# WHO Methodology for Point Prevalence Survey on Antibiotic Use in Hospitals

Version 1.1







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WHO Methodology for Point Prevalence Survey on Antibiotic Use in Hospitals, version 1.1 WHO/EMP/IAU/2018.01

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In October 2016, the World Health Organization (WHO) convened an expert meeting to define the objectives and contents of two methodologies to survey antimicrobial use in hospitals and community settings. Based on input from the meeting, a draft protocol for point prevalence survey on antibiotic use in hospitals was drafted by the WHO. Comments and contributions to the protocol have been received from participants of the expert meeting, WHO staff members from the Department of Essential Medicines and Health Products and WHO Regional Offices. The protocol has been reviewed and approved by the WHO Ethical Review Committee and undergone piloting in low- and middle-income countries before finalization.

Some section of this protocol are adapted from the technical document on *Point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals* (1) by the European Centre for Disease Prevention and Control (ECDC).

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## **Abbreviations and Acronyms**

Antimicrobial resistance
Anatomical Therapeutic Chemical
Defined daily dose
Days of therapy
Driving reinvestment in research and development and responsible antibiotic use
European Centre for Disease Prevention and Control
Global Action Plan
Intensive Care Unit
International Nonproprietary Name
Infection prevention and control
International Organization for Standardization
International unit
Intravenous
Medicines Utilisation Research in Africa
Outpatient parenteral antibiotic therapy
Point prevalence survey
Transatlantic Taskforce on Antimicrobial Resistance
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World Health Organization

### Background

Antimicrobial resistance (AMR) is a significant global health problem. Resistance occurs when bacteria, parasites, viruses or fungi are exposed to antimicrobials but not killed by them. Resistance is a natural phenomenon which gives organisms the opportunity to adapt and change, rendering medicines ineffective (2). Existing resistance patterns are spreading and new resistance patterns are emerging around the world (2). Growing resistance is of extreme concern for public health because resistant organisms lead to longer illnesses, increased costs of treatment and increased mortality (2,3).

Patients with infections caused by multidrug-resistant bacteria are generally at increased risk of worse clinical outcomes and death, and consume more healthcare resources than patients infected with the same bacteria that are not resistant. In addition to its direct impact on population health, AMR is associated with significant economic costs. When infections are resistant to first-line drugs more expensive therapies must be used, often requiring longer duration of treatment and hospitalized care, which increases healthcare costs and contributes to the economic burden of disease (*3*).

The current global AMR crisis is the result of a number of factors, including overprescribing and overdispensing of antimicrobial medicines by health workers, noncompliance with treatment courses, low-quality medicines and incorrect prescription with wrong dosage, poor infection prevention and control practices in hospitals and clinics, and lack of hygiene and poor sanitation.

AMR is a complex problem with many interrelated causes. Inappropriate use of antimicrobials and lack of surveillance systems are core contributors to the spread of AMR. Other factors influencing AMR, such as poor infection prevention and control in healthcare facilities and lack of available, inexpensive and rapid diagnostic tests, are also important factors that require urgent address (3).

In response, WHO has developed a Global Action Plan (GAP), as mandated by the World Health Assembly (WHA) 2015 resolution WHA 68.7 (4). The goal of the GAP is to ensure, for as long as possible, the successful treatment and prevention of infectious diseases with effective and safe medicines that are quality-assured, used in a responsible way, and accessible to all who need them (5). The GAP takes an integrated approach which promotes the principles of society engagement with a One Health approach, prevention of infection, and equitable access to healthcare and medicines. The GAP was reinforced by the political declaration on AMR made by the Heads of State during the UN General Assembly on 21 September 2016.

Optimizing the use of antimicrobial agents is one of the five key strategic objectives outlined in the GAP, and available studies indicate a high proportion of

inappropriate use of antimicrobials (6). Optimizing the use of antibacterial agents, referred to as antibiotics in this document, is a challenge and selecting the right antibiotic may not be straightforward. The number of antibacterial subclasses and substances is relatively large compared to other antimicrobial classes, antibiotics often target not one specific microorganism but a range of pathogens depending on the spectrum of activity of the antibiotic, bacteria may develop different mechanisms of resistance to antibiotics, and finally, the majority of the antibiotic treatments, at least in the community, are given empirically.

It is likely that inappropriate use of antibiotics is widespread; however, information on antibiotic consumption and use is scarce in low- and middle-income countries. In order to inform effective policies and interventions that optimize use and promote equitable access to medicines, it is essential to collect information on the current situation of antibiotic use in all countries.

Harmonized data collection and strengthening of monitoring systems is needed to provide a reliable global picture of the use of antibiotics. High level data on the quantity of antibiotics used nationally, e.g. through sales, provide important information on antibiotic consumption. In 2016, WHO developed a global methodology for monitoring antimicrobial consumption (7), including antibiotics, and supports countries in implementing surveillance of antimicrobial consumption to obtain national estimates of antimicrobial consumption. However, one limitation of consumption data is the lack of information on how antibiotics are prescribed and used at the patient level.

Data on antibiotic use at the patient level is sparse, due to the difficulties associated with collecting prescribing data from fragmented data sources. Hospitals are excellent settings for gaining understanding of antibiotic prescribing. They have a high concentration of patients with diverse pathologies, often requiring antibiotic treatment. This creates high selection pressure on bacteria due to the quantities and broader spectrum of antibiotics used, contributing to the development and emergence of resistant bacteria. Collecting hospital data and subsequently implementing informed interventions to optimize antibiotic use in hospitals has significant potential to lower antibiotic resistance at local and higher levels. Furthermore, the concentration of patients requiring antibiotics provides an excellent opportunity to survey antibiotic prescribing while reducing the workload of collecting prescribing data and providing a range of different situations where antibiotics are used.

In the vast majority of countries worldwide, continuous data collection on antibiotic prescribing is not possible due to the high workload and level of resources needed for regular monitoring. A viable alternative is to collect data at a specific point in time, which can be done successfully using the point prevalence survey (PPS) methodology. PPS on antibiotic use are already in use in hospitals around the world. The European Union (8) and the United States (9) have developed and carried out regional surveys using PPS. WHO has aimed to develop a similar methodology that meets the needs and reflects the level of resources in low- and middle-income countries while maintaining comparability with data collected in high-income countries.

A common methodology to survey antibiotic prescribing in hospitals encourages standardization and facilitates comparisons of antibiotic use over time and between hospitals, districts, countries, and regions. The WHO PPS methodology is an adaptation of the ECDC protocol for Point Prevalence Survey of healthcare-associated infections and antimicrobial use (1), complemented by methodologies from the Global PPS project from University of Antwerp (10), the US Centers for Disease Control and Prevention (9), and the Medicines Utilisation Research in Africa (MURIA) (11).

To account for challenges associated with data collection in resource-limited settings, the methodology has been developed with flexibility in mind. A set of core variables has been selected by the WHO that is necessary for data analysis and interpretation, and provides the possibility to implement follow-up activities. Depending on the resources and availability of information, hospitals and countries may include additional variables (e.g. microbiology results) that improve the understanding of antibiotic use in hospitals. For better comparability and interpretation of results, it is advisable to select the variables to be collected (core and optional) at country level and by hospital category, and not differ between hospitals.

The WHO PPS methodology collects basic information from medical records and associated patient documentation on all hospitalized patients, which are of relevance for treatment and management of infectious diseases regardless of whether these patients are on antibiotic treatment at the time of data collection. In addition to assessing the use of antibiotic treatment the information can be used for other objectives, such as improving quality of care or infection prevention and control (IPC) in hospitals. It is important to emphasize that this methodology does not collect additional information aside from what is already recorded through routine processes. Thus, there is no direct contact with patients where they are asked to provide supplementary information.

The WHO methodology has been developed with the aim of collecting baseline information on the use of antibiotics in hospitals, and is expected to be repeated once every few years. It is, however, possible to adapt and tailor the methodology for specific purposes, such as follow-up surveys to assess specific interventions or to support the objectives of improving quality of care or IPC.

### Objectives

The WHO methodology is a tool for surveillance and public health. The specific objectives are:

- To provide a standardized methodology for use in low-, middle- and highincome countries to estimate the prevalence of antibiotic use in hospitals;
- To collect information on the prescribing of antibiotics
  - by substance name;
  - by indication and category of patient; and
  - by specialty and healthcare facility.
- To support policy-makers and practitioners for improving antibiotic use
  - by raising awareness of antibiotic use in hospitals;
  - by training and building capacity in monitoring and evaluation;
  - by identifying problems related to antibiotic prescribing and use, and setting up priorities accordingly;
  - by informing local, regional and national policies, strategies and interventions; and
  - by evaluating the effect of policies, strategies and interventions to improve antibiotic use.
- To provide a standardized tool for hospitals
  - to monitor antibiotic use;
  - to identify targets for improved antibiotic use; and
  - to inform hospital interventions aiming to improve antibiotic prescribing and use, and antimicrobial stewardship programs.

### Framework

This methodology can be used for single-centre or multicentre surveys. In single-centre surveys, hospitals can carry out surveys independently in terms of objectives, organization, timeline and reporting. The survey might be part of a local antimicrobial stewardship programme and can serve as either baseline survey to understand the appropriateness of antibiotic prescribing or as follow-up survey after a local intervention has been carried out, to improve antibiotic prescribing. A hospital coordinator should be appointed to manage the survey at the facility level.

Multicentre surveys include surveys in selected hospitals, national surveys irrespective of representativeness at country level, and supranational surveys such as regional and global surveys. For national multicentre surveys, a national coordinator should be in charge of leading and coordinating the survey. For regional and global surveys, it might be necessary to appoint a regional or global coordinator for the participating countries in addition to the national coordinator. If the sample size and composition of the participating hospitals is representative at the country level, then the results from the multicentre survey can be considered a valid estimate of antibiotic use in other hospitals across the country. The implementation of single-centre and multicentre surveys is described in the chapter "Data collection".

### **Inclusion Criteria**

Inclusion criteria are stratified according to the following levels:

- 1. Hospital
- 2. Ward
- 3. Patient
- 4. Antibiotic

The inclusion criteria should first be applied to hospitals, secondly to wards in the hospitals that meet the inclusion criteria, then to patients in the selected wards, and finally to the antibiotics prescribed or dispensed to those patients. Table 1 provides a detailed overview of the inclusion criteria.

	stratification		
Level	Include	Exclude (examples)	
Hospital	l Acute care hospitals	Nursing homes	
		Rehabilitation centres	
		Psychiatric centres	
Ward	Acute care inpatient wards	Long-term care wards	
		Emergency departments (except for wards attached to the departments)	
		Day surgery wards	
		Day care wards (e.g. renal dialysis)	
Patient	Patients hospitalized as an inpatient at or before 08:00	Hospitalized after 08:00	
		Outpatient clinic	
		Day surgery/day treatment	
		Emergency room	
		Outpatient dialysis	
		Discharged patients waiting for transportation	
		Parents/relatives of admitted children	
		Outpatient parenteral antibiotic therapy (OPAT)	
Antibiotic	Listed antibiotics (Annex XI)	Topical antibiotics	
	Administered oral,	Ophthalmologic antibiotics	
	parenteral, rectal or through inhalation	Treatment initiated after 08:00	
	Ongoing treatment at 08:00	Treatment discontinued before 08:00	

### Table 1. Inclusion criteria and examples of exclusion criteria by the levels of stratification

### 1. Hospital

All types of acute care hospitals are eligible to carry out a survey based on this protocol. Non-acute care facilities, such as institutions providing only nursing care, rehabilitation centres or psychiatric centres, should not be included.

#### Hospital types

This protocol focuses on acute care hospitals. However, it is important to consider the type of care provided by the different hospitals as it has impact on the intensity of antibiotic prescribing and classes of antibiotics prescribed. Consequently, registering the type of hospital surveyed is necessary for interpretation of results for the individual hospitals.

The classification of hospitals in this protocol is based on the Disease Control Priorities in Developing Countries (*12*) complemented by ECDC.

Hospital types are divided into four categories:

- Primary hospital
- Secondary hospital
- Tertiary hospital
- Specialized hospital

These categories are defined as follows<sup>1</sup>:

- 1. Primary hospital
  - a. Few specialities (mainly internal medicine, obstetrics-gynaecology, paediatrics, general surgery or only general practice);
  - b. Limited laboratory services are available for general, but not for specialized pathological analysis;
  - c. Commonly referred to as "district hospital", "rural hospital", "community hospital", or "general hospital".
- 2. Secondary hospital
  - a. Hospital is highly differentiated by function with five to ten clinical specialities, such as haematology, oncology, nephrology, and intensive care unit (ICU);
  - b. Takes some referrals from other (primary) hospitals;
  - c. Can have teaching activities;
  - d. Commonly referred to as "regional hospital", "provincial (county) hospital", or "general hospital".

<sup>&</sup>lt;sup>1</sup> Adapted from ECDC (1).

#### 3. Tertiary hospital

- a. Highly specialized staff and technical equipment (ICU, haematology, transplantation, cardiothoracic surgery, and neurosurgery);
- b. Clinical services are highly differentiated by function;
- c. Specialized imaging units;
- d. Regularly takes referrals from other (primary and secondary) hospitals;
- e. Often a university hospital or associated to a university;
- f. Commonly referred to as "national hospital", "central hospital", or "academic or university hospital".
- 4. Specialized hospital
  - a. Single clinical specialty, possibly with subspecialties;
  - b. Highly specialized staff and technical equipment.

When a hospital has facilities with different levels of care, then the highest hospital category should be reported. For example, if one facility of the hospital belongs to the primary level and another facility belongs to the tertiary level, then the reported category should be tertiary hospital.

#### **Hospital groups**

A hospital group consists of multiple hospitals (sites) linked together administratively. Hospital groups can be referred to as trusts, mergers, fusions, boards, chains, and so forth. As part of a hospital group, the hospitals must follow the same common rules in terms of management, care to patients, policies or guidelines, and so forth. This tight relationship between hospitals of the same hospital group may affect their individual results by making them more homogenous than when compared with hospitals not belonging to the hospital group.

It is not mandatory for all hospitals (sites) belonging to a particular hospital group to participate in the survey; however, data must be reported separately for each surveyed hospital (site). When hospital groups participate in the survey, the variable "HospitalGroupCode" will anonymously identify the hospital group. All hospitals belonging to the same hospital group have the same value under "HospitalGroupCode", making it possible to group them together for analysis. When selecting and registering the participating hospitals, the national coordinator will request the hospitals to indicate if they are part of a hospital group. If one or more hospitalGroupCode" and request them to specify if all hospitals (sites) in the hospital group are participating in the survey. The variable "HospitalGroupCode" and request them to specify if all hospitals (sites) in the hospital group are participating in the survey. The variable "HospitalGroupAllSitesIncluded" is indicated as "Yes" if all hospitals are participating, and otherwise "No".

#### Hospital ownership<sup>1</sup>

Hospital ownership is defined as:

• **Public (PUB):** Hospitals that are owned or controlled by a government unit or a public corporation (where control is defined as the ability to determine the general corporate policy).

Adapted from ECDC (1).

- **Private, not for profit (PRVNFP):** Hospitals that are legal or social entities created for the purpose of producing goods and services, whose status does not permit them to be a source of income, profit, or other financial gain for the unit(s) that establish, control, or finance them.
- **Private, for profit (PRVFP):** Hospitals that are legal entities set up for the purpose of producing goods and services and are capable of generating a profit or other financial gain for their owners.
- Other (OTH) or unknown (UNK): Hospital ownership that cannot be categorized as one of the above, or hospital ownership is unknown.

If hospital ownership is unclear, prioritize management over ownership of the building and/or funding. For instance, if a hospital is managed privately (for profit) but the building is state-owned or the hospital receives public funding, then select "private, for profit".

### 2. Ward

All acute care inpatient wards in the facilities should be included. Non-acute wards should be excluded.

Excluded wards are defined as:

- Long-term care wards in the facilities (for example nursing homes, post-treatment)
- Emergency departments (except for wards attached to this type of department where patients are monitored for more than 24 hours)
- Day surgery wards, day care wards (for example renal dialysis ward)

Within one ward, some patients may fall into one of the above-mentioned excluded categories and other patients may meet the inclusion criteria. For example, a nephrology ward may include both outpatient care (for example day care dialysis patients) and inpatient care (for example kidney transplant patients). The ward should be included if the proportion of patients in the ward meeting the inclusion criteria is greater than or equal to 80%. If the proportion is lower, the ward should not be considered an inpatient ward and should thus be excluded entirely from the survey.

#### Ward types

Wards are categorized according to the following types<sup>1</sup>:

- Paediatric departments
  - PMW: paediatric medical ward
  - PSW: paediatric surgical ward
  - PHRW: paediatric high risk ward (see high risk units)
  - PICU: paediatric intensive care unit
- Neonatal departments
  - NMW: neonatal medical ward
  - NICU: neonatal intensive care unit
- Adult departments
  - AMW: adult medical ward
  - ASW: adult surgical ward
  - AHRW: adult high risk ward (see high risk units)
  - AICU: adult intensive care unit
- Mixed departments
  - MXW: mixed adult/paediatric ward
  - MXAW: mixed adult ward
  - MXPW: mixed paediatric ward

<sup>&</sup>lt;sup>1</sup> Adapted from the University of Antwerp Global PPS (10).

If patients within a ward belong to different specialties, the ward should be reported as a mixed specialty ward.

#### **High risk wards**

High risk units are defined as units or wards that are high consumers of antibiotics due to the type of care they provide. High risk units consist of wards with the following specialties:

- Haematology
- Oncology
- Burns
- Transplantation
- Infectious diseases (general or specialized infectious disease wards; e.g. HIV units)

Note that ICU is excluded as they have a separate category under "Ward type".

### 3. Patient

Only patients who are hospitalized in the ward at 08:00 on the day of the survey should be included in the survey. Patients admitted to the ward after 08:00 must be excluded.

Note that:

- All neonates born before 08:00 on the day of the survey are included and counted separately from their mother, that is mother and baby count as two different patients.
- All patients meeting the eligibility criteria should be included in the survey irrespective of whether they are receiving antibiotic treatment or not.
- If informed consent is required, all eligible patients should go through the consent approval processes.

All day care patients must be excluded, such as:

- Patients undergoing treatment or surgery and are discharged the same day
- Patients seen at outpatient departments
- Patients in the emergency room
- Outpatient dialysis patients
- Discharged patients who remain as lodgers while waiting for transportation
- Parents/relatives of admitted children who reside as lodgers in the ward to nurse them
- Patients receiving outpatient parenteral antibiotic therapy (OPAT)

### 4. Antibiotics

Antibiotics are classified according to the ATC methodology developed by the WHO Collaborating Centre for Drug Statistics Methodology in Oslo, Norway (13).

Only antibiotics listed in Annex XI and administered through oral, parenteral, rectal or inhalation routes are included in the survey. For example, topical applications, eye drops, ear drops and vaginal suppositories are excluded.

The following inclusion and exclusion criteria for antibiotic therapy (treatment or prophylaxis) apply:

- Include if the patient is on antibiotic therapy at 08:00 on the day of the survey.
- Exclude if the antibiotic therapy is initiated after 08:00 on the day of the survey.
- Exclude if the antibiotic therapy was stopped before 08:00 on the day of the survey.

Special cases:

- If the patient is on antibiotic therapy at 08:00 on the day of the survey but the antibiotic is not administered daily, then the antibiotic should still be reported. This includes, for example, patients with renal impairment with reduced dosing frequency or long-acting antibiotics that are administered with prolonged intervals, such as every 48 hours or more.
- Single-dose regimes, such as gentamycin in combination with other antibiotics, should be included if the dose was given within 24 hours prior to 08:00 on the day of the survey.
- If the patient is on treatment with antibiotic A at 08:00 on the day of the survey but the treatment is changed to antibiotic B at 10:00, then only antibiotic A should be reported.

# Data Collection Structure and coordination

#### **Hospital coordinator**

A lead hospital investigator (hospital coordinator) should be identified for each participating hospital. The hospital coordinator will be in charge of coordinating the survey in the hospital, and responsible for reporting the results to the hospital management and relevant staff. For multicentre surveys, the hospital coordinator is also responsible for submitting the data to the national coordinator. To reduce the workload, it is advisable to establish a team of investigators who will be responsible for conducting the survey under the supervision of the hospital coordinator.

#### **Investigator team**

The hospital and the hospital coordinator should establish an investigator team consisting of healthcare professionals from different disciplines at the hospital (for example infectious disease physicians, microbiologists, infection control practitioners and nurses, pharmacists, data managers). Patient privacy is best protected if the investigating team consists of members who would normally review clinical notes of the surveyed patients as part of their routine work. Where hospital staff cannot be released from routine duties to conduct the survey, it may be possible to have staff specifically employed to conduct the survey under the supervision of the hospital or unit staff, provided that the surveyors have been trained in data privacy and confidentiality and have signed a confidentiality agreement that can be enforced under national law.

It is essential that at least some of the team members have knowledge of local therapeutic guidelines to be able to assess compliance to the guidelines. The investigator team can consist of multiple groups comprising either one investigator or multiple investigators, preferably with a mix of senior and junior staff, who will be dispatched to the different wards of the hospitals. More than one investigator may be required to survey the large wards in order to complete the entire ward within one day. The hospital coordinator should assign anonymous codes to each investigator or investigator group in order to assess auditor biases.

#### Training

The hospital coordinator must be trained in the PPS methodology, is responsible for ensuring that the investigator team receives adequate training on the survey according to this protocol, and is expected to supervise the data collection.

Before initiating the full survey, a pilot study should be conducted in the participating hospitals by, for example, reviewing clinical notes for up to 10 patients involving the whole investigator team. The pilot provides the team with an

opportunity to review and agree on the data extraction procedure, which reduces auditor bias. It is recommended that each investigator assesses the 10 patients independently and then compare the results to ensure internal validity.

#### **Survey coordination**

The organization of the survey can be split into four main phases:

- 1. Preparation of the survey (ethical clearance, identifying investigators, survey design etc);
- 2. Conducting the survey (day-to-day management, daily ward surveys);
- 3. Data validation, analysis (entry, cleaning, storage) and reporting of results to the hospital;
- 4. Dissemination of the results outside the participating hospitals, for example in national reports, at scientific conferences, and to policy makers.

The specific roles of the hospital coordinator include:

- Applying for ethical clearance from the hospital management and/or the local research and ethics committees of the hospital depending on local and national requirements. If the hospital is part of a national survey, ethical clearance may have already been sought by the national coordinator. The national coordinator should then support the hospitals to obtain local ethical clearance if required;
- Identifying and establishing a team of investigators and supporting them in conducting the survey at the hospital;
- Practical planning for the survey, including identification of included wards, ensuring access to materials for data collection etc.;
- Informing relevant stakeholders at the hospital about the survey, such as the hospital medical council, the drug and therapeutic committee and the antimicrobial stewardship teams of the survey;
- Obtaining information from the hospital administrative departments in order to complete the hospital-related information (see "Hospital level data");
- Coordinating the survey, including informing and agreeing with each ward on a day to conduct the survey;
- Day-to-day management of the investigator team;
- Coordinating data validation and data entry;
- Coordinating data analysis and reporting results to the hospital management and other relevant stakeholders in the hospital; and
- Submitting survey data to the national coordinator if the hospital is part of a multicentre survey.

#### Timeline

Data collection should be completed for the entire hospital within maximum three consecutive weeks from the first day of data collection. The duration of the survey will vary depending on the size of the hospital and the investigator team. It is advisable to keep the duration as short as possible in order to avoid unexpected events that could change the context of the survey (for example holidays, strikes etc.). Note that all wards meeting the inclusion criteria must be included in the survey.

To minimize the impact of patients moving between wards, each ward must be completely surveyed within one day. The hospital coordinator should ensure that the capacity of the investigator team is adequate to meet this requirement. For example, a large ward may require more than one investigator. It is recommended to avoid conducting the survey during weekends and public holidays due to reduced staff availability.

As the survey collects information on surgical prophylaxis during a 24-hour period prior to 08:00 on the day of the survey, it is recommended to avoid conducting the survey in surgical wards following a weekend or a public holiday since elective procedures may be reduced during these days.

#### **Patient sampling**

In hospitals with < 500 total inpatient beds, all patients meeting the inclusion criteria must be surveyed. In large hospitals, however, including all eligible patients in the survey may become very resource-demanding and impossible to conduct within 3 weeks. Thus, in hospitals with 500 or more total inpatient beds, it may be acceptable to sample the eligible patients. While patient sampling is optional, in order to ensure representativeness it is important that sampling be conducted at the patient level and not at the ward level or facility level (if a hospital consists of several facilities).

The patient sampling is defined as follows:

- In hospitals with < 500 total inpatient beds, include all eligible patients in the wards.
- In hospitals with 500 to 800 total inpatient beds, one out of two patients per ward can be included in the survey.
- In hospitals with over 800 total inpatient beds, one out of three patients per ward can be included in the survey.

The sampling will be done in each ward on the day of the survey through the following procedure:

- 1. The staff of the surveyed ward will prepare a list of all eligible patients according to the inclusion criteria. The list should be ordered alphabetically according to patients' surnames (not by bed or patient number).
- 2. For hospitals with 500 to 800 beds:
  - a. Before reviewing patient records, the investigator will randomly select between the first and the second patient on the list as the starting point for the sampling (i.e. the first patient to be surveyed).
  - b. From this random starting point, the investigator will select every second patient until the end of the list is reached.
- 3. For hospitals with over 800 beds:
  - a. The investigator will randomly select between the first three patients on the list as the starting point for sampling.
  - b. From this random starting point, the investigator will select every third patient from the list until the end of the list is reached.

If a selected patient is not present in the ward, for example due to surgery or radiology exams, and his/her patient records and associated documentation are

not available at the time of survey, the investigator may either choose to return at a later time during the same day or select the next person on the list. However, the approach should be consistent across wards and defined from the beginning by the hospital coordinator and the investigator team.

#### **Representative hospital sampling**

#### Sampling methodology

In order to collect representative data at the national level, either all hospitals should be included in the survey or a representative random sample of hospitals should be selected. When random sampling is not possible, convenience sampling can be considered. However, this may not provide nationally representative estimates. In cases of convenience sampling, it is important to include different hospital types.

A representative random sample of hospitals can be achieved using the following systematic sampling design developed by ECDC. This should be done for each country either by the survey coordinator or the national subcoordinator.

Steps<sup>1</sup>:

- 1. Obtain a list (for example in spreadsheet format) of all hospitals in the country, including the number of inpatient beds (use the total number of beds if the number of inpatient beds is unknown).
- 2. Rank the list in ascending order according to the number of beds.
- 3. Calculate the number of hospitals to be sampled according to the "Sample size and design effect" approach specified below.
- 4. Divide the total number of hospitals by the number to be sampled = sampling interval k.
- 5. Choose a random number between 1 and k = i.
- 6. Select the *i*th hospital, the *i*th +k hospital, the *i*th +2k hospital, the *i*th +3k hospital, etc.
- 7. If the first selected hospital declines participation in the survey, select the next hospital on the list (*i*th+1 hospital, *i*th+k +1 hospital, etc.). If it is expected that more than one hospital will decline participation, make a second list of reserve hospitals.
- 8. Invite the sampled hospitals and replace them in case of decline.

Sorting the hospitals according to the number of inpatient beds before the selection procedure ensures that hospitals of different sizes are represented according to the same proportion as the actual distribution in the country.

In addition to sorting by number of beds, it is also possible to sort according to hospital type (for example primary, secondary or tertiary) or any other categories of hospitals related to case-mix in order to achieve representativeness of the different types of hospitals. In these cases, replace step 2 with (a) first sort the hospitals according to hospital type, and then (b) within the same hospital type, sort according to number of beds. Then continue the systemic sampling on this list according to step 3.

<sup>&</sup>lt;sup>1</sup> Adapted from ECDC (1).

#### Examples

**Country A** has 127 hospitals and should include at least 36 hospitals in the sample to achieve representativeness. For details on the calculation of the sample size, see "Sample size and design effect" below. All 127 hospitals should be listed according to the number of inpatient beds. The sampling interval k is 127/36 = 3 (3.5 rounded down to 3). The random number i is chosen between 1 and 3. If the random number is 3, then you select the 3rd, 6th, 9th,...,120th, 123rd, 126th. In this case using a sampling interval k of 3 will result in 42 hospitals in the sample.

#### Sample size calculation and design effect

The number of hospitals to include in the survey (sample size) depends on the expected prevalence of antibiotic use, the total number of hospital beds at the national level and the average number of inpatient beds per hospital (hospital size).

In the sample size calculation, the prevalence of antibiotic use among hospitalized patients is estimated to 40% with a precision of  $\pm$  4% at the national level.

Since hospitals can be considered as clusters of patients of the total population of hospital patients, there is a clustering effect that needs to be taken into consideration. For this reason, a correction has to be applied when calculating sample size. The number of hospitals to be included depends on the expected cluster effect (design effect) and on the average hospital size in each country, as the design effect depends on the size of the hospitals.

The design effect is not known at the time of sampling. However, ECDC have developed a table of design effects for antibiotic use based on PPS conducted in acute care hospitals in the European Union. The ECDC design effects will be used to estimate the sample size for the national surveys and is listed in Table 2.

To calculate the sample size, the national coordinator should collect information on the total number of inpatient beds at the national level, number of hospitals, and average hospital size according to the number of inpatient beds. Chose the correct design effect based on the average hospital size in Table 2. The sample size can be calculated using statistical tools that are freely available online. For example, the OpenEpi tool (www.openepi.com) can compute sample size using the design effect.

Hospital size	Design effect for antibiotic use	
< 80 beds	6.5	
[80 beds – 140 beds]	10.1	
[140 beds – 230 beds]	11.7	
[230 beds – 380 beds]	16.7	
≥ 380 beds	18.7	

 Table 2.
 Design effect for antibiotic use (8)

#### **Examples**

**Country A** has 23 114 hospital beds divided into 127 hospitals, generating an average hospital size of 182 beds per hospital.

To calculate sample size: The total number of hospital beds (population) is 23 114, the expected prevalence of antibiotic use is  $40\% \pm 4\%$ , and the design effect equals 11.7 that corresponds to the average of 182 beds per hospital (design effect value for hospital size between 140 and 230 beds). Based on these values, the calculated sample size is 6579 beds (at a 95% confidence level). As the average hospital size is 182 beds, 36 (6579/182) hospitals should be included in the survey.

Expand All | Collapse Start Enter Results Examples Help Home E C Info and Help Language/Options/Settings Clear Calculate Calculator E 🔁 Counts Std.Mort.Ratio Sample Size for % Frequency in a Population Proportion (Random Sample) Two by Two Table Dose-Response If large, leave as one R by C Table Population size 23114 Matched Case Control million Screening 🖻 😋 Person Time Between 0 & 99.99. If Anticipated % frequency(p) 40 1 Rate Compare 2 Rates unknown, use 50% E Continuous Variables Confidence limits as +/- percent of 100 Mean CI 4 Absolute precision % Median/%ile CI 11.7 t test Design effect (for complex sample surveys--DEFF) ANOVA 1.0 for random sample 🕀 🗀 Sample Size Power - Random numbers

Country A: Calculation using the OpenEpi tool

**Country B** has 230 045 hospital beds divided into 1655 hospitals, generating an average hospital size of 139 beds per hospital.

To calculate sample size: The total number of hospital beds (population) is 230 045, the expected prevalence of antibiotic use is 40%  $\pm$  4%, and the design effect corresponding to an average hospital size of 139 beds is 10.1 (design effect value for hospital size between 80 and 140 beds). Based on these values, the calculated sample size is 5806 beds (at a 95% confidence level). As the average hospital size is 139 beds, 42 (5806/139) hospitals should be included in the survey.

#### Country B: Results from the calculation in the OpenEpi tool

Start	Enter	Results	Examples	Help	
Sample Size for Frequency in a Population					
•	Population size(for finite population correction factor or fpc)(N): 230045				
			ome factor in the	population (	
	Confidence limits as % of 100(absolute $+/-\%)(d)$ : 4%				
Desig	Design effect (for cluster surveys-DEFF): 10.1				10.1
	Sample Size(n) for Various Confidence Levels				
	Confid	enceLevel(%)	San	ple Size	
<		95%		5806	>
80% 243			2486		
	90% 4092			4092	
	97% 7113			7113	
	99% 10009			0009	
	99	9%	1	6289	
	99.	99%	2	2716	

### 2. Ethical review and data privacy

The survey is designed for public health surveillance purposes; it is nonexperimental, does not involve any patient examination or patient interviews, and does not introduce any interventions. Collected data will be de-identified during data collection and it can therefore be considered to be a minimal risk study.

#### **Informed consent**

Depending on the national policies, it might be necessary to ask patients for consent before inclusion in the survey. The consent can be oral or written. If required, it is advisable that the informed consent is obtained by someone who has no direct impact on patient care, due to power balances. For example, if the treating health professional requests for consent, the patient may feel obliged to accept. It should be noted that the information will be gathered from patient notes or other medical records, so no interaction with the patient is necessary to obtain additional information. Also, this is not an intervention study so no experimental changes will be made to the care or treatment regime.

In cases where patient interaction is unavoidable, for example if the medical records and clinical notes are kept with the patient, an information and assent procedure may be necessary also in cases where informed consent is not required.

In countries that do not require informed consent by individual patients, a broader informed consent can be sought as substitution. This can be achieved through an informed opt-out procedure, i.e. the medical records and associated patient documentation are reviewed unless the patient in question explicitly objects. According to the *International Ethical Guidelines for Health-related Research Involving Humans* (14), the informed opt-out procedure must fulfil the following requirements:

- Patient should be aware that the survey is taking place
- Patient should be provided with sufficient information about the survey
- Patient should be informed that they can withdraw from the survey, and be given a genuine opportunity to do so

In practice, this can be achieved through several means, and patients may be informed verbally or in writing, for example through posters and pamphlets at the health facility.

In addition to the surveyed patients, hospital staff and in some cases medical associations and unions should also be informed about the PPS. Necessary information includes:

- Purpose of the survey
- How and when the data collection will take place

 How data related to their practice will be used (see "Hospital staff privacy" on fair processes to address prescribing or dispensing errors)

This information should be conveyed to the staff by the hospital management and hospital coordinator. In cases where external investigators are employed to conduct the survey, they should be introduced to the hospital staff in advance and briefed on, amongst other things, the best time of the day to conduct the survey in order to cause as little disruption to health service delivery as possible (for example, after the ward rounds).

#### **Patient privacy**

In a multicentre national or international survey, hospitals will be provided with an anonymous identifier by the survey coordinator or the national subcoordinator. In addition, wards will be assigned an anonymous code provided by the lead hospital investigator. In a single-centre survey, anonymizing the hospital and ward data is not mandatory.

It is always mandatory to anonymize the patients. The patient identifier (i.e. "Patient ID") should not contain any directly identifiable information, such as name and/ or date of birth, but registration number or patient record number consisting of numbers and letters can be used. The hospital coordinator should also assign an anonymous code to each surveyed patient (i.e. "Patient Code"). This code should be unique for each surveyed patient at the hospital level. In multicentre surveys, the combination of the hospital identifier and the patient identifier can generate unique identifiers for all patients. The patient identifier and the key between the patient identifier and the patient code may be stored safely for up to 6 months for validation purposes, but should be eliminated after this time period to irreversibly de-identify the individual patients. The hospital coordinator is responsible for ensuring that the de-identification of patient data takes place within the specified time period and that the data collected at the hospital by means of the PPS is safely stored. Some information may be difficult to de-identify, especially when the diagnosis or treatment is rare. In the context of this protocol, most diagnosis or treatments are general. However, it is important that data continue to be stored safely and be accessible only to authorized personnel after de-identification.

#### **Hospital staff privacy**

While patient data are being collected and used, hospital staff members are, in effect, the subjects of the PPS. As antibiotics are prescribed, dispensed and administered by staff members, their performance of these tasks may come under scrutiny. For example, the collected data may reveal inappropriate prescribing or dispensing, including missed doses, by one or a number of staff members. While errors should be addressed, staff members are entitled to be protected by ensuring that a "no-blame approach" is implemented at the facilities where the survey will be conducted. It is the responsibility of the hospital coordinator and the investigator team to ensure that a fair process is put in place to address such errors, where the focus should be on improving processes for prescribing and dispensing at the facility rather than reprimanding individual staff members. The national coordinator is responsible for supervising these processes and ensuring that a "no-blame approach" is indeed adopted.

#### Data storage

As the data collected by means of this survey may contain sensitive information identifiable at the patient level, it is important that the data are stored safely with only authorized personnel able to obtain access. The means of storage may vary depending on the resources of the hospital, but the lead investigator should ensure that safe storage is achieved and is in accordance with the ethical and data safety regulations in that country. For example, the data files may be encrypted with a password. When available, data files should preferably be stored on secure networks and VPNs of a hospital or university; permanent storage on external disks, e.g. USBs, should be avoided, as these devices may be lost.

#### **Ethical committee**

Before conducting the survey, the national and hospital coordinators must seek ethical clearance from the hospital management and/or the national, regional or local ethical committees as per institutional policies. As the scope of the methodology is public health surveillance, ethical clearance should be sought for surveillance and not for medical research when applicable. WHO published guidelines addressing ethical considerations in public health surveillance in 2017 (*15*). In addition to approval for data collection, it is also advisable to simultaneously seek clearance for sharing of de-identified data with the WHO. It is important to note that different rules may apply for local or national use versus international use of the collected data. For example, local regulations may not require informed consent if the data are to be shared outside of the national borders. In these cases, the national coordinator is responsible for ensuring that necessary requirements are met before sharing data with the WHO.

### 3. Data analysis and dissemination

It is important that data are analyzed at the hospital level and that the results are shared with the hospital administration and relevant hospital staff, including hospital pharmacies, drug and therapeutic committees, IPC, and antimicrobial stewardship teams. In the case of multicentre surveys, the survey coordinator should ensure that any comparisons of hospitals take case-mix and level of care into account. Depending on the aim of the analysis, aggregated data can be reported by ward, hospital or country, or alternatively by patient demographics (for example age groups, gender, comorbidities and risk factors etc.). Note that data should not be reported at the patient level or by responsible prescriber or dispenser.

Publications based on data collected by means of this protocol should reference the protocol and the version number.

### 4. Data structure

The data to be collected are structured according to the following four levels:

- 1. Country level data
- 2. Hospital level data
- 3. Ward level data
- 4. Patient level data



Figure 1. Schematic representation of the data structure

#### **Country level data**

Country level data are collected in the event of national multicentre surveys and the main purpose is to gain understanding of the representativeness of the participating hospitals. The information to be collected addresses the total number of hospitals by level and ownership in the country and the sampling strategy used, if any.

#### **Hospital level data**

The hospital level data provides general information on the type and size of the hospitals. The hospital questionnaire (see Annex XII, page 76) contains three

dimensions: infrastructure, policy and practices, and monitoring and feedback. The questionnaire integrates antimicrobial stewardship indicators defined by TATFAR (*17*) and DRIVE AB (*18*).

#### Ward level data

The ward level data include information on the type of ward, number of eligible and included patients, and characteristics of the ward.

#### **Patient level data**

The patient level data are split into three categories:

- 1. Information on the patient
- 2. Information on the indication of antibiotic use
- 3. Information on the antibiotic therapy

Patient data include information on patient characteristics and should be collected for *all* surveyed patients, irrespective of antibiotic treatment. The data collected includes sociodemographic information (e.g. age and gender) and information on risk factors for receiving antibiotic treatment during the current hospital stay. This information will be used to adjust for the case-mix population between hospitals.

Indication data include information on the reason for prescribing antibiotics, such as diagnosis, type of indication (treatment or prophylaxis), type of infection (healthcare associated, community acquired), etc. There may be several indications for antibiotic treatment, or the indication may be unknown.

Antibiotic data include information on the antibiotics prescribed, such as the type of antibiotics, route of administration, strength and dosing frequency, etc. There is also information on the adherence to clinical guidelines. One or more indications may be associated with the prescribed antibiotic (e.g. if the antibiotic has been prescribed to treat multiple coinfections) or the indication may be unknown.

Country-, hospital-, ward-, patient-, indication-, and antibiotic data are collected through paper or electronic forms, and contextual information is collected through the hospital questionnaire. Templates of the questionnaire and the data collection forms are accessible through a separate package.

#### Antibiotics

Information on antibiotic therapy is only to be registered for patients on treatment according to the inclusion criteria. Antibiotics should be reported both with the written name according to the clinical notes and with International Nonproprietary Names (INN) of the substance(s) (*16*). If the INN name is unknown at the time of review, the investigator can input the INN at a later stage but before data submission.

For patients on antibiotic therapy, report the total number of antibiotic substances prescribed to the patient since admission. Count each antibiotic substance only once, regardless of whether different formulations were prescribed or if the same substance was prescribed more than once with interrupted treatment in between.
#### Examples

- 1. If a patient received benzylpenicillin followed by ceftriaxone, the reported number of antibiotics should be 2.
- 2. If a patient received amoxicillin followed by amoxicillin and clavulanic acid, the reported number of antibiotics should be 2.
- 3. If a patient received ciprofloxacin but then the treatment was interrupted and reinitiated after a few days, the reported number of antibiotics should be 1 and not 2, as the same antibiotic substance was given at both occasions.

### Dosing

Prescribed daily dose is an important parameter for assessing antibiotic use. This parameter will be captured by collecting information on the unit dose and the daily frequency of the unit doses administered. The prescribed daily dose is thus calculated by multiplying the unit dose by the daily frequency.

### Examples

- 1. If an antibiotic is prescribed at 1 g three times daily, the unit dose is 1 g and the frequency 3. The prescribed daily dose is 1  $g \times 3 = 3$  g.
- 2. For long-acting antibiotics, for example 1 g administered once every 2 days, the unit dose will be 1 g and the frequency will be 0.5 (1/2), and the prescribed daily dose will be 1  $g \times 0.5 = 0.5$  g.
- 3. If 2 g of an antibiotic is administered once every 30 hours, the unit dose will be 2 g and the frequency is 0.8 (24/30). The prescribed daily dose will be 2  $g \times 0.8 = 1.6$  g.

When the dose is expressed in mg (or IU) per kg in adult patients, the dose should be translated into g (or IU) by using a standard weight of 70 kg regardless of the actual weight of the patient. In children below age 13, the dose should be calculated in g (or IU) using the actual weight of the patient. Children aged 13 and above are considered adults and a weight of 70 kg should be applied.

A list of conversion factors between MU (millions of IU) and g is provided in Annex XIII for selected antibiotics.

### Example

A male child of 7 kg is receiving treatment with amoxicillin. He is receiving a daily dose of 25 mg/kg administered every 8 hours. Thus the prescribed daily dose should be 25 mg  $\times$  7 kg = 175 mg. Since the doses are administered three times daily, the UnitDose variable should be reported as 58 (175/3), the UnitDoseMeasureUnit as mg, and the UnitDoseFrequency variable as 3.

### **Combination products**

Combination products contain two or more antibiotic substances or an antibiotic substance combined with an enzyme inhibitor.

To report the dose of combination products, the sum of each antibiotic substance excluding the enzyme inhibitors should be reported in the UnitDose variable, and

the dose of each substance including the enzyme inhibitors should be reported in the UnitDosesCombination variable in the same order as they are reported under the AntibioticINNName variable.

Thus for combination products of penicillins (e.g. amoxicillin, ampicillin, piperacillin or ticarcillin), cephalosporins and carbapenems, the amount of enzyme inhibitors (e.g. clavulanic acid, sulbactam or tazobactam) is not included in the UnitDose variable.

### Examples

**Product A** contains trimethoprim and sulfamethoxazole with strength of 160 mg/800 mg, one tablet administered every 12 hours:

- AntibioticINNName: trimethoprim, sulfamethoxazole
- UnitDose: 960
- UnitDoseMeasureUnit: mg
- UnitDosesCombination: 160 mg, 800 mg
- UnitDoseFrequency: 2

**Product B** contains amoxicillin and clavulanic acid with strength of 500 mg/125 mg, one tablet administered every 12 hours:

- AntibioticINNName: amoxicillin, clavulanic acid
- UnitDose: 500
- UnitDoseMeasureUnit: mg
- UnitDosesCombination: 500 mg, 125 mg
- UnitDoseFrequency: 2

#### Medical prophylaxis

Indications for medical prophylaxis include, amongst others, prevention of opportunistic infections in immunocompromised patients (e.g. HIV/AIDS patients), prevention of bacterial infections in patients with late-stage cirrhosis, upper gastrointestinal bleeding, and acute necrotizing pancreatitis. If the patient is on medical prophylaxis during the day of the survey, medical prophylaxis should be reported as MP in the IndicationType variable.

#### Surgical prophylaxis and site

For surgical patients present in the ward at 08:00 on the day of survey, the investigator should check if the patient has been prescribed surgical prophylaxis in the 24 hours prior to 08:00 on the day of survey. If the patient was on surgical prophylaxis during this period, report IndicationType as SP and report duration of the prophylaxis in the SurgicalProphylaxisDuration variable as:

- SP1: if one dose was administrated to the patient;
- SP2: if multiple doses were administered to the patient within 24 hours;
- SP3: if multiple doses were administered to the patient for a duration extending 24 hours.

If the patient had surgery within 24 hours from 08:00 on the day of survey, then select SP1 or SP2. If the patient had surgery more than 24 hours before 08:00 on the day of survey, then select SP3.

For patients receiving surgical prophylaxis, specify the anatomical location where the patient will undergo or already has undergone surgery. The surgical sites are listed in Annex X.

#### Antibiotic stock out

Antibiotic stock out information is recorded at two levels: at the hospital level through the hospital questionnaire and at the patient level through the patient form.

#### Stock out in hospital questionnaire

Review of the availability of antibiotics in the hospital pharmacy will be undertaken during the period of data collection for the survey and will include antibiotics that are routinely procured by the hospital.

Antibiotics are considered as out of stock when products for a specific substance are lacking for at least 1 day during the period of data collection. The missing antibiotic should be reported in the hospital questionnaire under the stock out variable using its INN.

If a product is lacking but another product of a different brand containing the same substance is available, then the antibiotic is not considered as out of stock. If antibiotics are out of stock more than once during the data collection period, it should be listed as stock out only once. If multiple antibiotics are unavailable during the period of the survey, list them all, separated by commas.

#### Examples

- If no product with antibiotic A is available for 3 days, list antibiotic A in the stock out variable.
- If product X containing antibiotic A is missing from day 1 to 5 but available on day 6, and product Z containing antibiotic A is available during day 1 and 2 but missing from day 3 to 6, then antibiotic A is considered as out of stock between day 3 and 5, as product Z is available during day 1 to 2 and product X is available from day 6 and onwards. List antibiotic A in the stock out variable.
- If antibiotic A that is unavailable from day 1 to 5 becomes available from day 6 to 8, but then becomes unavailable again from day 9 to 11, then antibiotic A should be listed as out of stock only once (even if the stock out occurred during two different periods).
- If there is an antibiotic A unavailable from day 1 to 3, an antibiotic B from day 2 to 5 and an antibiotic C from day 9 to 11, then antibiotic A, antibiotic B and antibiotic C should be listed in the stock out variable as A, B, C.

#### Missed doses in the patient form

The variable NbMissedDoses registers the number of times a dose could not be administered to the patient since the start of the current treatment. The variable MissedDosesReason registers the reason for the missed doses, including whether they are related to stock out issues at the hospital. If the reason for missed doses is not specified in the patient records, ward staff may be consulted.

#### Examples

- **Patient A** started antibiotic treatment 2 days before the survey, one tablet 3 times daily. On the second day, the second and third tablets were not administered due to unavailability. NbMissedDoses should be set to 2 and MissedDosesReason to S (stock out issues).
- **Patient B** started antibiotic treatment 3 days before the survey, one tablet 3 times daily. On the second day, doses were not administered because the patient was unable to purchase the treatment for that day. NbMissedDoses should be set to 3 and MissedDosesReason to P.
- **Patient C** started antibiotic treatment 3 days before the survey, one tablet 3 times a day. The second tablet on day 1 and all tablets on day 3 were not administered because the patient could not afford the antibiotic on day 1 and the antibiotic was unavailable on day 3 and onwards. NbMissedDoses should be set to 6 and MissedDosesReason to M (missed for multiple reasons).

## Variables

The variables are categorized as core and optional: core variables collect information that is necessary to achieve the objectives of the survey, including estimating the prevalence of antibiotic use and assessing the indication of treatment. The optional variables provide additional information on, amongst others, case-mix of the hospitals that is useful for in-depth analysis. Some optional variables might be more relevant to some regions than others. In national and multicentre surveys it is advised to predetermine which optional variables to include based on the objectives and available resources. Discarding optional variables should not impede on the analysis and interpretation of the results from the survey.

The different variables are split into four levels: country-, hospital-, ward-, and patient-level information. Patient-level information also includes specific variables on indications and antibiotics.

For ease of data management and analysis, it is necessary that responses to the survey are entered uniformly between the wards and hospitals. Refer to the variable description on the following pages. For Boolean and categorical variables, enter one of the options marked in bold. Enter dates in the following format as indicated in the variable list, i.e. YYYY-MM-DD.

# 1. Country data

#### **Core variables**

Country-specific information is collected by means of the country form, and contains information on the number of hospitals per level and hospital sampling procedure. The purpose is to obtain an overview of representativeness for the hospitals included in the national survey.

CountryName	Country Name	Free text
Name of country.		
CountryISO	ISO code of the country	Free text
Three letter country code acco	rding to ISO alpha-3. See Annex 2	KIV.
TotalNumberHospital	Number of hospitals in the	Number
	country	Positive integer
Total number of hospitals at ar country.	ny level (tertiary, secondary, prin	nary and specialized) in the
NumberPublicHospital	Number of public hospitals in	Number
	the country	Positive integer
Number of public hospitals in t variable refers to hospitals clas	the country. See section on Hosp ssified as PUB.	ital ownership (page 10). This
NumberNonPublicHospital	Number of private hospitals in the country	Number
		Positive integer
	ospitals in the country. See secti o all hospitals not classified as P	
NumberTertiaryHospital	Number of tertiary level hospitals in the country	Number
		Positive integer
Estimated number of tertiary lo Hospital types (page 9).	evel (central or university) hospit	als in the country. See section on
NumberSecondaryHospital	Number of secondary level hospitals in the country	Number
		Positive integer
Number of secondary level (reg Hospital types (page 9).	gional or provincial) hospitals in	the country. See section on

NumberPrimaryHospital	Number of primary level	Number
	hospitals in the country	Positive integer
Estimated number of primary types (page 9).	level (district) hospitals in the co	untry. See section on Hospital
NumberSpecialityHospital	Number of specialized	Number
	hospitals in the country	Positive integer
Estimated number of specializ	ed hospitals in the country. See s	ection on Hospital types (page 9)
NationalHospitalGroups	Hospital groups exist in the country	Boolean
		Y: yes
		<b>N</b> : no
If hospital groups exist in the c	ountry, respond Yes. See section	on Hospital group (page 10).
HospitalSampling	Hospital sampling strategy	Coded value
		A: All hospitals included
		<b>R</b> : Random sampling
		C: Convenience sampling
Specify the sampling strategy Representative hospital samp	for selection of hospitals to enrol ing (page 19).	in the survey. See section
HospConvenSampling	Describe convenience sampling approach	Free text
	onducted, describe the approach Ils, whether hospital type, owner	
InvitedHospital	Number of hospitals in the	Number
	country selected and invited for the survey	Positive integer
country that were invited to pa	ny level (tertiary, secondary, prim articipate in the survey. Note that enrol in the survey, and <i>not</i> the r y.	this variable specifies the
NationalGuideline	National treatment guidelines	Boolean
	exist	Y: yes
		<b>N</b> : no
Respond Yes if national treatm	ent guidelines exist and are upda	ated regularly.
LocalGuideline	Facility-based treatment	Boolean
	guidelines exist	Y: yes
		<b>N</b> : no
Respond Yes if facilities (such a	as hospitals) can develop their ov	vn treatment guidelines.
NationalAMS	A national hospital antimicrobial stewardship programme exists	Boolean
		Y: yes
		<b>N</b> : no
Respond Yes if there is a nation	nal antimicrobial stewardship pro	ogramme for hospitals.
		0

# 2. Hospital data

The hospital data are collected through the hospital form that includes variables related to the hospital, in addition to the hospital questionnaire (Annex XII) that collects information on structural indicators related to antibiotic use.

## **Core variables**

HospitalID	Official identifier of the hospital	Free text
This variable is an official identi	fier of the hospital.	
In a multicentre survey, this vari coordinator.	able must be discarded before s	sending the data to the survey
HospitalCode	Anonymous code of the hospital	Free text
This variable is an anonymous c	ode that uniquely identifies the	hospital.
This is important in multicentric	survey in order to anonymize t	he participating hospitals.
This anonymous code should be provided to the hospital by the survey coordinator (or national subcoordinator). Only the survey coordinator (or national subcoordinator) can link the anonymous HospitalCode to the HospitalID.		
SurveyStartDate	Starting date of the data	Date
	collection in the hospital	YYYY-MM-DD
This date corresponds to the first day of the data collection and not the date when the survey was initiated in the hospital.		
SurveyEndDate	Ending date of the data	Date
	collection in the hospital	YYYY-MM-DD
This date corresponds to the las was ended in the hospital (data data collection).		
HospitalGroup	Hospital is part of a hospital	Boolean
	group	Y: the hospital is part of a hospital group
		N: the hospital is not part of a hospital group
The hospital is either a part of a	hospital group or not. See secti	on on Hospital groups (page 10).

HospitalGroupCode	Anonymous code of the	Free text	
	hospital group		

When the hospital is part of a hospital group, provide an anonymous code of the hospital group. This will allow grouping hospitals from the same hospital group together.

The anonymous code should be provided by the survey coordinator (or national subcoordinator).

Only relevant when HospitalGroup is Yes.

HospitalGroupAllSites Included	have been included in the	Boolean Y: all sites of the hospital group included
		N: only some sites of the hospital group included

If all the sites of the hospital group have been included in the survey, specify Yes; otherwise No.

Only relevant when the HospitalGroup is set to Y.

The survey coordinator (or national subcoordinator) should contact the hospital group to ascertain whether all hospitals of the hospital group have been included in the survey.

-		
HospitalType	Type of hospital	Coded value
		Primary: primary hospital
		Secondary: secondary hospital
		Tertiary: tertiary hospital
		<b>Specialized</b> : specialized hospital
The type of the hospital. See	section on Hospital types (page 9	).
HospitalTypeSpeciality	Specialty of the specialized hospital	Free text
The speciality of specialized	hospitals. Only relevant when the	HospitalType is Specialized.
HospitalOwnership	The ownership of hospital	Coded value
	according to public/private status	PUB: public
	Status	<b>PRVNFP</b> : private, not-for-profit
		<b>PRVFP</b> : private, for-profit
		OTH: other
		UNK: unknown
If the hospital is publicly own section on Hospital ownershi	ned, privately owned or if it is a pu ip (page 10).	ıblic/private partnership. See
HospitalTotalBeds	Total number of beds in the	Number
	hospital	Positive integer
The total number of beds in t	he hospital including acute and r	non-acute beds.
HospitalAcuteBeds	Number of acute beds in the	Number
	hospital	Positive integer
The number of acute beds in	the hospital.	

HospitalICUBeds	Number of ICU beds in the	Number
	hospital	0 or positive integer
The number of ICU beds in the	hospital.	
HospitalHighRiskBeds	Number of high risk beds in	Number
	the hospital	0 or positive integer
The number of beds in high ris units (page 13).	k units in the hospital, <i>excluding</i>	ICU. See section on high risk
HospitalAnnualAdmissions	Annual number of overall	Number
	admissions	Positive integer
	admissions in the hospital for the sis not available, use the numb	
HospitalAnnualPatientDays	Annual number of overall	Number
	patient-days	Positive integer
	patient days in the hospital for tl t days is not available, use the n	
HospitalIncludedBeds	Number of beds included in the survey	Number
		Positive integer
Sum of the number of beds of t	the wards included in the survey	Ι.
HospitalEligiblePatients	Number of eligible patients	Number
		Positive integer
Number of patients eligible for	inclusion in the survey.	
HospitalIncludedPatients	Number of patients included in the survey	Number
		Positive integer
		d correspond to the sum of ible and included patients is the
PatientSampling	Sampling of patients was	Boolean
	conducted	Y: patient sampling conducted
		N: no patient sampling conducted, all patients

Specify if a patient sampling strategy was used or not. See section on Patient sampling (page 18). Patient sampling must be done according to the protocol.

included

## 3. Ward data

The ward data consists of information related to the ward such as ward type and number of patients present or eligible for the survey.

#### **Core variables**

WardID Official identifier of the ward Free text This variable is an official identifier of the ward. It should be unique within the hospital. In a multicentre survey, this variable must be discarded by the lead hospital investigator before sending the data to the survey coordinator. WardCode Anonymous code of the ward Free text This variable is an anonymous code that uniquely identifies the ward within the hospital. This anonymous code should be assigned by the lead hospital investigator. Only the lead hospital investigator can link the anonymous WardCode to the official WardID. WardInvestigator Code of the investigator or Free text investigator team The code of the investigator or of the investigating team that audited the ward. WardSurvevDate Date data are collected in the Date ward YYYY-MM-DD The date the ward was surveyed. It must be between SurveyStartDate and SurveyEndDate. It corresponds to the date of the 08:00 anchor period that is used by the survey. WardType Coded value Type of ward The type of ward. See Annex I. WardTotalPatients Total number of patients Number present in the ward at 08:00 Positive integer The total number of patients including inpatients, outpatients (also patients who are temporarily away, e.g. in the operating theatres, recovery and diagnostic suites, but who have a bed in the ward) at 08:00 on the day of the audit. This information should be collected by the ward staff. WardEligiblePatients Number of eligible patients Number present in the ward at 08:00 Positive integer

The number of eligible patients (inpatient) hospitalized in the ward at 08:00 on the day of the audit. This information should be collected by the ward staff.

WardIncludedPatients

Number of included patients Number

Positive integer

The number of patients included in the survey. This is the number of eligible patients minus patients who did not give consent to participate in the survey.

## **Optional variables**

WardSpecialties Li

List of specialties in the ward Coded values

The speciality/ies under which the audited patients were admitted. If the ward contains patients belonging to more than one speciality, register all specialities separated by comma. See Annex II.

## 4. Patient data

Patient data consist of a set of demographic variables and variables related to risk factors for receiving antibiotics.

The core variables should be collected in all hospitals, independent of the type of hospital, country, or region where the survey is conducted. These variables facilitate global comparison of the results by taking into account the case-mix of patients.

As the epidemiological context varies across the world, some patient data might be more relevant in some countries or regions. Thus the protocol includes an optional set of variables that can be collected when relevant. These optional variables are grouped according to themes (for example underlying infectious diseases).

Patient data should be collected for all eligible patients irrespective of whether they are receiving antibiotics or not (excluding patients who have not given their consent when applicable).

### **Core variables**

#### PatientID Official identifier of the patient Free text

This variable is an official identifier of the patient. It should be unique within the hospital.

This variable must be discarded by the hospital coordinator before analyzing the data or before sending the data to the national coordinator in cases of multicentre surveys.

PatientCode	Anonymous code of the patient	Free text
	patient	

This variable is an anonymous code that uniquely identifies the patient within the hospital.

Only the hospital coordinator should be able to link the anonymous PatientCode to the official PatientID.

Gender	Gender of the patient	Coded value
		M: male
		F: female
		T: transgender
		UNK: unknown
The gender of the patient.		
AgeYear	Age of the patient as number	Number
	of years	Integer ≥ 2
For patients aged greater or	equal to 2 years; age must be ente	ered as a number of years.

Age of the patient as number Number of months

Integer between 0 and 23

For patients aged less than 2 years, age must be entered as number of months. When the baby is less than a month, enter 0.

·····		
PreTermBirth	Type of preterm	Coded value
		<b>LP</b> : late preterm, born between 34 and 36 weeks of pregnancy
		<b>MP</b> : moderately preterm, born between 32 and 34 weeks of pregnancy
		<b>VP</b> : very preterm, born at less than 32 weeks of pregnancy
		<b>EP</b> : extremely preterm, born at or before 25 weeks of pregnancy
For preterm babies, specify th	e category. Only relevant for new	/borns.
Child12YearWeight	Weight of the child below age	Number
	13 in kg	Up to 3 decimals
5	date of the survey. Take the lates en below age 13. For neonates, n	t available weight in the patient eport weight up to grams
NeonatesBirthWeight	Weight of the neonates in kg	Number
		Up to 3 decimals
The birth weights of the neona	ates. Report weight up to grams	(for example 2.758 kg).
AdmissionDate	Date of admission of the	Date
	patient	YYYY-MM-DD
The date of admission of the p	patient to the hospital, not to the	ward.
SurgerySinceAdmission	Surgery since admission	Boolean
		Y: yes
		<b>N</b> : no
		UNK: unknown
If the patient had surgery betw	veen the date of admission and t	he date of the survey.
CentralVascularCatheter	Presence of central vascular	Boolean
	catheter	Y: yes
		<b>N</b> : no
		UNK: unknown
If the patient has a central vas	cular catheter at 08:00 on the da	y of the survey.
PeripheralVascularCatheter	Presence of peripheral	Boolean
-	vascular catheter	<b>Y</b> : yes
		<b>N</b> : no
		UNK: unknown
If the patient has a peripheral	vascular catheter at 08:00 on the	e day of the survey.

UrinaryCatheter	Presence of urinary catheter	Boolean
		Y: yes
		<b>N</b> : no
		UNK: unknown
If the patient has a urinary cat	heter at 08:00 on the day of the s	urvey.
Intubation	Presence of intubation device	Boolean
		Y: yes
		<b>N</b> : no
		UNK: unknown
If the patient has an intubation	n device present at 08:00 on the c	lay of the survey.
PatientOnAntibiotic	The patient is on antibiotic	Boolean
		Y: yes
		<b>N</b> : no
If the patient is on antibiotic a	ccording to the inclusion criteria.	
PatientNumberAntibiotics	Number of antibiotics prescribed since admission	Number
The number of different antibi	intics prescribed to the patient si	nce admission. This includes

The number of different antibiotics prescribed to the patient since admission. This includes antibiotics that have been discontinued before 8 a.m. on the day of the survey. Only relevant if PatientOnAntibiotic is Y.

## **Optional variables**

#### Underlying infectious disease variables

MalariaStatus	The patient has malaria	Boolean
		Y: yes
		<b>N</b> : no
		UNK: unknown
The current malaria status of the current hospitalization.	of the patient. Indicate as Y if the pa	atient has or had malaria during
TuberculosisStatus	The patient has tuberculosis	Boolean
		Y: yes
		<b>N</b> : no
		UNK: unknown
The current tuberculosis sta tuberculosis during the curr	atus of the patient. Indicate as Y if t rent hospitalization.	he patient has or had active
HIVStatus	The patient has HIV	Boolean
		Y: yes
		<b>N</b> : no

**UNK**: unknown

The HIV status of the patient.

HIVOnART	The patient is on ART	Boolean
		Y: yes
		<b>N</b> : no
		UNK: unknown
If the patient is on ART	or not. Only relevant if HIVStatus is Yes.	
If the patient is on ART HIVCD4Count	or not. Only relevant if HIVStatus is Yes. The CD4 count of HIV patient	Number
·	,	

Report the last available count if multiple counts are reported

### **Comorbidity variables**

McCabeScore	McCabe score of the patient	Coded value
		<b>RF</b> : rapidly fatal, death within a year
		<b>UF</b> : ultimately fatal, death between 1 year and 4 years
		NF: nonfatal, death after 5 years
The McCabe score of the pat	ient. See Annex III.	
MalnutritionStatus	The patient is malnourished	Boolean
		Y: yes
		<b>N</b> : no
		UNK: unknown
If the patient is malnourishe	d or not.	
COPDStatus	The patient has COPD	Boolean
		Y: yes
		<b>N</b> : no
		UNK: unknown
If the patient has COPD or no	ot.	
Hospitalisation varia	bles	
TransferFromHospital	Transfer from another hospita	l Boolean
		Y: yes
		<b>N</b> : no

If the patient has been transferred from another hospital.

TransferFromNonHospital Facility	Transfer from another health facility other than hospital	Boolean
		Y: yes
		<b>N</b> : no
		UNK: unknown
The patient has been transferre homes, residential care facility,		ot a hospital (for example nursing
Hospitalization90Days	Hospitalization within 90 days	Boolean
		Y: yes
		<b>N</b> : no
		UNK: unknown
If the patient had another hosp	vitalization within 90 days prior t	o the current admission.
Surgery variables		
TypeSurgerySinceAdmission	Type of surgery since	Coded value
	admission	<b>M</b> : minimal invasive surgery/ non NHSN
		NHSN: NHSN coded surgery

The patient has surgery between his admission and the date of survey. Only relevant if SurgerySinceAdmission is Y. See Annex IX.

**UNK**: unknown

# 5. Indication data

These variables collect information on the indication of antibiotic treatment and are to be filled out for all eligible patients on antibiotic treatment(s) at 08:00 on the day of the survey. If applicable, more than one indication may be filled out per patient.

## **Core variables**

IndicationCounter	Counter of the indication	Number	
		Sequential number	
The count value of the indication insert 1; for the second indication indication indication indication indication indication in the second indication in the second indication is the second indication in the second indication is the second indicat		by in the patient. For the first indication,	
IndicationType	The type of	Coded value	
	indication	HAI: hospital-associated infection	
		CAI: community-acquired infection	
		SP: surgical prophylaxis	
		MP: medical prophylaxis	
		<b>O</b> : Other	
The type of indication for antib symptoms since admission. See		tient. HAI is based on the date of onset of	
SurgicalProphylaxisDuration		Coded value	
	prophylaxis	SP1: one dose	
		SP2: multiple doses on one day	
		<b>SP3</b> : multiple doses on more than one day	
The duration of surgical prophy prophylaxis (page 30).	ylaxis. Only relevant if	IndicationType is SP. See section Surgical	
SurgicalProphylaxisSite	Site of surgery	Coded Value	
		CNS: Central nervous system	
		EYE: Ophthalmic	
		ENT: Otolaryngology	
		<b>RESP</b> : Respiratory	
		CVS: Cardiovascular system	
		GI: Gastrointestinal tract	
		SSTBJ: Skin, soft tissue, bone and joint	
		UTI: Urinary tract	
		GO: Gynaecology & obstetrics	
		UNK: Site not defined	
Only applicable if IndicationTyp	pe is SP. See Annex X.		

Diagnosis	Diagnosis	Coded value
The diagnosis underlying the indication for antibiotic therapy. See Annex IV. Only relevant if		

IndicationType is CAI or HAI.

StartDateTreatment	The start date of	Date
	treatment	

The date on which the *first* antibiotic treatment was initiated for this particular indication.

If the antibiotic treatment has changed during hospitalization, record the date when the first dose of the first antibiotic treatment was initiated for this indication.

This variable informs on the entire duration of antibiotic treatment for this indication.

The duration of treatment for the current antibiotic is recorded in the antibiotic variable StartDateAntibiotic.

ReasonInNotes	Reasons for antibiotics written in patient's notes	Boolean
		Y: yes, the indication was written in patient notes
		N: no, the indication was not written in patient notes
If the indication for treatme	nt is written in the patie	nt notes or other routine patient

documentation, e.g. temperature charts, drug list etc.

CultureSampleTaken	A sample has	Boolean	
	been taken for microbiology	Y: yes	
	diagnostic	<b>N</b> : no	
		UNK: unknown	

If a sample has been taken for microbiology diagnostics according to the patient notes or other routine patient documentation, or according to ward staff (doctor or nurses). Only relevant if IndicationType is CAI or HAI. If Y, continue with the Microbiology variables.

#### **Microbiology variables**

Microbiology data refers to any culture and susceptibility test result from relevant clinical samples. Screening samples should not be reported. The microbiology variables are to be filled out when CultureSampleTaken is Yes. If the results from the sample(s) are not available, indicate NA under CultureResults and proceed to the next section.

Type of specimen	Coded value
d for the microbiology diagnostics See Annex VII.	. Only relevant if
Results from the culture	Boolean
	NA: not available
	Pos: positive
	Neg: negative
	d for the microbiology diagnostics See Annex VII.

Report the culture results when available, only relevant if CultureSampleTaken is Y.

Negative samples include cultures with no growth or growth of microbes without clinical significance, for example normal flora and mixed flora without clinical significance.

For growth of mixed flora with clinical significance select Pos, and indicate "Microorganism not identified" [\_NONID] under the Microorganism variable.

Microorganism1	Isolated microorganism 1	Coded value
The first isolated microorgan	ism. Only relevant if Communicate	edCultureResults is Y. See Annex VI
Microorganism2	Isolated microorganism 2	Coded value
The second isolated microor Annex VI.	ganism. Only relevant if Commun	icatedCultureResults is Y. See
Microorganism3	Isolated microorganism 3	Coded value
The third isolated microorga Annex VI.	nism. Only relevant if Communica	atedCultureResults is Y. See
AntibioticSusceptibility	Antibiotic susceptibility test	Boolean
TestResults	conducted	Y: yes
		<b>N</b> : no
		UNK: unknown
If an antibiotic susceptibility relevant if CommunicatedCu	test has been undertaken and co IltureResults is Y.	mmunicated to the ward. Only
ResistantPhenotype1	Resistant phenotype 1	Coded value
The first resistant phenotype Annex VIII.	e. Only relevant if AntibioticSuscep	otibilityTestResults is Y. See
ResistantPhenotype2	Resistant phenotype 2	Coded value
The second resistant phenot Annex VIII.	ype. Only relevant if AntibioticSus	sceptibilityTestResults is Y. See
ResistantPhenotype3	Resistant phenotype 3	Coded value
The third resistant phenotyp	e. Only relevant if AntibioticSusce	ptibilityTestResults is Y. See

# 6. Antibiotic data

Collects information on each antibiotic prescribed and/or dispensed to the patient.

When the antibiotic is a combination product, register the combination product as one antibiotic. Conversely, if two or more single products have been prescribed to replace a combination product, enter each single product independently.

Note that one antibiotic can be linked to several indications, and one indication can be linked to several antibiotics using the variable IndicationCounters.

### **Core variables**

AntibioticCounter	Count of the antibiotic	Number	
		Sequential number	
The count value of the antibithe second antibiotic, insert	otic prescribed to the patient. Fo 2 etc.	or the first antibiotic, insert 1; for	
IndicationCounters	Count(s) of the related	List of integers	
	indications	1, 2, 3	
The count value of the indication(s). If the antibiotic cannot be linked to one indication, the field should be kept empty. If more than one indication is linked to the antibiotic, specify al count values of the linked indications separated by comma.			
AntibioticNotesName	Name of the antibiotic in patient notes	Free text	
The name of the antibiotic as written in the patient notes.			
AntibioticINNName	INN Name of the antibiotic	Coded value	
		See list of INN antibiotics	
The name of the antibiotic in	INN.		
If the product is a combination of antibiotics or antibiotic and enzyme inhibitor, list all active substances in the combination. See section on Combination products (page 29) and Annex XI.			
AntibioticWrittenInINN	Antibiotic written in INN	Boolean	
		Y: yes	
		<b>N</b> : no	
The name of the antibiotic was written in INN in the patient's notes.			
Start Date Antibiotic	The start dat of the curren antibiotic		
	ose of the current antibiotic was admission, record the date of ad		

UnitDose	The unit dose	Number
The unit dose administered	l to the patient. See section on Dosir	ng (page 29).
1 1	report the sum of the dose of each a bination products (page 29).	ctive substances except when
Unit Doses Combination	The doses of each active substance in the combination product	Free text
	n active substance in the combinatio ction on Combination products (pag roduct.	
UnitDoseMeasureUnit	The measurement unit of the unit dose	Coded value
The measurement unit of t	he unit dose. See Annex XIII.	
Unit Dose Frequency	The daily frequency of the administration of the unit dose	Number
The daily frequency of the	administered unit dose.	
If the antibiotic is given one every 30 hours, enter 0.8.	ce a day, enter 1; twice a day, enter 2	; once every two days, enter 0.5
Multiplying the single dose dose.	by the daily frequency allows calcul	ation of the prescribed daily
See section on Dosing (pag	e 29).	
AdministrationRoute	The route of administration of	Coded value
	the antibiotic	<b>O</b> : oral
		P: parenteral
		INH: inhalation
		R: rectal
	n of the antibiotic.	

## **Optional variables**

### Prescriber variables

PrescriberType	The type of prescriber	Coded value
		SP: specialist physician
		GP: non-specialist physician
		<b>O</b> : other
		UNK: unknown
Specifies the professional	l training of the prescriber (specia	list, non-specialist physician or

other).

ParenteralType	Type of parenteral	Coded value
	administration	IM: intramuscular
		IV-B: intermittent intravenous
		IV-C: continuous intravenous
		IV-E: extended intravenous
		<b>O</b> : other
The type of parenteral adr AdministrationRoute is P.	ninistration, either bolus or cor	ntinuous. Only relevant when

## Route of administration variables

OralSwitch	Oral switch	Boolean
		Y: yes
		<b>N</b> : no
		UNK: unknown

If the oral antibiotic is the result of switching from a parenteral formulation. Only relevant when AdministrationRoute is 0.

### Dose administration variables

NbMissedDoses	Number of missed doses	Number
		UNK: unknown
	s from the start date of the curre es have been missed, report as (	ent antibiotic treatment until the ). If unknown, report as UNK.
MissedDosesReason	Reason for missed doses	Coded value
		S: missed doses due to stock out
		<b>P</b> : the patient could not purchase the doses
		<b>O</b> : missed doses due to other reason
		M: missed doses due to multiple reasons
		UNK: unknown
Report the reason for the mi		stock out at the hospital pharmacy.

Only relevant when NbMissedDoses > 0.

### Treatment guideline variables

GuidelinesCompliance	Compliance to the guidelines Coded value
	Y: yes
	<b>N</b> : no
	<b>NA</b> : not assessable
	NI: no information
•	or the indication (antibiotic substance, route of administration e clinical guidelines at the facility (national or local guideline or rendation).
If no guidelines exist (either indication, report as "Not as	local or national) or if the antibiotic is used for more than one sessable".
If the antibiotic is not linked	to any indication report as "No information"

If the antibiotic is not linked to any indication, report as "No information".

TreatmentType	Directed or empirical	Coded value
	treatment	<b>D</b> : Directed treatment
		E: Empirical treatment
If the antibiotic was prescribed	l in response to microbiology re	esults, report as directed therapy.

If the antibiotic was prescribed in response to microbiology results, report as directed therapy Otherwise, report as empirical.

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# ANNEX I Types of ward

Departments	Ward type code	Ward type name
Paediatric	PMW	Paediatric medical ward
	PSW	Paediatric surgical ward
	PHRW	High risk paediatric ward (see high risk units)
	PICU	Paediatric intensive care unit
Neonatal	NMW	Neonatal medical ward
	NICU	Neonatal intensive care unit
Adult	AMW	Adult medical ward
	ASW	Adult surgical ward
	AHRW	High risk adult ward (see high risk units)
	AICU	Adult intensive care unit
Mixed	MXW	Mixed ward

## ANNEX II Specialties<sup>1</sup>

Ward/Patient specialty code	Ward/Patient specialty name	Ward/Patient specialty code	Ward/Patient specialty name
SURGEN	General surgery	MEDHEMA	Haematology
SURDIG	Digestive tract surgery	MEDBMT	Bone marrow
SURORTO	Orthopaedics		transplantation (BMT)
SURTR	Traumatology	MEDCARD	Cardiology
SURCARD	Cardio surgery	MEDDERM	Dermatology
SURVASC	Vascular surgery	MEDNEPH	Nephrology
SURTHO	Thoracic surgery	MEDNEU	Neurology
SURNEU	Neurosurgery	MEDPNEU	Pneumology
SURPED	Paediatric general surgery	MEDRHEU	Rheumatology
SURTRANS	Transplantation surgery	MEDID	Infectious diseases
SURONCO	Surgery for cancer	MEDTR	Medical traumatology
SURENT	Otorhinolaryngology	MEDOTH	Other medical
SUROPH	Ophthalmology	PEDGEN	Paediatrics general, not specialized
SURMAXFAC	Maxillofacial surgery	PEDNEO	Neonatology
SURSTODEN	Stomatology/Dentistry	ICUNEO	Neonatal ICU
SURBURN	Burn care	ICUPED	Paediatric ICU
SURURO	Urology	ICUMED	Medical ICU
SURPLAS	Plastic and reconstructive surgery	ICUSUR	Surgical ICU
SUROTH	Other surgery	ΙΟΜΙΧ	Mixed (polyvalent) ICU,
MEDGEN	General medicine		general intensive or critical care
MEDGAST	Gastroenterology	ICUSPEC	Specialized ICU
MEDHEP	Hepatology	ІСИОТН	Other ICU
MEDENDO	Endocrinology	GOOBS	Obstetrics/Maternity
MEDONCO	Oncology	GOGYN	Gynaecology

<sup>&</sup>lt;sup>1</sup> Adapted from ECDC (1).

## ANNEX III McCabe score<sup>1</sup>

Examples of diseases for different McCabe score categories:

Rapidly fatal: < 1 year

End-stage haematological malignancies (unsuitable for transplant, or relapsed), heart failure (EF < 25%) and end-stage liver disease (unsuitable for transplant with recalcitrant ascites, encephalopathy or varices)

Multiple organ failure on intensive care unit – APACHE II score > 30, SAPS II score > 70

Ultimately fatal: 1 year to 4 years

Chronic leukaemias, myelomas, lymphomas, metastatic carcinoma, end-stage kidney disease (without transplant)

Motor neuron disease, multiple sclerosis nonresponsive to treatment

Alzheimer's disease/dementia

Diabetes requiring amputation or post amputation

Nonfatal: > 5 years

Diabetes

Carcinoma/haematological malignancy with > 80% 5-year survival

Inflammatory disorders

Chronic GI, GU conditions

Obstetrics

Infections (including HIV, HCV, HBV – unless in above categories)

All other diseases

<sup>&</sup>lt;sup>1</sup> Adapted from ECDC (1).

## ANNEX IV Diagnoses<sup>1</sup>

Examples
Infections of the central nervous system
Endophthalmitis and other bacterial eye conditions
Infections of ear, nose, throat, larynx and mouth
Acute bronchitis or exacerbations of chronic bronchitis
Pneumonia
Cystic fibrosis
Cardiovascular infections: endocarditis, vascular graft
Gastrointestinal infections (e.g. salmonellosis, antibiotic-associated diarrhoea)
Intra-abdominal sepsis, including hepatobiliary
Surgical site infection involving skin or soft tissue but not bone
Cellulitis, wound, deep soft tissue not involving bone, not related to surgery
Septic arthritis, osteomyelitis of surgical site
Septic arthritis, osteomyelitis, not related to surgery
Symptomatic lower urinary tract infection (e.g. cystitis)
Symptomatic upper urinary tract infection (e.g. pyelonephritis)
Asymptomatic bacteriuria
Obstetric or gynaecological infections
Prostatitis, epididymo-orchitis
Sexually transmitted disease (e.g. syphilis, gonorrhea, chlamydia)
Laboratory-confirmed bacteraemia
Clinical sepsis (suspected bloodstream infection without lab confirmation/results are not available, no blood cultures collected or negative blood culture), excluding febrile neutropenia
Febrile neutropenia or other form of manifestation of infection in immunocompromised host (e.g. HIV, chemotherapy, etc.) with no clear anatomical site
Systemic inflammatory response with no clear anatomical site
Completely undefined; site with no systemic inflammation
Not applicable; for antibiotic use other than treatment

<sup>&</sup>lt;sup>1</sup> Adapted from ECDC (1).

## ANNEX V Definition of hospitalassociated infection<sup>1</sup>

Classification for hospital-associated infections (HAI) versus communityacquired infections is based on the date of onset of the infection after admission. Date of onset is defined as the date of first signs or symptoms of the infection. If unknown, record the date when treatment was started for this infection or the date when the first sample was taken. If dates are missing, please estimate. If signs or symptoms were present at admission, then the infection should not be considered as hospital-associated.

Infection categorized as HAI if date on onset is on:

Day 3 onwards

OR

Day 1 or Day 2 AND patient transferred from another hospital

OR

Day 1 or Day 2 AND patient discharged from a hospital (same hospital or another one) in preceding 48 hours

<sup>&</sup>lt;sup>1</sup> Adapted from ECDC (1).

## ANNEX VI Microorganism codes<sup>1</sup>

The microorganism code list has been defined by ECDC using the following criteria: frequency of occurrence in healthcare-associated infections and/or public health importance.

Family	Microorganism	Code
Gram + cocci	Staphylococcus aureus	STAAUR
	Staphylococcus epidermidis	STAEPI
	Staphylococcus haemolyticus	STAHAE
	Coagulase-negative staphylococci, not specified	STACNS
	Other coagulase-negative staphylococci (CNS)	STAOTH
	Staphylococcus spp., not specified	STANSP
	Streptococcus pneumoniae	STRPNE
	Streptococcus agalactiae (B)	STRAGA
	Streptococcus pyogenes (A)	STRPYO
	Other haemolytic streptococci (C, G)	STRHCG
	Streptococcus spp., other	STROTH
	Streptococcus spp., not specified	STRNSP
	Enterococcus faecalis	ENCFAE
	Enterococcus faecium	ENCFAI
	Enterococcus spp., other	ENCOTH
	Enterococcus spp., not specified	ENCNSP
	Gram-positive cocci, not specified	GPCNSP
	Other Gram-positive cocci	GPCOTH
Gram – cocci	Moraxella catharralis	MORCAT
	Moraxella spp., other	MOROTH
	Moraxella spp., not specified	MORNSP
	Neisseria meningitides	NEIMEN
	<i>Neisseria</i> spp., other	NEIOTH
	Neisseria spp., not specified	NEINSP
	Gram-negative cocci, not specified	GNCNSP
	Other Gram-negative cocci	GNCOTH

<sup>&</sup>lt;sup>1</sup> Adapted from ECDC (1).

Family	Microorganism	Code
Gram + bacilli	Corynebacterium spp.	CORSPP
	Bacillus spp.	BACSPP
	Lactobacillus spp.	LACSPP
	Listeria monocytogenes	LISMON
	Gram-positive bacilli, not specified	GPBNSP
	Other Gram-positive bacilli	GPBOTH
Enterobacteriaceae	Citrobacter freundii	CITFRE
	Citrobacter koseri (e.g. diversus)	CITDIV
	Citrobacter spp., other	CITOTH
	Citrobacter spp., not specified	CITNSP
	Enterobacter cloacae	ENBCLO
	Enterobacter aerogenes	ENBAER
	Enterobacter agglomerans	ENBAGG
	Enterobacter sakazakii	ENBSAK
	Enterobacter gergoviae	ENBGER
	Enterobacter spp., other	ENBOTH
	Enterobacter spp., not specified	ENBNSP
	Escherichia coli	ESCCOL
	Klebsiella pneumoniae	KLEPNE
	Klebsiella oxytoca	KLEOXY
	Klebsiella spp., other	KLEOTH
	Klebsiella spp., not specified	KLENSP
	Proteus mirabilis	PRTMIR
	Proteus vulgaris	PRTVUL
	Proteus spp., other	PRTOTH
	Proteus spp., not specified	PRTNSP
	Serratia marcescens	SERMAR
	Serratia liquefaciens	SERLIQ
	Serratia spp., other	SEROTH
	Serratia spp., not specified	SERNSP
	Hafnia spp.	HAFSPP
	Morganella spp.	MOGSPP
	Providencia spp.	PRVSPP
	Salmonella enteritidis	SALENT
	Salmonella typhi or paratyphi	SALTYP
	Salmonella typhimurium	SALTYM
	Salmonella spp., not specified	SALNSP
	Salmonella spp., other	SALOTH
	Shigella spp.	SHISPP
	Yersinia spp.	YERSPP
	Other enterobacteriaceae	ETBOTH
	Enterobacteriaceae, not specified	ETBNSP

Family	Microorganism	Code
Gram – bacilli	Acinetobacter baumannii	ACIBAU
	Acinetobacter calcoaceticus	ACICAL
	Acinetobacter haemolyticus	ACIHAE
	Acinetobacter lwoffii	ACILWO
	Acinetobacter spp., other	ACIOTH
	Acinetobacter spp., not specified	ACINSP
	Pseudomonas aeruginosa	PSEAER
	Stenotrophomonas maltophilia	STEMAL
	Burkholderia cepacia	BURCEP
	Pseudomonadaceae family, other	PSEOTH
	Pseudomonadaceae family, not specified	PSENSP
	Haemophilus influenza	HAEINF
	Haemophilus parainfluenzae	HAEPAI
	Haemophilus spp., other	HAEOTH
	Haemophilus spp., not specified	HAENSP
	Legionella spp.	LEGSPP
	Achromobacter spp.	ACHSPP
	Aeromonas spp.	AEMSPF
	Agrobacterium spp.	AGRSPP
	Alcaligenes spp.	ALCSPP
	Campylobacter spp.	CAMSPF
	Flavobacterium spp.	FLASPP
	Gardnerella spp.	GARSPF
	Helicobacter pylori	HELPYL
	Pasteurella spp.	PASSPP
	Gram-negative bacilli, not specified	GNBNSF
	Other Gram-negative bacilli, non enterobacteriaceae	GNBOTH
Anaerobic bacilli	Bacteroïdes fragilis	BATFRA
	<i>Bacteroïdes</i> other	BATOTH
	Clostridium difficile	CLODIF
	<i>Clostridium</i> other	CLOOTH
	Propionibacterium spp.	PROSPF
	Prevotella spp.	PRESPP
	Anaerobes, not specified	ANANSP
	Other anaerobes	ANAOTH
Other bacteria	Mycobacterium, atypical	MYCATY
	Mycobacterium tuberculosis complex	MYCTUE
	Chlamydia spp.	CHLSPP
	Mycoplasma spp.	MYPSPF
	Actinomyces spp.	ACTSPP
	Nocardia spp.	NOCSPF
	Other bacteria	встотн

Family	Microorganism	Code
Fungi		_FUNG
Microorganism not identified		_NONID
Examination not done		_NOEXA
Sterile examination		_STERI
Result not (yet) available or missing		_NA

# ANNEX VII Category of microbiology specimen

Code	Name
В	Blood
U	Urine
S	Sputum/Respiratory sample (incl. bronchoalveolar lavage)
W	Wound
F	Sterile fluids (cerebrospinal, synovial, peritoneal)
0	Other
## ANNEX VIII Resistant phenotypes<sup>1</sup>

Microorganisms			Codes		
Staphylococcus aureus	MSSA	MRSA	VRSA	VISA	UNK
Enterococcus spp.		VRE			UNK
Enterobacteriaceae		C3G	CAR		UNK
Pseudomonas aeruginosa		CAR			UNK
Acinotebacter spp.		CAR	COL		UNK

UNK, unknown.

#### Staphylococcus aureus

- MSSA
  - Susceptible to oxacillin, or
  - Susceptible to one of cefoxitin, cloxacillin, dicloxacillin, flucloxacillin, methicillin
- MRSA
  - Resistant to oxacillin, or
  - Resistant to one of cefoxitin, cloxacillin, dicloxacillin, flucloxacillin, methicillin
- VRSA
  - Resistant to glycopeptides, either vancomycin or teicoplanin
- VISA
  - Intermediate to glycopeptides, either vancomycin or teicoplanin

#### Enterococcus spp.

- VRE
  - Resistant to glycopeptides, either vancomycin or teicoplanin

<sup>&</sup>lt;sup>1</sup> Adapted from ECDC (1).

#### Enterobacteriaceae

- C3G
  - Resistant to third-generation cephalosporins, cefotaxime, ceftriaxone, ceftazidime
- CAR
  - Resistant to carbapenems, ertapenem, imipenem, meropenem, doripenem

#### Pseudomonas aeruginosa

- CAR
  - Resistant to carbapenems, imipenem, meropenem, doripenem

#### Acinetobacter spp.

- CAR
  - Resistant to carbapenems, imipenem, meropenem, doripenem
- COL
  - Resistant to colistin

## ANNEX IX Surgical categories<sup>1</sup>

Surgery is classified as NHSN or non-NHSN surgery. NHSN surgery is defined in the list below. Any surgery not included in this list is considered as non-NHSN surgery.

Abdominal aortic aneurysm repair	Knee prosthesis
Abdominal hysterectomy	Laminectomy
Appendix surgery	Limb amputation
Bile duct, liver or pancreatic surgery	Liver transplant
Breast surgery	Neck surgery
Cardiac surgery	Open reduction of fracture
Carotid endarterectomy	Ovarian surgery
Cesarean section	Pacemaker surgery
Colon surgery	Peripheral vascular bypass surgery
Coronary artery bypass graft with both chest	Prostate surgery
and donor site incisions	Rectal surgery
Coronary artery bypass graft with chest incision only	Refusion of spine
Craniotomy	Shunt for dialysis
Exploratory laparotomy	Small bowel surgery
Gallbladder surgery	Spinal fusion
Gastric surgery	Spleen surgery
Heart transplant	Thoracic surgery
Herniorrhaphy	Thyroid and/or parathyroid surgery
Hip prosthesis	Vaginal hysterectomy
Kidney surgery	Ventricular shunt
Kidney transplant	

**Examples of non-NHSN surgery** 

Obstetrical procedures: peri-delivery/labour (one or more) ICD-9-CM 75.3 and 75.9

Dental extraction: ICD-9-CM code 23.1 Surgical removal

Transurethral resection of prostate

Incision and drainage of abscess with secondary closure

Any diabetic forefoot amputation with healing by secondary intention

Any other operation where healing is by secondary intention

<sup>&</sup>lt;sup>1</sup> Adapted from ECDC (1).

#### Examples of non-NHSN surgery

Tonsillectomy

Application of external fixator/Olizarov

Extraventricular drain

Hysteroscopic removal of fibroids; evacuation of retained products of conception

## ANNEX X Sites for surgical prophylaxis

Code	Description
CNS	Central-nervous system
EYE	Ophthalmic
ENT	Otolaryngology
RESP	Respiratory
CVS	Cardiovascular system
GI	Gastrointestinal tract
SSTBJ	Skin, soft tissue, bone and joint
UTI	Urinary tract
GO	Gynaecology and obstetrics
UNK	Site not defined

#### Examples

Thorax surgery is classified as RESP for lung surgery, and CVS for heart surgery Liver and pancreatic surgery is classified as GI Spleen surgery is classified as CVS Kidney surgery is classified as UTI

## ANNEX XI Antibiotic and enzyme inhibitor names

Antibiotics (INN)	ATC code	Notes
amikacin	J01GB06	
amoxicillin	J01CA04	
ampicillin	J01CA01	
arbekacin	J01GB12	
aspoxicillin	J01CA19	
azanidazole	P01AB04	
azidocillin	J01CE04	
azithromycin	J01FA10	
azlocillin	J01CA09	
aztreonam	J01DF01	
bacampicillin	J01CA06	
bacitracin	J01XX10	
bekanamycin	J01GB13	
benzathine benzylpenicillin	J01CE08	
benzathine phenoxymethylpenicillin	J01CE10	
benzylpenicillin	J01CE01	
biapenem	J01DH05	
brodimoprim	J01EA02	
carbenicillin	J01CA03	
carindacillin	J01CA05	
carumonam	J01DF02	
catamoxef	J01DD06	
cefacetrile	J01DB10	
cefaclor	J01DC04	
cefadroxil	J01DB05	
cefalexin	J01DB01	
cefaloridine	J01DB02	
cefalotin	J01DB03	
cefamandole	J01DC03	
cefapirin	J01DB08	
cefatrizine	J01DB07	
cefazedone	J01DB06	

Antibiotics (INN)	ATC code	Notes
cefazolin	J01DB04	
cefbuperazone	J01DC13	
cefcapene	J01DD17	
cefdinir	J01DD15	
cefditoren	J01DD16	
cefepime	J01DE01	
cefetamet	J01DD10	
cefixime	J01DD08	
cefmenoxime	J01DD05	
cefmetazole	J01DC09	
cefminox	J01DC12	
cefodizime	J01DD09	
cefoperazone	J01DD12	
ceforanide	J01DC11	
cefotaxime	J01DD01	
cefotetan	J01DC05	
cefotiam	J01DC07	
cefoxitin	J01DC01	
cefozopran	J01DE03	
cefpiramide	J01DD11	
cefpirome	J01DE02	
cefpodoxime	J01DD13	
cefprozil	J01DC10	
cefradine	J01DB09	
cefroxadine	J01DB11	
cefsulodin	J01DD03	
ceftaroline fosamil	J01DI02	
ceftazidime	J01DD02	
ceftezole	J01DB12	
ceftibuten	J01DD14	
ceftizoxime	J01DD07	
ceftobiprole medocaril	J01DI01	
ceftolozane	J01DI54	
ceftriaxone	J01DD04	
cefuroxime	J01DC02	
chloramphenicol	J01BA01	
chlortetracycline	J01AA03	
cinoxacin	J01MB06	
ciprofloxacin	J01MA02	
clarithromycin	J01FA09	

Antibiotics (INN)	ATC code	Notes
clindamycin	J01FF01	
clofoctol	J01XX03	
clometocillin	J01CE07	
clomocycline	J01AA11	
cloxacillin	J01CF02	
colistin	J01XB01	
dalbavancin	J01XA04	
dalfopristin	J01FG02	
daptomycin	J01XX09	
demeclocycline	J01AA01	
dibekacin	J01GB09	
dicloxacillin	J01CF01	
dirithromycin	J01FA13	
doripenem	J01DH04	
doxycycline	J01AA02	
efonicide	J01DC06	
enoxacin	J01MA04	
epicillin	J01CA07	
ertapenem	J01DH03	
erythromycin	J01FA01	
faropenem	J01DI03	
fleroxacin	J01MA08	
flomoxef	J01DC14	
flucloxacillin	J01CF05	
flumequine	J01MB07	
flurithromycin	J01FA14	
fosfomycin	J01XX01	
furazidin	J01XE03	
fusidic acid	J01XC01	
garenoxacin	J01MA19	
gatifloxacin	J01MA16	
gemifloxacin	J01MA15	
gentamicin	J01GB03	
grepafloxacin	J01MA11	
hetacillin	J01CA18	
iclaprim	J01EA03	
imipenem	J01DH51	Do not refer to cilastatin
isepamicin	J01GB11	
josamycin	J01FA07	
kanamycin	J01GB04	

Antibiotics (INN)	ATC code	Notes
levofloxacin	J01MA12	
lincomycin	J01FF02	
linezolid	J01XX08	
lomefloxacin	J01MA07	
loracarbef	J01DC08	
lymecycline	J01AA04	
mandelic acid	J01XX06	
mecillinam	J01CA11	
meropenem	J01DH02	
metacycline	J01AA05	
metampicillin	J01CA14	
methenamine	J01XX05	
meticillin	J01CF03	
metronidazole	J01XD01 (parenter	al); P01AB01 (oral, rectal)
mezlocillin	J01CA10	
midecamycin	J01FA03	
minocycline	J01AA08	
miocamycin	J01FA11	
moxifloxacin	J01MA14	
nafcillin	J01CF06	
nalidixic acid	J01MB02	
nemonoxacin	J01MB08	
neomycin	J01GB05	
netilmicin	J01GB07	
nifurtoinol	J01XE02	
nimorazole	P01AB06	
nitrofurantoin	J01XE01	
nitroxoline	J01XX07	
norfloxacin	J01MA06	
ofloxacin	J01MA01	
oleandomycin	J01FA05	
oritavancin	J01XA05	
ornidazole	J01XD03 (parenter	al); P01AB03 (oral, rectal)
oxacillin	J01CF04	
oxolinic acid	J01MB05	
oxytetracycline	J01AA06	
panipenem	J01DH55	Do not refer to betamipron
pazufloxacin	J01MA18	
pefloxacin	J01MA03	
penamecillin	J01CE06	

Antibiotics (INN)	ATC code	Notes
penimepicycline	J01AA10	
pheneticillin	J01CE05	
phenoxymethylpenicillin	J01CE02	
pipemidic acid	J01MB04	
piperacillin	J01CA12	
piromidic acid	J01MB03	
pivampicillin	J01CA02	
pivmecillinam	J01CA08	
polymyxin b	J01XB02	
popicillin	J01CE03	
pristinamycin	J01FG01	
procaine benzylpenicillin	J01CE09	
propenidazole	P01AB05	
prulifloxacin	J01MA17	
quinupristin	J01FG02	
ribostamycin	J01GB10	
rokitamycin	J01FA12	
rolitetracycline	J01AA09	
rosoxacin	J01MB01	
roxithromycin	J01FA06	
rufloxacin	J01MA10	
secnidazole	P01AB07	
sisomicin	J01GB08	
sitafloxacin	J01MA21	
solithromycin	J01FA16	
sparfloxacin	J01MA09	
spectinomycin	J01XX04	
spiramycin	J01FA02	
streptoduocin	J01GA02	
streptomycin	J01GA01	
sulbenicillin	J01CA16	
sulfadiazine	J01EC02	
sulfadimethoxine	J01ED01	
sulfadimidine	J01EB03	
sulfafurazole	J01EB05	
sulfaisodimidine	J01EB01	
sulfalene	J01ED02	
sulfamazone	J01ED09	
sulfamerazine	J01ED07	
sulfamethizole	J01EB02	

Antibiotics (INN)	ATC code	Notes
sulfamethoxazole	J01EC01	
sulfamethoxypyridazine	J01ED05	
sulfametomidine	J01ED03	
sulfametoxydiazine	J01ED04	
sulfametrole	no ATC	Used in combination with trimethoprim (J01EE03)
sulfamoxole	J01EC03	
sulfanilamide	J01EB06	
sulfaperin	J01ED06	
sulfaphenazole	J01ED08	
sulfapyridine	J01EB04	
sulfathiazole	J01EB07	
sulfathiourea	J01EB08	
talampicillin	J01CA15	
tedizolid	J01XX11	
teicoplanin	J01XA02	
telavancin	J01XA03	
telithromycin	J01FA15	
temafloxacin	J01MA05	
temocillin	J01CA17	
tetracycline	J01AA07	
tetroxoprim	no ATC	Used in combination with
		sulfadiazine (J01EE06)
thiamphenicol	J01BA02	
ticarcillin	J01CA13	
tigecycline	J01AA12	
tinidazole	J01XD02 (parenteral	); P01AB02 (oral, rectal)
tobramycin	J01GB01	
trimethoprim	J01EA01	
troleandomycin	J01FA08	
trovafloxacin	J01MA13	
vancomycin	J01XA01 (parenteral	); A07AA09 (oral)
xibornol	J01XX02	

#### Beta-lactamase inhibitors

avibactam cilastatin clavulanic acid sulbactam tazobactam vaborbactam

## ANNEX XII Hospital questionnaire

	Question	Type of answer
	Infrastructure	
11	Does your facility have a functioning Drugs and Therapeutics Committee in the hospital?	Y/N
12	Does your facility have a functioning Infection Prevention & Control Committee in the hospital?	Y/N
13	Does your facility have a functioning committee on pharmacovigilance in the hospital?	Y/N
14	Does your facility have microbiological laboratory/division within the hospital?	Y/N
15	Does your facility have access to microbiological services outside the hospital?	Y/N
16	Does your facility have a formal antimicrobial stewardship programme accountable for ensuring appropriate antibiotic use?	Y/N
17	Does your facility have a formal organizational structure responsible for antimicrobial stewardship? (eg, a multidisciplinary committee focused on appropriate antibiotic use, pharmacy committee, patient safety committee, or other relevant structure)	Y/N
18	Is an antimicrobial stewardship team available at your facility? (eg, greater than one staff member supporting clinical decisions and implementing a comprehensive programme [= set of interventions] to ensure appropriate antibiotic use)	Y/N
19	How many full-time equivalent staff (physician, pharmacist, nurse) are part of the antimicrobial stewardship team and running these stewardship activities on a daily basis in your hospital as part of a dedicated antimicrobial stewardship programme?	Number
110	Is there a physician identified as a leader for antimicrobial stewardship activities at your facility?	Y/N
11	Is there a pharmacist responsible for ensuring appropriate antibiotic use at your facility?	Y/N
112	Does your facility provide any salary support for dedicated time for antimicrobial stewardship activities? (eg, percentage of full-time equivalent staff for ensuring appropriate antibiotic use)	Y/N
113	Does your facility have the information technology (IT) capability to support the needs of the antimicrobial stewardship activities?	Y/N
114	Does your facility have an outpatient parenteral antibiotic therapy (OPAT) unit?	Y/N

	Policy and practice	
P1	Does your facility have an antibiotic formulary (including unrestricted and restricted antibiotics) updated continuously?	Y/N
P2	Is your antibiotic formulary based on the Essential Drug List?	Y/N
P3	Does your facility have an antibiotic guideline?	Y/N
P4	Does your facility have a local antibiotic guideline?	Y/N
Р5	Are your local antibiotic guidelines based on local antibiotic susceptibility to assist with antibiotic selection for common clinical conditions?	Y/N
P6	Does your facility have a written policy that requires prescribers to document an indication in the medical record or during order entry for all antibiotic prescriptions?	Y/N
P7	Is it routine practice for specified antibiotic agents to be approved by a physician or pharmacist in your facility? (eg, preauthorization)	Y/N
P8	Is there a formal procedure for a physician, pharmacist or other staff member to review the appropriateness of an antibiotic at or after 48 hours from the initial order (post-prescription review)?	Y/N
	Monitoring and feedback	
M1	Does your facility monitor whether the indication is captured in the medical record for all antibiotic prescriptions?	Y/N
М2	Does your facility audit or review surgical antibiotic prophylaxis choice and duration?	Y/N
М3	Are results of antibiotic audits or reviews communicated directly with prescribers?	Y/N
М4	Does your facility monitor antibiotic use?	Y/N
M5	Does your facility monitor antibiotic use by grams (Defined Daily Dose [DDD]) or counts (Days of Therapy [DOT]) of antibiotic(s) by patient per day?	Y/N
M6	Is monitored antibiotic use reported by hospital activity denominator (by number of admissions/discharges or by number of bed-days/patient-days)?	Y/N
М7	Has an annual report focused on antimicrobial stewardship (summary antibiotic use and/or practices improvement initiatives) been produced for your facility in the past year?	Y/N
M8	Has your facility produced a cumulative antibiotic susceptibility report in the past year?	Y/N
М9	Is your facility participating in a national antibiotic resistance surveillance programme?	Y/N
M10	Is your facility participating in a national antibiotic use surveillance programme?	
M10	How many blood cultures have been made in the past year?	Number
M11	List of antibiotics out of stock at the facility during the survey period.	Text

### ANNEX XIII Measurement units

Code	Name
G	gram
MG	milligram
IU	international unit
MU	millions of international units

## ANNEX XIV ISO country codes

Country or Area Name	ISO ALPHA-3 Code	Country or Area Name	ISO ALPHA-3 Code
Afghanistan	AFG	Brunei Darussalam	BRN
Aland Islands	ALA	Bulgaria	BGR
Albania	ALB	Burkina Faso	BFA
Algeria	DZA	Burundi	BDI
American Samoa	ASM	Cambodia	КНМ
Andorra	AND	Cameroon	CMR
Angola	AGO	Canada	CAN
Anguilla	AIA	Cape Verde	CPV
Antarctica	ATA	Cayman Islands	СҮМ
Antigua and Barbuda	ATG	Central African Republic	CAF
Argentina	ARG	Chad	TCD
Armenia	ARM	Chile	CHL
Aruba	ABW	China	CHN
Australia	AUS	Hong Kong, SAR China	HKG
Austria	AUT	Macao, SAR China	MAC
Azerbaijan	AZE	Christmas Island	CXR
Bahamas	BHS	Cocos (Keeling) Islands	ССК
Bahrain	BHR	Colombia	COL
Bangladesh	BGD	Comoros	СОМ
Barbados	BRB	Congo (Brazzaville)	COG
Belarus	BLR	Congo (Kinshasa)	COD
Belgium	BEL	Cook Islands	СОК
Belize	BLZ	Costa Rica	CRI
Benin	BEN	Côte d'Ivoire	CIV
Bermuda	BMU	Croatia	HRV
Bhutan	BTN	Cuba	CUB
Bolivia	BOL	Cyprus	CYP
Bosnia and Herzegovina	BIH	Czech Republic	CZE
Botswana	BWA	Denmark	DNK
Bouvet Island	BVT	Djibouti	DJI
Brazil	BRA	Dominica	DMA
British Indian Ocean Territory	ΙΟΤ	Dominican Republic	DOM
British Virgin Islands	VGB	Ecuador	ECU

Country or Area Name	ISO ALPHA-3 Code	Country or Area Name	ISO ALPHA-3 Code
Egypt	EGY	Ireland	IRL
El Salvador	SLV	Isle of Man	IMN
Equatorial Guinea	GNQ	Israel	ISR
Eritrea	ERI	Italy	ITA
Estonia	EST	Jamaica	JAM
Ethiopia	ETH	Japan	JPN
Falkland Islands (Malvinas)	FLK	Jersey	JEY
Faroe Islands	FRO	Jordan	JOR
Fiji	FJI	Kazakhstan	KAZ
Finland	FIN	Kenya	KEN
France	FRA	Kiribati	KIR
French Guiana	GUF	Korea (North)	PRK
French Polynesia	PYF	Korea (South)	KOR
French Southern Territories	ATF	Kuwait	KWT
Gabon	GAB	Kyrgyzstan	KGZ
Gambia	GMB	Lao PDR	LAO
Georgia	GEO	Latvia	LVA
Germany	DEU	Lebanon	LBN
Ghana	GHA	Lesotho	LSO
Gibraltar	GIB	Liberia	LBR
Greece	GRC	Libya	LBY
Greenland	GRL	Liechtenstein	LIE
Grenada	GRD	Lithuania	LTU
Guadeloupe	GLP	Luxembourg	LUX
Guam	GUM	Macedonia, Republic of	MKD
Guatemala	GTM	Madagascar	MDG
Guernsey	GGY	Malawi	MWI
Guinea	GIN	Malaysia	MYS
Guinea-Bissau	GNB	Maldives	MDV
Guyana	GUY	Mali	MLI
Haiti	HTI	Malta	MLT
Heard and McDonald Islands	HMD	Marshall Islands	MHL
Holy See (Vatican City State)	VAT	Martinique	MTQ
Honduras	HND	Mauritania	MRT
Hungary	HUN	Mauritius	MUS
Iceland	ISL	Mayotte	MYT
India	IND	Mexico	MEX
Indonesia	IDN	Micronesia, Federated States	
Iran, Islamic Republic of	IRN	of	FSM
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TUN	Uzbekistan	UZB
TUR	Vanuatu	VUT
ТКМ	Venezuela (Bolivarian	
TCA	Republic)	VEN
TUV	Viet Nam	VNM
UGA	Virgin Islands, US	VIR
UKR	Wallis and Futuna Islands	WLF
ARE	Western Sahara	ESH
GBR	Yemen	YEM
USA	Zambia	ZMB
UMI	Zimbabwe	ZWE
	TTO TUN TUR TKM TCA TUV UGA UKR ARE GBR USA	TTOUruguayTUNUzbekistanTURVanuatuTKMVenezuela (BolivarianTCARepublic)TUVViet NamUGAVirgin Islands, USUKRWallis and Futuna IslandsAREWestern SaharaGBRYemenUSAZambiaZimbaburo

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## Country form: WHO Point Prevalence Survey on Antibiotic Use

	Question	Description		Answer
1	CountryName	Name of country	Free Text	
2	CountryISO	Three letter country code (ISO alpha-3). See Annex XIV	Text	
3	TotalNumberHospital	Total number of hospitals at any level in the country	Integer	
4	NumberPublicHospital	Number of public hospitals in the country	Integer	
5	NumberNonPublicHospital	Estimated number of private hospitals in the country	Integer	
6	NumberTertiaryHospital	Estimated number of tertiary level hospitals in the country	Integer	
7	NumberSecondaryHospital	Estimated number of secondary level hospitals in the country	Integer	
8	NumberPrimaryHospital	Estimated number of primary level hospitals in the country	Integer	
9	NumberSpecialityHospital	Estimated number of especialized hospitals in the country	Integer	
10	NationalHospitalGroups	If hospital groups exist in the country, = 'Yes'	Yes/No	
11	HospitalSampling	Specify the sampling strategy for selection of	A/R/C	
12	HospConvenSampling	If convenience sampling used, describe the approach	Free Text	
13	InvitedHospital	Total number of invited hospitals	Integer	
14	NationalGuideline	Are there national treatment guidelines?	Yes/No	
15	LocalGuideline	Are there hospital treatment guidelines?	Yes/No	
16	NationalAMS	Is there a national antimicrobial stewardship program for hospitals	Yes/No	



## Hospital form: WHO Point Prevalence Survey on Antibiotic Use

HospitalID		HospitalCode	
SurveyStartDate	yyyy-mm-dd	SurveyEndDate	yyyy-mm-dd
HospitalGroup	Yes / No	HospitalGroupCode	
HospitalGroupAllSitesIncluded	Yes / No	HospitalType	Primary / Secondary /Tertiary / Specialised
HospitalSpecialisedTypeSpeciality		Hospital Ownership	PUB / PRVNFP / PRVFP / OTH / UNK
HospitalTotalBeds		HospitalAcuteBeds	
HospitalICUBeds		HospitalHighRiskBeds	
HospitalAnnualAdmissions		HospitalAnnualPatientDays	
HospitalIncludedBeds		HospitalEligiblePatients	
HospitalIncludedPatients		PatientSampling	Yes / No

	Ward form: WH	O Point Prevalence	e Survey on	<b>Antibiotic Use</b>
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WardID		Hospital code	
WardCode		WardInvestigator	
WardSurveyDate	yyyy-mm-dd	WardType	Annex I
*WardTotalPatients		**WardEligiblePatients	
WardIncludedPatients			

\*Note: WardTotalPatients also includes day cases and/or long term care patients

\*\*When sampling is conducted, report the number of patients sampled and not the number of eligible patients in the ward

OPTIONAL: WardSpecialties. List all specialties represented in the ward (see Annex II), and separate by comma.



WHO



## Patient form: WHO Point Prevalence Survey on Antibiotic Use

#### CORE: Patient demographics

HospitalCode		WardID	
SurveyDate	yyyy-mm-dd	WardCode	
PatientID		PatientCode	
Gender	M / F /T / UNK	AgeYear (>2 years)	
AgeMonth (0-23 months)		PreTermBirth	LP / MP / VP / EP
Child12YearWeight		NeonatesBirthWeight	·
AdmissionDate	yyyy-mm-dd	SurgerySinceAdmission	Yes / No / UNK
CentralVascularCatheter	Yes / No / UNK	PeripheralVascularCatheter	Yes / No / UNK
UrinaryCatheter	Yes / No / UNK	Intubation	Yes / No / UNK
PatientOnAntibiotic	Yes / No	PatientNumberAntibiotics	
	· · · · · · · · · · · · · · · · · · ·		
OPTIONAL: Underlying infectious d	iseases variables		
MalariaStatus	Yes / No / UNK	TuberculosisStatus	Yes / No / UNK
HIVStatus	Yes / No / UNK	HIVOnART*	Yes / No / UNK
HIVCD4Count*	Number/UNKNOWN	*Only if HIVStatus = "Yes"	
OPTIONAL: Comorbidities variables	5		
McCabeScore	RF / UF / NF	MalnutritionStatus	Yes / No / UNK
COPDStatus	Yes /No / UNK		
OPTIONAL: Hospitalisation variable	25		
TransferFromHospital	Yes / No / UNK	TransferFromNonHospital	Yes / No / UNK
Hospitalization90Days	Yes / No / UNK		
OPTIONAL: Surgery variable (Only I	if SurgerySinceAdmission = Yes)		
TypeSurgerySinceAdmission		M / NHSN / UNK	
AdditionalComments:			

# Indication form: WHO Point Prevalence Survey on Antibiotic Use

Core variables

PatientCode	Wa	ardCode	HospitalCoo	de
IndicationCounter	1	2	3	4
IndicationType	HAI / CAI / SP / MP / O	HAI / CAI / SP / MP / O	HAI / CAI / SP / MP / O	HAI / CAI / SP / MP / O
	If IndicationType is SP:			
Surg.Proph.Duration	SP1 / SP2 / SP3	SP1 / SP2 / SP3	SP1 / SP2 / SP3	SP1 / SP2 / SP3
Surg.Proph.Site	Annex X	Annex X	Annex X	Annex X
Diagnosis	Annex IV	Annex IV	Annex IV	Annex IV
StartDateTreatment	yyyy-mm-dd	yyyy-mm-dd	yyyy-mm-dd	yyyy-mm-dd
ReasonInNotes	YES / NO	YES / NO	YES / NO	YES / NO
CultureSampleTaken	Yes / No / UNK	Yes / No / UNK	Yes / No / UNK	Yes / No / UNK

If Culture Sample taken is YES then proceed to **Microbiology Form** 

Comments:	



# Antibiotic form (1): WHO Point Prevalence Survey (PPS) on Hospital Antibiotic Use

		HospitalCode	Ward	WardCode			PatientCode			
Core v	ariables									
Antibiotic Counter	Indication Counters	Antibiotic Notes Name	Antibiotic INN Name	Antibiotic WrittenInINN	StartDate Antibiotic	UnitDose	UnitDoses Combination	UnitDose MeasureUnit	UnitDose Frequency	Administration Route
1				YES NO	yyyy-mm-dd			MG G IU MU		O P I R
2				YES NO	yyyy-mm-dd			MG G IU MU		O P I R
3				YES NO	уууу-mm-dd			MG G IU MU		O P I R
4				YES NO	yyyy-mm-dd			MG G IU MU		O P I R
5				YES NO	yyyy-mm-dd			MG G IU MU		O P I R
6				YES NO	уууу-mm-dd			MG G IU MU		O P I R



## Antibiotic form (2): WHO Point Prevalence Survey (PPS) on Hospital Antibiotic Use

	HospitalCode	2		WardCode		PatientCode		
Optional variables								
Antibiotic Counter	PrescriberType	ParenteralType	OralSwitch	Number MissedDoses	MissedDoses Reason	Guidelines Compliance	TreatmentType	
1	SP GP O N	IM IV-B IV-C IV-E O	YES NO UNK		S P O M UNK	Y N NA NI	D	
2	SP GP O N	IM IV-B IV-C IV-E O	YES NO UNK		S P O M UNK	Y N NA NI	D E	
3	SP GP O N	IM IV-B IV-C IV-E O	YES NO UNK		S P O M UNK	Y N NA NI	D	
4	SP GP O N	IM IV-B IV-C IV-E O	YES NO UNK		S P O M UNK	Y N NA NI	D	
5	SP GP O N	IM IV-B IV-C IV-E O	YES NO UNK		S P O M UNK	Y N NA NI	D	
6	SP GP O N	IM IV-B IV-C IV-E	YES NO UNK		S P O M	Y N NA NI	D	



# Microbiology form: WHO Point Prevalence Survey on Antibiotic Use

HospitalCode		Pati	PatientCode			
WardCode						
Microbiology data refers to a	any culture & susceptibility result from	m a relevant	clinical sample. Screenii	ng samples	should not be reported.	
Specimen 1:	SpecimenType		Annex VII			
	CultureResult		NA / Pos / Neg			
If CultureResult is Pos:						
Microorganism:	1 annex VI	2	annex VI	3	annex VI	
AntibioticSusceptibilityTestR						
	1 Yes / No / UNK	2	Yes / No / UNK	3	Yes / No / UNK	
ResistantPhenotype	(Only if AntibioticSusceptibil					
	1 annex VIII	2	annex VIII	3	annex VIII	
Specimen 2:	SpecimenType		Annex VII			
	CultureResult		NA / Pos / Neg			
If CultureResult is Pos:						
Microorganism:	1 annex VI	2	annex VI	3	annex VI	
AntibioticSusceptibilityTestR	esults					
	1 Yes / No / UNK	2	Yes / No / UNK	3	Yes / No / UNK	
ResistantPhenotype	(Only if AntibioticSusceptibil					
	1 annex VIII	2	annex VIII	3	annex VIII	
Specimen 3:	SpecimenType		Annex VII			
	CultureResult		NA / Pos / Neg			
If CultureResult is Pos:						
Microorganism:	1 annex VI	2	annex VI	3	annex VI	
AntibioticSusceptibilityTestR	esults					
	1 Yes / No / UNK	2	Yes / No / UNK	3	Yes / No / UNK	
ResistantPhenotype	(Only if AntibioticSusceptibil	ityTestResul	ts is Yes)			
	1 annex VIII	2	annex VIII	3	annex VIII	
Specimen 4:	SpecimenType		Annex VII			
	CultureResult		NA / Pos / Neg			
If CultureResult is Pos:						
Microorganism:	1 annex VI	2	annex VI	3	annex VI	
AntibioticSusceptibilityTestR	esults					
	1 Yes / No / UNK	2	Yes / No / UNK	3	Yes / No / UNK	
ResistantPhenotype	(Only if AntibioticSusceptibil	(Only if AntibioticSusceptibilityTestResults is Yes)				
	1 annex VIII	2	annex VIII	3	annex VIII	



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