



TECHNICAL DOCUMENT

Protocol for validation of point prevalence surveys of healthcareassociated infections and antimicrobial use in European long-term care facilities

2016-2017 Version 1.1

www.ecdc.europa.eu

ECDC TECHNICAL DOCUMENT

Protocol for validation of point prevalence surveys of healthcare-associated infections and antimicrobial use in European long-term care facilities

2016-2017 Version 1.1



This protocol was commissioned by the European Centre for Disease Prevention and Control (ECDC), coordinated by Pete Kinross and Carl Suetens.

Authors

Enrico Ricchizzi, Maria Luisa Moro (Agenzia sanitaria e sociale regionale; Italy); Katrien Latour, Béatrice Jans (WIV-ISP, Belgium); Tommi Kärki, Carl Suetens, Pete Kinross (ECDC).

Acknowledgements]

All designated national representatives from EU/EEA Member States that attended the 'Train-the-trainer workshop for surveillance of HAI and antimicrobial use in long-term care facilities' on 1–2 December 2015 in Stockholm, Sweden, for their critical feedback regarding this validation survey.

Eratum: 1 February 2017 – the case definition for superficial incisional surgical site infections (SSSI-C and SSSI-I) has been corrected in Annex 4, by aligning its final sub-bullet point to the appropriate hierarchical level.

Suggested citation: European Centre for Disease Prevention and Control. Protocol for validation of point prevalence surveys of healthcare-associated infections and antimicrobial use in European long-term care facilities - 2016–2017 version 1.1. Stockholm: ECDC; 2016.

Stockholm, May 2016 ISBN 978-92-9193-855-1 doi 10.2900/963258 Catalogue number TQ-01-16-424-EN-N

© European Centre for Disease Prevention and Control, 2016 Reproduction is authorised, provided the source is acknowledged

Contents

Abbreviations	İV
1. Summary	1
2. Introduction	
3. Validation survey methodology	5
4. Preparation for the validation survey	8
5. Performing the validation survey	10
6. After the validation survey	
7. References	
8. Contact information	23
Annex 1. Validation survey – institutional questionnaire	24
Annex 2. Validation survey – resident questionnaire	27
Annex 3. Primary HALT-3 PPS ward list	29
Annex 4. Case definitions of infections	

Figures

Figure 1. No. of eligible residents to recruit to HALT-3 validation survey	6
Figure 2. Validation survey – institutional questionnaire; section A	
Figure 3a. Validation survey – institutional questionnaire; section A	
Figure 3b. Validation survey – institutional questionnaire; section D	
Figure 4. Validation survey – institutional questionnaire; section E	
Figure 5. Validation survey – institutional questionnaire; section B	
Figure 6. Validation survey – institutional questionnaire; section V	
Figure 7. Validation survey – resident questionnaire; essential survey-related information	
Figure 8. Validation survey – resident questionnaire; part A	
Figure 9. Validation survey – resident questionnaire; part B	
Figure 10. Validation survey – resident questionnaire;	

Tables

Table 1. Sensitivity and specificity of data collection in HALT-2 (2013)	3
Table 2. Question categories in HALT-3 validation survey institutional guestionnaire and resident guestionnaires,	
2016–2017	5
Table 3. Description of LTCF types in the HALT-3 PPS	6

Abbreviations

AMR	Antimicrobial resistance
EEA	European Economic Area
ESAC-NH	European Surveillance of Antimicrobial Consumption in Nursing Homes
EU	European Union
GP	General practitioner
HAI	Healthcare-associated infection
HALT	Healthcare-associated infections in long-term care facilities project
HALT project (2010)	Healthcare-associated infections in long-term care facilities project, May–September 2010
HALT-2 project (2013)	Healthcare-associated infections and antimicrobial use in long-term care facilities project, April–May 2013
HALT-3 project	Healthcare-associated infections and antimicrobial use in long-term care facilities project, 2016–2017
IPC	Infection prevention and control
IPSE	Improving Patient Safety in Europe project
LTCF	Long-term care facility
NSC	National survey coordinator
PPS	Point prevalence survey
PT	Primary team
RTI	Respiratory tract infection
SSI	Surgical site infection
UTI	Urinary tract infection
VT	Validation team

1. Summary

This protocol provides national survey coordinators (NSCs) and national/regional validation teams (VTs) with the methodology, data collection forms and definitions of variables to collect data in a validation survey synchronous with the third point prevalence survey (PPS) of healthcare-associated infections (HAIs) and antimicrobial use in European long-term care facilities (LTCFs) during the HALT-3 project.

Data from this validation survey will be used to estimate the sensitivity and specificity of data collected by primary data collectors during the HALT-3 PPS, i.e. those who use the main HALT-3 PPS protocol [1]. The data will be used to adjust European prevalence and burden estimates, and thereafter to adjust national estimates. The validation survey will also assess the quality of selected structure and process indicators of infection prevention and control (IPC), to improve interpretation of national/European data.

To achieve this data should be collected by VTs:

- in at least one LTCF, but preferably more than two LTCFs per country, so that 50–100 residents per country are included. A convenience sample of LTCFs (rather than a systematic random sample) is permitted for this validation survey. NSCs/VTs should aim to recruit LTCFs that are as typical as possible of the country's LTCFs, preferably not champions of infection control and antimicrobial stewardship;
- on the same day as the HALT-3 PPS (primary survey) in that LTCF i.e. in April–June 2016, September– November 2016, April–June 2017 or September–November 2017;
- blinded, i.e. the VTs and primary data collectors should not view each others' assessments of individual residents.

The validation survey does not aim to validate <u>national</u> HALT PPS data. Countries seeking to validate their entire national data (i.e. measure sensitivity and specificity of their primary data collectors) should recruit approximately 1 500 residents in their country (this is the same sample size as for the entire European PPS as the calculation is a product of the study design and expected prevalence).

Using the experience of the previous HALT projects including data from the HALT-2 validation survey [2,3], the feasibility of the validation survey has been increased by:

- a greatly reduced number of items to validate compared to the HALT-2 validation survey, e.g. only one question on antimicrobial use
- the option for support from an international assessor if the validation survey is linked to an EU Member State-invited onsite assessment visit [4]
- the promotion of purposive sampling in larger facilities of wards/departments likely to have a higher than average HAI prevalence
- the presentation of the validation methodology to EU Member State representatives at the 'HAI-Net Meeting and train-the-trainers workshop for surveillance of HAIs and antimicrobial use in long-term care facilities, 2016–2017' on 1–2 December 2015 and direct consultations with the HALT-3 Advisory Committee
- the availability of an interactive 'Questions and Answers' forum on an extranet (<u>https://extranet.ecdc.europa.eu/HAINet/</u>).

The activities of the primary data collector and VT on the day(s) of the PPS are summarised in the flow diagram on Page 2.

The activities of specifically the VT are further presented in sequential Chapters: '4. Preparing the validation survey', '5. Performing the validation survey' and '6. After the validation survey.'

If you have questions regarding any aspect of the HALT-3 project, please consult the 'Question and Answer' section of the extranet (you can post your question there) or contact the HALT-3 Management Team (see Chapter '8 Contact information').

Flowchart summarising the data collection process

Primary PPS Team (PT)

Validation Team (VT)



D. Final meeting between PT and VT Important: do not alter the responses on any resident forms, except:

1. On the <u>validation survey – resident questionnaires</u>, enter whether the primary team considered the resident to be eligible or not.

2. Verify that the field 'Resident survey number in primary PPS' entered on the primary PPS <u>resident questionnaires</u> and <u>validation survey – resident questionnaires</u> identify the same residents. Correct these if necessary.

3. Write the 'Resident survey number in validation PPS' "V..." on the top right corner of every primary PPS <u>resident</u> <u>questionnaire</u>.

2. Introduction

2.1 The HALT (2010) and HALT-2 (2013) projects

From 2005 to 2008, a feasibility study of surveillance of HAIs in European nursing homes was performed under the Improving Patient Safety in Europe (IPSE) project financed by the European Commission¹. In December 2008, ECDC initiated surveillance of HAIs and antimicrobial use in European long-term care facilities (LTCFs) under the Healthcare-Associated Infections in Long-Term Care Facilities (HALT) project. It integrated variables from the European Surveillance of Antimicrobial Consumption in Nursing Homes (ESAC-NH) subproject into a protocol for repeated point prevalence surveys (PPSs) in LTCFs, thus providing an integrated methodology for continued assessment of the prevalence of HAIs, antimicrobial use, and infection prevention and control (IPC) resources in European LTCFs.

The general objectives of ECDC surveillance of HAIs and antimicrobial use in European LTCFs are:

- to provide EU/EEA Member States and LTCFs with a standardised tool to follow trends in HAIs and antimicrobial use
- to identify priorities for national and local intervention measures and evaluate their implementation in EU/EEA Member States and LTCFs
- to estimate and monitor the burden of HAIs and antimicrobial use in LTCFs at national and European level.

The specific objectives of the PPS of HAIs and antimicrobial use in LTCFs are to support the abovementioned objectives for European surveillance, i.e. to estimate the prevalence of HAIs and antimicrobial use in European LTCFs and to measure structure and process indicators of IPC in these LTCFs [1].

In May–September 2010, a first PPS in European LTCFs (HALT project, 2010) collected data from 722 LTCFs across 25 European countries [3]. It showed a prevalence of residents with at least one HAI in participating LTCFs of 2.4%. The crude prevalence of residents receiving at least one antimicrobial agent was 4.3%.

In April–May 2013, a second PPS in European LTCFs (HALT-2 project, 2013) collected data from 1 181 LTCFs in 17 European countries [2]. The HALT-2 project showed prevalence of residents with at least one HAI of 3.4% and a prevalence of residents with at least one antimicrobial agent of 4.4%. The HALT-2 project also included a validation survey.

The national representativeness of the LTCF sample in HALT-2 was categorised as 'good' in 10 (53%) of 19 participating countries, 'poor' in 5 (26%), and 'very poor' in four (21%) [2]. None of the countries used systematic random sampling [2].

2.2 The HALT-2 validation survey

In April–May 2013 a validation survey was performed in 10 of the 19 participating European countries that participated in the HALT-2 project, in 20 of the 1 056 participating LTCFs. Its data were used to estimate the sensitivity and specificity of data collection by 'primary data collectors' in the primary HALT PPS, permitting calibration of European estimates including burden estimation [2].

The sensitivity of collection of population denominators and antimicrobial use data was relatively high (>90%), but far lower for HAI (76%), although the specificity for HAIs data collection was near 100% (Table 1). In other words, primary data collectors were less likely to make a false positive identification of a HAI (n=9 of 822) than a false negative assessment (n=8 of 33).

Table 1. Sensitivity and	specificity of data	collection in HALT-2 (2013)
--------------------------	---------------------	-----------------------------

Data	Sensitivity (95% CI)	Specificity (95% CI)
Population denominators	96.9% (95.9–97.7%)	98.5% (98.1–98.8%)
Antimicrobial use	90.2% (78.6–96.7%)	99.9% (99.3–100%)
Structural and process indicators of IPC	82.6% (78.1–86.5%)	85.0% (80.3–89.0%)
HAI	75.8% (57.7–88.9%)	98.9% (98.1–99.6%)

Source: Report of the HALT-2 (2013) project [2]

¹ Improving Patient Safety in Europe Technical Implementation Report 2005-2008. ISPE, November 2008. Available from: <u>http://ecdc.europa.eu/en/healthtopics/Healthcare-associated_infections/HAI-Net/Documents/healthcare-associated-infections-IPSE-Technical-Report.pdf</u>

2.3 The HALT-3 project

In May 2015, ECDC launched the third HALT project (HALT-3) to support PPSs of HAIs and antimicrobial use in LTCFs.

Major priorities in the HALT-3 project are supporting Member States' recruitment of a representative sample of LTCFs and residents, the promotion of accurate data collection, and measurement of the degree of accuracy through a validation survey performed in each participating Member State.

EU/EEA Member States were invited to collect data in the HALT-3 PPS in LTCFs (primary survey) in their country using the HALT-3 PPS protocol during one or more of four surveillance periods [1]. If data are collected from a LTCF in more than one of these periods, only data from their first participation should be included in the dataset sent to ECDC. The four surveillance periods are April–June 2016, September–November 2016, April–June 2017, and/or September–November 2017.

A two-day onsite assessment visit can be arranged if an invitation is received by ECDC from a participating EU/EEA Member State [4]. The international assessor will be a HALT-3 management team member with experience in HAI epidemiology, familiar with the specificities of LTCF settings and trained in the onsite assessment methodology. The objectives of the visit are for the international assessor to support the completion of a questionnaire on national data and IPC needs and to accompany the national team during a validation survey. In other words, the international assessor can support a validation team (VT) in their preparation and completion of a validation survey. The international assessor will also complete a questionnaire and perform interviews of national and local teams to qualitatively assess the comparability of national validation surveys.

The outputs from the HALT-3 PPS will include a European report, national feedback reports, and feedback reports for each participating LTCF – comparing their data to national and European results; all distributed to national teams for onward distribution. The European report will be published on the ECDC webpage for PPSs in LTCFs [5].

2.4 Objectives of this HALT-3 validation survey

The objectives of the validation survey are:

- to calculate European-level sensitivity and specificity of the detection of HAIs and antimicrobial use in the primary HALT PPS by primary data collectors, thus <u>enabling the adjustment of European estimates</u>
- to assess the quality of selected structure and process indicators of IPC, thus contributing to the interpretation of national/European data.

The validation survey neither aims to validate <u>national</u> HALT PPS data (although this would be achievable by recruiting 1 250–1 500 residents per country - see 3.4), nor to measure the true prevalence of HAI/antimicrobial use in LTCFs participating in validation surveys (although this would be achievable by validating all residents in a LTCF – see 4.3). Rather, the validation survey seeks to estimate the accuracy of all primary data collectors in the HALT-3 PPS by measuring the accuracy of primary data collectors in LTCFs that participate in validation survey. The planned analyses assume that the sensitivity and specificity of primary data collectors will be the same in the primary survey as in the validation study, despite the potential for indirect influences (e.g. the Hawthorne effect). Therefore, blinded data collection is required, and adjustment of primary or validation data during or after the validation survey should not be done (see 3.2 Blinding).

The validation survey design aims to maximise its feasibility for VTs through:

- a greatly reduced number of items to validate (see 3.3)
- the option for support from an international assessor during onsite assessment visits (see 2.3 and 4.2.2)
- promotion of purposive sampling of wards/departments likely to have a higher than average HAI
 prevalence, resulting in a smaller required sample size in larger LTCFs (see 5.A)
- presentation of the validation methodology to EU Member State representatives on 1-2 December 2015 ('HAI-Net Meeting and train-the-trainers workshop for surveillance of HAIs and antimicrobial use in longterm care facilities, 2016-2017') and direct consultations with the HALT-3 Advisory Committee.

2.5 Frequently asked questions (FAQs)

Answers to frequently asked questions (FAQs) from National Survey Coordinators (NSCs) and primary data collectors regarding all aspects of the HALT-3 project are published on the ECDC HAI-Net extranet (URL: <u>https://extranet.ecdc.europa.eu/HAINet/</u>). These will be updated throughout the project. Please consult these FAQs and/or email <u>HALT@wiv-isp.be</u> or otherwise <u>HAI-Net@ecdc.europa.eu</u> or any of the persons listed in section 8 'contact information'.

3. Validation survey methodology

3.1 Timing

This validation survey should be performed by a separate VT, but on the same day as the primary HALT-3 PPS performed by primary data collectors in the same LTCF. Optionally, NSCs may choose to combine the validation survey with an onsite assessment visit (see 4.2.2). In the HALT-2 (2013) validation survey, approximately eight hours were required to collect data on 100 residents. The HALT-3 validation survey will collect less data and aims to recruit 50–100 residents per Member State.

3.2 Blinding

Important: The primary data collectors and the VT must complete their forms independently. It is essential that they do not adjust the responses on their resident or institutional forms, i.e. do not cross-check, discuss or 'correct' discordant results (see 2.4).

3.3 Which data should be collected?

The HALT-2 (2013) project identified that the collection of antimicrobial use and denominator data had a high sensitivity and sensitivity (see 2.2 and [2]). The HALT-3 validation survey therefore contains little validation of these data and focuses on the identification of HAIs and on structure and process indicators of IPC (Table 2).

 Table 2. Question categories in HALT-3 validation survey institutional questionnaire and resident questionnaires, 2016–2017.

Variable	Description	No. of questions
Institutional questionnaire	General information (validation survey details, staffing, LTCF rooms)	15
	Infection control practice (established systems, hand hygiene)	8
	Antimicrobial policy	1
	Denominator data	7
	Validation survey descriptors	5
Total		36
Resident questionnaires	Resident descriptors	7
	Antimicrobial treatment	1
	HAIs	No signs/symptoms of infection: 1 Signs/symptoms of infection: 12
Total		9 or 20 (depending on the absence or presence of signs/symptoms of infection)

3.4 Sample size

3.4.1 European validation survey

The number of residents required to measure a sensitivity of 82% with a 10% false positivity rate, assuming that the prevalence of HAIs is 4%, is 1 500 eligible residents (Figure 1). Therefore, if all countries perform a validation survey, 50 residents should be recruited in each Member State. This sample size is a property of the study design, i.e. if fewer Member States participate in the validation survey, then more than 50 residents per country should be recruited in each of the remaining Member States to achieve the sample size required to validate the HALT-3 PPS data. Therefore **we recommend to recruit 50-100 residents per Member State to this validation survey**.

The overall usefulness of the HALT-3 PPS will be improved by recruiting as many LTCFs as possible, thus reducing the effect of non-representative attributes of any one recruited LTCF. In 2013, the average LTCF size in EU/EEA Member States ranged from 14–236 beds, with 10/30 Member States having fewer than 50 beds/LTCF, on average [1,2]. In the HALT-3 PPS, a third of participating member States will therefore need to validate residents from more than one LTCF. We recommend that each Member State recruits more than one LTCF to this validation survey.

In 2013, 8/30 Member States had on average more than 75 beds/LTCF. Options to purposefully select subpopulations within the recruited LTCF are provided in section 3.4.3.





Key: UL – upper limit; LL – lower limit; pr – prevalence of HAIs

3.4.2 Choice of LTCFs for validation purposes?

Practical considerations for recruiting 1–2 LTCFs dictate that purposive sampling of 'typical' LTCFs will be required in most Member States. Preferably, the recruited LTCFs should neither be untypically large or small, nor a notable champion in IPC and antimicrobial stewardship. In the HALT (2010) and HALT-2 (2013) projects, the most frequently reported LTCF types were, general nursing homes, residential homes and mixed type facilities, respectively (Table 3). Therefore, LTCFs should be recruited to the validation survey in that order of preference.

Table 3. Description of LTCF types in the HALT-3 PPS

LTCF types	Description
General nursing homes	In these facilities, residents need medical or skilled nursing and supervision 24 hours a day. These facilities principally provide care to older persons with severe illnesses or injuries.
Residential homes	In these facilities residents are unable to live independently. They require supervision and assistance for the activities of daily living (ADL). These facilities usually include personal care, housekeeping and three meals a day.
Mixed LTCFs	These facilities provide different types of care in the same facility.

3.4.3 Purposive sampling of resident sub-populations

If the LTCF is large, i.e. if it would not be possible to validate all residents, NSCs can recommend, but only in this case, that VTs perform validation on a subset rather than all LTCF residents. The recommended sample size is 50–100 residents per Member State. In the HALT-2 (2013) validation survey, it took on average eight hours to validate data for 100 residents.

Many larger LTCFs have residents with similar care needs within distinct wards, buildings, departments or similar. In these scenario, wards with the highest staff-to-resident ratio may be purposefully sampled, as residents in these wards are at highest risk of a HAI due to the higher prevalence of relevant risk factors. If all geographical locations within the LTCF are equal in terms of care load, validation should continue until 50–100 residents are validated.

If only a sample of residents is reviewed for validation (e.g. large LTCF), it is of paramount importance that the same residents were also surveyed in the primary HALT-3 PPS. But as the protocol for the primary HALT-3 PPS recommends that all eligible LTCF residents are surveyed, this should not be an issue.

3.4.4 Validation of national data

If NSCs wish to estimate the sensitivity and specificity of their national primary PPS data collection, they should include at least 1 250–1 500 residents in their validation survey, as the calculation is dependent on the design and attributes of the survey. If fewer residents are included in the validation survey, the width of the confidence intervals for sensitivity and specificity will increase (see upper and lower limits for 95% confidence intervals in Figure 1). Considering the average LTCF size in Member States, systematic random sampling may be a feasible approach for national validation surveys. One methodology for this is described in detail in the main HALT-3 PPS protocol [1].

4. Preparation for the validation survey

4.1 Composing a validation team (VT)

NSC's should compose national/regional VT(s) and train them in the use of this protocol and the primary HALT-3 PPS protocol [1]. At least one member of the team should be a senior expert with experience in HAI surveillance (especially application of case definitions) to act as a ,gold standard' data collector.

The responsibilities of the VT include collection of validation data following this protocol; ensuring accurate linkage of resident identifiers on the validation survey and primary HALT PPS questionnaires; and reporting any acquired information to the NSC that may aid the NSC's understanding of the validation data.

The NSC should also recruit (at least) one staff member from the recruited LTCF to be a member of the VT for that LTCF's validation (see 4.2.2).

4.2 Recruiting LTCFs to participate in the validation survey

4.2.1 Which LTCFs should be recruited?

The objective is to collect validation data on 50–100 residents from 1–2 LTCFs that participate in the primary HALT-3 PPS.

If a convenience sampling method is used, the NSC should select LTCFs that are as 'typical' as possible of LTCFs in the country, i.e. the LTCFs should be:

- not untypically large or small
- not a notable champion in IPC and antimicrobial stewardship
- preferably a general nursing home or otherwise a residential home or mixed facility (Table 3).

The selected LTCF(s) should be able to provide:

- at least one internal staff member available to support the VT during the data collection
- access to all health documents of all residents
- collaborative assistance regarding the accurate use of this validation protocol in their facility.

4.2.2 Role of LTCF staff members

In many LTCFs, the primary data collectors will be LTCF staff members. In the validation survey, the VT should include at least one LTCF staff member. The experience from the HALT-2 (2013) project is that LTCF staff members are crucial members of the team. Importantly, as part of the VT, they should be entirely independent from the primary data collectors (see 3.2 Blinding).

Their role will be:

- to introduce the VT to other LTCF staff members. In particular, if the LTCF staff member in the VT is not a nurse and physician responsible of resident care within that LTCF, they should enable access to such persons.
- to provide institutional information for the <u>institutional questionnaire</u>, or providing the VT with access to this information.
- to provide access to and explain relevant facilities information systems, particularly for the <u>resident</u> <u>questionnaire</u> (e.g. clinical, pharmacy or microbiological records).

4.2.3 Pairing the validation survey with an onsite assessment visit

In Member States that request an onsite assessment visit from ECDC, NSCs will recruit one LTCF for participation in the onsite assessment. The international assessor can assist the NSC in preparations for the validation survey, but all contacts with the LTCF will be made by members of the national team.

The recommendations for recruitment of a LTCF for the onsite assessment visit are available in the onsite assessment protocol [4]. The additional requirements in that protocol, above those described in this validation survey protocol (see 4.2.1), are (A) that at least one staff member of the LTCF speaks one of the languages spoken by the international assessor, or that the NSC or someone appointed by the NSC provides translation; and (B) that a staff member of the LTCF is available to participate in a structured interview with the international assessor to provide local contextual information.

4.3 Countries with few data collectors and/or LTCFs

The 'HAI-Net Meeting and train-the-trainers workshop for surveillance of HAIs and antimicrobial use in long-term care facilities, 2016–2017' took place on 1–2 December 2015. During this meeting, a few EU/EEA Member States indicated that there were only a few persons capable of performing a validation survey in their country and that these persons were likely to also be the primary data collector. If possible, these Member States should achieve the validation survey by having at least one member of the team acting as a primary data collector and another as the validator, i.e. measuring inter-rater agreement. Representatives (e.g. NSCs) from Member States requiring different/additional solutions should contact ECDC directly to discuss potential options to participate by emailing HAI-Net@ecdc.europa.eu.

4.4 Ethical considerations

Member States will have different requirements for ethical approval for a PPS in LTCFs. The experience from the HALT (2010) and HALT-2 (2013) projects is that some countries required approval from an ethics committee. Some of the committees requested that written consent be obtained from each resident with a HAI or receiving an antimicrobial agent on the day of the PPS, or if not possible (e.g. in case of cognitive impairment) from a 'proxy' such as a carer or a medical professional. Data collectors in these Member States found that was relatively feasible to acquire the signatures, as simply explaining the necessity of the PPS to the resident or their 'proxy' was sufficient.

Confidentiality of LTCF data and resident data is assured by:

- NSCs attributing an LTCF survey number to each participating LTCF. The participating LTCFs will not be identifiable by other LTCFs/persons since all reports and presentations will only use LTCF survey numbers and never LTCF names. The key to the LTCF names from the LTCF survey number will not be sent to ECDC.
- A unique resident survey number will be allocated to each resident for whom a questionnaire is completed. Patient identifiers are not stored in the software and should not be written on the data collection forms.

The <u>ward list</u> (optional, for internal use) for the primary HALT-3 PPS protocol includes resident identifiers. It must be kept in the LTCF in a secure and confidential manner and should be destroyed at the end of the HALT-3 project, i.e. December 2018.

Data collected within the framework of the HALT-3 project should not be used for purposes other than those described in the objectives of the present protocol.

5. Performing the validation survey

5.A Selecting the wards to review

If possible, wards/departments of LTCFs that have the highest staff-to-resident ratio (i.e. residents with the highest care need) should be surveyed first to ensure that residents with infections are surveyed. Purposive sampling may increase the feasibility of the validation in larger LTCFs, but is not relevant for many Member States (see 3.4.3).

5.B Completing the validation survey institutional questionnaire (Annex 1)

LTCF staff members that participate in the HALT-3 PPS should collect indicator data prior to the validation visit to save time for the primary data collectors and VT and enable data quality assurance of the selected indicators.

5.B.1 A – General information

Variable	Description/definition
Validation survey date and time	Record the day of the validation survey (format day/month/year) and its start time and end time (e.g. 09:00–17:00).
Facility survey number:	Use the primary PPS facility survey number allocated by the NSC.
Total number of FTEs of registered nurses	Total number of full-time equivalent registered (graduated, qualified) nurses working in the LTCF (not only on the day of the PPS). Describe the current situation if possible, or the most recent available situation. A 'registered nurse' is a nurse who has graduated from a college's nursing program or from a school of nursing and has passed a national licensing exam to obtain a nursing license. Do include 'agency nurses', 'bank nurses', 'interim nurses' or other registered nurses who are not permanently employed for that position in the LTCF. No distinction should be made between the administrative, scientific and/or clinical work of a nurse. Do not include students.
Total number of FTEs of nursing assistants	Total number of full-time equivalent (FTE) nursing assistants working in the LTCF (not only on the day of the PPS). Provide the current situation if possible, or the most recent available situation. A 'nursing assistant' is also referred to as 'nurses' aide', 'healthcare assistant', 'nursing auxiliary', 'auxiliary nurse', 'patient care assistant' or similar terms. Also include nursing assistants who are not permanently employed for that position in the LTCF. Nursing assistants work under the supervision of nurses or physicians to address the most fundamental elements of a resident's care. In general, they feed, dress, bathe and groom patients, but they can also perform more medically-oriented but basic duties such as measuring and recording temperature, blood pressure, and other vital signs. No distinction should be made between the administrative, scientific and/or clinical work of a nursing assistant. Do not include other licensed health professionals such as dietitians, physiotherapists or speech or occupational therapists, logistic personnel, students of any kind or volunteers who provide basic patient care without pay.
Qualified nurses are available 24h per day:	Qualified nurses are available day and night, i.e. physically present and/or contactable by phone/beeper 24 hours a day.
Correct reporting of partial FTEs? (e.g. 10% of full-time = 0.1 FTE)	Current LTCF only – i.e. the correct option. FTEs for other institutions (e.g. hospital) are included; separate reporting of FTEs for current LTCF was not possible. NA: data not available. Specify in comments field if answers only apply to some but not all FTE variables.
Other comments regarding FTEs	Free text. Describe other factors that may have influenced the accuracy of the reported FTEs or need to be taken into account for their interpretation, particularly if the response to previous question was 'FTEs for other institutions are included'
Other validation team comments, e.g. data quality issues.	Free text field which will be read by the NSC and the HALT-3 team.

Figure 2. Validation survey – institutional questionnaire; section A (page 1 of 3)

Validation of main protocol Institutional Questionnai	re
DATE OF THE VALIDATION SURVEY / / 2 0 (dd/mm/yyyy)	STARTTIME:
FACILITY STUDY NUMBER	END TIME:
Validation team's assessment of full-time equivalents (FTEs)	
Qualified nursing care available 24hrs / 24hrs in the facility	□ Yes □ No
Total number of FTEs of registered nurses	FTEs
Total number of FTEs of nursing assistants	FTEs
Validation team's assessment of the primary team's assessment	of FTEs
Correct reporting of partial FTEs? (e.g. 10% of full-time = 0.1 FTE) □ Yes □ No	
FTE = Current situation or average situation on 1 day (not e.g. 'cumu	llative' FTEs for 1 year)
Current Average	
How were the FTEs reported? (tick one)	
Current LTCF only	
FTEs for other institutions are included	
🗆 NA: data not available	
Other comments regarding FTEs	
Other validation team comments, e.g. data quality issues.	

Variable	Description/definition
How many rooms are there in the facility designated for single occupancy?	Total number of rooms in the facility that are designated for single occupancy (e.g. rooms with one bed). A room shared by partners should not be considered as a single occupancy room.
How many single/private rooms with individual toilet and washing facilities are there in the facility	Number of single occupancy rooms with individual toilet and washing facilities (sink and/or shower). An individual toilet alone or a commode (toilet chair) is not sufficient to qualify as a 'single occupancy room with individual toilet and washing facilities'. Rooms which have toilet and washing facilities in a communal area should not be counted.
How did you acquire the information on single/private rooms (e.g. description from LTCF staff, from a building plan, etc.)	Free text field. Please report how the information is collected possibly using concise example.

Figure 3a. Validation survey – institutional questionnaire; section A (top of page 2 of 3)

Reporting LTCF rooms and occupancy

How many rooms are there in the facility designated for single occupancy? (A room with a double bed shared by partners should not be considered as a single room)

Total number of single/private rooms in the facility with individual toilet and washing facilities

How did you acquire information on single/private rooms (e.g. description from LTCF staff, from a building plan, etc) _____

5.B.2 D – Infection control practice

Variable	Description/definition
Registration of residents	Documenting resident information e.g. on a paper-based or computerised system.
Infection prevention and control (IPC) committee	A multidisciplinary committee consisting of at least the person with training in infection prevention and control (IPC) (IPC practitioner), the administrator, the coordinating physician (if present at the facility), the nursing supervisor(s) or by persons they designate. The IPC committee functions may be merged with the performance improvement or patient safety programmes, but IPC must remain identifiable as a distinct programme. The IPC committee should meet regularly to review infection control data, review policies, and monitor programme goals and activities. Written records of meetings should be kept (Source: SHEA/APIC guidelines: Infection prevention and control in the LTCF, 2008).
How many litres of hand alcohol were used last year?	Total number of litres used during the course of the calendar year preceding the PPS, e.g. those collecting data in May 2016 should provide data for January–December 2015.
Hand hygiene opportunities	Number of hand hygiene opportunities or indications (moments) measured as part of hygiene campaigns or audits. Only the number of observed opportunities needs to be recorded, not how many of these were observed to be processed correctly (=compliance). The four moments for hand hygiene in residential facilities should at least include (1) before touching a patient, (2) before a clean/aseptic procedure, (3) after a body fluid exposure risk and (4) after touching a patient. In specialised LTCFs, where residents are mainly cared for in dedicated space with dedicated equipment, moment 5 (i.e. after touching patient surroundings) also applies. Source [6].

Figure 3b. Validation survey – institutional questionnaire; section D (page 2 of 3)

D – INFECTION CONTROL PRACTICE	
 3. In the facility, is there: Registration of residents colonised/infected with multi-resistant microorganisms Feedback on surveillance results to the nursing/medical staff of the facility Organisation, control, feedback on hand hygiene in the facility on a regular basis 4. In the facility, is there an infection control committee (internal or external)? Yes 	
8. Is a surveillance programme of healthcare-associated infections in place in the facility? (e.g. an annu report of number of urinary tract infections, respiratory tract infections, etc)	al summary
9. In the facility, which of following products are available for hand hygiene? - Alcohol rub solution Yes No - Wipes (alcohol) Yes No - Liquid soap (antiseptic/ other) Yes No - Bar soap in clinical areas Yes No	
11. How many litres of hand alcohol were used last year? Total annual consumption in litres	year
 Alcohol hand rub consumption, data source: who provided the data on AHR and what do they repr Quantity dispensed/delivered in one year period Quantity purchased in one year period Other, please specify (in comment field) NA: data not available Alcohol hand rub consumption, other comments:	resent?
13. How many hand hygiene opportunities were there observed in your facility last year?	
Number of observed opportunities Opportunities	last year

5.B.3 E – Antimicrobial policy

Variable	Description/definition	
Written guidelines for appropriate antimicrobial use (good practice) in the facility	Any international, national or regional written guideline(s) or recommendations for empirical and targeted treatment.	
Data available on annual antimicrobial consumption by antimicrobial class	Data is available to the LTCF on the annual use within the LTCF. An appropriate example of 'antimicrobial classes' are the ATC codes (see http://www.whocc.no/atc_ddd_index/?code=301).	
Antimicrobial resistance profile summaries	A periodic summary of antimicrobial susceptibilities of local bacterial isolates submitted to a clinical microbiology laboratory, i.e. an 'antibiogram'.	

Figure 4. Validation survey – institutional questionnaire; section E (page 3 of 3)

E – ANTIMICROBIAL POLICY

- 3. Which of following elements are present in the facility?
 - D Written guidelines for appropriate antimicrobial use (good practice) in the facility
 - Data available on annual antimicrobial consumption by antimicrobial class
 - A system to remind healthcare workers of the importance of microbiological samples to inform the best antimicrobial choice
 - Local (i.e. for that region/locality or national if small country) antimicrobial resistance profile summaries available in the LTCF or in the GP surgeries who prescribe
 - □ A therapeutic formulary, comprising a list of antibiotics

5.B.4 B – Summary of the resident population validated

Variable	Description/definition	
Total number of beds in the facility	Report the total number of beds in the facility as assessed by VT.	
No. of occupied beds in the facility	On the day of the survey, total number of beds allocated to a resident as assessed by the VT, irrespective of whether the resident is there on the day of the survey.	
No. of eligible residents according to the primary team	Acquire this data from the primary survey team's <u>ward list</u> / <u>institutional questionnaire</u>	
No. of eligible residents according to the validation team	Assessment of the VT. Residents are eligible, and should therefore be included in the survey, if they are:	
	 living full-time (24 hours a day) in the LTCF AND present at 8:00 AM on the day of the PPS AND 	
	 not discharged from the LTCF at the time of the survey. 	
	Note: Do include residents who meet these criteria and are recorded on the resident administration system if they were temporarily outside the LTCF (e.g. for diagnostic investigations or medical procedures; with family/friends; etc).	
	 The following residents should be excluded: residents not living full-time in the LTCF (e.g. residents from day care centres) OR residents living full-time in the LTCF but not present at 8:00 AM (e.g. absent for leave or admitted to a hospital) OR residents hospitalised on the day of the PPS (i.e. inpatient in a hospital with a stay of at least one night) OR residents who choose not to participate. 	
	Note: Residents receiving chronic ambulatory care on a regular basis in an acute care hospital (e.g. haemodialysis or chemotherapy) should not be excluded from the PPS if they are not hospitalised on the day of the PPS (i.e. hospital stay of at least one night).	
No. of residents receiving at least one antimicrobial agent	Total number of eligible residents receiving one or more systemic antimicrobial agents on the day of the PPS as assessed by the VT.	
No. of residents with signs/symptoms of an infection	Assessment of the VT. The number of eligible residents for whom the VT consulted the case definition algorithm to ascertain whether the resident had one or more HAIs on the day of the PPS (Annex 4), i.e. analogous to column 8a on the <u>ward list</u> (Annex 3).	
No. of residents with at least one infection matching a case definition	Assessment of the VT. The number of eligible residents for whom the VT assigned a HAI code, after consulting the case definition algorithm (Annex 4). This is analogous to category 8b on the <u>ward list</u> (Annex 3).	
Total No. of resident forms completed by the validation team	This field will be used to verify the completeness of data transfer to the HALT-3 team.	

Figure 5. Validation survey – institutional questionnaire; section B (page 3 of 3)

B - DENOMINATOR DATA; SUMMARY DATA FOR THE VALIDATION STUDY

Total no. of beds in the facility	
No. of occupied beds in the facility, i.e. allocated to a resident	
No. of eligible residents <u>according to the primary team</u> (acquire these data from the `ward list', column 3)	
No. of eligible residents according to the validation team	
No. of residents receiving at least one antimicrobial agent	
No. of residents with signs/symptoms of an infection	
No. of residents with at least one infection matching a case definition	
Total no. of resident forms completed by the validation team	

5.B.5 V – How was the validation performed in this facility?

Variable	Description/definition	
Timing. Timing of the validation survey in this LTCF. Simultaneous (same day, same time): validation is done at the same time as the collection (note: communication between the VT and the primary data collectors minimized). Also mark this answer if only part of the data collection occurred sin Same day, after PPS: validation is done on the same day as the primary PPS but primary PPS was completed. Other (please specify): Free text.		
Validation method.	 <u>Blinded</u> (obligatory): neither the primary data collectors nor the VT are aware of the other team's assessment during or following their own assessment. <u>Non-blinded (not permitted)</u>: the HAI or antimicrobial use status of the patient was disclosed by the VT to the primary data collectors, or <i>vice versa</i>, permitting a change in the assessment of the primary team. Please specify relevant additional details in the comments field. 	
Data source (for the diagnosis of HAI only)		
Local staff Indicate which supporting staff were members of the VT for the majority of the valid Tick all that apply: <u>Nurse</u> . At least one nurse who is aware of recent clinical status changes in this LTCF <u>Physician</u> . At least one physician (e.g. medical coordinator or medical staff member) involved in the care of all residents and/or is aware of their recent clinical status changes of <u>Other</u> . Personnel other than nurses or medical doctors. Please specify their role/spectrother VT comments/data quality issues.'		
Population	Indicate whether a subset of residents were selected, and how the selection was made. For example "A building was identified by LTCF staff within the LTCF complex that had 60 residents who require a higher care load, i.e. provided by more nurses per resident".	
Other validation team comments/data quality issues.	Free text. Other VT comments, data quality issues at the LTCF level or elements that should be	

Figure 6. Validation survey – institutional questionnaire; section V (page 3 of 3)

ming	3	Valida	tion method
	Simultaneous (same day, same time)		Blinded
	Same day, after Primary PPS		Non-blinded
	Other (specify)		
	ource for the diagnosis of HAI	Local s	staff
	tick all that apply		Nurse
	Written records		Physician
	Local staff		Other (specify)
– Popula	Attending physician		
	All residents		
	Selected residents (specify selection metho	od, e.g. how v	vards were selected)
y othe	er comments regarding performance of	the validatio	on study in this facility:

5.C Completing the validation survey – resident questionnaire (Annex 2)

5.C.1. Essential questions

Variable	Description/definition	
Resident survey number in validation survey	Add a sequential number to uniquely identify each resident in the LTCF. Ideally this should be completely identical to the 'resident survey number in primary PPS'. If there is a discrepancy, please provide additional details to explain this, on the final page of the form to aid interpretation by the analysis team.	
Complete at the start of the day		
Facility survey number (allocated by HALT-3 coordinator)	Acquire from the National Survey Coordinator (NSC)	
Resident survey number in primary PPS	The primary PPS team should complete columns 1-3 of this <u>ward list</u> prior to the start of the validation survey, allocating a resident survey number to each resident.	
Complete when assessing the resident		
Birth year	Year the resident was born (YYYY)	
Gender	Current assignment: male, female or other. The latter category is not included on the main protocol. For transgender residents, please record the self-identified gender rather than sex. If the category other is used, please consider providing further details in the free text field so that future questionnaires can be improved (e.g. intersex).	
Resident considered eligible by validation team	 Residents are eligible, and should therefore be included in the survey, if they are: living full-time (24 hours a day) in the LTCF, AND present at 8:00 a.m. on the day of the PPS, AND not discharged from the LTCF at the time of the survey. 	
	Note: Do include residents who meet these criteria and are recorded on the resident administration system if they were temporarily outside the LTCF (e.g. for diagnostic investigations or medical procedures; with family/friends; etc).	
	 The following residents should be excluded: residents not living full-time in the LTCF (e.g. residents from day care centres), OR residents living full-time in the LTCF but not present at 8:00 a.m. (e.g. absent for leave or admitted to a hospital), OR residents hospitalised on the day of the PPS (i.e. inpatient in a hospital with a stay of at least one night) OR residents who choose not to participate. 	
	Note: Residents receiving chronic ambulatory care on a regular basis in an acute care hospital (e.g. haemodialysis or chemotherapy) should not be excluded from the PPS if they are not hospitalised on the day of the PPS (i.e. hospital stay of at least one night).	
Complete at the end of the day		
Resident considered eligible by primary PPS team	Aided by the ward list, consult with the primary PPS team to identify the resident survey numbers of residents that they had considered eligible according to the eligibility criteria. (They should not alter or omit any forms after this step).	
The PPS primary team completed a questionnaire for this resident	Same as for the previous variable.	
Tick box if validation team not able to assess resident for the validation survey	Some residents may be present for the primary team, but unavailable for review by the validation team. For example, those who leave the premises. If the resident has not returned for validation by the end of the validation survey in that LTCF, tick this box. This is required to understand discrepancies between the primary and validation datasets	

Figure 7. Validation survey – resident questionnaire; essential survey-related information (page 1 of 2)

	Healthcare-associated infections and antimi in European long-term care facilities (H		Resident stud	
	Validation Study – Resident Question	naire		
One form has to	be completed for every resident recorded on the wa	nd list provide	ed by the primar	y PPS team
Complete at the start of the day:	Facility study number (<i>allocated by national survey co</i> Resident study number in primary PPS:	oordinator) _ 		
Complete when assessing the resident:	Birth year: Gender: Resident considered eligible by validation team?	□ Male □ F □ Yes □ N	⁻ emale □ Other Io	
Complete at the	Resident considered eligible by primary PPS team? The PPS primary team completed a questionnaire for	this resident	□ Yes □ Yes	□ No □ No

Tick box if validation team <u>not</u> able to assess resident for the validation study \Box

5.C.2. Part A – ANTIMICROBIAL TREATMENT

Variable	escription/definition	
Is the resident receiving at least one antimicrobial agent on the day of the PPS?	 The following antimicrobial agents should be included if their route of administration is oral, parenteral (intravenous), intramuscular, subcutaneous, inhalation or rectally: antibacterial (ATC group J01), antimycotics (J02) and antifungals (D01BA) for systemic use; antibiotics used as intestinal antiinfectives (A07AA); antiprotozoals (P01AB); antimycobacterials (J04) when used for treatment of mycobacteria including tuberculosis or as reserve treatment for multidrug-resistant bacteria The following antimicrobial agents should be excluded: Antiviral agents for systemic use; preparations of antimicrobial agents for topical use; antiseptic agents. 	

Figure 8. Validation survey – resident questionnaire; part A (page 1 of 2)

PART A: ANTIMICROBIAL TREATMENT

end of the day:

Is the resident receiving at least one antimicrobial agent on the day of the PPS?

□ Yes □ No

5.C.3. Part B – HEALTHCARE-ASSOCIATED INFECTIONS.

Variable	Description/definition		
Does this patient have any signs/symptoms (s/s) of an active infection?	 No (Resident presents no s/s of an infection and does not receive antimicrobial(s) to treat an infection on the PPS day→ Stop, this is the end of this questionnaire.) Yes (→ Continue: complete the remaining questions using the exact same principles as the main protocol) 		

Complete the remainder of Part B by consulting the HALT-3 PPS main protocol section 4.3.3 Infection data [1].

Figure 9. Validation survey – resident questionnaire; part B (page 1 of 2)

PART B: HEALTHCARE-ASSOCIATED INFECTIONS

Does this patient have any signs/symptoms (s/s) of an active infection?

□ No (Resident presents no s/s of an infection and does not receive antimicrobial(s) to treat an infection on the PPS day → Stop, this is the end of this questionnaire.)

□ Yes (→ Continue: complete the remaining questions using the exact same principles as the main protocol)

		Infection 1	Infection 2	Infection 3	Infection 4
INFECTION CODE					
IF 'OTHER', PLEAS	E SPECIFY				
Present at (re-) admi	SSION	🗆 No 🗆 Yes			
DATE OF ONSET (DD/N	IM/YY)	//	/_/	//	/_/
ORIGIN OF INFECTION		 Current LTCF Other LTCF Hospital Unknown 	 Current LTCF Other LTCF Hospital Unknown 	 Current LTCF Other LTCF Hospital Unknown 	 Current LTCF Other LTCF Hospital Unknown
A. NAME OF ISOLATED	1. A				
MICROORGANISM (PLEASE USE CODE LIST)	В				
B. TESTED ANTIMICROBIAL(S)	2. A				
AND RESISTANCE ONLY FOR STAAUR, ENC***, ACIBAU,	В				
PSEAER OR ENTEROBACTERIACEAE (CIT***, ENB***,	3. A				
ESCCOL, KLE***, MOGSPP, PRT***, SER***)	В				

¹Tested antibiotic(s): STAAUR: oxacillin (OXA) or glycopeptides (GLY); ENC***: GLY only; Enterobacteriaceae: 3^d-gen cephalosporins (C3G) or carbapenems (CAR); PSEAER and ACIBAU: CAR only. ² Resistance: S=sensitive, I=intermediate, R=resistant, U=unknown

5.C.4. Additional notes

Variable	Description/definition	
Resident survey number in validation survey	Note this field on the top right corner. It is a repeat of the data recorded on the top right hand corner of the previous page and must be completed as questionnaires may be scanned by for reading software.	
Resident survey number in the primary PPS	As for the previous item.	

On the remainder of the form, please provide any additional details that will be useful for those interpreting the information on this resident form, particularly the national team.

Figure 10. Validation survey – resident questionnaire; page 2 of 2



Healthcare-associated infections and antimicrobial use in European long-term care facilities (HALT-3) Resident study number in validation study:

Validation Study – Resident Questionnaire

RESIDENT DATA

Resident study number in primary PPS

ADDITIONAL NOTES (tick all that apply)

- $\hfill\square$ \hfill No problems were encountered during validation of this resident
- Attending physician directly assisted the validation of this resident
- Incomplete health records made it impossible to answer some questions for this resident
- Signs/symptoms incompletely documented AND an infection diagnosed by an attending physician
- Signs/symptoms no longer present AND signs/symptoms not documented AND infection treated with antimicrobials

VT comments regarding this resident form.

(Please provide any details that will be useful for those interpreting the information on this resident form, particularly the national team. The HALT-3 team will also read this information but will not be analyse it systematically).

6. After the validation survey

6.1 At the end of the day of the validation survey

At the end of the day of the validation survey, the VT and primary PPS data collectors should meet and use the completed <u>ward list</u> to double-check that the fields 'Resident survey number in primary PPS' entered on the <u>validation survey - resident questionnaire</u> and the primary PPS <u>resident questionnaire</u> (Annex 3 of main protocol) identify the same resident.

In addition, on the <u>validation survey</u> - <u>resident questionnaire</u>, the field 'the PPS primary team completed a questionnaire for this resident' should now be completed by ticking the box for 'Yes' or 'No'.

Optional: write the 'resident survey number in validation survey' on the top right corner of each primary PPS resident questionnaire.

Important: do not alter the responses on any resident forms (see 3.2 Blinding)

6.2 Data entry; submitting completed validation survey data

The **primary PPS data** of the validated LTCFs should be included in the national PPS dataset for HALT-3. During data entry for these data, also provide the 'resident survey number in validation survey' from the '<u>Validation Survey – Resident Questionnaire</u>'. A free text field is available in the HALT-3 software for this purpose (see software manual).

Questionnaires from this **validation survey** should be sent to the NSC. The NSC should send the HALT-3 team scanned copies of questionnaires for central data entry. We recommend emailing <u>HALT@wiv-isp.be</u> a password-protected zip file, or using similar a data protection methodology. If possible, the primary PPS's resident forms should also be sent, to ensure that the residents are correctly matched.

NSCs should also email a summary of the validation survey to HALT@wiv-isp.be:

- Primary PPS data: date of the primary PPS, survey number(s) of the LTCF(s), total number of main protocol <u>resident questionnaires</u> collected by the primary PPS team.
- Validation data: date of the validation survey, survey number(s) of the LTCF(s), total number of validation survey – resident questionnaires collected by the VT.

7. References

- 1. European Centre for Disease Prevention and Control (ECDC). Protocol for point prevalence surveys of healthcareassociated infections and antimicrobial use in European long-term care facilities. 2. Version v2.1. Stockholm: ECDC. 2016.
- European Centre for Disease Prevention and Control (ECDC). Point prevalence survey of healthcare-associated infections and antimicrobial use in European long-term care facilities. April–May 2013. Stockholm: ECDC. 2014.
- 3. European Centre for Disease Prevention and Control (ECDC). Point prevalence survey of healthcare-associated infections and antimicrobial use in European long-term care facilities. May–September 2010. Stockholm: ECDC. 2014.
- 4. European Centre for Disease Prevention and Control (ECDC). Protocol for national onsite assessment during the HALT-3 project. 2016-2017. Stockholm: ECDC. 2016.
- 5. European Centre for Disease Prevention and Control (ECDC). Point prevalence survey: Long-term care facilities [1 February 2016]. Available from: <u>http://ecdc.europa.eu/en/healthtopics/Healthcare-associated_infections/point-prevalence-survey-long-term-care-facilities.aspx</u>.
- 6. World Health Organization (WHO). Hand hygiene in outpatient and home-based care and long-term care facilities: a guide to the application of the WHO multimodal hand hygiene improvement strategy and the "My Five Moments For Hand Hygiene" approach. URL: <u>http://www.who.int/gpsc/5may/EN_GPSC1_PSP_HH_Outpatient_care/en/</u>. Geneva: WHO. 2012.

8. Contact information

For questions relating to use of this protocol, please contact the HALT-3 Management Team (HALT@wiv-isp.be). The HAI-Net extranet (URL: <u>https://extranet.ecdc.europa.eu/HAINet/</u>) contains a Question and Answer section, particularly suited to those who may perform a validation survey, collect primary PPS data or provide training to primary data collectors. All ECDC 'Operational Contact Points' for 'Healthcare-Associated Infections In Long-Term Care Facilities (HAI-HALT)' and 'National Focal Point for Healthcare-associated infections (ARHAI Programme)' do have access to the extranet and may request that ECDC provides access to other named individuals.

Annex 1. Validation survey – institutional questionnaire

CONTRACTOR	Healthcare-associated infections and antimicrobial use in European long-term care facilities (HALT-3) Validation Study – Institutional Questionnaire					
Validation of main p	protocol Institutional Questionn	aire				
	A – GENERAL INFORMAT	ION				
DATE OF THE VALIDATION SU	JRVEY / / 2 0 (dd/mm/yyyy)	START TIME	:			
FACILITY STUDY NUMBER		END TIME	;			
TACILITY STODY NOMBER						
Validation team's assess	sment of full-time equivalents (FTEs)					
	vailable 24hrs / 24hrs in the facility	🗆 Yes 🗆 No				
Total number of FTEs o	f registered nurses		FTEs			

 Validation team's assessment of the primary team's assessment of FTEs

 Correct reporting of partial FTEs? (e.g. 10% of full-time = 0.1 FTE)

 Yes
 No

 FTE = Current situation or average situation on 1 day (not e.g. 'cumulative' FTEs for 1 year)

 Current
 Average

 How were the FTEs reported? (tick one)

 Current LTCF only

 FTEs for other institutions are included

 NA: data not available

FTEs

Other comments regarding FTEs

Total number of FTEs of **nursing assistants**

Other validation team comments, e.g. data quality issues.

Page 1 of 3

Reporting LTCF rooms and occupancy						
How many rooms are there in the facility designated for single occupancy?(A room with a double bed shared by partners should not be considered as a single room)						
Total number of single/private rooms in the facility with individual toilet and washing facilities						
How did you acquire information on single/private rooms (e.g. description from LTCF staff, from a building plan, etc)						
D – INFECTION CONTRO	OL PRACTICE					
 3. In the facility, is there: Registration of residents colonised/infected with mul Feedback on surveillance results to the nursing/med Organisation, control, feedback on hand hygiene in t 4. In the facility, is there an infection control committee (internation) 	ical staff of the facilit he facility on a regu	ty				
Yes □ No	for external):					
8. Is a surveillance programme of healthcare-associated infection report of number of urinary tract infections, respiratory tract in		ility? (e.g. an annual summary □ No				
9. In the facility, which of following products are available for har - Alcohol rub solution - Wipes (alcohol) - Liquid soap (antiseptic/ other) - Bar soap in clinical areas	nd hygiene? Yes Yes Yes Yes Yes	□ No □ No □ No □ No				
11. How many litres of hand alcohol were used last year? Total annual consumption in litres		Litres last year				
 Alcohol hand rub consumption, data source: who provided to Quantity dispensed/delivered in one year period Quantity purchased in one year period Other, please specify (in comment field) NA: data not available Alcohol hand rub consumption, other comments:	the data on AHR and	d what do they represent?				

13. How many hand hygiene opportunities were there observed in your facility last year? Number of observed opportunities ______ Opportunities last year

E – ANTIMICROBIAL POLICY

- 3. Which of following elements are present in the facility?
 - Written guidelines for appropriate antimicrobial use (good practice) in the facility
 - Data available on annual antimicrobial consumption by antimicrobial class
 - A system to remind healthcare workers of the importance of microbiological samples to inform the best antimicrobial choice
 - Local (i.e. for that region/locality or national if small country) antimicrobial resistance profile summaries available in the LTCF or in the GP surgeries who prescribe
 - A therapeutic formulary, comprising a list of antibiotics

B - DENOMINATOR DATA; SUMMARY DATA FOR THE VALIDATION STUDY

Total no. of beds in the facility	
No. of occupied beds in the facility, i.e. allocated to a resident	
No. of eligible residents <u>according to the primary team</u> (acquire these data from the `ward list', column 3)	
No. of eligible residents according to the validation team	
No. of residents receiving at least one antimicrobial agent	
No. of residents with signs/symptoms of an infection	
No. of residents with at least one infection matching a case definition	
Total no. of resident forms completed by the validation team	

V- HOW WAS THE VALIDATION PERFORMED IN THIS FACILITY?

Timing

- Simultaneous (same day, same time)
- Same day, after Primary PPS
- □ Other (specify)___

Data source for the diagnosis of HAI

(only) tick all that apply

- Written records
- Local staff
- Attending physician

Population

All residents

Selected residents (specify selection method, e.g. how wards were selected)

Any other comments regarding performance of the validation study in this facility:

- Local staff
 - Nurse

Validation method

Blinded

Non-blinded

- Physician
- Other (specify) ______

Annex 2. Validation survey – resident questionnaire

Healthcare-associated infections and antimicrobial use in European long-term care facilities (HALT-3) Resident study number in validation study:

🗆 Yes 🗆 No

Validation Study – Resident Questionnaire

One form has to be completed for every resident recorded on the ward list provided by the primary PPS team						
Complete at the start of the day:	Facility study number (allocated by national survey coordinator)					
Complete when assessing the resident:	Birth year: Gender: Image: Male image: Gender: Other Resident considered eligible by validation team? Image: Yes image: Mode No					
Complete at the end of the day:	Resident considered eligible by primary PPS team? Yes No The PPS primary team completed a questionnaire for this resident Yes No Tick box if validation team not able to assess resident for the validation study Image: Complete team completed team comple					

PART A: ANTIMICROBIAL TREATMENT

Is the resident receiving at least one antimicrobial agent on the day of the PPS?

		PART B: HEA	LTHCARE-ASSOCIATED IN	NFECTIONS			
		INFECTION 1	INFECTION 2	INFECTION 3	INFECTION 4		
INFECTION CODE							
IF 'OTHER', PLEASE SPEC							
PRESENT AT (RE-)ADMISS	SION	🗆 No 🗆 Yes	🗆 No 🗆 Yes	🗆 No 🗆 Yes	🗆 No 🗆 Yes		
DATE OF ONSET (DD/MM,	/YY)						
ORIGIN OF INFECTION		Current LTCF	Current LTCF	Current LTCF	Current LTCF		
		Other LTCF	Other LTCF	Other LTCF	Other LTCF		
		🗆 Hospital	🗆 Hospital	🗆 Hospital	🗆 Hospital		
		🗆 Unknown	🗆 Unknown	🗆 Unknown	🗆 Unknown		
A. NAME OF ISOLATED MICROORGANISM	1. A						
(PLEASE USE CODE LIST)	В						
B. Tested ANTIMICROBIAL(S) ¹ AND RESISTANCE ²							
	2. A						
ONLY FOR STAAUR,	В						
ENC***, ACIBAU, PSEAER OR ENTEROBACTERIACEAE (CIT***, ENB***, ESCCOL, KLE***, MOGSPP, PRT***,							
	3. A						
	В						
SER***)							

¹Tested antibiotic(s): STAAUR: oxacillin (OXA) or glycopeptides (GLY); ENC***: GLY only; Enterobacteriaceae: 3rd-gen cephalosporins (C3G) or carbapenems (CAR); PSEAER and ACIBAU: CAR only. ² Resistance: S=sensitive, I=intermediate, R=resistant, U=unknown



Healthcare-associated infections and antimicrobial use in European long-term care facilities (HALT-3)

Resident study number in validation study:

Validation Study – Resident Questionnaire

RESIDENT DATA

Resident study number in primary PPS

ADDITIONAL NOTES (tick all that apply)

- □ No problems were encountered during validation of this resident
- □ Attending physician directly assisted the validation of this resident
- □ Incomplete health records made it impossible to answer some questions for this resident
- Signs/symptoms incompletely documented AND an infection diagnosed by an attending physician
- Signs/symptoms no longer present AND signs/symptoms not documented AND infection treated with antimicrobials

VT comments regarding this resident form.

(Please provide any details that will be useful for those interpreting the information on this resident form, particularly the national team. The HALT-3 team will also read this information but will not be analyse it systematically).

Annex 3. Primary HALT-3 PPS ward list

HALT-3: WARD LIST

PPS DENOMINATOR DATA BY WARD (for internal use only)*

DATE OF THE PPS IN YOUR FACILITY/..... FACILITY STUDY NUMBER.....

NAME OF THE WARD:

HOW MANY BEDS IN THIS WARD? (INCLUDES BOTH OCCUPIED AND NON-OCCUPIED BEDS):..... beds

The ward list is a form developed to aid surveyors' collection of denominator data for the Institutional Questionnaire. Its use is not mandatory, i.e. it is optional.

The surveillance protocol specifies that surveyors should collect information from each resident eligible resident, i.e. those living full-time in the facility, present in the ward at 8am and not discharged at the time of the survey. This ward list collects data from each resident. Once these data have been collected for all wards, surveyors can sum the denominators from each ward and transfer these totals to the institutional questionnaire. Facilities that do not have different wards only need to complete one ward list.

Instructions:

- List all residents in columns 1 and 2.
- Add a code in column 3 that is unique for every resident in the facility. Numbers and/or letters can be used. This resident survey number should be entered on all forms for the same resident.
- If the resident meets the eligibility criteria (i.e. living full-time in the facility, present at 8:00 am and not discharged at the time of the survey), complete columns 4 to 15 by writing an 'X' if the risk factor or care load indicator is present on the day of the survey.
- Sum the Xs in each column.
- Write the totals of each column in the summary table at the end of the ward list.
- Sum the totals of the summary tables in the different ward lists and report the totals in part B of the institutional questionnaire.
- If a resident on the ward list has an X in columns 7 and/or 8 (i.e. they were receiving at least one antimicrobial agent and/or had at least one infection on the day of the survey, complete a resident form for this resident.

*As this ward list may contain personal identifiers of individual residents, ECDC asks that you do not send this ward list to us. Instead, please keep this ward list safely in your LTCF until the end of the HALT-3 project.

	COMPLETE THIS PART OF THE LIST FOR ALL RESIDENTS IN THE WARD				COM W	1PLETE rite a X	THIS PA in the co	RT <u>FOR A</u> Dumn if t	LL EL he co	<u>IGIBLE</u> ndition	RESIDE	<u>NTS (re</u> ON THE	<u>esidents</u> DAY 0	F THE S	<u>column 3)</u> SURVEY	2
Room & bed number	Resident name	Study number of the resident	Present at 8 AM and not discharged at time of PPS	Age over 85 years	Male resident	Antimicrobial agent	Signs/symptoms of an infection	Infection matching a case definition	Urinary catheter	Vascular catheter	Pressure sore	Other wound	Disorientation in time and/or space	Wheelchair bound or bedridden	Surgery in the previous 30 days	Urinary and/or faecal incontinence
1	2	3	4	5	6	7	8a	8b	9	10	11a	11b	12	13	14	15

Summary table: total numbers for this ward

Use this table to add the number of X' from each column from each ward list from the facility. Transfer the total number into Part B of the institutional questionnaire, i.e. 'Denominator Data'

On the day of the PPS, TOTAL number of:	Column	TOTAL NUMBERS
Total number of beds on this ward (total bed capacity)	1	
Occupied beds in the ward	2	
Eligible residents, present at 8 AM and not discharged at time of PPS	4	
Age over 85 years	5	
Male residents	6	
Residents receiving at least one antimicrobial agent	7	
Residents with at least one infection	8b	
Residents with any urinary catheter	9	
Residents with any vascular catheter	10	
Residents with pressure sores	11a	
Residents with other wounds	11b	
Residents disorientated in time and/or space	12	
Residents using wheelchair or being bedridden	13	
Residents with surgery in the previous 30 days	14	
Residents with urinary and/or faecal incontinence	15	

Keep this ward list safely in your LTCF until the end of the HALT-3 project (December 2018)

Annex 4. Case definitions of infections



IMPORTANT REMARK:

All **active infections** present on the day of the survey should be reported. An infection is **active** when signs/symptoms of the infection are present on the survey date **OR** signs/symptoms were present in the past and the resident is (still) receiving treatment for that infection on the survey date. The presence of symptoms and signs in the two weeks (14 days) preceding the PPS day should be verified in order to determine whether the treated infection matches one of the case definitions. Infections can only be reported as 'imported' for residents recently transferred from another healthcare facility (i.e. hospital or other LTCF) and still treated for an infection on the PPS day in the absence of documentation on (all) signs/symptoms that were present in the past.

- * Fever: 1) single > 37.8°C oral/tympanic membrane or 2) repeated > 37.2°C oral or > 37.5°C rectal or 3) > 1.1°Cover baseline from any site (oral, tympanic, axillary)
- ** Leucocytosis: 1) Neutrophilia > 14,000 leucocytes/mm3 or 2) left shift (>6% bands or \geq 1500 bands/mm3)
- § Acute change in mental status from baseline: Acute onset + fluctuating course + inattention AND either disorganized thinking or altered level of consciousness
- §§ Acute functional decline: New 3 point increase in total ADL score (Range 0-28) from baseline based on 7 ADL items (bed mobility, transfer, locomotion, dressing, toilet use, personal hygiene, eating) each scored from 0 (independent) - 4 (total dependence) OR increased dependency defined by scales other than ADL

URINARY TRACT INFECTIONS

Resident without a urinary catheter	Resident with a urinary catheter			
↓	↓			
SIGNS/SYMPTOMS	<u>SIGNS/SYMPTOMS</u>			
 AT LEAST <u>ONE</u> OF THE FOLLOWING (1, 2 or 3) CRITERIA: 1 Acute dysuria OR acute pain/swelling or tenderness of the testes, epididymis, or prostate 2 Fever* OR leukocytosis** AND One or more of the following: Acute costovertebral angle pain Suprapubic pain/tenderness Gross hematuria New or marked increase in frequency New or marked increase in incontinence 3 Two or more (in the absence of fever or leucocytosis): Frequency (new/increased) Suprapubic pain Urgency (new/increased) Gross hematuria 	 AT LEAST ONE OF THE FOLLOWING (1, 2, 3 or 4) CRITERIA: 1 Fever*, rigors, OR new onset hypotension with NO alternate site of infection 2 Acute change mental status § OR acute functional decline §§ with NO alternate diagnosis AND leukocytosis** 3 New onset suprapubic or costovertebral angle pain or tenderness 4 Purulent discharge around catheter or acute pain, swelling or tenderness of testes, epididymis, or prostate 			
□ Incontinence (new/increased)	URINE CULTURE			
URINE CULTURE	 Not done, negative or test results unknown Urine culture <u>done</u> AND: 			
 Not Done, negative or test results unknown Urine culture <u>done</u> AND: At least 10⁵ cfu/ml of no more than 2 species of microorganisms in a voided urine sample <u>OR</u> 	At least 10 ⁵ cfu/ml of any organism(s) in a urinary catheter specimen			
□ At least 10 ² cfu/ml of any number of organisms in a specimen collected by in-and-out catheter				
INFECTION CONFIRMATION				
 Signs/symptoms <u>AND</u> urine culture positive: Signs/symptoms <u>AND</u> urine culture not done, negative or no Infection treated on PPS day but no documentation of sign (hospital or other LTCF infections only) 				
22				

RESPIRATORY TRACT INFECTIONS



LOWER RESPIRATORY TRACT INFECTIONS



SKIN INFECTIONS

CELLULITIS/SOFT TISSUE/WOUND INFECTIONS	SCABIES
ONE OF THE FOLLOWING (1 or 2) CRITERIA MUST BE MET: 1 Pus at a wound, skin, or soft tissue site 2 Four or more new or increasing signs/symptoms at affected site: Heat Tenderness or pain Redness Serous drainage Swelling One constitutional sign/symptom (fever, leucocytosis, confusion, acute functional decline; for definitions see top of page 1)	BOTH OF THE FOLLOWING CRITERIA MUST BE MET: Maculopapular and/or itching rash AND At least one of the following: Physician diagnosis Laboratory confirmation (positive scraping or biopsy) Epidemiological linkage to a case of scabies with lab confirmation
INFECTION CONFIRMATION Infection criteria fully met: INFECTION CONFIRMED (= SKIN-C) Infection treated on PPS day but no documentation of signs/symptoms: INFECTION IMPORTED (hospital or other LTCF only) (= SKIN-I)	INFECTION CONFIRMATION Infection criteria fully met: INFECTION CONFIRMED (= SCAB-C) Infection treated on PPS day but no documentation of signs/symptoms: INFECTION IMPORTED (hospital or other LTCF only) (= SCAB-I)
NOTE: If the infection matches one of the Surgical Site Infection (SSI) definitions, please give priority to the SSI. Do not apply another case definition for the same infection.	
HERPES SIMPLEX OR ZOSTER INFECTION	FUNGAL INFECTION
BOTH OF THE FOLLOWING CRITERIA MUST BE MET: A vesicular rash AND Physician diagnosis or laboratory confirmation	BOTH OF THE FOLLOWING CRITERIA MUST BE MET: Characteristic rash or skin lesions AND Physician diagnosis or lab confirmed fungal pathogen from scraping or biopsy
\downarrow	
INFECTION CONFIRMATION Infection criteria fully met: INFECTION CONFIRMED (= HERP-C) Infection treated on PPS day but no documentation of signs/symptoms: INFECTION IMPORTED (hospital or other LTCF only) (= HERP-I)	INFECTION CONFIRMATION Infection criteria fully met: INFECTION CONFIRMED (= FUNG-C) Infection treated on PPS day but no documentation of signs/symptoms: INFECTION IMPORTED (hospital or other LTCF only) (= FUNG-I)

SURGICAL SITE INFECTIONS



NOTE:

If the infection matches one of the Surgical Site Infection (SSI) definitions, please give priority to the SSI. Do not apply another case definition for the same infection.

EYE, EAR, NOSE AND MOUTH INFECTIONS



(= SINU-C)
 Infection treated on PPS day but no documentation of signs/symptoms: *INFECTION IMPORTED* (hospital or other LTCF only) (= SINU-I)

(= ORAL-C)
 Infection treated on PPS day but no documentation of signs/symptoms: INFECTION IMPORTED (hospital or other LTCF only) (= ORAL-I)

GASTROINTESTINAL INFECTIONS



BLOODSTREAM INFECTIONS

ONE OF THE FOLLOWING (1 or 2) CRITERIA MUST BE MET:
 □ 1 Two or more blood cultures positive for the same organism

2 A single blood culture documented with an organism thought not to be a contaminant AND

At least **<u>one</u>** of the following:

- □ Fever (for definition see top of page 1)
- □ New hypothermia (<34.5° C, or does not register on the thermometer being used)
- □ A drop in systolic blood pressure of >30 mm Hg from baseline
- □ Worsening mental or functional status

UNEXPLAINED FEVER

□ The resident must have documentation in the medical record of fever *(for definition see top of page 1)* on two or more occasions at least 12 hours apart in any 3-day period, with no known infectious or non-infectious cause

INFECTION CONFIRMATION

□ Infection criteria fully met:

(= FUO-C) Infection treated on PPS day but no documentation of signs/symptoms: INFECTION IMPORTED (hospital or other LTCF only) (= FUO-I)

INFECTION CONFIRMED

OTHER INFECTION(S)

Please specify (= **OTHER**)



□ Infection criteria fully met: *INFECTION CONFIRMED* (= **BSI-C**)

□ Infection treated on PPS day but no documentation of signs/symptoms: *INFECTION IMPORTED* (hospital or other LTCF only) (= **BSI-I**)