent in hospital.

Column 5 Was sensitivity testing conducted? Enter *Y* if the patient had a sensitivity test, *N* if not. At the bottom of the column, total the number of *Y*s.

Column 6 Name of antimicrobial prescribed? Write the name of the antimicrobial exactly as it appears in the CH. At the bottom of the column, total the number of antimicrobials prescribed.

Column 7 Was an INN used? Enter *Y* or *N* according to whether the generic name was used. At the bottom of the column, total the number of *Y*s.

Column 8 Was the antimicrobial that was used on the formulary list? Enter *Y* or *N* according to whether the antimicrobial appears on the hospital formulary list by its generic name or INN. At the bottom of the column, total the number of *Y*s.

Column 9 Dosage form and strength. Enter tab, cap, amp, and so on, and mg/unit or ml.

Column 10 Days of treatment. Enter the number of days the dose was prescribed by looking at the start date and stop date for each antimicrobial given. At the bottom of the column, total the number of days.

Column 11 If the patient was given two different forms of the same generic (see columns 6 and 9), for example, an injection and capsules of ampicillin, then

the number of generics is only one, not two. Enter in this column each generic the patient received. At the bottom of the column, total the number of generics received.

Column 12 Dosage frequency. Enter the number of times the dosing unit was to be given each day.

Column 13 Doses prescribed. Figure the dosage per day by dividing dosage frequency in column 12 into 24 hours. Multiply the result by the corresponding number in column 10 (treatment days). At the bottom of the column, total the number of doses prescribed.

Column 14 Doses administered. Count the actual doses administered according to nursing records and enter in this column. At the bottom of the column, total the number of doses received.

Column 15 Unit cost. Enter the unit cost from column 4 of Instrument 5.

Column 16 Cost of prescribed treatment. Multiply column 13 by column 15 and enter the result. At the bottom of the column, total the treatment cost.

Column 17 Cost of administered (received) treatment. Multiply column 14 by column 15 and enter the result. At the bottom of the column, total the cost of treatment received.

Important Notes:

If an antimicrobial is prescribed for a patient (*Y* in column 3), then all remaining cells in the row should be filled in. If no antimicrobial was prescribed, leave columns 4–17 blank.

If the patient has tuberculosis and is being prescribed antituberculosis medicines, enter column 1 and 6 and put an asterisk (*) in the rest of the columns for antituberculosis medicines.

If the patient has HIV and is being treated with antiretrovirals, enter column 1 and 6 and put an asterisk (*) in the rest of the columns for antiretroviral medicines.

Do not use this instrument for recording antimicrobial surgical prophylaxis; use instrument 3.

Instrument 2—SAMPLE

Form to Record Antimicrobial Treatments

Name of unit: *General Hospital* Data collector: *John Thomas* Date: *March 2, 2008*

Patient Information				Antimicrobial Information												
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Clinical History No.	Pneumonia Case? (Y/N)	Was Antimicrobial Prescribed? (Y/N)	No. of Days in Hospital	Was Sensitivity Test Done? (Y/N)	Name(s) of Antimicrobial(s) Prescribed	INN Used? (Y/N)	Antimicrobial on FL? (Y/N)	Dosage Form and Strength	Total of Days of Treatment	No. Antimicrobials of Same Generic Type Prescribed	Dosage Frequency per Day	Doses Prescribed	Doses Administered	Unit Cost of Dose	Cost of Prescribed Treatment	Cost of Administered Treatment
216980	*N*	*Y*	*35*	*N*	*Ampicillin*	*Y*	*Y*	*Inj. 1gm*	*4*	*1*	*Every 6h*	*16*	*12*	*7,420*	*118,720*	*89,040*
	N				*Ampicillin*	*Y*		*Cap. 1gm*	*8*		*Every 6h*	*32*	*25*	*1,650*	*52,800*	*41,250*
217087	*N*	*Y*	*27*	*N*	*Gentamicin*	*Y*	*Y*	*Inj. 160mg*	*10*	*2*	*Every 8h*	*30*	*30*	*3,165*	*94,950*	*94,950*
	N				*Clindamycin*	*Y*	*N*	*Inj. 600mg*	*10*		*Every 8h*	*30*	*14*	*2,7320*	*819,600*	*382,480*
103899	*N*	*N*														
217288	*N*	*Y*	*28*	*N*	*Cefacin*	*N*	*N*	*Susp. 500mg*	*10*	*1*	*Every 8h*	*30*	*16*	*1,3160*	*394,800*	*210,560*
47854	*N*	*Y*	*5*	*N*	*Ampicillin*	*Y*	*Y*	*Inj. 1gm*	*2*	*1*	*Every 6h*	*8*	*8*	*7,420*	*59,360*	*59,360*
	N				*Ampicillin*	*Y*		*Cap. 1gm*	*8*		*Every 6h*	*32*	*22*	*1,650*	*52,800*	*36,300*
206041	*N*	*Y*	*	*N*	*Rifadin*	*N*	*Y*	*Cap. 600mg*	*	*	*	*	*	*	*	*
	N		*		*Isoniazid*	*Y*	*Y*	*Tab. 300mg*	*	*	*	*	*	*	*	*
216584	*N*	*N*														
114043	*N*	*Y*	*7*	*N*	*Ampicillin*	*Y*	*Y*	*Inj. 1gm*	*2*	*1*	*Every 6h*	*8*	*4*	*7,420*	*59,360*	*29,680*
	N				*Ampicillin*	*Y*	*N*	*Cap. 500mg*	*3*		*Every 6h*	*12*	*10*	*875*	*10,500*	*8,750*
49445	*N*	*Y*	*6*	*Y*	*Ampicillin*	*Y*	*Y*	*Inj. 1gm*	*2*	*1*	*Every 6h*	*8*	*8*	*7,420*	*59,360*	*59,360*
	N				*Ampicillin*	*Y*	*N*	*Cap. 500mg*	*4*		*Every 6h*	*16*	*12*	*875*	*14,000*	*10,500*
212646	*N*	*Y*	*18*	*Y*	*Cefacin*	*N*	*N*	*Tab.*	*4*	*1*	*Every 6h*	*16*	*8*	*3,601*	*57,616*	*28,808*

Patient Information				Antimicrobial Information												
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Clinical History No.	Pneumonia Case? (Y/N)	Was Antimicrobial Prescribed? (Y/N)	No. of Days in Hospital	Was Sensitivity Test Done? (Y/N)	Name(s) of Antimicrobial(s) Prescribed	INN Used? (Y/N)	Antimicrobial on FL? (Y/N)	Dosage Form and Strength	Total of Days of Treatment	No. Antimicrobials of Same Generic Type Prescribed	Dosage Frequency per Day	Doses Prescribed	Doses Administered	Unit Cost of Dose	Cost of Prescribed Treatment	Cost of Administered Treatment
								300mg								
217278	*N*	*Y*	*2*	*N*	*Ampicillin*	*Y*	*Y*	*Inj. 1 gm*	*1*	*1*	*Every 6h*	*4*	*2*	*7,420*	*29,680*	*14,840*
	N				*Ampicillin*	*Y*	*N*	*Cap. 500mg*	*7*	*1*	*Every 6h*	*28*	*16*	*875*	*24,500*	*14,000*
	N				*Gentamicin*	*Y*	*Y*	*Inj. 160mg*	*1*		*1*	*1*	*1*	*3,165*	*3,165*	*3,165*
218078	*N*	*Y*	*14*	*N*	*Ciprofloxacin*	*Y*	*N*	*Tab. 300mg*	*10*	*2*	*Every 12h*	*20*	*16*	*8,900*	*178,000*	*142,400*
	N				*Cefacin*	*N*	*N*	*Cap. 500mg*	*10*		*Every 8h*	*30*	*44*	*3,601*	*108,030*	*158,444*
218383	*N*	*Y*	*3*	*N*	*Ampicillin*	*Y*	*Y*	*Cap. 1gm*	*10*	*1*	*Every 6h*	*40*	*28*	*1,650*	*66,000*	*46,200*
134171	*N*	*Y*	*8*	*Y*	*Ciprofloxacin*	*Y*	*N*	*Tab. 300mg*	*10*	*1*	*Every 8h*	*30*	*42*	*8,900*	*267,000*	*373,800*
44370	*N*	*Y*	*10*	*N*	*Cefacin*	*N*	*N*	*Inj.1gm*	*2*	*1*	*Every 6h*	*8*	*8*	*16,395*	*131,160*	*131,160*
218789	*N*	*Y*	*3*	*N*	*Ampicillin*	*Y*	*Y*	*Inj. 1gm*	*9*	*1*	*Every 6h*	*36*	*24*	*7,420*	*267,120*	*178,080*
192679	*N*	*Y*	*4*	*N*	*Ciprofloxacin*	*Y*	*N*	*Tab. 300mg*	*4*	*1*	*Every 12h*	*8*	*8*	*8,900*	*71,200*	*71,200*
Total Cases	Total *Y*s	Total *Y*s	Total Days	Total *Y*s	Total	Total *Y*s	Total *Y*s	—	Total Days	Total Generics	—	Total Doses	Total Doses	—	Total Cost	Total Cost
17	*0*	*15*	*170*	*3*	*24*	*19*	*11*		*131*	*17*		*443*	*358*		*2,939,721*	*2,184,327*

[Instrument 2 is used to collect information for Indicators 6, 7, 8, 9, 10, 13, 14, 15, 16, and 17.]

Notes: No. = number, Y = Yes, N = No, INN = international nonproprietary name, FL = formulary list, h = hours, * = TB treatment provided by central Ministry of Health program, Inj. = injection, Cap. = capsule, Susp. = suspension, Tab. = tablet.

Instructions

Column 1	Enter the serial number of the clinical history (CH). At the bottom of the column, total the number of clinical records entered.
Column 2	Was the patient diagnosed with pneumonia? Enter *Y* (yes) or *N* (no). At the bottom of the column, total the number of *Y*s.
Column 3	Was an antimicrobial prescribed? Enter *Y* or *N*. At the bottom of the column, total the number of *Y*s.
Column 4	Enter the number of days spent in hospital between entry and discharge. At the bottom of the column, total the number of days spent in hospital.
Column 5	Was sensitivity testing conducted? Enter *Y* if the patient had a sensitivity test, *N* if not. At the bottom of the column, total the number of *Y*s.
Column 6	Name of antimicrobial? Write the name of the antimicrobial exactly as it appears in the CH. At the bottom of the column, total the number of antimicrobials prescribed.
Column 7	Was an INN used? Enter *Y* or *N* according to whether the generic name was used. At the bottom of the column, total the number of *Y*s.
Column 8	Was the antimicrobial that was used on the formulary list (FL)? Enter *Y* or *N* according to whether the antimicrobial appears on the hospital FL by its generic name or INN. At the bottom of the column, total the number of *Y*s.
Column 9	Dosage form and strength. Enter tab, cap, amp, and so on, and mg/unit or ml.
Column 10	Days of treatment. Enter the number of days the dose was to be given by looking at the start date and stop date for each antimicrobial. At the end of the column, total the number of days.
Column 11	If the patient was given two different forms of the same generic (see columns 6 and 9), for example, an injection and capsules of ampicillin, then the number of generics is only one, not two. Enter in this column each generic the patient received. At the bottom of the column, total the number of generics received.
Column 12	Dosage frequency. Enter the number of times the dosing unit was to be given each day.
Column 13	Doses prescribed. Figure the dosage per day by dividing dosage frequency in column 12 into 24 hours. Multiply the result by the corresponding number in column 10 (treatment days). At the bottom of the column, total the number of doses prescribed.
Column 14	Doses administered. Count the actual doses administered according to nursing records and enter in this column. At the bottom of the column, total the number of doses received.
Column 15	Unit cost. Enter the unit cost from column 4 of Instrument 5.
Column 16	Cost of prescribed treatment. Multiply column 13 by column 15 and enter the result. At the bottom of the column, total the treatment cost.
Column 17	Cost of administered (received) treatment. Multiply column 14 by column 15 and enter the result. At the bottom of the column, total the cost of treatment received.

Calculation of Indicators:

Indicator 6 = Add the total *Y*s of column 3, divide by the total number of patients in column 1, and multiply by 100. In the example, 15/17 × 100 = 88%.

Indicator 7 = Add the total of column 11 and divide by the total of *Y*s in column 3. In the example, 17/15 = 1.1.

Indicator 8 = Add the total *Y*s of column 8, divide by the total of column 6, and multiply by 100. In the example, 11/24 × 100 = 46%.

Indicator 9 = Add the total costs of column 16 and divide by the total *Y*s of column 3. In the example, 2,939,721/15 = 195,981.

Indicator 10 = Add the total of column 10 and divide by the total of column 3. In the example, 131/15 = 8.7.

Indicator 13 = Add at the *Y*s in column 2 and compare with the STG for (1) choice of antibiotic and (2) dosage.

Indicator 14 = Add the total *Y*s of column 7, divide by the total of column 6, and multiply by 100. In the example, 19/24 × 100 = 79%.

Indicator 15 = Add the total of column 14, divide by the total of column 13, and multiply by 100. In the example, 358/443 × 100 = 81%.

Indicator 16 = Add the total of column 4 and divide by the total *Y*s of column 3 (remembering that if no antimicrobials were given this column should be blank). In the example 170/15 = 11.3.

Indicator 17 = Add the total *Y*s of column 5, dividing by the total *Y*s of column 3 (that are curative), and multiply by 100. In the example, 3/15 × 100 = 20%.

Important Notes: If an antimicrobial is prescribed for a patient (*Y* in column 3), then all remaining cells in the row should be filled in. If no antimicrobial was prescribed, leave columns 4–17 blank.

If the patient has tuberculosis and is being prescribed antituberculosis medicines, enter column 1 and 6 and put an asterisk (*) in the rest of the columns for antituberculosis medicines.

If the patient has HIV and is being treated with antiretrovirals, enter column 1 and 6 and put an asterisk (*) in the rest of the columns for antiretroviral medicines.

Do not use this instrument for recording antimicrobial surgical prophylaxis; use Instrument 3.

Instructions for Completing Instrument 3: Form to Record Surgical Prophylaxis

This form is used for the following indicators:

Indicator 11. Percentage of patients who receive surgical antimicrobial prophylaxis for cesarean section in accordance with hospital guideline

Indicator 12. Average number of doses of surgical antimicrobial prophylaxis prescribed for cesarean section

Data collection summary:

Information for this form is collected from the surgical theater records for the last year (or other study period).

Instructions:

1. **Name of unit:** Record the name of hospital and/or service.

2. **Data collector:** Record the name of the person collecting the data.

3. **Date:** Record the date on which the data are collected.

4. **Numbered columns:**

   Column 1 Clinical history (CH) number.

   Column 2 Surgical procedure: Transcribe the name of the procedure from records.

   Column 3 Prophylaxis: Indicate whether antimicrobial prophylaxis was prescribed by entering *Y* (yes) or *N* (no).

   Column 4 Indicate whether antimicrobial prophylaxis for cesarean section is in accordance with hospital guideline.

   Column 5 Antimicrobial prescribed: Transcribe the name, form, dosage, and strength from the record.

   Column 6 Number of antimicrobial doses prescribed: Transcribe the number of doses from the record.

Note: In some cases, the form and strength of the antimicrobial may not be shown on surgical records. Record only the antimicrobial name.

Instrument 3—SAMPLE

Form to Record Cesarean Section Surgical Prophylaxis

Name of unit: *General Hospital* Data collector: *John Thomas* Date: *March 2, 2008*

1	2	3	4	5	6
CH No.	**Surgical Procedure**	**Prophylaxis (Y/N)**	**Surgical Antimicrobial Prophylaxis for Cesarean Section in Accordance with Hospital Guidelines (Y/N)**	**Antimicrobial Prescribed (Name, Dosage Form, and Strength)**	**Number of Doses**
216930	*Cesarean section*	*Y*	*N*	*Ceftriaxone 1g*	*12*
478514	*Cesarean section*	*Y*	*Y*	*Ampicillin inj. 1g*	*3*
494415	*Cesarean section*	*Y*	*N*	*Ampicillin cap. 500 mg*	*21*
217278	*Cesarean section*	*Y*	*Y*	*Ampicillin inj. 1g*	*3*
139030	*Cesarean section*	*Y*	*N*	*Ampicillin 1 gm* *Gentamicin inj. 160mg*	*3* *3*
Total 5		5	2		45

[Instrument 3 is used to collect information for Indicators 11 and 12.]

Notes: A dash (—) indicates that no antimicrobial was prescribed. CH = clinical history, No. = number, Y = yes, N = no, Inj. = injection, Cap. = capsule, Tab. = tablet.

Instructions:

1. Record in column 1 the number of each CH for which a cesarean section surgical procedure was performed.
2. Enter in column 2 the name of the surgical procedure.
3. Verify carefully whether antimicrobial prophylaxis was prescribed and enter *Y* or *N* in column 3.
4. Determine if antimicrobial prophylaxis for cesarean section is in accordance with hospital guidelines.
5. Record which antimicrobials were prescribed (name, form, and strength) in column 5.
6. Record the number of doses in column 6.
7. Patients with preexisting infections as indicated in the admission notes or diagnosis and patients with a high potential for infection, e.g., premature rupture of membranes (PROM) 6-12 hours (or more) before onset of labor, should be excluded from this indicator study.

Calculations:

Indicator 11 = Add the total of *Y*s in column 4, divide by the total number of cesarean section procedures listed in column 2, and multiply by 100. In the example, 2/5 × 100 = 40%.

Indicator 12 = Add up the total in column 6 and divide by total of *Y*s in column 3. In the example, 45/5 = 9.

Instructions for Completing Instrument 4: Form to Record Medicine Purchases

This form is used for the following indicator:

Indicator 5. Expenditure on antimicrobials as a percentage of total hospital medicine costs

Data collection summary:

Information for this form is collected from the medicine purchase records for the last year (or other study period). The value of all medicine purchases must be calculated for the year. If accounting records are computerized, merely consult the account for medicine purchases and record the total on the last line of column 4 (the actual detail of purchases is not necessary). If medicine purchases are not conveniently accounted for and totaled for the year, it will be necessary to record information from each invoice according to the instructions below.

Instructions:

1. **Name of unit:** Record the name of hospital and/or service.

2. **Data collector:** Record the name of the person collecting the data.

3. **Date:** Record the date on which the data are collected.

4. **Numbered columns:**

Column 1	Invoice number. Record from the source document.
Column 2	Supplier. Record the name of the laboratory or distributor as it appears on the invoice.
Column 3	Date of purchase. Record dd/mm/yy.
Column 4	Cost of purchase. Review the invoice to ensure that only medicines are billed. Record the total billed in local currency, subtracting any nonmedicine items from the total.

Note: Only the total spent on medicines is of interest. The detail of purchases is not important.

Instrument 4—SAMPLE

Form to Record Medicine Purchases

Name of unit: *General Hospital* Data collector: *John Thomas* Date: *March 2, 2008*

1	2	3	4
Invoice No.	**Supplier**	**Date of Purchase**	**Cost of Purchase**
0012-99	*Pharma Inc.*	*15/03/07*	*154.20*
5498-1527	*LIFF*	*21/05/07*	*1,008.34*
99-000345	*Rhone-Poulenc*	*13/07/07*	*254.96*
0047-99	*Pharma Inc.*	*29/08/07*	*382.67*
			Total: *1,800.17*

[Instrument 4 is used to collect information for Indicator 5. (Instrument 6 is also necessary to calculate this indicator.)]

Instructions:

1. Collect invoices for all medicine purchases during the past year (or other study period). Record the number of the invoice, name of the supplier, date of the invoice, and total amount billed for medicines in columns 1 to 4.

2. Add the amounts billed for all medicine purchases and enter in the last row of column 4.

Instructions for Completing Instrument 5: Antimicrobials Purchased

This form is used for the following indicator:

Indicator 9. Average cost of antimicrobials prescribed per hospitalization in which antimicrobials were prescribed

Data collection summary:

Information for this form is collected from the medicine purchase invoices for the last year (or other study period). However, if unit cost information is available for the antimicrobials from accounting or pharmacy, it can be entered directly without consulting the source documents (invoices).

Instructions:

1. **Name of unit:** Record the name of hospital and/or service.

2. **Data collector:** Record the name of the person collecting the data.

3. **Date:** Record the date on which the data are collected.

4. **Generic name of the antimicrobial:** For each block of data, enter the INN of a single active antimicrobial ingredient (e.g., gentamicin).

5. **Numbered columns:** For each purchase of a given active ingredient, enter—

   Column 1 Brand name. If medicine was billed by brand name, enter it here.

   Column 2 Dosage form and strength. Record the pharmaceutical form, e.g., tab, cap, syr, etc., and strength.

   Column 3 Dispensing unit. Enter the dispensing unit of the product, e.g., blis, bot, tab.

   Column 4 Unit cost. Record the cost per dispensing unit in local currency.

   Column 5 Quantity. Fill in the total number of dispensing units purchased.

   Column 6 Total cost. Multiply unit cost (column 4) by quantity (column 5), and enter the result. Enter the total cost of antimicrobials in column 6 in the last cell of the last row.

Instrument 5—SAMPLE

Antimicrobials Purchased

Name of unit: *General Hospital* Data collector: *John Thomas* Date: *March 2, 2008*

Generic name of the antimicrobial: *AMPICILLIN*

1	2	3	4	5	6
Generic or Brand Name	**Dosage Form and Strength**	**Dispensing Unit**	**Unit Cost**	**Quantity**	**Total Cost**
Ampibex	*Tab 500 mg*	*Tab*	*3*	*1,000*	*3,000*
Ampicillin MK	*Inj 1,000 mg*	*Ml*	*35*	*100*	*3,500*
Binotal	*Tab 500 mg*	*Tab*	*28*	*1,000*	*28,000*
				Total Cost of Antimicrobials:	*34,500*

Generic name of the antimicrobial: *GENTAMICIN*

1	2	3	4	5	6
Generic or Brand Name	**Dosage Form and Strength**	**Dispensing Unit**	**Unit Cost**	**Quantity**	**Total Cost**
Gentamicin MK	*Inj 40 mg/ml*	*Ml*	*9*	*1,000*	*9,000*
Gentibex	*Cap 500 mg*	*Cap*	*89*	*50*	*4,450*
				Total Cost of Antimicrobials:	*13,400*

[Instrument 5 is used to collect information to perform ABC analysis by active ingredient and to collect information for Instruments 2 and 6 and Indicator 9.]

Instructions:

Use one block for each active antimicrobial ingredient, and record one purchase on each line. Record for each antimicrobial purchase the generic or brand name, form and strength, dispensing unit, and the value of each purchase.

Instructions for Completing Instrument 6: Cumulative Purchase of Antimicrobials

This form is used for the following indicator:

Indicator 5. Expenditure on antimicrobials as a percentage of total hospital medicine costs

Data collection summary:

Information for this form is a ranked summary of information from Instrument 5. Begin by ranking each active antimicrobial ingredient (i.e., a single generic name) listed in Instrument 5 according to the total cost (i.e., last cell of column 6). Then, enter the antimicrobials in descending order of value, one on each line of this instrument. Finally, calculate the total cost of antimicrobials purchased and the percentage of the total contributed by each antimicrobial.

Instructions:

1. **Name of unit:** Record the name of hospital and/or service.

2. **Data collector:** Record the name of the person collecting the data.

3. **Date:** Record the date on which the data are collected.

4. **Numbered columns:**

   Column 1 Generic name. Enter generic name in descending order of value per Instrument 5.

   Column 2 Total cost of antimicrobials. Transcribe the last cell of column 6 from Instrument 5. When all antimicrobials are entered, total this column in the last row (Total).

   Column 3 Percentage of total. Divide each cell in column 2 by the total, multiply by 100, and enter the percentage for each antimicrobial.

   Column 4 Cumulative percentage. Enter the first percentage of the total in row 1 in column 4. Add the next percentage in column 3 to the percentage from the previous line in column 4 and enter. Repeat for each row.

Note: The result in column 4 is an ABC analysis of antimicrobial purchases and provides insights into antimicrobial purchasing behavior by the hospital.

Instrument 6—SAMPLE

Cumulative Purchase of Antimicrobials

Name of unit: *General Hospital* Data collector: *John Thomas* Date: *March 2, 2008*

1 Generic Name of Antimicrobial	2 Total Cost of Antimicrobial	3 Percentage of Total	4 Cumulative Percentage
Ampicillin	*34,500*	*35.8*	*35.8*
Gentamicin	*13,450*	*13.9*	*49.7*
Cephaloxicin	*12,835*	*13.3*	*63.0*
Amoxicillin	*11,419*	*11.8*	*74.8*
Co-trimoxazole	*9,876*	*10.2*	*85.0*
Penicillin v	*8,943*	*9.3*	*94.3*
Benzylmethyl penicillin	*5,471*	*5.7*	*100*
	Total: *96,494*		

[Instrument 6 is used to collect information for Indicator 5.]

Instructions:

1. Rank antimicrobials (high to low) by Total Cost of Antimicrobial (Instrument 5).

2. Total all purchases of antimicrobials (add numbers in column 2), calculate the percentage that each active ingredient represents of the total, and enter in column 3.

3. Add each percentage to the cumulative percentage in column 4.

Instructions for Completing Instrument 7: Availability of a Set of Key Antimicrobials and Time Out of Stock

This form is used for the following indicators:

Indicator 3. Availability of a set of key antimicrobials in the hospital stores on the day of the study

Indicator 4. Average number of days that a key set of antimicrobials is out of stock

Data collection summary:

Information for this form is collected from the pharmacy and/or medicines storage facility of the hospital. For each antimicrobial, the stock currently on hand is counted and entered. Then, the stock register (Kardex, computer, bin cards) is consulted for each of the previous 12 months (other study period) and the number of days counted for which there was zero stock of unexpired antimicrobial. The total of days out of stock for the prior 12 months is entered in the last column.

Instructions:

Name of unit: Record the name of hospital and/or service.

Data collector: Record the name of the person collecting the data.

Date: Record the date on which the data are collected.

Numbered columns:

Column 1	Product: Record the generic name, dosage form, and strength of each key antimicrobial on the hospital formulary list (use key antimicrobials that have been approved by the DTC or other authority for this study).
Column 2	Current Stock: Count the dispensing units currently on hand and enter.
Columns 3–14	Days Out of Stock: Enter the count of days in each month in which the stock of unexpired product was zero, beginning with the last month (M1) and working back through the 12 previous months (or other study period). If there was stock all month long, enter zero (0). If stock goes to zero on a given day, add that day and any other day during the month with no stock to obtain the total number of days out of stock for that month, e.g., for zero stock on April 4 and this remains zero through the end of the month enter 27 (3 days of the month had stock and the remaining 27 days had no stock). If there is zero stock for the whole month, enter the number of days in the month, e.g., May = 31.
Column 15	Total Days Out of Stock: Add the days out of stock during the 12 months, M1 through M12.

Note: Stock that is on hand *but expired* is not counted for this indicator. *All* blanks should be filled in on this data collection form. Enter zero (0) if counts are nil or N/A if data for a particular item is not available.

Instrument 7—SAMPLE

Availability of a Set of Key Antimicrobials and Time Out of Stock

Name of unit: *General Hospital* Data collector: *John Thomas* Date: *March 2, 2008*

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
		Days Out of Stock												
Product (Generic Name, Form, and Strength)	**Current Stock**	**M1 Last month**	**M 2**	**M 3**	**M 4**	**M 5**	**M 6**	**M 7**	**M 8**	**M 9**	**M10**	**M11**	**M12**	**Total Days Out of Stock**
Ampicillin tab 500mg	*960*	*0*	*0*	*0*	*0*	*7*	*15*	*0*	*0*	*0*	*0*	*0*	*0*	*22*
Ampicillin cap 2000mg	*34*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*12*	*0*	*0*	*0*	*12*
Amoxicillin cap 250 mg	*150*	*0*	*0*	*31*	*30*	*31*	*31*	*7*	*0*	*0*	*0*	*0*	*0*	*130*
Amoxicillin cap 1gm	*0*	*31*	*30*	*31*	*30*	*31*	*31*	*7*	*0*	*0*	*0*	*0*	*0*	*191*
Gentamicin cap 250mg	*453*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Gentamicin cap 1gm	*54*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*5*	*30*	*6*	*0*	*41*
														Total: *396*

[Instrument 7 is used to collect information for Indicators 3 and 4.]

Instructions:

1. Review the stock sheet for each essential or referenced antimicrobial. Record the current stock quantity in column 2 and then, for each month, record the number of days for which the product was out of stock, starting with last month and working backward.

2. Add the number of days out of stock for each month and enter the total in the last column.

Calculations:

Indicator 3 = Add the total numbers of entries in column 2 that are more than 0 and divide by the number of products in column 1.

Indicator 4 = Add the total numbers of entries in column 15 and divide by the number of products in column 1.

ANNEX B. BLANK DATA COLLECTION FORMS

Instrument 1

Basic Information

Name of unit: _____ Data collector: _____ Date: _____

1. Does the hospital have a Drug and Therapeutics Committee? _____
2. If affirmative, when was the last meeting? _____ [Review the minutes.]
3. Does the hospital have a formulary list or EML authorized for acquisition of medicines by the hospital? _____
4. Date of last revision of the formulary list or EML? _____
5. If yes, how many antimicrobials are on the formulary list or EML? _____ [Request a copy of the list.]
6. Are all of the medicines on the formulary list identified by generic name (INN)? _____
7. Are the formulary or EML medicines based on those recommended in the STG? _____
8. Does the hospital have standard treatment guidelines (STGs) for infectious diseases for the most prevalent conditions? _____ For pneumonia? _____ [Request a copy.]
9. Date of last revision of the STGs for infectious diseases? _____
10. How many infectious disease treatments are listed in the STGs? _____
11. Does the hospital laboratory routinely perform antimicrobial drug sensitivity tests (antibiograms, cultures)? _____
12. How many discharges did the hospital have during the last calendar year? _____
13. How many surgical interventions were performed during the last calendar year? _____
14. Does the hospital have protocols or norms for surgical prophylaxis with antimicrobials? _____
15. How much did the hospital spend on medicines last year? _____
16. How much was budgeted or allotted for medicines by the hospital or Ministry of Health last year?

[Instrument 1 is used to collect information for Indicators 1 and 2.]

Instrument 2

Form to Record Antimicrobial Treatments

Name of unit: _____ Data collector: _____ Date: _____

Patient Information				Antimicrobial Information												
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Clinical History No.	Pneumonia Case? (Y/N)	Was Antimicrobial Prescribed? (Y/N)	No. of Days in Hospital	Was Sensitivity Test Done? (Y/N)	Name(s) of Antimicrobial(s) Prescribed	INN Used? (Y/N)	ntimicrobial on FL? (Y/N)	Dosage Form and Strength	Total Days of Treatment	No. Antimicrobials of Same Generic Type Prescribed	Dosage Frequency per Day	Doses Prescribed	Doses Administered	Unit Cost of Dose	Cost of Prescribed Treatment	Cost of Administered Treatment
Total Cases	Total *Y*s	Total *Y*s	Total Days	Total *Y*s	Total	Total *Y*s	Total *Y*s	___	Total Days	Total Generics	___	Total Doses	Total Doses	__	Total Cost	Total Cost

[Instrument 2 is used to collect information for Indicators 6, 7, 8, 9, 10, 13, 14, 15, 16, and 17.]

Notes: No. = number, Y = Yes, N = No, INN = international nonproprietary name, FL = formulary list, * = TB treatment provided by central Ministry of Health program

Instructions

Column 1	Enter the serial number of the clinical history (CH). At the bottom of the column, total the number of clinical records entered.
Column 2	Was the patient diagnosed with pneumonia? Enter *Y* (yes) or *N* (no). At the bottom of the column, total the number of *Y*s.
Column 3	Was an antimicrobial prescribed? Enter *Y* or *N*. At the bottom of the column, total the number of *Y*s.
Column 4	Enter the number of days spent in hospital between entry and discharge. At the bottom of the column, total the number of days spent in hospital.
Column 5	Was sensitivity testing conducted? Enter *Y* if the patient had a sensitivity test, *N* if not. At the bottom of the column, total the number of *Y*s.
Column 6	Name of antimicrobial? Write the name of the antimicrobial exactly as it appears in the CH. At the bottom of the column, total the number of antimicrobials prescribed.
Column 7	Was an INN used? Enter *Y* or *N* according to whether the generic name was used. At the bottom of the column, total the number of *Y*s.
Column 8	Was the antimicrobial that was used on the formulary list (FL)? Enter *Y* or *N* according to whether the antimicrobial appears on the hospital FL by its generic name or INN. At the bottom of the column, total the number of *Y*s.
Column 9	Dosage form and strength. Enter tab, cap, amp, and so on, and mg/unit or ml.
Column 10	Days of treatment. Enter the number of days the dose was to be given by looking at the start date and stop date for each antimicrobial. At the end of the column, total the number of days.
Column 11	If the patient was given two different forms of the same generic (see columns 6 and 9), for example, an injection and capsules of ampicillin, then the number of generics is only one, not two. Enter in this column each generic the patient received. At the bottom of the column, total the number of generics received.
Column 12	Dosage frequency. Enter the number of times the dosing unit was to be given each day.
Column 13	Doses prescribed. Figure the dosage per day by dividing dosage frequency in column 12 into 24 hours. Multiply the result by the corresponding number in column 10 (treatment days). At the bottom of the column, total the number of doses prescribed.
Column 14	Doses administered. Count the actual doses administered according to nursing records and enter in this column. At the bottom of the column, total the number of doses received.
Column 15	Unit cost. Enter the unit cost from column 4 of Instrument 5.
Column 16	Cost of prescribed treatment. Multiply column 13 by column 15 and enter the result. At the bottom of the column, total the treatment cost.
Column 17	Cost of administered (received) treatment. Multiply column 14 by column 15 and enter the result. At the bottom of the column, total the cost of treatment received.

Calculation of Indicators:

Indicator 6 = Add the total *Y*s of column 3, divide by the total number of patients in column 1, and multiply by 100.

Indicator 7 = Add the total of column 11 and divide by the total of *Y*s in column 3.

Indicator 8 = Add the total *Y*s of column 8, divide by the total of column 6, and multiply by 100.

Indicator 9 = Add the total costs of column 16 and divide by the total *Y*s of column 3.

Indicator 10 = Add the total of column 10 and divide by the total of column 3.

Indicator 13 = Add at the *Y*s in column 2 and compare with the STG for (1) choice of antibiotic and (2) dosage.

Indicator 14 = Add the total *Y*s of column 7, divide by the total of column 6, and multiply by 100.

Indicator 15 = Add the total of column 14, divide by the total of column 13, and multiply by 100.

Indicator 16 = Add the total of column 4 and divide by the total *Y*s of column 3 (remembering that if no antimicrobials were given this column should be blank).

Indicator 17 = Add the total *Y*s of column 5, dividing by the total *Y*s of column 3 (that are curative), and multiply by 100.

Important Notes: If an antimicrobial is prescribed for a patient (*Y* in column 3), then all remaining cells in the row should be filled in. If no antimicrobial was prescribed, leave columns 4–17 blank.

If the patient has tuberculosis and is being prescribed antituberculosis medicines, enter column 1 and 6 and put an asterisk (*) in the rest of the columns for antituberculosis medicines.

If the patient has HIV and is being treated with antiretrovirals, enter column 1 and 6 and put an asterisk (*) in the rest of the columns for antiretroviral medicines.

Do not use this instrument for recording antimicrobial surgical prophylaxis; use Instrument 3.

Instrument 3

Form to Record Cesarean Section Surgical Prophylaxis

Name of unit: _____ Data collector: _____ Date: _____

1	2	3	4	5	6
CH No.	Surgical Procedure	Prophylaxis (Y/N)	Surgical Antimicrobial Prophylaxis for Cesarean Section in Accordance with Hospital Guidelines (Y/N)	Antimicrobial Prescribed (Name, Dosage Form, and Strength)	Number of Doses

[Instrument 3 is used to collect information for Indicators 11 and 12.]

Instructions:

1. Record in column 1 the number of each clinical history (CH) for which a cesarean section surgical procedure was performed.
2. Enter in column 2 the name of the surgical procedure.
3. Verify carefully whether antimicrobial prophylaxis was prescribed and enter *Y* or *N* in column 3.
4. Determine if antimicrobial prophylaxis for cesarean section is in accordance with hospital guidelines.
5. Record which antimicrobials were prescribed (name, form, and strength) in column 4.

6. Record number of doses administered in column 6.
7. Patients with preexisting infections as indicated in the admission notes or diagnosis and patients with a high potential for infection, e.g., premature rupture of membranes (PROM) 6-12 hours (or more) before onset of labor, should be excluded from this indicator study.

Calculations:

Indicator 11 = Add the total of *Y*s in column 4, divide by the total number of cesarean section procedures listed in column 2, and multiply by 100.

Indicator 12 = Add up the total in column 6 and divide by total of *Y*s in column 3.

Instrument 4

Form to Record Medicine Purchases

Name of unit:_____ Data collector:_____ Date:_____

1	2	3	4
Invoice No.	**Supplier**	**Date of Purchase**	**Cost of Purchase**
			Total:

[Instrument 4 is used to collect information for Indicator 5. (Instrument 6 is also necessary to calculate this indicator.)]

Instructions:

1. Collect invoices for all medicine purchases during the past year (or other study period). Record the number of the invoice, name of the supplier, date of the invoice, and total amount billed for medicines in columns 1 to 4.

2. Add the amounts billed for all medicine purchases and enter in the last row of column 4.

Instrument 5

Antimicrobials Purchased

Name of unit:_____ Data collector:_____ Date:_____

Generic name of the antimicrobial: _____

1	2	3	4	5	6
Generic or Brand Name	**Dosage Form and Strength**	**Dispensing Unit**	**Unit Cost**	**Quantity**	**Total Cost**
				Total Cost of Antimicrobials:	

Generic name of the antimicrobial: _____

1	2	3	4	5	6
Generic or Brand Name	**Dosage Form & Strength**	**Dispensing Unit**	**Unit Cost**	**Quantity**	**Total Cost**
				Total Cost of Antimicrobials:	

[Instrument 5 is used to collect information to perform ABC analysis by active ingredient and to collect information for Instruments 2 and 6 and for Indicator 9.]

Instructions:

Use one block for each active antimicrobial ingredient, and record one purchase on each line. Record for each antimicrobial purchase the generic or brand name, form and strength, dispensing unit, and the value of each purchase.

Instrument 6

Cumulative Purchase of Antimicrobials

Name of unit:_____ Data collector:_____ Date:_____

1	2	3	4
Generic Name of Antimicrobial	**Total Cost of Antimicrobial**	**Percentage of Total**	**Cumulative Percentage**
	Total:		

[Instrument 6 is used to collect information for Indicator 5.]

Instructions:

1. Rank antimicrobials (high to low) by Total Cost of Antimicrobial (Instrument 5).

2. Total all purchases of antimicrobials (add numbers in column 2), calculate the percentage that each active ingredient represents of the total, and enter in column 3.

3. Add each percentage to the cumulative percentage in column 4.

Instrument 7

Availability of a Set of Key Antimicrobials and Time Out of Stock

Name of unit:_____ Data collector:_____ Date:_____

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Product (Generic Name, Form, and Strength)	**Current Stock**	**Days Out of Stock**												
		M1 Last month	**M2**	**M3**	**M4**	**M5**	**M6**	**M7**	**M8**	**M9**	**M10**	**M11**	**M12**	**Total Days Out of Stock**
														Total:

[Instrument to collect information for Indicators 3 and 4.]

Instructions:

1. Review the stock sheet for each essential or referenced antimicrobial. Record the current stock quantity in column 2 and then, for each month, record the number of days for which the product was out of stock, starting with last month and working backward.

2. Add the number of days out of stock for each month and enter the total in the last column.

Calculations:

Indicator 3 = Add the total numbers of entries in column 2 that are more than 0 and divide by the number of products in column 1.
Indicator 4 = Add the total numbers of entries in column 15 and divide by the number of products in column 1.