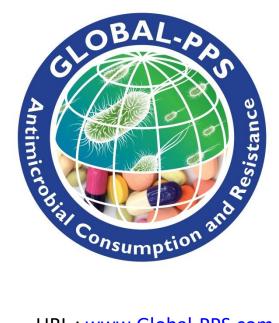
Global Point Prevalence Survey of Antimicrobial Consumption and Resistance (2023 GLOBAL-PPS)



URL : <u>www.Global-PPS.com</u>

PROTOCOL to collect OUTPATIENT prescribing data

-version November 2023 -

Lead Investigator: Erika Vlieghe (University of Antwerp, Belgium)

<u>Coordinating Centre & Technical Support</u>: Ann Versporten, Ines Pauwels, Annelies Boven, Nico Drapier, Jimmy Keustermans, Anna Ivanova, Laboratory of Medical Microbiology, University of Antwerp, Antwerp, Belgium.

Private Funding Authority: bioMérieux

Contents

BACKGROUND - AIMS	.4
GLOBAL-PPS PROTOCOL SPECIFICS	. 5
« WEBPPS - STEP BY STEP PROCEDURE »	.9
DATA COLLECTION FORMS	11
 The UNIT form The OUTPATIENT form	11 12
EXPORT YOUR DATA	15
VALIDATION PROCESS	15
FEEDBACK	15

THE DATA COLLECTION FORMS AND APPENDICES ARE AVAILABLE AS SEPARATE DOCUMENTS TO THIS PROTOCOL:

OUTPATIENT FORMS:

- > UNIT FORM
- > OUTPATIENT FORM
- > ADDITIONAL OUTPATIENT FORM short version for outpatients NOT on antimicrobials

APPENDICES for the OUTPATIENT FORMS:

- > APPENDIX I : Clinical diagnostic codes
- > APPENDIX II : Type of Indication
- > APPENDX III : Combination of anti-infective agents
- Print one unit form for each different unit or room.
- Print one outpatient form <u>for each outpatient</u> seen in the surveyed timeslot on the day of the survey AND <u>been prescribed at least one antimicrobial</u>.
- Print one additional outpatient form (short version) for the recording of outpatients seen in the surveyed timeslot on the day of the survey who are <u>NOT on antimicrobials</u>.

Any healthcare facility from any country worldwide is welcome to participate. They can choose one or more appropriate periods of participation.

November 2023 version of protocol:

- Correction of exclusion criteria
- Correction of link to Global-PPS tool

BACKGROUND - AIMS

The Global Point Prevalence Survey (Global-PPS or G-PPS) provides a simple, freely available web-based tool to measure and monitor antimicrobial prescribing and resistance in institutions worldwide. The Global-PPS has established a global network of institutions conducting point prevalence surveys and provides quantifiable measures to assess and compare quantity and quality of antimicrobial prescribing, prevalence of health-care associated infections (HAI) and resistance in hospitalized adults, children and neonates worldwide.

The Global-PPS was first piloted in 2014, with worldwide studies conducted in 2015¹ and 2017. Since 2018, three survey periods a year are available. The Global-PPS is coordinated at the University of Antwerp, Belgium and sponsored through an unrestricted grant given to them annually by bioMérieux.

This outpatient Global-PPS protocol is produced thanks to the cooperation of <u>several Global-PPS</u> <u>participants</u>. Their valuable comments and recommendations were taken into account when drafting this protocol. For the first time, it is also possible to monitor antimicrobial prescribing among patients in outpatient care facilities using the method of a point prevalence survey. This protocol is an extension of the existing Global-PPS protocol to monitor inpatients.

The outpatient module offers a trustworthy way to collect antimicrobial use data in outpatients in highas well as low- and middle- income countries. Participating institutions receive extensive, high-quality information about prescribing patterns in their outpatient units.

Main aims of the outpatient Global-PPS

- Survey performance indicators and *identify targets for quality improvement of antimicrobial prescribing (identify burden!)*
- Helps in designing tailor-made interventions that aim at promoting prudent use of antimicrobials (change practice!)
- > Allows to assess the effectiveness of such interventions, through repeated PPS (measure impact!)

The Global-PPS tool supports the concept of simplicity and feasibility by providing a user-friendly hands-on tool that can be repeated easily to support stewardship programs.

This tool has illustrated many core benefits:

- The web-based tool supports real-time data collection, is easy to use, requires minimal training, speeding up and simplifying data entry;
- The institution (hospital or healthcare facility) will be able to download a real-time one-point report which can be used for local communications and presentations (foreseen later in 2023);
- > There is evidence of consistency and reproducibility with the data entry using this tool;
- Participation in the survey has encouraged thorough engagement and feedback, enhancing communication between prescribers and the local infectious diseases colleagues;
- The Global-PPS enables sharing of best practices and raises awareness of inappropriate antimicrobial prescribing with broad adaptability and suitability for a range of healthcare resource settings.

¹ Versporten A, Zarb P, Caniaux I, Gros MF, et al. Antimicrobial consumption and resistance in adult hospital inpatients in 53 countries: results of an internet-based global point prevalence survey. Lancet Glob Health. 2018;6:e619-e629.

GLOBAL-PPS PROTOCOL SPECIFICS

1. Outpatient units involved

The following units/departments and **institutions (hospital or healthcare facility)** can be monitored using the Global-PPS outpatient module:

- Emergency, outpatient departments and day surgery departments of hospitals
- <u>Outpatient clinics</u> or out-of-hospital clinics such as primary care clinics, urgent care clinics, ambulatory surgery centres including day surgery units <u>not</u> requiring overnight admission or stay.
- Primary healthcare centres or community health centres for outpatients that:
 - \circ have a limited number of inpatients beds available and/or
 - \circ $\$ have observation beds for patients not staying overnight or
 - have no inpatients or observation beds available.

All outpatient units (wards/departments) or rooms within the participating institution should preferably be included if you participate for the very first time in this outpatient module.

Each unit or room included in the survey has to be surveyed <u>only once on a single day within a timeslot of</u> <u>at least 4 hours</u> (see also point : Timeframe of surveillance). However, different units or rooms can be surveyed on different days.

Each institution shall decide on which days data collection shall take place (depends on the size of the institution and own organization) as long as it is within the stipulated time frame.

2. <u>Timeframe of surveillance</u>

Data should be "collected" within three predefined time frames a year:

- May-August 2023
- September-December 2023
- January–April 2024

"Data collection" should be finished within the period it was started. Preferably, the institution completes the Point Prevalence Survey (PPS) within a maximum of *4 consecutive weeks* from the start of the data collection.

Survey the unit or room for at least 4 hours; or about a half a day (unless the duration of the consultation session is shorter, in which case, survey for the whole session duration). Preferably start the survey at the beginning of the session. The approximate starting hour (e.g. 8 a.m.), and approximate ending hour (e.g. 3 p.m.) should be specified (see data collection "Unit form").

3. Inclusion criteria

Include ALL outpatients seen during the defined timeslot of the PPS. Outpatients are defined as patients who are not admitted as an inpatient, who do not require overnight admission or stay. These patients are seen on consultation for any reason by appointment or not by appointment. Sampling of outpatients is not allowed (see also point 10 - ethical approval, page 7).

<u>Important exception</u>: patients on specific units such as <u>emergency units</u> (wards) or <u>observation units</u> (wards) who slept overnight due to specific reasons (e.g. waiting for transfer to inpatient ward) should also be included **if they are still present on the unit** and occupying a bed **during the timeframe of surveillance on the day of the PPS**. For these patients, an outpatient form should be completed as well.

4. Exclusion criteria

- Patients on consultation beyond the monitoring period of at least 4 hours (see timeframe surveillance).

5. Denominator and numerator data

<u>Denominator</u> data are collected at <u>patient level</u> whereby for each patient on consultation and seen within the timeframe of the survey, a minimum set of data is collected. For patients on antimicrobials, detailed patient and antimicrobial use information is collected (=<u>numerator</u>).

Note the difference with the inpatient module where denominators are collected at ward level.

6. Which antimicrobial agents to include ?

- > A **newly prescribed antimicrobial** = an antimicrobial prescribed during consultation.
- Ongoing antimicrobials = an antimicrobial for therapeutic or prophylactic use that the patient was already taking at the time of the consultation and this antimicrobial was not stopped at the time of the consultation. Include also antimicrobials the patient only takes e.g. every 48 hours.

Antimicrobials to include:

- Antibacterials for systemic use: J01
- Antimycotics and antifungals for systemic use: J02 & D01BA (including griseofulvin and terbinafine)
- **Drugs for treatment of tuberculosis**: J04A (these are the antibiotics as well as all other drugs to treat tuberculosis)
- Antibiotics used as intestinal anti-infectives: A07AA
- Antiprotozoals used as antibacterial agents, nitroimidazole derivatives: P01AB
- Antivirals for systemic use: J05
- Antimalarials: P01B

Antimicrobials for topical use are <u>excluded</u> from the survey.

The Global-PPS online application provides the list of all antimicrobials to be surveyed according to the WHO ATC classification². The antimicrobial list (excel) is available at <u>www.global-pps.com/documents</u>. The file contains all substances with their route of administration. The file also provides information on the antimicrobial (sub)classes. In case an antimicrobial is not in the provided list, contact <u>Global-PPS@uantwerpen.be</u>

Extra information for surgical prophylaxis : The "**intended duration**" of the administration of antibiotics for surgical prophylaxis administered on "day surgery departments" **should be checked** in order to encode the duration of prophylaxis as either **one dose**, **one day** (=multiple doses given in one day) or **>1 day**. The duration of surgical prophylaxis is recorded under the variable 'Type of indication' (see outpatient data collection forms, page 5).

7. Multidisciplinary team

The healthcare facilities are invited to create a multidisciplinary team of colleagues familiar with reading patient notes and having adequate knowledge on local guidelines. A *local administrator* has to be assigned and he/she will be the main contact person for the Global-PPS Coordinating Centre & Technical Support team at the University of Antwerp, Belgium. If the institution already participated in the Global-PPS before (inpatient protocol), you need to get in touch with the already existing local administrator for your institution. If the local administrator is not known or you do not know whether the institution participated in the Global-PPS before, please get in touch with global-pps@uantwerpen.be. It is important to enter outpatient antimicrobial prescribing data to the already existing database for your institution, because this

² http://www.whocc.no/atc_ddd_index/

is the only way to get access to all previously entered inpatient data for your institution, which will allow you to retrieve longitudinal feedback reports, including previously entered data. In this way, all antimicrobial use data will be entered in one single database for your institution including inpatient and outpatient data.

The local administrator is responsible for:

- the online registration of the institution (hospital or healthcare facility)
- entering patient-specific data into the Global-PPS tool,
- the data validation and
- the production of the local feedback reports.

Extra hospital users may, however, be registered within the Global-PPS tool in order to help the local administrator with data entry (see IT manual – add supplementary hospital users, for more information with respect to centralized data entry by a network coordinator; available on the online data entry application).

8. Data Privacy

A sequence number is assigned to each <u>institution (hospital or healthcare facility)</u> after registration in the Global-PPS tool. Institution names will never be revealed in any report or publication without approval from the participant (e.g. for peer-reviewed articles).

<u>Patients</u> are completely anonymised in the Global-PPS tool. Every patient record will be given a unique non-identifiable survey number. This number is automatically generated by the software application, based on several internal codes. This number identifies the patient uniquely in the Global-PPS database. For more information, consult the data privacy excerpt (contact global-pps@uantwerpen.be).

9. Data ownership

- Data are the property of the respective institution. (Previously) entered inpatient and/or outpatient data remain available to the institution at all times.
- The Global-PPS coordinating centre & technical support team at the University of Antwerp, Belgium is guardian of the data within the database;
 - will analyse the data and programme the automatic reports. These analyses and reports are property of the Global-PPS;
 - facilitates country- and/or region-specific analyses.

For more information, consult the data privacy excerpt (contact global-pps@uantwerpen.be).

10. Ethical approval

For approval by ethical committee & privacy legislation requirements, the Global-PPS coordinating centre & technical support team can provide, on request, a data privacy excerpt that can be submitted to institutions ethical committees if needed. Further, depending on the local setting and mode of data collection, a patient informed consent form or other common form may be required. Please note that the aim is to collect complete data within the defined timeframe of at least 4 hours (see point 2, page 5), sample-based data collection should be avoided. For more information contact <u>Global-PPS@uantwerpen.be</u>.

11. **Technical support**

The Global-PPS coordinating centre & technical support team at the University of Antwerp provides a "help

desk" for software or any other issues encountered and/or questions during the data collection and data entering (<u>Global-PPS@uantwerpen.be</u>). The team is constantly available for general queries about the project.

The Global-PPS tool <u>https://app.globalpps.uantwerpen.be/globalpps_webpps/</u> offers:

- 1. internal checks to avoid invalid or erroneous figures (e.g. for out-of-range values)
- 2. boxes popping up to guide you to fill out a field
- 3. help functions which provide supplementary information on each screen
- 4. Help pages, IT manual, FAQ list.

Web page layout for the forms is similar to the paper version.

Regular backups of the database will guarantee the integrity of data. The format to export data is Microsoft Excel[®].

The software and database are hosted on a server at the University of Antwerp in Belgium, Europe. The Global-PPS coordinating centre & technical support team can provide more details on ensured data protection and safeguarding (contact <u>global-PPS@uantwerpen.be</u>).

12. Publication policy

The Global-PPS coordinating centre & technical support team looks for opportunities for dissemination and encourages country-specific analyses. For publications at national or regional level, participants need to comply with the publication strategy as designed by the Global-PPS coordinating centre & technical support team. The publication strategy will guide you on how to proceed. The publication policy is available at <u>www.global-pps.com/documents</u>.

The Global-PPS collects information about the indication for antimicrobial prescriptions. This is to be interpreted as <u>what the clinician or prescriber aims at treating</u>. If needed, the investigator should be looking at all [medical, nursing and drug prescription chart] patient records, if available. If the information available is not sufficient, surveyor/s may request additional information from the healthcare workers.

At no point shall there be any discussion about the appropriateness (or lack thereof) of the prescribed antimicrobial. The staff MUST NOT feel evaluated at the individual level.

« <u>WebPPS - STEP BY STEP PROCEDURE</u> » ALL THE FOLLOWING STEPS MUST BE COMPLETED BEFORE ENTRY OF ANY OUTPATIENT SURVEY DATA

1. Log in on the Global-PPS website

It is important that inpatient and outpatient data collected for an institution are kept in <u>one database</u> at institutional level.

Applicable for institutions who <u>previously participated</u> at least once in the Global-PPS:

Institutions (hospital or healthcare facility) that have previously participated in the Global-PPS should <u>log in with their existing password</u> linked to an email address! Only then will they be able to activate a new survey using the same institution number as the one previously assigned. Only then will they be able to download a longitudinal feedback report, including the results of previous surveys conducted for their institution.

- The already registered participant must use his existing login (username) and password. If this information is lost, contact <u>Global-PPS@uantwerpen.be</u>
- New participants belonging to an institution that has previously participated should contact the local administrator of the institution. If the local administrator is no longer working at the institution, please contact <u>Global-PPS@uantwerpen.be</u>. The Global-PPS team will make the necessary arrangements to connect you to the existing institution. Important, do not create a new institution (with a different ID number) as you will not be able to download a longitudinal feedback report!

2. <u>Register yourself and the institution on the Global-PPS website</u>

Applicable for institutions (hospitals or healthcare facilities) participating for the first time:

First-time participants **for** <u>institutions that have never participated</u> in the Global-PPS should register at <u>https://app.globalpps.uantwerpen.be/globalpps_webpps/register</u>. They will receive an email to confirm their email address (to avoid spam registration). They can then login to the Global-PPS tool (do not forget to tick the captcha): <u>https://app.globalpps.uantwerpen.be/globalpps_webpps/login</u>.

The participant must then register the institution (hospital or healthcare facility) in the Global-PPS tool. Included institutions are:

- Several **hospital types**³: primary, secondary, tertiary, specialized, infectious diseases, paediatric hospitals.
- Outpatient clinics
- Primary healthcare centres or community health centres for outpatients.

By default, the person who first registers the hospital is the **local administrator**. He/she has access to all functionalities of the programme. The local administrator can add additional users to give other people the rights to also enter data for his/her institution (see **IT manual** available on the Global-PPS tool).

³ **Primary level:** often referred to as a district hospital or first-level referral. The hospital has few specialities, mainly internal medicine, obstetrics-gynaecology, paediatrics, and general surgery, or only general practice; limited laboratory services are available for general, but not for specialized pathological analysis. Often corresponds to general hospital without teaching function. <u>Secondary level</u>: often referred to as provincial hospital. A hospital highly differentiated by function with five to ten clinical specialities including some haematology, oncology, renal and ICU beds; takes some referrals from other (Primary) hospitals. Often corresponds to general hospital with highly specialized staff and technical equipment, e.g., ICU, Haematology, Transplantation, cardio-thoracic surgery, neurosurgery and specialized imaging units; clinical services are highly differentiated by function; provides regional services and regularly takes referrals from other (primary and secondary) hospitals. Often correspond to University hospital. <u>Specialized hospital:</u> Single clinical speciality, possibly with sub-specialties; highly specialized staff and technical equipment.

3. Prepare the department list.

Hospitals who participated before need to add new outpatient departments.

After login, one first needs to define ALL the outpatient units at institutional level as departments. At survey level, these so-called "units" specific for outpatient settings then appear in the drop-down list when entering survey data.

The definition of a department at institutional level follows a hierarchical structure, they are entered manually in the Global-PPS tool. For each department, the following information is needed:

- The NAME of the department. This field is mandatory and uniquely identifies the department in the database. This uniquely defined name is used in the drop-down lists while entering the survey data. All outpatient departments/units under surveillance should be included.
- Code and description = optional. It allows you to describe the department/unit name in more detail. •
- Patient Care Type. Mandatory field. Choose 'Outpatients' for outpatient units. •
- Specialty Type. Mandatory field. Choose, if available in the institution (hospital or healthcare facility) ٠ between the following 24 outpatient specialties:
 - EM (Emergency)
- GM (General Medicine mixed)¹
- OB (Observation) SM (Surgical Mixed) RESP (Respiratory)
 - HO (Haematology-Oncology)

ENT (Ear Nose and Throat)

EYE (Ophthalmology)

ENDO (Endoscopy)

- ID (Infectious disease)
- PLAS (Plastic Reconstructive Surgical) ORT (Orthopaedic)

- HIV/TB (HIV-Tuberculosis) REN (Nephrology-urology)
- DIAL (Dialyses)
- GAS (Gastroenterology)

- HCP (Healthcare Practice)
- GP (General Practitioner practise)
- MAL (Malnutrition)
- NM (Neonatal Medical)
- ANC (Antenatal care)
- GYN (Gynaecology)
- OBST (Obstetrics)
- DEN (Dental Clinic)

4. Select the appropriate survey

Select the survey online: go to Surveys/available surveys and "register" for the correct survey according the appropriate time frame (Jan-Apr; May-Aug; Sept-Dec). Select the module(s) (functionalities) you want to participate in. Thereafter go to Surveys/subscribed and click on the appropriate survey to activate the survey for data entry.

5. Enter patient data

ONLY after all of the steps mentioned above have been carried out (1 to 4), one can start entering patient data.

Important difference with the inpatient module of the Global-PPS: denominators for the outpatient module are collected at patient level. This means that a minimum set of variables is collected for each patient who is seen in the unit during a specific time slot, with more detailed information collected only for patients with an antimicrobial prescription (numerator).

DATA COLLECTION FORMS

To distinguish outpatient forms from inpatient forms, a department or ward is called a unit, even if they belong to a hospital (e.g. emergency ward).

To facilitate the data collection in the outpatient units, print :

- 1. one single paper **Unit form** for each unit or room under surveillance (page 1 of outpatient data collection forms).
- 2. a number of detailed '**Outpatient forms**' depending on the number of outpatients on consultation and seen in the unit/room during the timeslot surveyed (page 2 of outpatient data collection forms).
- 3. Alternatively, the "Outpatient GPPS data collection form-short version for patients not on antimicrobials.doc" can be used to collect baseline information for patients NOT on antimicrobials. For these patients the detailed Outpatient form (item 2) does not need to be completed; and this detailed form can then be used only for those outpatients on at least one antimicrobial.

Print also the corresponding appendices. The data collection forms correspond to the online web forms.

After data collection for each unit or room, attach to the unit form all the individual outpatient forms; these are the patients on antimicrobial treatment or prophylaxis and those <u>not</u> on antimicrobials during the timeslot studied.

The online application also supports direct online data entry. However, in this case all patient data should be readily available during online data entry because most of the variables are mandatory to collect and enter online before one can register the patient in the database.

* <u>The UNIT form</u>

> Unless otherwise defined, all variables below are mandatory to complete.

Date of survey – The date on which the unit, or room belonging to the particular unit, is surveyed: dd/mm/yyyy.

Auditor code – *optional field* - Code, initials or else of the person completing the form. The code can be used to track possible bias linked to the auditor.

Institution name- Name of institution (hospital or healthcare facility) .

Unit name–<u>Unique</u> name of the unit/department/ward.

Room name – *optional field* - <u>Unique</u> name of the room belonging to a particular unit. Of note, a unit can have several rooms. Define these uniquely!

Unit Type of specialty – Defines the most appropriate type of outpatient unit. Select only one type. The complete list is available in the outpatient data collection forms, p. 1, and in this protocol p. 9.

Total number of prescribers on the unit/room during defined timeslot of the survey – Count the number of doctors, nurses, pharmacists and/or others who were prescribing the antimicrobials to the outpatients during the timeslot of the survey. Fill in the number 0 if (one of these) prescribers are not present during the timeslot of the survey. Fill in 0 if the healthcare professionals were present, but not prescribing antimicrobials.

Timeslot of data gathering on the day of the survey – specify the approximate starting time and ending time (in hours and minutes AM or PM) on the day of the survey. The unit must be <u>surveyed for at least 4 hours or</u> <u>about half a day</u>, unless the duration of the consultation session is shorter, then survey for the whole session duration. Preferably start the survey at the beginning of the session.

The OUTPATIENT form

During the survey timeslot of at least 4 hours (see p. 10), all data are collected at patient level.

The outpatient form allows to collect three types of information:

- 1. General patient information: to collect for ALL patients seen during the timeslot of survey, whether the patient was on antimicrobials or not (=denominator)
- 2. Detailed patient information
- 3. Antimicrobial information
- to collect for each patient on antimicrobials (=numerator)

(1) General patient information:

Unit (Name/code)– This is the unique **name** of the unit studied. This name is selected using the drop-down list in the Global-PPS tool, as this outpatient unit name has been defined during the preparation of the department list at institutional level (see step "prepare the department list", page 10)

Room (Name/code) – This is the unique name of a room within the unit. If the unit does not contain separate rooms, please use the same room name for all patients or leave the room name blank. *Optional field*.

Unique Patient Identifier – This is a unique number allowing local tracing at patient-level for any clarifications (e.g. the clinical record/note number, sequential number). This information will not (and cannot) be reported or submitted in the Global-PPS database.

Survey Number – It's a unique non-identifiable number generated by the Global-PPS tool for each patient record. Please ensure that the person entering the data online *writes down this number immediately when it is generated by the tool as it will not be displayed again*. This number identifies the patient uniquely in the Global-PPS database, and starts with OP-[number]. Important, this number will be generated when all data has been correctly entered online and will be given to you after clicking :

Save and add new patient registration

Only then, the patient is stored in the database !

Patient age group – This is the age category of the patient. Choose one of three options: adults (\geq 18 years old), child (\leq 17 years old) or neonate (\leq 30 days old).

Sex – This is the sex of the patient. Choose one of three options: Male, Female or Unknown.

Admission status – For emergency and observation units, it is requested to also register patients who slept overnight due to specific reasons, e.g. they are waiting for transfer to another institution or ward and are still present during the timeslot of survey (see inclusion criteria page 5). For these specific units only, the *status of admission needs to be recorded "as decided during the 4-hour survey period (see timeslot)"*. There are 5 possibilities:

- already admitted = decision of admission is taken;
- suspected admission = awaiting for admission, final decision not yet taken;
- referral other institution,
- home,
- ► UNK.

Presenting symptoms or reason of consultation on the day of the survey – These are the presenting symptoms of a patient on the day of the survey. Choose at least 1 and maximum 6 symptoms (see outpatient data collection form, page 2).

(2) Detailed patient information

Complete only if the <u>outpatient had a new/ongoing antimicrobial prescription</u> during the defined survey time.

Age – Optional field. Three fields, one for the year, one for the month and one for the days, are available. **Only** one of these fields needs to be completed as follows:

- If \leq 30 days old, write the exact numbers of days.
- > For patients older than 1 month and younger than 2 years, fill in month field. (e.g. 19 months)
- If the patient is at least 2 years old, then only the year field is to be recorded.

Current weight - Write the current weight in Kg with one decimal number (Optional field)

Birth weight – Write the birth weight in Kg with one decimal number. **Only for neonates** (optional field)

Treatment based on biomarker data or white blood cell count (WBC) – Tick 'Yes' or 'No'. It refers to whether or not biomarker results are used to initiate the antibiotic treatment. If yes, next lines should also be completed with 4 possible answers (report the most relevant one):

- CRP = in case the treatment is based on results of CRP (*C-reactive protein*)
- PCT = in case the treatment is based on results of PCT (procalcitonin)
- WBC = in case the treatment is based on elevated white blood cell count. Normal number of WBCs in the blood is ± 4,500 to 11,000 WBCs per microliter.

Type of biological fluid sample: choose between Blood, Urine or Other.

Complete if available also the **most relevant value close to the start of the antibiotic treatment** (numeric optional field) in mg/L, µg/L, ng/L, ng/dL, ng/dL, ng/mL, µg/mL, nmol/L. In thousand per microliter (µL) for WBC count.

For conversion calculator see: <u>http://unitslab.com/node/67</u> (CRP) and <u>http://unitslab.com/node/103</u> (procalcitonin).

Treatment based on POCT (Point of Care Test) or RDT (Rapid Diagnostic Test) – Tick 'Yes' or 'No'. It refers to whether or not POCT or RDT results are used to initiate the antibiotic treatment. If yes, specify only 1 single POCT or RDT (report the most appropriate one) (see list outpatient data collection form, page 3).

Underlying morbidity – Refers to underlying morbidities a patient has at time of the survey. Select at least 1 and maximum 3 choices (see list outpatient data collection form, page 2).

(3) Antimicrobial information

Complete only if the <u>outpatient had a new/ongoing antimicrobial prescription</u> during the defined survey time.

Antimicrobial Drug Name – This is the generic name (e.g. amoxicillin and beta-lactamase inhibitor and not Augmentin[®]). Antimicrobials for **topical use** applied on the skin/eye/ear etc are **not** included. The antimicrobial data are automatically recorded in the Global-PPS tool with its ATC5 code following the ATC classification system of the WHO Collaborating Centre for Drug Statistics. (<u>https://www.whocc.no/atc_ddd_index/</u>). See page 6 of this protocol for antimicrobials to include.

Prescription/course: Tick 'New' or 'Ongoing'. It refers to whether the antimicrobial treatment is first prescribed on the day of the survey ('new'), or if it was already prescribed before and not stopped during the day of the survey ('ongoing').

Administered "Single Unit Dose" and "Unit" of Dose – Administered dose is the actual prescribed single unit dose per administration, expressed in mg, g, IU or MU. Provide number of times/day given in next variable (doses/day).

- For <u>combination with one active ingredient as the main antimicrobial agent</u>, like penicillins with betalactamase inhibitors, only the content of active ingredient should be recorded and entered in the Global-PPS tool. E.g. amoxicillin and beta-lactamase inhibitor 500/125 (amoxicillin 500 mg and clavulanic acid 125 mg as potassium salt) should be entered as 500 mg. Important: this must still be listed as amoxicillin and beta-lactamase inhibitor and NOT amoxicillin!
- For <u>combinations with two or more active ingredients</u> like sulfamethoxazole and trimethoprim, the total content should be entered in Global-PPS *tool*. For example sulfamethoxazole 200 mg/ trimethoprim 40 mg will be recorded as 240 mg.

Combinations of an antibiotic and an enzyme inhibitor:

J01CR01 Ampicillin and beta-lactamase inhibitor: report only ampicillin dose J01CR02 Amoxicillin and beta-lactamase inhibitor: report only amoxicillin dose J01CR03 Ticarcillin and beta-lactamase inhibitor: report only ticarcillin dose J01CR05 Piperacillin and beta-lactamase inhibitor: report only piperacillin dose

Examples can be found on: https://www.whocc.no/ddd/list_of_ddds_combined_products/

Doses per Day – This refers to the number of actual prescribed doses per 24 hours. For example every 6 hours = 4; every 8h = 3, every 12h = 2, every 16h = 1.5, every 36h = 0.67, and every 48h = 0.5 doses per day.

Route – Route of Administration. Five routes of administration are included: Oral=O, Intravenous and intrathecal and intraperitoneal=P, Intramuscular=IM, Rectal=R, Inhalation=I. For analyses intravenous, intrathecal and intramuscular are all parenteral use (=P).

Prescribed / intended duration in N days or UNK– This refers to number of <u>days</u> the antimicrobial is prescribed. Specify the number of days (if it exceeds 100 days, please write down 100 days).

Clinical diagnosis – This is the reason to treat the patient (see appendix I, page 4 of outpatient data collection forms). <u>Select ONLY ONE</u> of the possibilities. If more categories are possible, write the one most applicable. Request additional information from doctors, nurses or pharmacists if needed.

Type of indication – Refers to whether it concerns therapeutic treatment (Community Acquired Infection=CAI or Healthcare-Associated Infection=HAI) or prophylactic use (Medical or surgical). The indication should be obtained from ward staff if missing (See appendix II, page 5 of outpatient data collection forms for available codes).

For surgical patients, The "intended duration" of the administration of antibiotics for surgical prophylaxis administered on "day surgery departments" should be checked in order to encode the duration of prophylaxis as either one dose, one day (=multiple doses given in one day) or >1 day.

Local guidelines exist – This refers to (e.g. local/national/WHO) guidelines used in the institution. Tick **Y**=Yes; **N**=No guidelines for the specific indication; **NI**=No Information because diagnosis/indication is unknown; **U**=Unknown.

Guideline compliance – depending on whether a local guideline exist, three additional variables can be completed: Guideline compliance according to :

- the type or choice of the antimicrobial,
- the dosing
- the duration of the therapy/prophylaxis.

Tick : **Y**=Yes, compliant to the guideline; **N**=Not compliant to the guideline; **NI**=Not indicated because the choice of drug is not compliant according to guideline; **U**=Unknown.

EXPORT YOUR DATA

Data can be exported to a Microsoft Excel[®] file. One can do this at any time during the data entry process. The excel export of outpatient data is added to the existing export of inpatient data. It contains the raw recorded data of :

- **Institution**: provides details on the institution (first worksheet)
- Unit registrations: provides information recorded for the unit forms (second last worksheet)
- Outpatient forms: provides information on all patients whether on antimicrobials or not (last worksheet).
 Please note, for patients receiving antimicrobials, each line is one antimicrobial. If a patient received >=2 antimicrobials, the patient-level information collected such as age, symptoms, etc. is repeated on the corresponding rows for a given patient. A unique patient is defined by their survey number.

The export in excel allows the user/s to verify their own data (accuracy and completeness of data). It also allows institutions to perform analysis on their own data.

VALIDATION PROCESS

A validation procedure after data entry for this outpatient module is not provided. Instead, several internal controls have been implemented to prevent erroneous data entry, for example:

- ✓ Surveys without data entry
- ✓ Patient data with duplicated antimicrobials
- ✓ Extremely high dosing values
- ✓ Inconsistencies between presenting symptoms (e.g. patient scored with fever > 38.3°C and < 38.3°C)
- ✓ Inconsistency between underlying morbidity (e.g. chronic/Long COVID and None are scored)
- ✓ Inconsistency between age group at denominator level and detailed age at numerator level
- ✓ Incorrect data entry of detailed age
- ✓

The web-based tool supports **real-time data collection**. However, be aware that **most data is mandatory to be completed online before you can save the patient in the database**. If you assume that you cannot retrieve all the information immediately, use the paper data collection forms so that you can then complete the missing information on paper before entering the data online.

FEEDBACK

The Global-PPS tool is designed to produce an automated feedback for each participating institution. We anticipate sending data back in a simple, easy-to-use feedback, with own data ready to use for local presentations. The feedback compares hospital data to i] National (if N \ge 3 institutions) and ii] Continental results. The first slides for the outpatient feedback report will become available in the beginning of 2024. The slides will be similar to what is provided by the inpatient module for the Global-PPS. An example is available at https://www.global-pps.com/documents/

In case of questions or difficulties, contact <u>Global-PPS@uantwerpen.be</u>