TECHNICAL REPORT

Point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals

ECDC PPS validation protocol version 3.1.2

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Abbreviations

FTE	Full-time equivalent
HAI	Healthcare associated infections
HAI-Net	ECDC-coordinated network for the surveillance of healthcare-associated infections
ICU	Intensive care unit
PPS	Point prevalence survey
TESSy	The European Surveillance System (ECDC's web-based data reporting system for the surveillance of communicable diseases)
VT	Validation team

Background and objectives

In accordance with article II.8.c of Council Recommendation 2009/C 151/01 of 9 June 2009 on patient safety, including the prevention and control of healthcare-associated infections (HAIs) [1], ECDC developed a methodology for repeated point prevalence surveys (PPS) of HAIs and antimicrobial use in acute care hospitals [2]. The main objective of the ECDC PPS of HAIs and antimicrobial use in acute care hospitals is to estimate the total burden of HAIs and antimicrobial use in acute care hospitals in the EU.

During the first EU-wide PPS in 2011–2012, a validation protocol developed by ECDC with Member State experts was tested in 10 countries [3]. After the 2011 pilot study, the protocol was adapted [4] and implemented by five countries in 2012. The results of these five validation surveys showed that a large number of HAIs were not detected or reported by hospital PPS staff (false negatives), resulting in a low sensitivity (country average 71.9%). False positives, or low specificity, was less of a problem, except in the country that reported the highest prevalence. The results suggested that the observed large differences in HAI prevalence between countries (ranging from 2.3% to 10.8%) were in reality less important because of low sensitivity and high specificity in low-prevalence countries and high sensitivity and low specificity in high prevalence countries [5]. The results also showed that performing validation during a national PPS is crucial in order to interpret PPS results, in particular for the main outcome of such a survey, i.e. to estimate the burden of HAIs in Europe.

It was therefore strongly recommended by the ECDC Advisory Forum that all countries must perform validation studies during future prevalence surveys. Accordingly, all Member States were expected to perform a validation study of their national PPS during the second ECDC PPS in 2016–2017. The objectives of the validation study are to assess the validity, reliability and inter-country comparability of the data collected during the national/regional PPS of HAI and antimicrobial use in acute care hospitals, and to assess the data accuracy of selected process and structure indicators at the hospital level.

The current protocol version 3.2.1 is the ECDC PPS validation protocol used during the second EU-wide PPS of HAIs and antimicrobial use in 2016–2017. This protocol version is an accompanying document to the ECDC protocol for the point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals version 5.3 [2].

Conditions for participation

- The PPS validation study needs to be performed at the same time as a national or regional PPS. The national/regional PPS is hereafter referred to as the primary PPS.
- The national PPS coordinating centre should train and coordinate a national/regional PPS validation team (VT).
- The validation study should be performed in a minimum sample of five randomly selected hospitals and re-examine 250 patients (50 patients per hospital). In order to obtain representative data at the national/regional level, a sample of 25 hospitals and 750 patients (30 patients re-examined per hospital) is recommended. If the total number of hospitals included in the primary PPS is five or lower, all hospitals should be validated (50 patients per hospital).
- Validation data collected by the national/regional validation team should be entered in the software provided by ECDC (HelicsWin.Net) or in another software compatible with the current protocol. Data should be made available to ECDC in HelicsWin.Net or TESSy format, together with the primary PPS data collected by the hospital PPS staff. The specifications of the data format and file names are described elsewhere.

Methodology

Timing and blinding

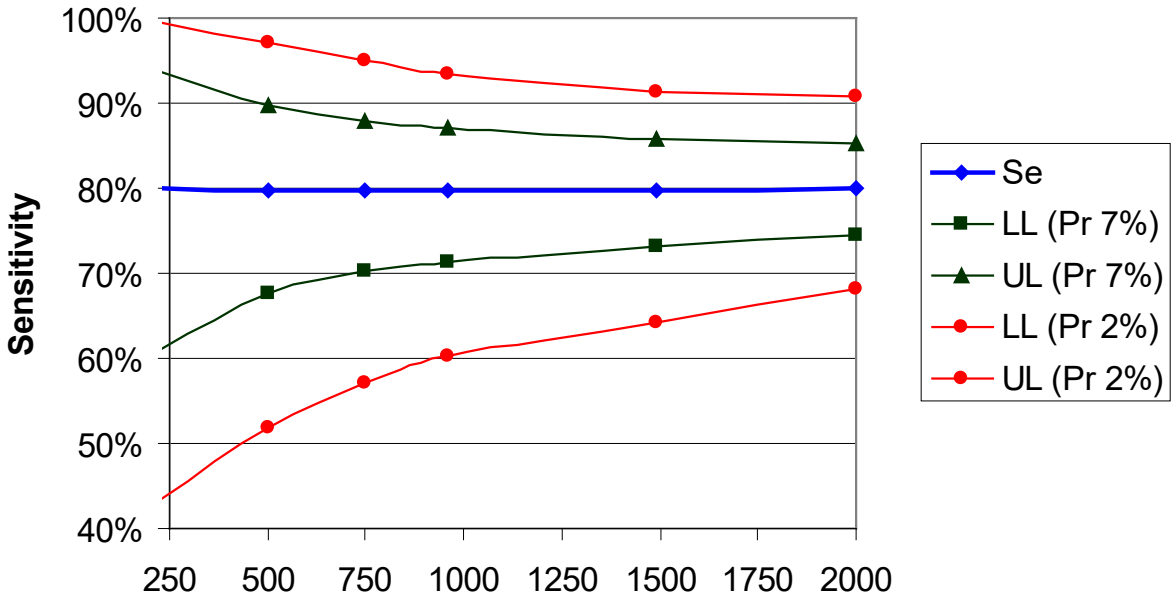
Based on the results of the pilot PPS validation study in 2011 [3], it is recommended to perform the validation PPS survey on the same day as the primary PPS, at the same time or shortly after the primary data collection, using blinded data collection. The VT member(s) is/are not allowed to look at the primary PPS forms during the data collection. Exceptionally, retrospective validation is allowed within one week after primary PPS data collection. Participants should also specify if data collection was unblinded (e.g. if blinded data collection was impossible). Data on timing and blinding should be reported at the ward level.

Sample size

The minimum sample size is five hospitals and 250 patients (50 patients re-examined per hospital). If the total number of hospitals included in the primary PPS is five or lower, all hospitals should be included.

In order to obtain representative data at the national/regional level, a sample of 25 hospitals and 750 patients (30 patients re-examined per hospital) is recommended. Countries preferring better precision of the sensitivity at the national level may consider including more patients. For example, a sample size of 2 000 patients in at least 25 hospitals would result in precision of approximately +/-5% around an estimated sensitivity of 80% for a HAI prevalence of 7% (Figure 1).

Figure 1. Variation of the confidence interval around a sensitivity of 80% according to the number of patients included in the validation sample, for an outcome with prevalence of 7% and for an outcome with prevalence of 2%, with 10% of false positives



Se: sensitivity
LL: 95% confidence interval lower limit
UL: 95% confidence interval upper limit
Pr: prevalence percentage

Selection of hospitals, wards and patients

Hospitals taking part in validation should be selected randomly from the list of hospitals participating in the primary PPS, e.g. using systematic sampling after sorting the hospital list by hospital type and size.

Wards for validation should be selected among wards in which the primary PPS is done on the same day.

There are three possible methods for the sampling of wards and patients for the validation survey:

- Wards with an expected higher HAI prevalence (e.g. intensive care units – ICU; HIPREV). This method is referred to as purposive sampling and results in HAI oversampling. All patients of a ward should be included.
  Advantages:
  - best precision of the validation results (specificity and sensitivity) due to higher number of HAI cases, therefore recommended method; and
  - can be used for validation of 'standard' (patient-based) and 'light' (unit-based) data.

  Disadvantages:
  - requires careful planning of the validation visit on a day that at least one high-prevalence ward is surveyed for the primary PPS
  - availability of HAI-related data in high-prevalence wards may not be representative of data availability in the entire hospital.

- Wards included in the PPS on the day of the validation study (until the required number of validation records per hospital is obtained) without purposive sampling (PPSDAY), i.e. the choice of the validation day did not take into account the inclusion of high-prevalence wards. The order/choice of the wards can follow the normal planning of the primary PPS. All patients of a ward should be included.
  Advantages:
  - easier planning; and
  - can be used for validation of 'standard' (patient-based) and 'light' (unit-based) data.

  Disadvantages:
  - lower precision of validation results.
- Random selection of patients from all wards included in the primary PPS (RANDOM).
  Advantages:
  - produces the most representative results.

  Disadvantages:
  - requires several days of (same-day) validation and collecting more ward data (more labour-intensive)
  - cannot be used if primary PPS data were collected using 'light' (unit-based) protocol option; and
  - lower precision of validation results than in purposive sampling because of a lower number of HAIs.

Composition of the validation team (VT)

The PPS coordinating centre should compose and train a national/regional VT. VT surveyors will visit the selected hospitals and do a repeated collection of basic demographic, HAI and antimicrobial use data for the patients included in the validation study, applying the exact definitions of the ECDC PPS protocol ('gold standard' data collection). Hospital staff do not participate in the validation process/data collection as such.

The national/regional VT should be composed of at least one senior expert with experience in HAI surveillance (especially case definitions). Less experienced surveillance staff or clinicians who were recruited and trained can join the VT to speed up the data collection process. The VT should ideally be the same for all validated hospitals to ensure consistency of the gold standard. If large numbers of hospitals are validated with different validation teams, the training of VT members should ensure that all teams perform the validation in the same way. It is recommended to test the inter-rater reliability (IRR) of VT members prior to the validation survey. Standard case studies to perform this IRR testing can be obtained from ECDC by contacting HAI-Net (HAI-Net@ecdc.europa.eu).

In case the primary data collection in all included hospitals is performed by the national PPS coordination team (e.g. in smaller countries), the national team should be composed of at least two data collectors so that data collector A can repeat the primary PPS data collection performed by data collector B and vice versa. In this case, only IRR can be calculated (kappa statistic) since there is no gold standard. Alternatively, the validation survey in these countries may be performed by an external expert trained for this purpose.

Data collection

Data collection process

The estimated time needed for data collection is on average approximately 10 minutes per validated patient or 8.3 person-hours for 50 patients. The recommended method for data collection by the validation team is blinded data collection on the same day as the primary PPS, so that the availability of the data is as similar as possible [3].

In order to ensure that the same patients are included in the primary and validation survey, it is recommended to prepare a list of eligible patients used by both primary and validation PPS data collectors. The list should also contain the anonymised patient counter (number) that will be entered in the primary database. In addition, it is useful to add the time when the data collection for each patient (in the primary survey) was completed on the list so that the validation team can verify the availability of information at the time of the primary survey. This also applies in the case of validation of primary data collected using the 'light' (unit-based) protocol option, since surveyors should go through the notes for every patient in both protocol options. Such a list contains patient identifiers and should therefore never leave the hospital.

Table 1. Sample form of a single patient list to be used by primary and validation PPS data collectors

THIS SHEET SHOULD NOT LEAVE THE HOSPITAL FORM REQUIRED FOR DATA VALIDATION		
Primary data collector should collect these data for each patient on ward. **In order to cross validate patient level data, please pre-number each patient on the ward in the column 'Patient Counter', record unique hospital patient number/identifier and record the end time of primary data collection for each patient. The patient counter for these patients should be manually filled in on the database.**		
Patient counter (primary PPS)	**Hospital patient identifier**	**End time of data collection (primary PPS)**

Sample form to pre-assign patient counters to PPS patients in the primary data collection (these should be entered manually in the software) and to ensure that the same patients are included in the primary and validation surveys.

The validation results should not be cross-checked with the results of the primary PPS nor discussed with the hospital PPS data collector(s) to avoid bias due to possible corrections of the primary data by the hospital PPS staff following a discussion with the validation team. The results of the validation study should therefore not be communicated to the hospital PPS staff on the day of the validation survey. The primary PPS data should never be corrected following the findings of the VT as this would completely invalidate the validation study results.

Which data should be collected?

Data to be collected in the validation study can be summarised as follows:

- data regarding the methodology of validation at hospital and ward level
- repeated data collection of selected variables at the patient level; and
- data accuracy on selected structure and process indicators at the hospital level. To perform the assessment of the selected indicators, it is recommended to ask the hospital PPS staff to collect the indicator data prior to the validation visit.

Hospital data

Definition of variables

PPS survey variables, validation methods

- Hospital code primary PPS: hospital code used for primary PPS data to be entered in validation tab (sub-screen) of hospital survey screen in HelicsWin.Net.
- Hospital code validation survey: use primary PPS hospital code with 'v' added to it. Hospital code should be defined in hospital definition screen of HelicsWin.Net.
- Start date primary PPS: start date of primary PPS in this hospital to be entered in the validation tab of hospital survey screen in HelicsWin.Net.

- Validation survey dates: From ... to ...: start and end dates of validation survey to be entered in general tab of hospital survey screen in HelicsWin.Net ('Survey start date' and 'Survey end date'). Start and end date of validation survey for one hospital will be the same, particularly if VT is composed of more than one person.
- Hospital size: total number of beds in hospital as re-assessed by VT – general tab of hospital survey screen; mandatory field in HelicsWin.Net.
- Protocol validation survey: validation survey must be carried out using the 'standard' protocol – enter 'standard' in 'PPS Protocol' field of general tab of the hospital survey screen in HelicsWin.Net.
- Protocol primary PPS: protocol option used for primary PPS in the hospital ('standard' or 'light') – enter in validation tab of hospital survey screen in HelicsWin.Net.
- Sampling validation survey: sampling design used for validation survey – enter in the validation tab of hospital survey screen in HelicsWin.Net.
  - Wards included on day of visit only, high prevalence wards privileged. Recommended method. Order in which wards are visited and/or choice of validation day(s) are dependent on expected prevalence of HAI in these wards (e.g. ICUs – haematology) to improve precision of validation results (purposive sampling).
  - Wards included on day of visit only, no selection of wards. Order in which wards are visited and choice of validation day(s) independent on expected prevalence of HAI in these wards, no 'HAI oversampling'/purposive sampling.
  - Random selection of patients in all wards included in primary PPS. This method, which yields the most representative sample of patients, can only be applied if hospital is visited on all primary PPS days for same-day validation or in combination with retrospective validation within one week after primary PPS (not recommended). Timing of validation should be specified for each ward at ward PPS data level.
  - Other (please specify in comments): other selection method of wards – describe in comments field.

Data accuracy of selected structure and process indicators (interview of hospital PPS coordinator)

- Are hospital indicator data reported for the same hospital population as HAI, antimicrobial use and denominator data?
  - Yes: Only reply yes if all indicator data, HAI, antimicrobial use and denominator data and risk factors were collected for the same population, e.g. as recommended: all wards in hospital except day cases for one hospital site (not for the entire administrative hospital group).
  - Partially, please specify: Specify which indicator data were not available for the same population as the main PPS (HAI/AM/patient/denominator) data and which population they were reported or estimated.
  - No, please specify: All indicator data concern another hospital population, e.g. the administrative hospital group, while the main PPS data were collected and reported for a single hospital site. Specify for which population the indicator data were reported or estimated.
- Alcohol hand rub consumption, data source: Who provided the data on alcohol hand rub consumption and what do they represent?
  - PHADIS: pharmacy, quantity dispensed/delivered to wards in one year period
  - PHAPUR: pharmacy, quantity purchased by hospital in one year period
  - WARD: wards, quantity actually used in one year period
  - OTH: other, please specify (in comment field); and
  - NA: data not available.
- Correct reporting of full-time equivalents (FTEs): Assess accuracy of the reported FTEs (infection control staffing levels, antimicrobial stewardship, registered nurses, nursing assistants) by checking the following questions:
  - Correct reporting of partial FTEs ? (e.g. 10% of full-time = 0.1 FTE)
  - FTE antimicrobial stewardship included in job description?
  - Correct distinction between FTEs for infection prevention and control (IPC) and antimicrobial stewardship?
- Other validation team comments/data quality issues: Free text. Other validation team comments on data quality issues at the hospital level, such as:
  - factors that may have influenced the reported quantity of alcohol hand rub, e.g. how much alcohol hand rub is used for other purposes than hand hygiene, use of other hand hygiene products than alcohol hand rub, etc.
  - deviations from ECDC PPS protocol, e.g. different HAI case definitions or inclusion criteria
  - existence of disincentives or incentives for reporting HAIs; and
  - other elements that should be taken into account when interpreting data for this hospital.

European Prevalence Survey of Healthcare-Associated Infections and Antimicrobial Use
Form VTH. Validation study. Hospital data.

Hospital code primary PPS: ☐

Hospital code validation survey: ☐ Add a small 'v' to the primary hospital code

Protocol option (standard/light) STD Validation survey MUST use standard

Start date primary PPS ___/___/___

Start date validation survey: ___/___/___

End date validation survey: ___/___/___

Hospital size ☐ Hospital size as re-assessed by VT

Sampling of wards for validation survey

- ☐ Wards on PPS day, high prevalence wards privileged (recommended)
- ☐ Wards on PPS day, no selection of wards
- ☐ All PPS wards, random patient selection
- ☐ Other method, please specify: _____

Are the reported numbers of the hospital indicator data for the same hospital population as HAI and AM use data?

O Yes O Partially, please specify: O No, please specify:

_____

_____

Alcohol hand rub (AHR) consumption/year represents:

- ☐ Quantity dispensed to wards in one year period
- ☐ Quantity purchased by hospital in one year period
- ☐ Quantity actually used in the wards in one year period
- ☐ Other, please specify: _____

Are FTEs (full-time equivalents) correctly reported?

Correct interpretation of the term FTE? (e.g. 10% of full-time = 0.1 FTE)	O Yes	O No
FTE Antimicrobial Stewardship: included in job description?	O Yes	O No
Correct distinction between FTE Infection Control (IPC) and antimicrobial stewardship?	O Yes	O No

Other validation team comments/data quality issues for the current hospital:

_____

_____

_____

Ward data

Ward PPS and validation methodology

- Ward name (abbreviated)/unit ID: abbreviated name of validated hospital ward. Ensure spelling is exactly the same as in primary PPS data. To be entered in the general tab of the ward PPS data screen in HelicsWin.Net.
- Ward specialty: main ward specialty (≥ 80% of patients requiring this specialty) as re-assessed by VT. If lower than 80%, choose mixed ward (MIX). GER=geriatrics, GO=gynecology/obstetrics, ICU=intensive care, LTC=long-term care, MED=medicine, MIX=mixed, NEO=neonatal, OTH=other, PED=paediatric, PSY=psychiatry, RHB=eehabilitation, SUR=surgery. Allows combination with patient specialty to refine specialties, e.g. paediatrics: ward specialty PED + patient specialty: PEDICU=paediatric ICU, NEOICU=neonatal ICU, SURCARD=paediatric cardiac surgery). A ward with healthy newborns either must be allocated to GO (GOBAB) when located in obstetrics or PED (PEDBAB) if located in paediatrics. To be entered in the general tab of the ward PPS data screen in HelicsWin.Net.
- Ward validation survey date: date validation survey was carried out in this ward. To be entered in general screen of ward PPS data screen in HelicsWin.Net. It is recommended to collect data from a single ward on the same day.

- Ward primary PPS date: date primary survey was carried out in this ward. To be entered in the validation screen of the ward PPS data screen in HelicsWin.Net.
- Patients included in the validation survey: method of selection of patients in the ward. To be entered in validation screen of ward PPS data screen in HelicsWin.Net.
  - All eligible patients included: all eligible patients were included for this ward. Recommended.
  - Selection of patients: selection of eligible patients made, e.g. a random selection of x patients in y (systematic sampling) or not all patients validated. Specify reason for patient selection in ward VT comments field.

Note: If primary PPS was performed using the 'light' (unit-based) protocol, all patients in ward should be validated with or without HAI and/or antimicrobial use. Selection of patients is not allowed for validation of 'light' protocol.

- Timing: Timing of validation survey in this ward. To be entered in validation screen of ward PPS data form in HelicsWin.Net. The first two options (same day as primary PPS) are recommended. Retrospective validation in the week after primary PPS (third option) is not recommended, but allowed.
  - Simultaneous (same day, same time): validation done at same time as primary PPS collection. To ensure blinded data collection, communication between VT member(s) and primary PPS data collector(s) should be minimised. Select this answer if only part of data collection occurred simultaneously.
  - Same day, after PPS: validation done on same day as the primary PPS collection, but after primary PPS completely finalised.
  - Retrospective (PPS <+/- 1 week ago):primary PPS data collection occurred less than one week ago, most patients are still in the hospital. Not recommended.
  - Other: other timing of validation (e.g. > 1 month after the primary PPS) not recommended. Specify in comments field which timing was chosen and why.
- Validation method. Blinded or unblinded data collection. To be entered in validation screen of ward PPS data form in HelicsWin.Net. Recommended method is blinded. If data collection was considered un-blinded, specify why in comments field.
  - Blinded: HAI or antimicrobial use status of patient not disclosed to VT before start of data collection.
  - Unblinded: HAI or antimicrobial use status of patient disclosed to VT before start of data collection.
- Who collected primary PPS data in this ward? ICN=infection control nurse; ICP=infection control physician or equivalent; WN=ward nurse; WP=ward physician; IDP=infectious disease physician; MIC=hospital microbiologist; MDST=MD specialist trainee; PHA=hospital pharmacist; LINK=infection control link nurse; DNU=data nurse; AID=nurse aid/nursing assistant; MDSTU=MD students; NUSTU=nursing students; PSQUAL=hospital patient safety or quality of care staff; CONAT=national PPS coordination staff; COREG=regional PPS coordination staff; OTH=other (specify). In HelicsWin.Net, data collectors should be defined in hospital survey screen. This will create a dropdown list from which the data collector for the current ward can be selected in the ward PPS data screen.
- Validation team comments for this ward: other validation team comments, data quality issues at the ward level (e.g. deviations from ECDC PPS protocol) or elements that should be taken into account when interpreting the data for this ward (e.g. existence of disincentives or incentives for reporting HAIs). Specify reasons for deviations from recommended validation method here.

European Prevalence Survey of Healthcare-Associated Infections and Antimicrobial Use
Form VTW. Validation study. Ward data.

Hospital code ☐

Ward name (abbreviated) /Unit ID ☐ Exactly the same ward code/ID as in primary PPS data

Ward Specialty : O PED O NEO O ICU O MED O SUR O GO O GER O PSY O RHB O LTC O OTH O MIX

Ward validation survey date ___/___/___ Ward primary PPS date ___/___/ ____

Patients included in the ward validation survey: O All eligible patients O Selection of patients ☐

(Note: selection of patients not allowed if primary PPS used LIGHT protocol)

Validation timing: O Simultaneous O Same day after PPS O Retrospective (Within one week) O Other

Validation method: O Blinded O Unblinded (not recommended)

Who collected the primary PPS data in this ward? (more than one answer possible)

O Infection control nurse O Infection control physician O Ward nurse O Ward physician/Consultant
O Infectious diseases physician O Hospital microbiologist O MD specialist trainee O Hospital pharmacist
O Infection control link nurse O Data nurse O Nurse aid O MD student O Nurse student
O National PPS coordination staff O Regional PPS coordination staff O Other, specify: _____

Other validation team comments for the current ward:

_____
_____
_____
_____

Patient, HAI and antimicrobial use

Files for all patients present at 8:00 am on the PPS day need to be re-examined (with or without HAI/antimicrobial). For each patient, collect and enter the following data:

- Hospital code: hospital identifier/code assigned by national/regional PPS coordinating centre; unique code per surveillance/PPS network.
- Ward name (abbr.)/Unit ID:. abbreviated name of validated hospital ward. Ensure spelling is exactly the same as in primary PPS data.
- Patient Counter validation: patient counter for this patient in the validation survey. Not necessarily be the same as patient counter of primary PPS (which is collected in a separate variable). Enter in main field 'Patient Counter' on the general screen of the patient screen in HelicsWin.Net.
- Patient Counter primary PPS: patient counter (not internal patient identifier) of patient for which data are validated. This field is mandatory for validation because it is needed to make the link with primary PPS patient data. Enter in field 'Patient Counter Primary PPS' on validation tab (sub-screen) of patient screen in HelicsWin.Net. If this field is missing, the link with the primary PPS file can only be made by the combination of other fields (age, gender), which is not 100% precise, or using information from one of the optional text fields in HelicsWin.Net.
- Age in years: patient age in years. Enter in the general tab of the patient screen in HelicsWin.Net.
- Age in months: patient's age in months if the patient is less than two years old. Enter in the general tab of the patient screen in HelicsWin.Net.
- Sex: gender of patient – M (male), F (female). Enter in general tab of patient screen in HelicsWin.Net.
- Date of hospital admission: date patient was admitted to hospital for current hospitalisation (dd/mm/yyyy). Enter in general tab of the patient screen in HelicsWin.Net.
- Consultant/patient specialty: specialty of physician in charge of the patient or specialty of main disease of the patient. If consultant specialty differs from patient specialty, give priority to patient specialty. For paediatric patients on PED ward, use subspecialty (MEDGEN, MEDSUR, etc.). LTC is in principle a ward specialty and should only exceptionally be used as a consultant/patient specialty. Enter in field on general screen of patient screen in HelicsWin.Net.
- McCabe score (optional): classification of severity of underlying medical conditions. Enter in field on general screen of patient screen in HelicsWin.Net. See primary PPS protocol for details.

- Patient receives at least one antimicrobial on PPS day: patient receives at least one systemic antimicrobial agent on date of the survey (given or planned treatment, including intermittent treatments, e.g. alternate day, or medical prophylaxis). For surgical antimicrobial prophylaxis, check whether any surgical prophylaxis was given in the 24 hours prior to 8:00 a.m. on day of the survey (yes/no). Enter in field on general screen of patient screen in HelicsWin.Net. If yes, collect antimicrobial use data (optional). See primary PPS protocol for details.
- Patient has active HAI: patient has active HAI on survey date (yes/no). Enter in field on general screen of patient screen in HelicsWin.Net. If yes, collect all HAI data. See primary PPS protocol for details.
- If PN: number of X-rays (additional field in HAI data). How many chest x-rays or CT-scans with suggestive image of pneumonia are available for the current pneumonia episode? To be filled only in case of healthcare-associated pneumonia (PN1-5) in patients with underlying cardiac or pulmonary disease. This variable is added to estimate the number of cases of pneumonia that would not have been reported using the PPS 2011–2012 case definition since in the PPS 2016–2017 protocol, the following note was added: 'One definitive chest X-ray or CT-scan for the current pneumonia episode may be sufficient in patients with underlying cardiac or pulmonary disease if comparison with previous X-rays is possible'. Enter in validation tab of patient screen in HelicsWin.Net (not in HAI screen)**.**
- VT comments for this patient/AM/HAI: free text. Possible comments or encountered problems with the data collection for the current patient. Enter in the validation tab of the patient screen in HelicsWin.Net.

European Prevalence Survey of Healthcare-Associated Infections (HAIs) and Antimicrobial Use (AU)
Form VTP. Patient validation form

Patient data

Hospital code [_____]

Ward name (abbr.)/Unit Id [_____]

Patient Counter validation: [_____]

Patient Counter primary PPS: [_____]

Age in years: [____] yrs; Age if < 2 year old: [____] months

Sex: M / F **Date of hospital admission:** ___ / ___ / _____
dd / mm / yyyy

Consultant/Patient Specialty: [_____]

McCabe score (optional):

O Non-fatal disease O Ultimately fatal disease

O Rapidly fatal disease O Unknown

Patient receives **antimicrobial(s)**(1): ☐ No ☐ Yes

Patient has **active HAI**(2): ☐ No ☐ Yes

IF YES

AU data: Optional validation

Antimicrobial (AM) (generic or brand name)	Route	Indication	Diagnosis (site)	Reason in notes	Date start AM	Changed? (+ reason)	If changed: Date start 1st AM	Dosage per day: Number of doses	Dosage per day: Strength of 1 dose	Dosage per day: mg/g/IU
					/ /		/ /			
					/ /		/ /			
					/ /		/ /			

	HAI 1	HAI 2
Case definition code		
If PN(3): Number of x-rays		
Relevant device (4)	O Yes O No O Unknown	O Yes O No O Unknown
Present on admission	O Yes O No	O Yes O No
Date of onset (5)	/ /	/ /
Origin of infection	O current hospital O other hospital O other origin/ unk	O current hospital O other hospital O other origin/ unk
HAI associated to current ward	O Yes O No O Unknown	O Yes O No O Unknown
If BSI: source (6)		

	MO code	AMR: AB (7)	AMR: SIR	PDR	MO code	AMR: AB (7)	AMR: SIR	PDR
Microorganism 1								
Microorganism 2								

(1) At the time of the survey, except for surgical prophylaxis 24h before 8:00 am on the day of the survey; if yes, fill antimicrobial use data; if patient receives >3 antimicrobials, add a new form;
(2) [nfection with onset ≥ Day 3, OR SSI criteria met (surgery in previous 30/90d, OR discharged from acute care hospital <48h ago, OR CDI and discharged from acute care hospital < 28 days ago OR onset < Day 3 after invasive device/procedure on D1 or D2] AND [HAI case criteria met on survey day OR patient is receiving (any) treatment for HAI AND case criteria are met between D1 of treatment and survey day]; if yes, fill HAI data; if patient has > 2 HAIs, add new form.
(3) If pneumonia: only record number of x-rays/ct-scans for pneumonia episode in patients with underlying cardiac or pulmonary disease
(4) Relevant device use before onset infection (intubation for PN, CVC/PVC for BSI, urinary catheter for UTI);
(5) Only for infections not present/active on admission (dd/mm/yyyy);
(6) C-CVC, C-PVC, S-PUL, S-UTI, S-DIG, S-SSI, S-SST, S-OTH, UO, UNK;
(7) AB: tested antibiotic(s): STAAUR: oxacillin/meticillin (OXA) + glycopeptides (GLY); Enterococci: GLY; Enterobacteriaceae: 3rd-gen cephalosporins (C3G) + carbapenems (CAR); PSEAER and ACIBAU: CAR; SIR: S=sensitive, I=intermediate, R=resistant, U=unknown; PDR: Pan-drug resistant: N=no, P=possible, C=confirmed, U=Unknown

Validation team comments for this patient:_____

_____

_____

Please do NOT communicate the validation results to the primary data collector(s)

Data entry and transfer

Validation data should in principle be entered in the HelicsWin.Net software (see HelicsWin.Net manual). If a national software package is used to enter data, they should be exported to the TESSy 'HAIPPSVAL' format and .csv files submitted as a compressed Zip file. Validation teams will as a rule enter validation data for validated hospitals in a different HelicsWin.Net database than the primary PPS data. Data for several validated hospitals can be entered in a single validation database.

After completion of the validation data entry, validation data will be transmitted by the national VT (usually the PPS coordinating centre) to ECDC. The primary PPS data of the validated hospital will either only be submitted to TESSy as part of the national PPS database (TESSy .csv format) or separately in HelicsWin.Net format (.mdb export format). Separate TESSy submission of the primary hospital PPS data is always required if the national PPS database cannot be submitted by the same date as submission of the validation data.

The following files should be transmitted to ECDC. It is recommended that HelicsWin.Net files are renamed as follows:

- Validation data: export of original hospital database from HelicsWin.Net (automatically named as 'HWN_yyyymmdd_hhmmss.zip'). Rename this .zip file to 'HWN_yyyymmdd_country(+region if applicable)code_hospitalid.zip' (i.e. 'HWN_20111001_UKEN_1234v.zip'). Note that hospital codes for validation hospitals should end with a small "v".
- Primary PPS data:
  - Submit primary PPS data in TESSy format to TESSy by the same date as submission of validation data.
  - If an HelicsWin.Net Access data file is available: export of the original hospital database from HelicsWin.Net (automatically named as 'HWN_yyyymmdd_hhmmss.zip'). Rename this file to 'HWN_yyyymmdd_country(+region if applicable)code_hospitalid.zip' (i.e. 'HWN_20111001_UKEN_1234.zip') and transfer file together with validation data. Hospital codes for primary data hospital identifiers should be the same as in validation data, but without a small 'v'.

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