



TECHNICAL DOCUMENT

Point prevalence survey validation protocol – Version 2.1

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

ECDC TECHNICAL DOCUMENT

PPS Validation protocol - Version 2.1

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



This manual from the European Centre for Disease Prevention and Control (ECDC) was coordinated by Pete Kinross. Contributing authors Carl Suetens and Pete Kinross.

This document applies to HelicsWin.Net version 1.3.4, and to any future product release unless contra-indicated in the new editions.

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Contents

Abbreviations	iv
1. Background	1
2. Objectives	1
3. Requirements	1
3.1 Conditions for participation	1
3.2 PPS Validation contracts.....	1
4. Methodology.....	2
4.1 Patient-based data collection.....	2
4.2 Timing and blinding.....	2
4.3 Selection of hospitals, wards and patients	2
4.4 Sample size	2
4.5 Composition of the validation team (VT) and role of team members	3
4.6 Data collection	3
4.7 Variables and forms.....	4
5. Data entry and transfer	8
5.1 Data entry (software)	8
5.2 Data transfer	10
5.3 Deadlines for data submission	11
References	12

Abbreviations

ECDC	European Centre for Disease Prevention and Control
EU	European Union
FTE	Full-time equivalent
HAI	Healthcare-associated infection
HAI-Net	Healthcare-Associated Infections surveillance Network
HELICS	Hospitals in Europe Link for Infection Control through Surveillance project
HelicsWin.Net	Software developed by the former HELICS surveillance centre (IPH Brussels) at ECDC's request (outsourced) for the ECDC-PPS, in Microsoft.Net framework (free stand-alone software). Further developed by ECDC (Epidemiological Tools Section) from September 2011 onwards.
HPA	Health Protection Agency (United Kingdom)
HPS	Health Protection Scotland (United Kingdom)
ICU	Intensive care unit
InVS	French Institute for Public Health Surveillance (France)
IPSE	Improving Patient Safety in Europe project
NHSN	National Healthcare Safety Network (US Centers for Disease Control and Prevention, Atlanta)
PPS	Point prevalence survey
TESSy	The European Surveillance System (ECDC's web-based data reporting system for the surveillance of communicable diseases)
THL	National Institute for Health and Welfare (Finland)
VT	Validation team

1. Background

In accordance with the Improving Patient Safety in Europe project (IPSE) transition plan and 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), ECDC developed a methodology for carrying out point prevalence surveys (PPSs) of HAIs and antimicrobial use in European acute care hospitals. The main objective of this ECDC PPS is to estimate the total burden of HAI and antimicrobial use in acute care hospitals in the European Union.

In 2011, together with experts from Member States, ECDC developed a pilot validation study protocol to test the feasibility and appropriateness of different methods to assess the validity and reliability of the PPS data. The protocol was implemented at 20 hospitals in 10 of the countries participating in the project 'Pilot validation study of the ECDC point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals' (OJ/23/06/2011-PROC/2011/060). The study was outsourced to the Glasgow Caledonian University (Contract ECD.2971) following an Open Call for Tender (OJ/23/06/2011-PROC/2011/060) and coordinated by the Glasgow Caledonian University, in collaboration with Health Protection Scotland (HPS, UK), the Health Protection Agency (HPA, UK), National Institute for Health and Welfare (THL, Finland), French Institute for Public Health Surveillance (InVS, France), Charité - Universitätsmedizin Berlin (Germany) and ECDC.

The current protocol is the final ECDC PPS validation protocol, which was adapted according to the findings of the pilot validation study and discussed with experts from Member States at a meeting in London on 5 March 2012. The protocol was implemented in five countries during the final phase of the first ECDC PPS at acute care hospitals in May–June 2012. The ECDC Advisory Forum recommended that all Member States perform a validation survey during future ECDC PPSs to enable better interpretation of PPS results.

2. Objectives

The objectives of the ECDC PPS validation study are to assess the validity, reliability and inter-country comparability of data collected during the national/regional PPSs of HAIs and antimicrobial use in acute care hospitals carried out following the ECDC PPS methodology.

3. Requirements

3.1 Conditions for participation

- The PPS validation study needs to be performed concurrently with a national or regional PPS (i.e. at the same time). The national/regional PPS is hereafter referred to as the primary PPS.
- Presence of a national/regional PPS validation team (VT), trained and coordinated by the national/regional PPS coordinating centre.
- Perform the validation study in a minimum of five randomly selected hospitals and re-examine 250 patients (50 patients per hospital). To obtain validation data that are representative at the national/regional level, a minimum 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 fewer, all hospitals should be validated (50 patients per hospital).
- Validation data collected by the national/regional VT should be delivered to ECDC according to the specifications of the HAIPPSVAL metadata in TESSy, or entered in the HelicsWin.Net software module provided by ECDC, and then transferred to ECDC, together with the primary PPS data collected by the hospital PPS staff, following the procedures for data transfer defined in this protocol.

3.2 PPS Validation contracts

To ensure that the national/regional PPS coordinating centre will be able to conduct the validation study of the national PPS data, ECDC foresees direct service contracts with the national/regional PPS coordinating centre (using a 'Request for Offer' procedure). Payments will be admissible after delivery of the verified validation and primary PPS data and, following data approval by ECDC, delivery of the corresponding invoice to ECDC. The amount should contribute to covering personnel costs of PPS coordinating centre validation study staff (or experts recruited by the centre for this purpose), and/or other costs incurred in the context of the validation study of the national PPS (e.g. training the VT members, travel and subsistence costs, organisation of a national/regional meeting for participating hospitals or costs to obtain ethical or legal approval of the validation study).

4. Methodology

4.1 Patient-based data collection

Data collection for the PPS validation study must always be patient-based, even if the primary PPS data collection was performed using the 'light' (unit-based) protocol. This is necessary because in the event of random or incomplete patient selection, false negatives and false positives would not be identifiable during data analysis.

4.2 Timing and blinding

- Timing: The validation survey should be performed on the same day as the primary PPS, at the same time or shortly after the primary data collection. In exceptional circumstances, retrospective validation is allowed within one week of the primary PPS data collection.
- Blinded data collection: VT member(s) are not permitted to look at the primary PPS forms during data collection. During data entry, please specify whether validation data collection was not blinded, e.g. because blinded data collection was impossible.

Both timing and blinding should be reported at the ward level.

4.3 Selection of hospitals, wards and patients

- Selection of hospitals: random. Validated hospitals 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). When selecting each hospital for validation, select the next hospital as reserve hospital.
- Selection of wards: not random¹. For the validation survey, select the wards in which the primary PPS was done on the same day. HAIs can be oversampled by ensuring that wards with a higher expected HAI prevalence (e.g. ICUs) are included on the selected primary PPS day among other wards².
- Selection of patients: there are two possibilities:
 - Include all patients in the selected wards, at least until the required number of validation records per hospital is obtained. In this case, some wards included in the primary PPS on the validation day may not be included in the validation sample, resulting in a less representative validation sample. This method is mandatory if the primary PPS was performed using the 'light' protocol.
 - Make a random selection of patients from all wards surveyed on the validation day. In this case, select 1 in k patients from the list of patients prepared by the primary PPS data collector, where k (sampling interval) = total number of patients in wards included on that day/number of patients to be validated in the hospital. Patients may not be selected within the validated ward if the primary PPS was performed using the 'light' protocol.

4.4 Sample size

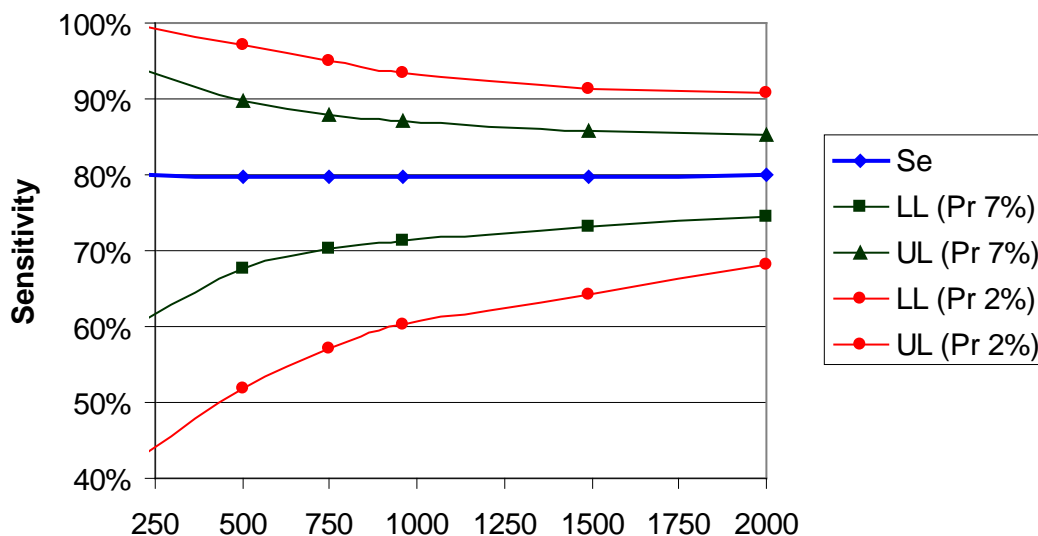
The recommended sample size at the national level is 750 patients in 25 hospitals (with 30 patients re-examined in each validated hospital). This sample design will yield a representative sample at the national level and make it possible to estimate a PPS sensitivity of 80% with a precision of +/-10% for the overall prevalence of HAI estimated at 7% (Figure 1).

The minimum sample size is 250 patients in five hospitals (50 patients per hospital). If the total number of hospitals included in the primary PPS is five or fewer, all hospitals should be validated (50 patients per hospital). Countries preferring greater 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 a precision of approximately +/-5% for the example mentioned above and as shown in the figure below.

¹ The sampling methodology in this validation protocol has been simplified for feasibility reasons. However, by allowing a selection of wards on a single PPS day instead of a random selection of patients in the entire hospital, the 'design effect' of the validation study and the confidence interval around the sensitivity and specificity estimates will increase.

² Oversampling of HAIs improves the precision of the specificity estimate, which is mainly represented by the confidence interval around the percentage of false positives found in the validation sample. Sensitivity and specificity estimates are corrected for oversampling by applying the percentage of false positives (1 – positive predictive value) and the percentage of false negatives (1 – negative predictive value) to the total primary PPS population from which the validation study sample is drawn.

Figure 1. Variation of the 95% 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% (e.g. HAI) and for an outcome with prevalence of 2% (e.g. pneumonia), with 10% of false positives



LL: lower limit; UL: upper limit; Pr: prevalence percentage

4.5 Composition of the validation team (VT) and role of team members

The national/regional PPS coordinating centre should recruit and train a national/regional validation team (VT). The VT surveyors should visit the selected hospitals and do a repeated collection of basic demographic data, HAI data and antimicrobial use data for the patients included in the validation study, applying the exact definitions of the ECDC PPS protocol. The VT will therefore act as the 'gold standard' in the validation study, against which the primary PPS data of the validated patients will be compared.

The national/regional VT should be composed of:

- at least one senior expert with experience in HAI surveillance (especially in HAI case definitions) in charge of the 'gold standard' data collection;
- less experienced surveillance staff or clinicians, recruited and trained to speed up data collection.

IMPORTANT: The national/regional VT should ideally be the same for all validated hospitals to ensure the consistency of the 'gold standard'. If a large number of hospitals undergo validation with different VTs, training should be organised with the VT members to ensure that all VTs perform validation in the same manner.

Hospital staff members do not participate in the validation process/data collection as such, but at least one hospital staff member is required as a contact person and to perform the following tasks:

- at the start of the VT visit, to introduce the VT to other hospital staff members as required, hold a short explanatory meeting with the VT, describe how the PPS was/is performed in the hospital and explain the hospital information system;
- to prepare patient lists for the validated wards;
- to ensure that the VT is given access to all relevant data sources including, as a minimum, information on the patients selected in the validation sample;
- to accompany the VT to the different wards and introduce the VT to ward staff.

4.6 Data collection

4.6.1 Estimated time per patient

As estimated in the pilot validation survey, the estimated time needed for data collection is approximately 10 minutes per validated patient, or five person-hours for 30 patients, or 8.3 person-hours for 50 patients.

4.6.2 Recommended method

The recommended method for data collection by the VT is blinded data collection – i.e. the results of the primary PPS are not disclosed to the VT, done on the same day as the primary PPS, so that the availability of the data is as similar as possible.

4.6.3 Procedure in the event of discordant findings

After the data collection, validation results should be cross-checked with the results of the primary PPS. Discordant findings should be discussed with survey staff and/or ward physician at the end of the validation day, particularly if HAI findings are discordant: verify criteria of case definition and assess reasons for discordant results.

The VT may change a decision after discussion with the survey staff and/or ward physician. In the patient comments field, specify the reason for the discordant findings (and for which variable).

IMPORTANT: Primary PPS data should never be corrected, even if the VT finds a discordant result, as this would strongly bias the results and use of the validation study.

4.6.4 Data sources

- The VT will acquire validation data using all available data sources, as explained by the hospital staff contact person at the start of the validation survey day;
- the VT should always go through patient notes;
- the VT should also consult nursing notes, and/or hospital information system(s).


4.7 Variables and forms

Data to be collected can be summarised as follows:

- Limited hospital and ward level data (e.g. no hospital indicator data).
- For each validated patient, demographic data and other data necessary to link the validation data to the primary PPS patient data. Patient risk factor data, such as the presence of invasive devices, are excluded, except for McCabe score (optional).
- All HAI and antimicrobial use data are included in the validation protocol.

4.7.1 Hospital data

Figure 2. Hospital validation data form



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

Hospital code validation survey

Hospital code primary PPS

Validation survey dates: From / / To: / /
dd / mm / yyyy dd / mm / yyyy

Start date primary PPS: / /

Hospital size (total number of beds)

Protocol Validation survey: **Standard (default)** *Protocol Primary PPS:* Standard Light

Sampling validation survey:

- Wards included on day of visit only, no selection of wards
- Wards included on day of visit only, high prevalence wards prioritised
- Random selection of patients in all wards included in primary PPS
- Other (please specify in comments)

Validation team comments/observations: _____

Note: Variables in italic should be entered in the validation tab of the hospital data form in the HelicsWin.Net software. Variables in bold non-italic should be entered on the first (general) hospital data screen. Please also check the validation checkbox in the general screen. Other hospital data (e.g. hospital statistics) should not be filled for the validation survey.

This form must be completed. It is different from the primary PPS hospital data form. There is no need for the VT to complete the hospital data form.

Definition of variables:


Note: all data should be entered in the form ‘Hospital survey’ in HelicsWin.Net

- Hospital code validation survey: use the primary PPS hospital code and add the letter ‘v’ to the code. This should be entered on the login screen of HelicsWin.Net.
- Hospital code primary PPS: the hospital code used for the primary PPS data. Enter this in the validation tab.
- Validation survey dates: start and end date of the validation survey. Enter this in the general tab, in ‘Survey start date’ and ‘Survey end date’. Often the start and end date of the validation survey will be the same (e.g. one hospital, 30 to 50 patients, approximately 10 minutes per patient, particularly if the VT is composed of more than one person).
- Start date primary PPS: start date of the primary PPS at this hospital. Enter in the validation tab.
- Hospital size: total number of beds in the hospital (same as in the ECDC PPS protocol). Enter this in the general tab.
- Protocol validation survey: the validation survey must be carried out using the standard (patient-based) protocol. Enter ‘standard’ in the ‘PPS Protocol’ field of the general tab.
- Protocol primary PPS: protocol used for the primary PPS in the hospital. Enter in the validation tab.
- Sampling validation survey: sampling design used for the validation survey. Enter in the validation tab.
 - Wards included on day of visit only, no selection of wards: the order in which wards are visited and the choice of the validation day(s) are not connected to the expected prevalence of HAI in these wards, no ‘HAI oversampling’.
 - Wards included on day of visit only, high prevalence wards prioritised: the order in which wards are visited and/or the choice of the validation day(s) should be dependent on the expected prevalence of HAIs in these wards – i.e. de facto ‘HAI oversampling’ through ward selection (e.g. ICUs, haematology) to improve the precision of the validation results.
 - 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 the hospital is visited on all primary PPS days for same-day validation, or in combination with retrospective validation within one week of the primary PPS (not recommended). Timing of the validation should be specified for each ward at the ward PPS data level.
 - Other (please specify in comments): other ward selection method for validation survey. Describe in the comments field.
- VT comments/observations: VT comments or observations at the hospital level. These comments should be entered in the ‘Comments/observations’ field of the general tab.

4.7.2 Ward data

Note: When entering data in HelicsWin.Net, be careful to enter the ward codes (Unit Id) exactly as in the original hospital database.

Figure 3. Ward validation data form



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

Ward name (abbr.) /Unit Id¹

Ward specialty

Hospital code

Ward validation survey date²: / /
dd / mm / yyyy

Patients included in ward validation survey: All eligible patients included³ Selection of patients

Timing⁴: Simultaneous (same day, same time) Same day, after PPS
 Retrospective (PPS <+/- 1 week ago) Other

Validation method⁴: Blinded Unblinded

Validation team comments for this ward: _____

¹Please make sure the Unit Id is spelled exactly as in the primary PPS data
²Patients on the same ward should be included on a single day if possible
³Eligible patient = Admitted to the ward before or at 8:00 AM and not discharged from the ward at time of the survey
⁴Underlined = Recommended method (if non-recommended methods are used, specify reason in comments)
 Note: Variables in *italic* should be entered in the validation tab of the ward PPS data form in the HelicsWin.Net software. Variables in bold non-italic should be entered on the first (general) ward PPS date and denominator screen.

Definition of variables:

Note: all should be entered in the form 'Wards: PPS date and denominator data' in HelicsWin.Net

- Ward name (abbreviated)/Unit ID. Abbreviated name of the validated hospital ward. Please ensure the spelling is exactly the same as in the primary PPS data. Enter in the general tab.
- Ward specialty. Main ward specialty ($\geq 80\%$ of patients requiring this specialty) as assessed by the VT. If fewer than 80%, choose mixed ward (MIX). See specialty code list in ECDC PPS protocol version 4.3 (incl. codebook). Enter in the general tab.
- Ward validation survey date. Date on which the validation survey was carried out in this ward. Enter in the general tab. Although it is possible to enter more than one validation survey date for the same ward in HelicsWin.Net, it is recommended that data be collected from a single ward on the same day.
- Patients included in the validation survey. Enter in the validation tab.
 - All eligible patients included: all eligible patients were included for this ward. In principle, this should be the same number of patients as in the primary PPS for this ward.
 - Selection of patients: eligible patients were selected (e.g. a random selection of x patients in y (systematic sampling) or not all patients were validated because the required number of validated patients (30–50) was reached for this hospital. Please specify in comments.

Note: If the primary PPS was performed using the 'light' protocol, all patients in the ward should be validated, whether or not they have been diagnosed with an HAI and/or are using antimicrobials. In other words, selection of patients is not permitted when validating primary PPS data collected using the 'light' protocol.

- Timing. This relates to the timing of the validation survey in this ward. It is recommended that the validation is performed on the same day as primary PPS (first two options below). Although retrospective validation during the week following the primary PPS (third option) is not recommended, it is allowed. Enter in the validation tab of the 'Wards: PPS date and denominator data' form in HelicsWin.Net.
 - Simultaneous (same day, same time): validation is done at the same time as the primary PPS collection (note: to ensure blinded data collection, communication between the VT member(s) and the primary PPS data collector(s) should be minimised). Choose this answer even if only part of the data collection occurred simultaneously.
 - Same day, after PPS: validation is done on the same day as the primary PPS collection but after the primary PPS has been completed.
 - Retrospective (PPS $\leq \pm 1$ week ago): the primary PPS data collection occurred <1 week ago, most patients are still in the hospital.
 - Other: other timing of the validation (e.g. >1 month after the primary PPS) is not recommended; please specify in the comments field which timing was chosen and why.
- Validation method: Blinded or non-blinded data collection. Enter in the validation tab. The recommended validation method is 'blinded'. If data collection was not considered to be blinded, specify why in the comments field.
- VT comments for this ward: specify reasons for deviations from the recommended methodology (e.g. feasibility), which selection of patients if any, other comments. Enter in the validation tab.

4.7.3 Patient data, HAI data and antimicrobial use data

Data collection is repeated for the same variables as in the primary PPS protocol at the patient, HAI and antimicrobial use levels. The two exclusions are the patient risk factors 'surgery since admission' and 'presence of invasive devices'. Validation of the McCabe score is optional. Please refer to the ECDC PPS protocol version 4.3 (incl. codebook) for definitions of the variables. Additional variables are defined below.

IMPORTANT: Primary PPS data should never be corrected, even if the VT finds a discordant result, as this would bias the results and use of the validation study.

- VT comments for this patient/HAI/antimicrobial use: free text. Specify reason for discordant results, in particular for HAI data (false negative or false positive), e.g. problems with case definitions, other comments for this patient. To be entered in the validation tab of the patient/HAI/antimicrobial use screen in HelicsWin.Net.

4.7.4 National data

National data are not entered in HelicsWin.Net. A national questionnaire will be provided to the national PPS coordinating centres for this purpose.

5. Data entry and transfer

5.1 Data entry (software)

Validation data should be entered in HelicsWin.Net version 1.3 or above (also see manual). HelicsWin.Net can be downloaded by the PPS coordinating centres from the HAI-Net Extranet at:

<https://extranet.ecdc.europa.eu/HAINet/default.aspx> using the user name and password provided by ECDC.

- Primary PPS data may be entered in HelicsWin.Net, or using a national/regional software designed for the PPS.
- VTs will, as a rule, enter the validation data for all validated hospitals in a separate HelicsWin.Net database (i.e. different from that of the primary PPS data). Data for several validated hospitals can be entered in a single validation database.

Figure 5. HelicsWin.Net Hospital survey form - General tab

The screenshot shows the 'General' tab of the HelicsWin.Net Hospital survey form. The form is divided into several sections:

- General Information:** Hospital code (H001v), PPS Protocol* (STD=Standard (patient-base)), Survey start date* (02/12/2013), Survey end date (04/12/2013), Hospital size (total number of beds: 250), Number of acute care beds, Number of ICU beds, Exclusion of wards for PPS?, Yes, please specify which ward types were excluded, Total number of beds in included wards, Total number of patients included in PPS, Hospital type, and Specialization of hospital (if any).
- Validation:** A checked checkbox labeled 'Validation: (checked if current PPS is validation survey)'. Below this are several data entry fields: Number of discharges/admissions in year, Number of patient days in year, Alcoholic hand rub consumption liters/year, Number of patient rooms in hospital, Number of single patient rooms in hospital, Number of FTE infection control nurses, and Number of FTE infection control doctors. Each of these fields has a 'Number' input box, a 'Year' input box, and an 'Incl. wards/Total (1)' dropdown menu.
- Comments/observations:** A text area containing the text: 'Unusually, we observed abc. Unexpectedly, we observed xyz.'

Fields for the validation study should be completed.

Figure 6. HelicsWin.Net Hospital survey form - Validation tab

HelicsWin.Net - Hospital survey

1 of 1 | Not saved

General Validation User

Hospital code primary PPS: H001

Date start primary PPS: 22/11/2013

Sampling for validation survey: PPSDAY=Wards included on PPS day only, no selection of wards

All fields need to be completed.

Figure 7. HelicsWin.Net Ward PPS data entry screen - General tab

HelicsWin.Net - Wards: PPS date and denominator data

1 of 1 | Not saved

General Validation User Wards list

Hospital code: H001v

Ward name (abbr.)/Unit Id: S1

Ward specialty: SURGEN=General surgery

PPS light and standard protocol:

Hospital survey period: 02/12/2013 - 04/12/2013 (standard protocol)

Ward survey date: 02/12/2013

All fields need to be completed.

Figure 8. HelicsWin.Net Ward PPS data entry screen - Validation tab

HelicsWin.Net - Patients | Risk factors

1 of 1 | Not saved

General Validation User Patients list AM list HAI list

Patient counter primary PPS:

Internal patient code primary PPS (not exported): ABC1234

Validation results checked with primary PPS results after data collection? Y=Yes

Discordant results discussed: NA=Not applicable

VT decision changed? NA=Not applicable

Validation team comments for this patient/HAI/AM: Patient had abc, so xyz

All fields need to be completed.

Figure 9. HelicsWin.Net Patient data entry screen - General tab

HelicsWin.Net - Patients | Risk factors

1 of 1

General Validation User Patients list AM list HAI list

Hospital code: H001v Patient counter: + 1

Ward code	Survey date	Ward specialty
S1	02/12/2013	SURGEN

Internal patient code (optional, not exported): ABC1234

Age in year(s): 105

Age in month(s):

Sex: M=Male

Date of hospital admission: 02/12/2013

Consultant/Patient specialty: SURGEN=General surgery

Patient receives antimicrobial(s): N=No Antimicrobial use

Patient has at least one HAI: N=No HAI

Patients settings

Ward code: S1 Survey date: 02/12/2013

Patient based (standard) protocol only

Surgery since admission: Peripheral line:

McCabe score: ULTFATAL=Ultimately fatal Indwelling Urinary Catheter:

Central vascular catheter: Intubation:

Fields to be entered for the validation study are completed (McCabe score is optional).

Figure 10. HelicsWin.Net Patient data entry screen - Validation tab

HelicsWin.Net - Patients | Risk factors

1 of 1

General Validation User Patients list AM list HAI list

Patient counter primary PPS:

Internal patient code primary PPS (not exported): ABC1234

Validation results checked with primary PPS results after data collection? Y=Yes

Discordant results discussed: NA=Not applicable

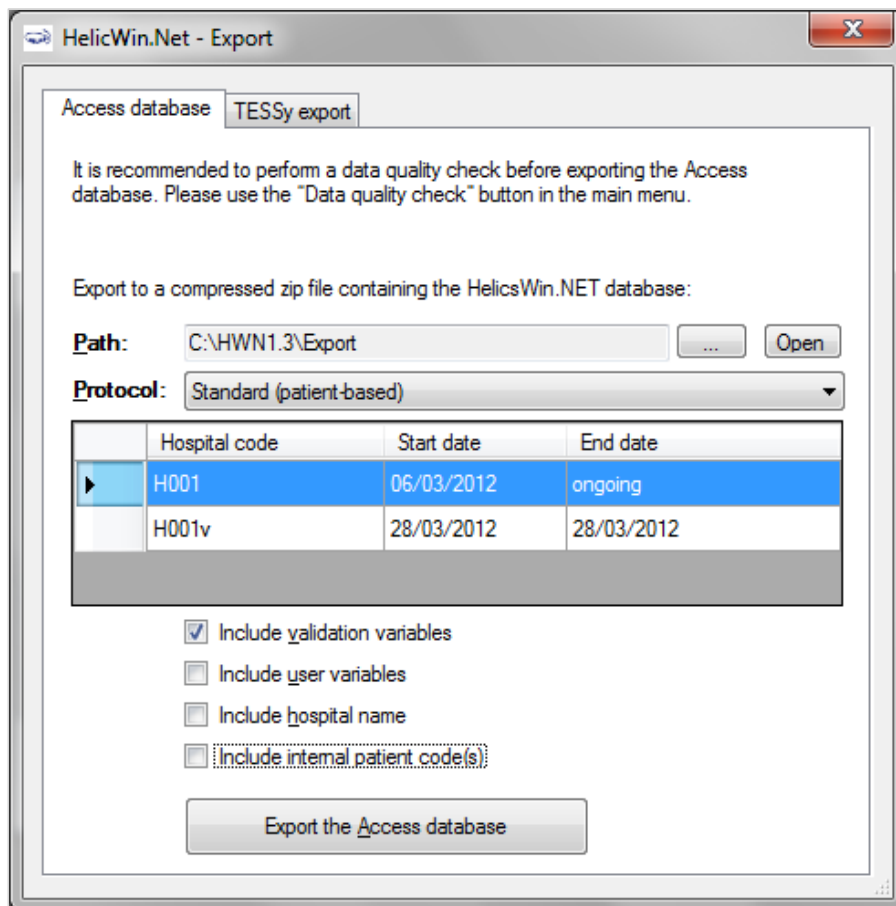
VT decision changed? NA=Not applicable

Validation team comments for this patient/HAI/AM: Patient had abc, so xyz

All fields must be completed. If the patient counter in the primary PPS database is unknown for the patient in question when entering validation data, a previously defined anonymous number/code can be entered in the field 'internal patient code primary PPS'. The patient counter primary PPS should be completed at a later stage.

5.2 Data transfer

- After completion of the validation data entry, data will be transmitted by the national VT (usually the national/regional PPS coordinating centre) to ECDC together with the primary PPS data of the validated hospitals. If the primary PPS data were collected using national/regional software, they should be submitted in TESSy HAIPPSVAL format (e.g. upload in TESSy). The HelicsWin.Net data export of the validation data should include the validation variables (Figure 11).

Figure 11. Export of the HelicsWin.Net Access validation database

Mark the 'Include validation variables' checkbox.

If HelicsWin.Net was used to collect validation data, the following files should be submitted to ECDC, renamed as below:

- Validation data: HWN_YYYYMMDD_hhmmss.zip (where YYYYMMDD_hhmmss is the date and time of the export).
 - When exporting the hospital database for the hospital that performed validation, include the file 'HelicsWinNet_export.mdb'. Rename the .zip file (not the included database) to 'HWN_YYYYMMDD_country (+region if applicable)code_hospitalidv.zip', for example 'HWN_20111001_UKEN_1234v.zip'. Note that hospital codes for validation hospitals should end with a small 'v'.
- Primary PPS data:
 - Submit the primary PPS data in TESSy format to TESSy by the same date as submission of the validation data
 - If HelicsWin.Net Access data file is available: rename to 'HWN_YYYYMMDD_country (+region if applicable)code_hospitalid.zip', for example HWN_20111001_UKEN_1234.zip' and transfer together with the validation data.

5.3 Deadlines for data submission

- First uncorrected data: at the latest by 30 September of the year in which validation of the national/regional PPS is performed.
- Corrected data after feedback from ECDC: at the latest by 1 November of the year in which validation of the national/regional PPS is performed, together with the invoice required according to the contract specifications.

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