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TECHNICAL REPORT

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

Version 4.0

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

Contributing authors
Katrien Latour, Laura Int Panis (Sciensano, Belgium); Enrico Ricchizzi (Agenzia sanitaria e sociale regionale – Regione Emilia-Romagna, Italy); Tommi Kärki, Pete Kinross, Angelo D'Ambrosio, Carl Suetens (ECDC).

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Contents

Figures

Tables

Abbreviations

AMR	Antimicrobial resistance
APIC	Association for Professionals in Infection Control and Epidemiology
EEA	European Economic Area
ESAC-NH	European Surveillance of Antimicrobial Consumption in Nursing Homes
EU	European Union
GP	General practitioner
HAI	Healthcare-associated infection
HAI-Net	Healthcare-associated infections surveillance network
HALT (2010)	The first point prevalence survey of healthcare-associated infections and antimicrobial use in European long-term care facilities, May–September 2010
HALT-2 (2013)	The second point prevalence survey of healthcare-associated infections and antimicrobial use in European long-term care facilities, April–May 2013
HALT-3 (2016–17)	The third point prevalence survey of healthcare-associated infections and antimicrobial use in European long-term care facilities, April 2016 – November 2017
HALT-4 (2023–24)	The fourth point prevalence survey of healthcare-associated infections and antimicrobial use in European long-term care facilities, April 2023 – June 2024
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
RTI	Respiratory tract infection
SHEA	The Society for Healthcare Epidemiology of America
SSI	Surgical site infection
UTI	Urinary tract infection

1 Background and changes to the protocol

In 2008, the coordination of the surveillance of healthcare-associated infections (HAIs) and antimicrobial use in Europe was transferred to the European Centre for Disease Prevention and Control (ECDC). This created the healthcare-associated infections surveillance network (HAI-Net). A feasibility study of the surveillance of HAIs in European nursing homes had already been performed in 2006 under the Improving Patient Safety in Europe (IPSE) project, financed by the European Commission [1].

In December 2008, ECDC initiated the 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. The HALT project 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 the continued assessment of the prevalence of HAIs, antimicrobial use, and infection prevention and control (IPC) resources in European LTCFs.

From May to September 2010, the first PPS in European LTCFs (HALT project, 2010) collected data from 722 LTCFs across 28 European countries/administrations[i] [2]. It showed a prevalence of 2.4% for residents with at least one HAI in participating LTCFs. The crude prevalence of residents receiving at least one antimicrobial agent was 4.3%.

From April to May 2013, a second PPS in European LTCFs (HALT-2 project, 2013) collected data from 1 181 LTCFs in 19 European countries/administrations [3]. The HALT-2 project showed a prevalence of 3.4% for residents with at least one HAI in participating LTCFs, and a prevalence of 4.4% for residents with at least one antimicrobial agent. The HALT-2 project also included a validation survey.

Data for 3 052 LTCFs were submitted by 24 EU/EEA countries/administrations to ECDC in the third PPS (HALT-3 project, 2016–2017). The final EU/EEA HALT-3 dataset included 117 138 eligible residents from 2 232 LTCFs. General nursing homes, residential homes and mixed LTCFs represented 80.5% of all the participating LTCFs. The crude prevalence of residents with at least one HAI was 3.7%. The majority of the reported HAIs (n=3 269/3 858) were mostly associated with the current LTCF (84.7%), while 7.5% and 1.4% were associated with a hospital or another LTCF, respectively. When only considering the HAIs that were associated with the current LTCF, the crude prevalence of residents with at least one HAI decreased to 3.1%. The overall crude prevalence of residents with at least one antimicrobial agent was 4.9%. Ten countries/administrations recruited 17 LTCFs to participate in the validation study. Optional onsite assessment visits by a member of the HALT-3 management team were requested by 13 countries. These provided the HALT-3 management team with valuable insights into country/administration-specific differences and provided assistance to countries/administrations in their collection of national-level structure and process indicators [4].

Subsequent to ECDC's open call for tender for 'HAIs and antimicrobial use in European LTCFs: Support to a PPS and a longitudinal study' (OJ/2020/DPR/11546), ECDC signed the Framework Contract (ECDC/2020/006) in September 2020 with Sciensano (Brussels) in collaboration with the Agenzia sanitaria e sociale regionale – Regione Emilia Romagna (ASSR, Bologna). This call for tender also included the organisation of a fourth PPS of HAIs and antimicrobial use in LTCFs in the EU/EEA in 2023. The protocols and survey tools from the HALT, HALT-2 and HALT-3 projects were adapted and discussed by the HALT-4 management team and advisory committee. This protocol provides national survey coordinators (NSCs) and local data collectors in the HALT-4 project with the methodology, data collection forms and definitions of variables to collect LTCF data in 2023–2024.

All changes to the HALT protocol are listed below.

- At the LTCF level:
  - Removal of the questions: a) ownership of the facility, qualified nursing care available; b) total number of full-time equivalent registered nurses and nursing assistants; c) total number of single-occupancy resident rooms with individual toilet and washing facilities; d) consultation of medical/clinical records by coordinating physicians and nursing staff; e) details of personnel with training in infection control (internal or external); f) availability of products for hand hygiene; g) the number of hand hygiene opportunities; h) availability of a restrictive list of antimicrobials and associated details; i) urine dipstick test for the detection of urinary tract infections (UTIs); j) supply of antimicrobials to the LTCF; k) total number of microbiological laboratories; l) details of how the PPS was performed in the LTCF.
  - Addition of the questions: a) estimated percentage (%) of residents and healthcare workers who are fully vaccinated against COVID-19 and seasonal influenza; b) offer of vaccination against COVID-19 (booster dose) to all residents in the LTCF; c) written protocol available for the management of local outbreaks of gastrointestinal infections and respiratory tract infections (RTIs); d) policy of universal masking in the LTCF.

[i] The United Kingdom (UK) is a former Member State of the European Union (EU), and participated in the HALT, HALT-2 and HALT-3 projects. As UK devolved administrations are counted separately, 'countries/administrations' are used to refer to the participants in the first three HALT projects. The UK withdrew from the EU on 31 January 2020, and will not take part in HALT-4.

  - Clarification to the question (and definition): Are there persons (internal or external) with training in infection prevention and control available to the staff of the LTCF? This person is available to staff in the LTCF and can be either an external or an internal person.
  - Change in denominator data for: a) residents disoriented in time and/or space, b) residents with impaired mobility i.e. using a wheelchair or bedridden, c) residents with urinary and/or faecal incontinence. In the previous protocol, these were assessed if present, on the day of the PPS. For this PPS, information is collected on the 'general' condition of the LTCF (even though it may be temporarily different from the information available 'on the day of the PPS').
- Antimicrobial use data:
  - Addition of COVID-19 antivirals: PF-07321332/ritonavir/nirmatrelvir (Paxlovid™), regdanvimab (Regkirona™), casirivimab/imdevimab (Ronapreve™), remdesivir (Veklury™), sotrovimab (Xevudy™), molnupiravir (Lagevrio™), and tixagevimab/cilgavimab (Evusheld™).
- HAI data:
  - Addition of the HAI codes for COVID-19 by severity (COV-ASY, COV-MM, COV-SEV), and the microorganism code (VIRCOV) for SARS-CoV-2.
  - Adaptation of the definition of an 'active HAI' in the resident questionnaire by the removal of 'HAIs associated with other healthcare facilities', and the consequent removal of the questions on 'origin of the HAI' and 'presence of infection at (re)admission to the LTCF'. Exceptions to the definition of an active HAI for surgical site infections and *Clostridioides* (*Clostridium*) *difficile* are included.
  - Change of the labels of the antimicrobial susceptibility codes, 'S' and 'I' to align with the new terminology by the European Committee on Antimicrobial Susceptibility Testing (EUCAST).
- Code lists:
  - HAI case definitions:
    - Removal of case definitions of surgical site infections.
    - Removal of infection codes for imported infections.
    - COVID-19 (COV): addition of a case definition of confirmed COVID-19 by severity (COV-ASY, COV-MM, COV-SEV).
    - CDI-C: renamed *Clostridioides difficile* infection.
    - The name of the order *Enterobacterales* is used in place of the name of the family Enterobacteriaceae.
    - The taxonomy change of *Enterobacter aerogenes* to *Klebsiella aerogenes* was adopted in the code list for microorganisms with the introduction of the code, 'KLEAER'. Both the new and the old code ('ENBAER') are accepted in HALT-4 in 2023–2024. For other microorganisms, possible name changes are also indicated in the Annex 5[ii], but the pertinent codes remain unchanged.
    - Definition of lower respiratory tract infections (LRTI): Positive chest X-ray replaced by positive thoracic imaging (including chest X-ray, CT-scan and ultrasound).
- National data:
  - Addition of the national definition of full vaccination against COVID-19 in residents/healthcare workers at the time of the study, supply of antimicrobials to the LTCF, collaboration between LTCFs and microbiological laboratories.
  - Relabelling of the national representativeness categories as 'optimal', 'good', 'medium' and 'poor' (instead of 'optimal', 'good', 'poor' and 'very poor'). The label 'medium' has been selected to reflect that the categories, 'optimal' and 'good' can be combined in the final analysis.

Answers to frequently asked questions (FAQs) from NSCs and local data collectors will be shared by ECDC throughout the HALT-4 project.

The outputs from the PPSs of HAIs and antimicrobial use in European LTCFs include a comprehensive European report as well as feedback reports for each participating LTCF, comparing their respective data to national and European results; both are distributed to national teams for onward distribution.

[ii] The Annexes 1, 2, 3, 4 and 5 are available as downloadable documents: https://www.ecdc.europa.eu/en/publications-data/protocol-point-prevalence-surveys-healthcare-associated-infections-4-0

2 Objectives

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

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

The overall aim of the protocol is to support the implementation of a PPS of HAIs and antimicrobial use in European LTCFs, to meet the abovementioned objectives for ECDC surveillance. The specific objectives of the PPSs in European LTCFs are:

- to estimate the prevalence of HAIs and antimicrobial use in LTCFs in the EU/EEA;
- to measure structure and process indicators of infection prevention and control (IPC) in these LTCFs.

The data obtained through these PPSs are considered useful:

- to quantify the prevalence of HAIs and antimicrobial use in LTCFs, in EU/EEA countries and in the EU/EEA overall;
- to identify needs for intervention, training and/or additional IPC resources;
- to identify priorities for intervention and raising awareness at the national and local levels;
- to ensure the availability of healthcare and safety of residents in LTCFs, and more generally the ageing population in the EU/EEA.

3 Survey design

3.1 Time schedule for the repeated PPSs

Ideally, data should be collected from each LTCF on a single day. In LTCFs with a large number of beds, data collection can be spread over two or more consecutive days. However, all beds in one ward should be surveyed on the same day.

Countries can organise the PPS in LTCFs during one or more surveillance periods, with a recommendation to perform the PPS during the year 2023. If data are collected from an LTCF in more than one of the surveillance periods, the data sent to ECDC should only include the data specific to the first period. The surveillance periods are:

- April–June 2023;
- September–November 2023;
- April–June 2024.

3.2 Survey population

3.2.1 Countries

All EU/EEA countries are invited to participate in HALT-4, through ECDC's healthcare-associated infections surveillance network (HAI-Net).

3.2.2 National survey coordinators

In each country, one or more national survey coordinators (NSCs) are responsible for the invitation of the LTCFs, the organisation of training activities for data collectors, and the organisation of the PPS in the participating LTCFs (see Section 7, 'Role of the national survey coordinator'). Ideally the NSC should be a nominated ECDC operational contact point (OCP) for healthcare-associated infections in long-term care facilities (HAI-HALT), either for epidemiology or interactions with The European Surveillance System (TESSy). The NSC could also be a national focal point (NFP) for HAI-Net or their alternates, as ECDC is only authorised to contact such designated persons[iii] through coordinating competent bodies[iv] in EU/EEA countries.

3.2.3 Eligibility criteria for LTCFs

The term 'long-term care services' refers to the organisation and delivery of a broad range of services and assistance to people who are limited in their ability to function independently on a daily basis, i.e. to autonomously perform the basic activities of daily living, over an extended period of time. Additionally, there is often a need for medical services (wound dressing, pain management, administering medication, health monitoring, disease prevention, rehabilitation, or palliative care). Long-term care comprises a mix of both health and social components, and therefore pertains to both healthcare and social sectors.

LTCFs typically have residents who:

- need constant supervision (24 hours a day);
- need 'high-skilled nursing care', i.e. more than 'basic' nursing care and assistance for daily living activities;
- are medically stable and do not need constant 'specialised medical care' (i.e. care administered by specialised physicians);
- do not need invasive medical procedures (e.g. ventilation).

[iii] ECDC Coordinating Competent Bodies: structures, interactions and terms of reference https://www.ecdc.europa.eu/sites/default/files/media/en/aboutus/governance/competent-bodies/Documents/coordinating-competent-bodies-structures-terms-of-reference-and-interactions-w-Annexes.pdf

[iv] ECDC Competent Bodies https://www.ecdc.europa.eu/en/about-ecdc/who-we-are/governance/competent-bodies

The types of LTCF are:

General nursing homes	In these facilities, residents need medical and/or skilled nursing care and supervision 24 hours a day. These facilities principally provide care to older adults 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.
Specialised LTCFs	These facilities specialise in one specific type of care, e.g. physical impairment, chronic diseases such as multiple sclerosis, dementia, psychiatric illnesses, rehabilitation care, palliative care, intensive care, etc.
Mixed LTCFs	These LTCFs provide different types of care at the same facility (a mix of the above-mentioned types of LTCF).
Other LTCFs	Other facilities, which are not classifiable under the above-mentioned types of LTCF.

Remark: This classification does not imply that the characteristics of residents within each LTCF type are strictly homogeneous.

All types of LTCF are eligible to participate in the PPS. Subsequently, each participating LTCF will receive individual feedback about their results. To increase the comparability of national data, data from the most similar types of LTCF will be aggregated in the main European report for most analyses, if there are sufficient numbers of LTCFs within a specific type (see Section 3.3, 'Recruiting LTCFs to the PPS'). Comparable to HALT-3, the main HALT-4 results from the types of LTCF that are not included in aggregate analyses will be summarised in a separate chapter. In the previous surveys, these were mostly 'specialised LTCFs'.

The following facilities should be excluded: hospital long-term care wards, hostel care (hotel without any kind of nursing care), sheltered care houses, day centres, home-based centres, and protected living.

3.2.4 Eligible residents

Residents are eligible to participate, and can 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: Include residents who meet these criteria and are recorded on the resident administration system even 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 on the day of the PPS (e.g. absent for leave or admitted to a hospital);
  OR
- residents hospitalised on the day of the PPS (e.g. in-patient 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, unless they are hospitalised on the day of the PPS (i.e. a hospital stay of at least one night).

3.3 Recruiting LTCFs to the PPS

Data from the most similar types of LTCF will be aggregated in the main European report, to promote the comparability of national results. In the HALT, HALT-2 and HALT-3 projects, the main European PPS reports aggregated data from general nursing homes, residential homes and mixed facilities. This was because these types of LTCF represented approximately 90% or more of the LTCFs which participated in the surveys.

The HALT-4 report will contain one chapter presenting the main results from the types of LTCF that were not included in the aggregated analyses (e.g. specialised LTCFs). National survey coordinators will receive reports for each participating LTCF, irrespective of their type.

The PPS data should be ideally acquired from LTCFs that are representative of all the LTCFs in the respective country. Systematic random sampling using a national register of LTCFs is the preferred method to acquire a nationally representative sample of LCTFs. A suitable method for this is described in Section 3.3.2, 'Obtaining a systematic random sample of LTCFs from a national register'.

For HALT-4, each country may choose to collect data from LTCFs in one or more surveillance periods (i.e. April–June 2023, September–November 2023 and/or April–June 2024). If an individual LTCF performs the PPS more than once in these surveillance periods, only the data specific to the first period are included in the data sent to ECDC.

Given the voluntary nature of the PPS, it may not be possible for countries to recruit LTCFs nationally, even though this is preferable. In that scenario, recruitment may be limited to LTCFs from one or more sub-national regions (i.e. regional data).

3.3.1 The number of LTCFs to recruit to the PPS

The recommended number of LTCFs to recruit to the PPS in each country is provided in Table 2. Preferably, these should be recruited from a systematic random sampling using a national register of LTCFs (see Section 3.3.2, 'Obtaining a systematic random sample of LTCFs from a national register').

The estimation of the sample size of LTCF residents per country assumed that LTCFs in the current HALT-4 project share attributes with those which participated in HALT-3 and the EU register of LTCFs and LTCF beds collated through the previous HALT projects.

The sample size of LTCF residents was calculated for each EU/EEA country, anticipating a national crude prevalence of four residents with at least one HAI per 100 LTCF beds, with a 95% confidence interval of 3–5% (1% precision), using R version 4.1.3 (R Foundation for Statistical Computing, Vienna, Austria) and the packages, 'samplesize4surveys: Sample Size Calculations for Complex Surveys'[v] and 'sampler: Sample Design, Drawing & Data Analysis Using Data Frames'[vi]. The design effect[vii] (DEFF), due to clustering of residents in LTCFs intrinsic to the survey design, was estimated from a dataset containing all the LTCFs which participated in the HALT-3 project, from all the participating countries. The DEFF was estimated by calculating intraclass correlation by deciles of LTCF size, and using the average size of the LTCFs in each country (see Table 2). The number of LTCFs to recruit per country was estimated by dividing the number of residents specified by the sample size calculation (estimated sample size for simple random sample multiplied by the DEFF) by the mean number of eligible residents per LTCF in each country reported in the register.

If any of these data were unavailable in the register, the denominator sizes were derived from the estimation for the HALT-3 project in 2016–2017. All EU/EEA countries were asked to check the denominator sizes prior to the calculation of the sample size.

In HALT-4, the national representativeness of the LTCF sample will be categorised into four levels ('optimal', 'good', 'medium' and 'poor'; Table 1), depending on compliance with the recommended sampling methodology. The label, 'medium' has been selected to reflect that the categories, 'optimal' and 'good' can be combined in the final analysis. The evaluation will include all the LTCFs for which all eligible residents were included.

[v] https://cran.r-project.org/web/packages/samplesize4surveys/index.html

[vi] https://cran.r-project.org/web/packages/sampler/index.html

[vii] The design effect (DEFF) of a statistic is the ratio of actual variance for a given sample design to the variance if the residents were selected randomly (i.e. from all LTCFs or from a much larger sample size). The DEFF is proportionate to the size of the clusters (i.e. LTCF size) and the frequency (i.e. prevalence) of the outcome under study (i.e. higher for antimicrobial use than for HAIs). Sample size increases proportionally to DEFF to ensure that prevalence can be estimated with the same precision, despite the over-dispersion within clusters.

Table 1. Criteria to categorise the national representativeness of the LTCF sample for the PPS

Optimal	• Systematic random sample of at least 25 LTCFs, or at least 75% of the recommended number of LTCFs to be sampled (as specified in Table 2); or • Inclusion of at least 75% of all LTCFs, or occupied LTCF beds in the country and recommended sample size achieved (as specified in Table 2).
Good	• Selection of at least 25 LTCFs, or at least 75% of the recommended number of LTCFs and/or residents to be sampled using another methodology (e.g. voluntary participation), as specified in Table 2; or • Recommended sample size not achieved, but inclusion of ≥75% of all LTCFs or occupied LTCF beds in the country.
Medium	• Between five and 25 LTCFs included in countries with more than 25 LTCFs and recommended sample size not achieved; or • Less than five LTCFs included in countries with more than five LTCFs, but inclusion of 50–75% of all LTCFs or occupied LTCF beds in the country.
Poor	• Inclusion of less than five LTCFs, less than 50% of all LTCFs, and less than 50% of all occupied LTCF beds.

Table 2. Number of LTCFs and residents needed to estimate an HAI prevalence of 4% with 1% precision, by country

Country	Population >65 years[a]	No. of LTCFs[b]	No. of beds	Average LTCF size (beds)	Estimated DEFF[c]	Recommended sample size (beds)	Recommended no. of LTCFs to recruit
Austria	1 716 287	817	72 602	89	2.1	3 449	39
Belgium	2 229 378	1 545	146 462	95	2.2	3 623	39
Bulgaria	1 504 048	33	486	15	1.2	447	30
Croatia	864 847	325	37 249	115	2.4	3 966	35
Cyprus	147 304	90	3 436	38	1.5	1 635	44
Czechia	2 158 322	73	17 204	236	3.9	6 387	28
Denmark	1 176 272	827	42 668	52	1.6	2 571	50
Estonia	270 641	59	1 849	31	1.4	1 209	39
Finland	1 255 938	1 928	50 373	26	1.3	1 999	77
France	13 999 377	9 744	687 936	71	1.9	3 097	44
Germany	18 271 636	10 389	852 849	82	2.0	3 352	41
Greece	2 407 856	263	10 849	41	1.5	2 117	52
Hungary	1 976 666	1 177	57 929	49	1.6	2 527	52
Iceland	54 359	64	3 021	47	1.6	1 711	37
Ireland	739 001	578	30 531	53	1.6	2 561	49
Italy	13 941 531	3 219	186 872	58	1.7	2 778	48
Latvia	393 698	82	5 798	71	1.9	2 472	35
Lithuania	557 048	154	11 722	76	1.9	2 859	38
Luxembourg	92 737	62	6 966	112	2.4	3 347	30
Malta	97 418	41	5 035	123	2.5	3 333	28
Netherlands	3 457 535	700	80 500	115	2.8	4 050	36
Norway	965 742	907	39 583	44	1.5	2 387	55
Poland	7 085 122	373	17 291	46	1.6	2 324	51

Country	Population >65 years[a]	No. of LTCFs[b]	No. of beds	Average LTCF size (beds)	Estimated DEFF[c]	Recommended sample size (beds)	Recommended no. of LTCFs to recruit
Portugal	2 309 648	360	8 400	23	1.3	1 690	74
Romania	3 704 996	628	37 727	60	1.7	2 739	46
Slovakia	932 024	677	27 497	41	1.5	2 284	56
Slovenia	435 715	90	20 777	231	3.8	6 367	28
Spain	9 370 921	5 529	389 677	70	1.8	3 067	44
Sweden	2 088 086	1 700	85 000	50	1.6	2 571	52
Total	**90 750 010**	**42 434**	**2 938 289**	**69**	**2.1**	**82 919**	**1 277**

LTCFs: general nursing homes, residential homes and mixed facilities (only); [a]Source: Eurostat, 2021; [b]Data provided by countries in HALT-3 (2016–2017) and the EU register of LTCFs and LTCF beds collated through previous HALT projects; [c]Design effect (DEFF) by deciles of LTCF size in HALT-3 (2016–2017).

3.3.2 Obtaining a systematic random sample of LTCFs from a national register

The probability sampling method described in this section sorts through a comprehensive national register of LTCFs according to a given attribute before selection (e.g. the number of beds). This ensures that the selected sample of LTCFs represents the national register in terms of that particular attribute. This method is of particular significance if an LTCF declines to participate in the PPS, and the next LTCF in the list is contacted to 'replace' it. It is recommended that national registers are sorted according to more than one attribute, if possible, e.g. LTCF type and size.

These are the steps to obtain a systematic random sample of LTCFs from a national register:

1. Obtain a national list of all eligible types of LTCF (i.e. general nursing homes, residential homes and/or mixed facilities), that includes the number of LTCF beds.
2. Rank the list in an ascending order of the number of beds from 1 to N (the total number of LTCFs).
3. Consult Table 2 to find out the recommended number of LTCFs that should be recruited to the survey (n).
4. Divide the total number of LTCFs (N) by the number to be sampled (n) to get the sampling interval (k), i.e. N/n=k.
5. Choose a random number between 1 and k=i.
6. Select LTCF i, i+k, i+2k, …, i+nk.
7. Invite these selected LTCFs to participate in the PPS.
8. If an LTCF declines the invitation to participate in the PPS, invite the next LTCF on the list, i.e. i+1, i+k+1, i+2k+1, …, i+nk+1. If the next LTCF declines to participate as well, invite the next on the list, and so on.

3.3.3 Non-representative samples and reporting of results

Although representative sampling remains strongly recommended, a comprehensive national register of LTCFs may not be available in some EU/EEA countries. If no national or regional register is available, purposive sampling, such as convenience sampling may be used to recruit LTCFs to the PPS. If possible, the recruited LTCFs should include eligible LTCF types and sizes.

Alternative methods to recruit LTCFs, that EU/EEA countries may choose to follow, include convenience sampling (i.e. selection of LTCFs by the PPS coordinating centre), voluntary participation after inviting all LTCFs, and mandatory participation. The LTCF sampling/recruitment method is recorded at the national/regional level and have to be categorised into four levels ('optimal', 'good', 'medium' and 'poor'). The label 'medium' has been selected to reflect that the categories, 'optimal' and 'good' can be combined in the final analysis.

Moreover, some countries may want to perform the PPS in LTCFs both from a nationally representative sample as well as from voluntary participation, after inviting all LTCFs. In this case, only the data from a nationally representative sample will be included in the main European report. However, if all data are submitted by a country, ECDC will provide the national survey coordinators with individual feedback reports for all participating LTCFs by comparing their results to the total national results. A variable at the LTCF level, entered by the national survey coordinator(s), records whether an LTCF belongs to the representative sample. This variable will aid in the selection of LTCFs for the consolidated report at the European level.

3.4 Data collectors

Depending on the available resources, data can be collected by local data collectors (e.g. designated physician, infection control and prevention (IPC) doctor/nurse, head nurse, etc.), or local data collectors supported by an external data collector (i.e. a person recruited by the national focal points (NFPs) or operational contact points (OCPs), or members of the national PPS coordination team, e.g. doctor, infection control nurse).

Trained data collectors – both local and external – should visit the facility on the day of the PPS to review each resident with the nurse-in-charge, nurses' aide(s) and healthcare workers of the LTCF. They should look for recent symptoms suggestive of infection, by examining resident records/charts, case notes and drug charts. Residents with suspected infection(s) and residents receiving antimicrobial agents should be further reviewed and discussed with the attending physician, if possible.

It is recommended that extra staff are involved during this period to take into account the additional workload that the PPS is foreseen to generate.

Training materials were developed by the HALT-4 coordination group. Training of data collectors is strongly recommended (see Section 6, 'Training').

4 Data collection

Data are collected using two questionnaires: an institutional questionnaire and a resident questionnaire. An institutional questionnaire (Annex 1) collects general information, denominator data (demographic data, risk factors and care load indicators for the entire LTCF population), and information about medical care and coordination, antimicrobial policies and infection control resources in the LTCF. These data will be used for descriptive analyses of the participating LTCFs and their population in order to make appropriate adjustments to the case mix of the LTCFs, during comparative analyses at the national/regional and European levels.

A ward list (Annex 2; optional, for internal use only) is provided for data collectors to facilitate their collection of denominator data from the LTCF population on the day of the PPS, for subsequent entry in the institutional questionnaire.

A resident questionnaire (Annex 3) is for each resident who receives at least one antimicrobial agent and/or presents with at least one active HAI on the day of the PPS. The case definitions of infections (Annex 4) should be used to identify active HAIs in eligible residents. The code list for microorganisms (Annex 5) should be consulted when completing the resident questionnaire, to identify the appropriate codes for detected microorganisms and their antimicrobial resistance profiles.

4.1 Institutional questionnaire (see Annex 1)

The institutional questionnaire (Annex 1) collects data related to each participating LTCF with questions grouped into five sections:

- A: General information (Figure 1)
- B: Denominator data (Figure 2)
- C: Medical care and coordination (Figure 3)
- D: Infection prevention and control practice (Figure 4)
- E: Antimicrobial policy (Figure 5)

It is recommended that the person completing this questionnaire is the person in charge of the facility. If this person cannot answer some of the questions or locate the relevant information, they should request assistance from persons who will be able to answer those questions. This is especially relevant for questions related to antimicrobial policy.

4.1.1 A: General information

Variable	Description/definition
Date of survey	Date of the survey in your LTCF.
Facility survey number	LTCF identifier; Code allocated by the national coordinating centre.
LTCF type	Types of LTCF: General nursing home, residential home, mixed LTCF, palliative care facility, LTCF for physically disabled persons, LTCF for mentally disabled person; psychiatric LTCF, rehabilitation centre, sanatorium, other LTCF. For eligibility, see Section 3.2.3, 'Eligibility criteria for LTCFs'.
Total number of resident rooms	Sum of all resident rooms including single rooms and multi-bedded rooms. Public areas, utility rooms, etc. should be excluded.
Total number of single-occupancy resident rooms in the facility	The 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 a single occupancy room.

Figure 1. HALT-4 Institutional Questionnaire: A – General information

A – GENERAL INFORMATION

DATE OF THE SURVEY IN YOUR FACILITY (dd/mm/yyyy) ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋ ⌊_⌋⌊_⌋⌊_⌋⌊_⌋

FACILITY STUDY NUMBER (*allotted by your national HALT-4 coordinator*) ⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋⌊_⌋

LTCF TYPE:

- ☐ *General nursing home*
- ☐ *Residential home*
- ☐ *Mixed LTCF*
- ☐ *Palliative care facility*
- ☐ *LTCF for physically disabled*
- ☐ *LTCF for mentally disabled*
- ☐ *Psychiatric LTCF*
- ☐ *Rehabilitation*
- ☐ *Sanatorium*
- ☐ *Other*

IN THE FACILITY:

Total number of RESIDENT ROOMS ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ *Rooms*

Total number of SINGLE-OCCUPANCY RESIDENT ROOMS ⌊_⌋⌊_⌋⌊_⌋⌊_⌋ *Single-occupancy rooms*

4.1.2 B: Denominator data

Variable	Description/definition
Beds in the facility	The total number of resident beds in the LTCF, both occupied and unoccupied. Beds shared by partners should be counted as two beds.
Occupied beds	The total number of beds occupied by residents on the day of the PPS. This figure also includes beds occupied by residents who are absent on the day of the PPS due to hospitalisation, on holiday, or with family, etc. Beds shared by partners should be counted as two beds.
Eligible residents, living full-time in the facility, present at 8:00 am and not discharged at the time of the survey	The total number of residents living full-time in the facility, present at 8:00 am and not discharged on the day of the PPS.
Age over 85 years	The total number of eligible residents older than 85 years on the day of the PPS.
Male residents	The total number of eligible male residents on the day of the PPS.
Residents with any urinary catheter	The total number of eligible residents with a urinary catheter, i.e. any tube system in place to drain and collect urine from the bladder, e.g. an indwelling urinary catheter, suprapubic or abdominal wall catheter, or a cystostomy. External catheters that do not drain urine directly from the bladder (e.g. condom catheters) should not be included.
Residents with any vascular catheter	The total number of eligible residents with a tube system in place to access the vascular system (i.e. venous, arterial) on the day of the PPS, e.g. a peripheral intravenous catheter, an implanted venous access system, or any other intravascular access system (including arteriovenous fistulae).
Residents with pressure sores	The total number of eligible residents with a pressure sore on the day of the PPS. All grades of pressure sores should be included (e.g. the lowest grade, non-blanchable erythema, characterised by discolouration of intact skin not affected by light finger pressure).
Residents with other wounds	The total number of eligible residents with a wound other than a pressure sore on the day of the PPS, including leg ulcers, traumatic or surgical wounds and insertion sites for percutaneous endoscopic gastrostomy (PEG), tracheostomy, urostomy, colostomy or suprapubic and peritoneal dialysis catheters.
Residents disoriented in time and/or space	The total number of eligible residents who suffer from periods of confusion, especially related to time, place or identification of persons (e.g. they cannot find their room, have no idea of time and/or are unable to recognise persons they know very well).
Residents using a wheelchair or bedridden	The total number of eligible residents who need a wheelchair or are bedridden.
Residents with surgery in the previous 30 days	The total number of eligible residents who had surgery in the 30 days preceding the day of the PPS. Surgery is defined as a procedure where an incision is made (not just a needle puncture), with breach of mucosa and/or skin (including laparoscopic approaches). The procedure does not necessarily have to take place in operating theatres/rooms, but can also take place in interventional radiology rooms, cardiac catheterisation rooms, endoscopic rooms, etc.
Residents with urinary and/or faecal incontinence	The total number of eligible residents with urinary and/or faecal incontinence (i.e. lack of control of the bladder or bowel sphincters resulting in an uncontrolled loss of urine or faeces) necessitating the use of diapers (during the day and/or night). A resident with a urinary catheter should not be considered as incontinent for urine (this indicator is designed to measure the workload of the LTCF staff).
Residents receiving at least one systemic antimicrobial agent	The total number of eligible residents receiving one or more systemic antimicrobial agents (see Section 4.3.2, 'Antimicrobial data use') on the day of the PPS.
Residents with at least one active healthcare-associated infection	The total number of eligible residents with one or more active healthcare-associated infections (see Section 4.3.3, 'Infection data') on the day of the PPS.

Figure 2. HALT-4 Institutional Questionnaire: B – Denominator data

B – DENOMINATOR DATA

This table, when completed, will summarise the data collected in each ward (ward list) for the total population.

IN YOUR FACILITY, ON THE DAY OF THE SURVEY, THE TOTAL NUMBER OF:

BEDS IN THE FACILITY *(both occupied and non-occupied beds)*	⌊_⌊_⌊_⌊_⌋
OCCUPIED BEDS	⌊_⌊_⌊_⌊_⌋
ELIGIBLE RESIDENTS:	
PRESENT AT 8:00 AM AND NOT DISCHARGED AT THE TIME OF THE SURVEY	⌊_⌊_⌊_⌊_⌋
AGE OVER 85 YEARS	⌊_⌊_⌊_⌊_⌋
MALE RESIDENTS	⌊_⌊_⌊_⌊_⌋
RESIDENTS WITH ANY URINARY CATHETER	⌊_⌊_⌊_⌊_⌋
RESIDENTS WITH ANY VASCULAR CATHETER	⌊_⌊_⌊_⌊_⌋
RESIDENTS WITH PRESSURE SORES	⌊_⌊_⌊_⌊_⌋
RESIDENTS WITH OTHER WOUNDS	⌊_⌊_⌊_⌊_⌋
RESIDENTS DISORIENTED IN TIME AND/OR SPACE	⌊_⌊_⌊_⌊_⌋
RESIDENTS USING A WHEELCHAIR OR BEDRIDDEN	⌊_⌊_⌊_⌊_⌋
RESIDENTS WITH SURGERY IN THE PREVIOUS 30 DAYS	⌊_⌊_⌊_⌊_⌋
RESIDENTS WITH URINARY AND/OR FAECAL INCONTINENCE	⌊_⌊_⌊_⌊_⌋
RESIDENTS RECEIVING AT LEAST ONE SYSTEMIC ANTIMICROBIAL AGENT	⌊_⌊_⌊_⌊_⌋
RESIDENTS WITH AT LEAST ONE ACTIVE HEALTHCARE-ASSOCIATED INFECTION	⌊_⌊_⌊_⌊_⌋

4.1.3 C: Medical care and coordination

Variable	Description/definition
Personal general practitioner (GP)	A medical doctor, chosen by the resident, who provided medical care outside of the hospital environment to the LTCF resident at a time before their residence at the present LTCF.
GP group practice	GPs in either individual GP practices or a network of single GP practices who collaborate to attend to the everyday medical needs of individuals within a geographical area.
Medical staff employed by the facility	Medical doctors hired by the LTCF management to provide care to the residents. These physicians are not the residents' personal GPs (see above).
Coordinating medical physician (CP)	A medical doctor in charge of the coordination of medical activities and standardisation of practices/policies in the facility.
Estimated percentage of residents fully vaccinated against COVID-19	An estimation of residents who are fully vaccinated against COVID-19. National guidelines on the definition of 'full vaccination' should be followed.
Estimated percentage of healthcare workers fully vaccinated against COVID-19	An estimation of healthcare workers who are fully vaccinated against COVID-19. National guidelines on the definition of 'full vaccination' should be followed.
Estimated percentage of residents vaccinated against seasonal influenza	An estimation of residents who are vaccinated against seasonal influenza.

Variable	Description/definition
Estimated percentage of healthcare workers vaccinated against seasonal influenza	An estimation of healthcare workers who are vaccinated against seasonal influenza.

Figure 3. HALT-4 Institutional Questionnaire: C – Medical care and coordination

C – MEDICAL CARE AND COORDINATION

1. Is medical care for residents in the facility, including antimicrobial prescribing, provided by the:
   - ☐ *Personal general practitioners (GPs) or group practice(s) only.*
   - ☐ *Medical staff, employed by the facility only.*
   - ☐ *Both personal GPs/group practice(s) and medical doctor(s) employed by the facility.*

2. Are medical activities in the facility coordinated by a coordinating medical physician (CP)?
   - ☐ *No, there is no internal or external coordination of the medical activities.*
   - ☐ *Yes, there is a physician from inside the facility (internal) who coordinates the medical activities.*
   - ☐ *Yes, there is a physician from outside the facility (external) who coordinates the medical activities.*
   - ☐ *Yes, there is both a physician from inside and outside the facility (internal and external) who coordinates the medical activities.*

3. What percentage of the residents in the facility are fully vaccinated against COVID-19?

   Estimated percentage (%) ⌊_⌋⌊_⌋⌊_⌋ %

4. What percentage of the healthcare workers in the facility are fully vaccinated against COVID-19?

   Estimated percentage (%) ⌊_⌋⌊_⌋⌊_⌋ %

5. What percentage of the residents in the facility are vaccinated against seasonal influenza?

   Estimated percentage (%) ⌊_⌋⌊_⌋⌊_⌋ %

6. What percentage of the healthcare workers in the facility are vaccinated against seasonal influenza?

   Estimated percentage (%) ⌊_⌋⌊_⌋⌊_⌋ %

4.1.4 D: Infection prevention and control practice

Variable	Description/definition
Person (internal or external) with training in infection prevention and control available to the staff of the facility	An infection prevention and control (IPC) practitioner, is usually a registered nurse or a medical doctor or other medical practitioner with specialised training in infection control and hospital hygiene, and responsible for infection control tasks such as training of hospital/LTCF employees in infection control, design and implementation of infection control procedures, management (implementation, follow-up, evaluation) of an infection control work, audits and evaluation of performance, procedures for disinfection of medical devices, etc. This person can work full-time on infection control and prevention activities, or combine this with other duties such as general nursing duty, nursing supervision, quality assurance, etc. This person is available to staff in the facility and can be either an external or an internal person. If possible, also report if the IPC practitioner is a nurse, or a doctor, or if both a nurse and a doctor are available.

Variable	Description/definition
Infection prevention and control practices	• Training the nursing and paramedical staff in infection prevention and control practices; • Appropriate training of general practitioners and medical staff in infection prevention and control; • Development of care protocols; • Registration of residents colonised/infected with multi-resistant microorganisms; • Designation of a person responsible for the reporting and management of outbreaks; • Feedback on surveillance results to the nursing/medical staff of the facility; • Supervision of disinfection and sterilisation of medical and care material; • Decisions on isolation and additional precautions for residents colonised with resistant microorganisms; • Offer of annual immunisation for flu to all residents; • Offer of (booster) vaccination against COVID-19 to all residents; • Organisation, control and feedback on hand hygiene in the facility on a regular basis; • Organisation, control and feedback of a process involving the surveillance/audit of infection policies and procedures (on regular basis); • None of the above.
Infection prevention and control (IPC) committee	A multidisciplinary committee consisting of at least the person with training in IPC (IPC practitioner), the administrator, the coordinating physician (if present at the facility), the nursing supervisor(s) or the persons designated by these professionals. IPC committee members could also include quality assurance personnel, risk management personnel, representatives from microbiology, surgery, central sterilisation, pharmacy, environmental services, etc. The functions of the IPC committee 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, policies, and monitor programme goals and activities. Written records of meetings should be maintained (Source: SHEA/APIC Guideline: Infection Prevention and Control in the Long-Term Care Facility, 2008). If possible, also report how many infection control committee meetings were organised in the previous year.
Help and expertise from an external infection control (IC) team on a formal basis	Can the facility ask for help and expertise from an external infection control (IC) team on a formal basis (e.g. IC team from a local hospital)?
In the facility, a written protocol is available for:	• the management of methicillin-resistant *Staphylococcus aureus* (MRSA) and/or other multidrug resistant organisms; • the observation of hand hygiene; • the management of urinary catheters; • the management of vascular catheters; • the management of enteral feeding; • the management of local outbreaks of: – gastrointestinal infections; – respiratory tract infections.
Surveillance programme for HAIs in place	Surveillance system(s) in place (e.g. with annual summary report of the number of urinary tract infections, respiratory tract infections).
Most frequently used method for hand hygiene	The hand hygiene method most frequently used in your facility when hands are not soiled: hand disinfection with an alcohol-based hand rub solution, hand washing with water and a non-antiseptic soap, hand washing with water and an antiseptic soap.
Litres of hand alcohol	The total number of litres of hand alcohol used in the course of the year preceding the PPS.
Hand hygiene training	Education of healthcare professionals (i.e. nurses, nurse aides, doctors, physiotherapists, cleaning staff, etc.), especially those new to the LTCF, on the following points (at least): the importance of hand hygiene, the indications for hand hygiene, the technique, and the products to use.

Variable	Description/definition
Universal masking	Is there a policy of universal masking in place in the LTCF, currently? Universal masking in this context refers to the mandatory wearing of face masks or respirators inside the LTCF, during activities other than care for COVID-19 patients. These are the three categories of universal masking policies in the context of LTCFs: • No policy of universal masking. Face masks are only required during COVID-19 care and in other circumstances where the use of face masks is recommended. • Yes, for routine care only. Face masks are required by healthcare workers for all routine care (all contact with non-COVID-19 patients) but not in other areas of the LTCF. • Yes, for routine care and in all common areas of the LTCF (e.g. doctor's room). It is a requirement for all persons (staff, patients, visitors, service providers and others) to wear a mask at all times, except for when eating or drinking. Note that only the last category matches the definition of 'universal masking' according to the World Health Organization (WHO)[viii], while the second category is referred to as 'targeted continuous medical use'.

[viii] World Health Organization (WHO). Infection prevention and control during health care when coronavirus disease (COVID-19) is suspected or confirmed. Interim Guidance. Geneva: WHO; 2021 12 July: WHO/2019-nCoV/IPC/2020.4. Available at: https://www.who.int/publications/i/item/WHO-2019-nCoV-IPC-2021.1

Figure 4. HALT-4 Institutional Questionnaire: D – Infection prevention and control practice

D – INFECTION PREVENTION AND CONTROL PRACTICE

1. Are there (internal and/or external) persons with training in infection prevention and control available to the staff of the facility?

☐ *Yes* ☐ *No*

2. If a person with training in infection control/prevention is available, is this person:

☐ *A nurse* ☐ *A doctor* ☐ *Both a nurse and a doctor are available.*

3. In the facility, is/are there:
(Please complete this question even if there is no person with training in infection prevention and control available in the facility.)

☐ *Infection prevention and control training of the nursing and paramedical staff*

☐ *Appropriate training of general practitioners and medical staff in infection prevention and control*

☐ *Development of care protocols*

☐ *Registration of residents colonised/infected with multi-resistant microorganisms*

☐ *Designation of a person responsible for the reporting and management of outbreaks*

☐ *Feedback on surveillance results to the nursing/medical staff of the facility*

☐ *Supervision of disinfection and sterilisation of medical and care material*

☐ *Decisions on isolation and additional precautions for residents colonised with resistant microorganisms*

☐ *Offer of annual immunisation for flu to all residents*

☐ *Offer of (booster) immunisation for COVID-19 to all residents*

☐ *Organisation, control, feedback on hand hygiene in the facility on a regular basis*

☐ *Organisation, control, feedback of a process surveillance/audit of infection policies and procedures (on a regular basis)*

☐ *None of the above.*

4. In the facility, is there an infection control committee (internal or external)? ☐ *Yes* ☐ *No*

5. How many infection control committee meetings were organised in the previous year?

Total number of meetings last year ⌊_⌊_⌊_⌋ *meetings previous year*

6. Can the facility ask for help and expertise from an external infection control (IC) team on a formal basis (e.g. IC team from a local hospital)?

☐ *Yes* ☐ *No*

7. In the facility, is a written protocol available for:

- *the management of MRSA and/or other multidrug-resistant microorganisms* ☐ *Yes* ☐ *No*
- *hand hygiene* ☐ *Yes* ☐ *No*
- *the management of urinary catheters* ☐ *Yes* ☐ *No*
- *the management of vascular catheters/lines* ☐ *Yes* ☐ *No*
- *the management of enteral feeding* ☐ *Yes* ☐ *No*
- *the management of local outbreaks of:*
  - *gastrointestinal infections* ☐ *Yes* ☐ *No*
  - *respiratory tract infections* ☐ *Yes* ☐ *No*

8. Is a surveillance programme of healthcare-associated infections in place in the facility? *(annual summary report of number of urinary tract infections, respiratory tract infections, etc.)*

☐ *Yes* ☐ *No*

9. Which hand hygiene method is most frequently used in your facility when hands are not soiled? (only **one answer** is possible)

☐ *Hand disinfection with an alcohol rub solution*

☐ *Hand washing with water and a non-antiseptic soap*

☐ *Hand washing with water and an antiseptic soap*

10. How many litres of alcohol rub solution for hand hygiene were used in the previous year?

Total annual consumption in litres ⌊_⌋⌊_⌋⌊_⌋ *litres used in previous year*

11. In the previous year, was a hand-hygiene training session organised for healthcare professionals of the facility?

☐ *Yes* ☐ *No*

12. Is there currently a policy of universal masking in place in the facility?

☐ *No*

☐ *Yes, for routine care only.*

☐ *Yes, for routine care and in all common areas (e.g. lunch/dining room, physiotherapy room).*

4.1.5 E: Antimicrobial policy

Variable	Description/definition
Antimicrobial stewardship	The facility has the following mechanisms in place: • An antimicrobial committee; • Regular annual training on appropriate antimicrobial prescribing; • 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 the country is small) antimicrobial resistance profile summaries available in the LTCF or in the local general practitioner surgeries; • A system that requires permission from a designated person(s) for prescribing restricted antimicrobials, not included in local formulary; • Advice from a pharmacist for antimicrobials, not included in the formulary; • A therapeutic formulary, comprising a list of antimicrobials; • Feedback to the local general practitioner on antimicrobial consumption in the facility; • None of the above. Antimicrobial committee: This committee is in charge of the development of local guidelines and protocols for antibiotic use in the LTCF. The team should comprise (at least) healthcare providers prescribing antimicrobial agents to LTCF residents, a pharmacist, a co-ordinating physician (if present), an infection prevention and control practitioner, and (if possible) a microbiologist. Written guidelines for appropriate antimicrobial use: Recommendations for empirical and targeted treatment of the most frequent infections, including dosage of antimicrobial agents, administration route and duration of treatment. Commonly a first and second therapy choice is proposed. Annual antimicrobial consumption data: A report on the quantity of antimicrobial agents prescribed/received during the previous year, classified by group. Antimicrobial resistance profiles: These profiles are used to monitor antimicrobial resistance patterns for key micro-organisms in order to guide the choice of antimicrobial agents for treatment. Data are obtained by the surveillance of antimicrobial susceptibility testing results provided by clinical microbiology laboratories. Therapeutic formulary: A list of eligible pharmaceutical agents by indication, intended as a manual for prescribers to guide their prescriptions. The therapeutic formulary should include a specific chapter on antimicrobial therapy.
Written therapeutic guidelines	Written therapeutic guidelines for respiratory tract infections, urinary tract infections and/or wound and soft tissue infections.
Surveillance programme for antimicrobial consumption	Is there a programme in place for the surveillance of antimicrobial consumption in the facility?
Surveillance programme for antimicrobial-resistant microorganisms	This could be, for e.g. annual summary reports for MRSA, *Clostridioides (Clostridium) difficile,* carbapenem-resistant *Klebsiella pneumoniae*, etc.

Figure 5. HALT-4 Institutional Questionnaire: E – Antimicrobial policy

E – ANTIMICROBIAL POLICY

1. Which of following elements of antimicrobial stewardship are present in the facility?

☐ *An antimicrobial committee*

☐ *Regular annual training on appropriate antimicrobial prescribing*

☐ *Written guidelines for appropriate antimicrobial use (good practice) in the facility*

☐ *Availability of data on annual antimicrobial consumption by antimicrobial class*

☐ *A system to remind healthcare workers of the importance of microbiological samples to inform th 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 local general practitioner surgeries*

☐ *A system that requires permission from a designated person(s) for prescribing of restricted antimicrobials, not included in local formulary*

☐ *Advice from a pharmacist for antimicrobials not included in the formulary*

☐ *A therapeutic formulary, comprising a list of antibiotics*

☐ *Feedback to the local general practitioner on antimicrobial consumption in the facility*

☐ *None of the above.*

2. If written therapeutic guidelines are present in the facility, are they on?

- Respiratory tract infections	☐ *Yes*	☐ *No*
- Urinary tract infections	☐ *Yes*	☐ *No*
- Wound and soft tissue infections	☐ *Yes*	☐ *No*

3. Is a programme for surveillance of antimicrobial consumption in place in the facility?

☐ *Yes* ☐ *No*

4. Is a programme for surveillance of resistant microorganisms in place in the facility?
(for example, annual summary report for MRSA, Clostridioides (Clostridium) difficile, etc.)

☐ *Yes* ☐ *No*

4.2 Ward list (see Annex 2)

The ward list is a form (Figure 6) developed to support data collectors in the collection of denominator data for the institutional questionnaire (Figure 2). Its use is not mandatory, i.e. it is optional, for internal use only.

Data collectors should collect information from each resident living full-time in the facility, present in the ward at 8:00 am and not discharged at the time of the survey (Figure 6). Once these data have been collected for all the wards in an LTCF, data collectors can sum the denominators from each ward (Figure 7) and transfer these totals to the institutional questionnaire (Figure 2). Facilities that do not have different wards should only complete one ward list.

Instructions:

- List all the residents present at the facility on the day of the survey, in columns 1 and 2.
- Add a code (study number) in column 3 that is unique for every resident in the facility. Numbers and/or letters can be used. This resident study number should be entered on all forms for the same resident.
- Complete column 4, i.e. if the resident meets the eligibility criteria: living full-time at the facility, present at 8:00 am and not discharged at the time of the survey (see Section 3.2.4, 'Eligible residents').
- Complete columns 5 to 15 by writing an 'X' if the risk factor or care load indicator is present.

- Sum the 'X's 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 (i.e. Denominator data) of the institutional questionnaire (Figure 2).
- If a resident on the ward list has an 'X' in columns 14 and/or 15b (i.e. they were receiving at least one systemic antimicrobial agent and/or had at least one active healthcare-associated infection on the day of the survey, complete a resident form for this resident (Annex 3).

Figure 6. HALT-4 ward list: collection of resident-level data

COMPLETE THIS PART OF THE LIST FOR ALL RESIDENTS IN THE WARD				COMPLETE THIS PART FOR ALL ELIGIBLE RESIDENTS (residents from column 4) Write an 'X' in the column if the condition is present												
Room and bed number	Resident name	Study number of the resident	Living full-time, present at 8:00 am and not discharged at the time of PPS	Age over 85 years	Male resident	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	Systemic antimicrobial agent	Signs/symptoms of an active healthcare-associated infection	Infection matching a case definition
1	2	3	4	5	6	7	8	9a	9b	10	11	12	13	14	15a	15b

Figure 7. HALT-4 ward list: Calculation of denominators

Use this table to add the number of 'X's from each column from each ward list in the facility.

Transfer the total number into Part B of the institutional questionnaire, i.e. 'Denominator data'.

On the day of the PPS, the TOTAL number of:	Columns	TOTAL NUMBERS
Total number of beds in this ward (total bed capacity)	1	
Occupied beds in the ward	2	
Eligible residents, living full-time, present at 8:00 am and not discharged at time of PPS	4	
Age over 85 years	5	
Male residents	6	
Residents with any urinary catheter	7	
Residents with any vascular catheter	8	
Residents with pressure sores	9a	
Residents with other wounds	9b	
Residents disorientated in time and/or space	10	
Residents using a wheelchair or bedridden	11	
Residents with surgery in the previous 30 days	12	
Residents with urinary and/or faecal incontinence	13	
Residents prescribed any systemic antimicrobial agent	14	
Residents with signs/symptoms of at least one active healthcare-associated infection	15a	
Residents with an infection matching a case definition	15b	

4.3 Resident questionnaire (see Annex 3)

A resident questionnaire has to be completed for each resident who is:

- receiving at least one systemic antimicrobial agent on the day of the PPS (see Section 4.3.2, 'Antimicrobial use data');
  AND/OR
- presenting at least one active healthcare-associated infection on the day of the PPS (see Section 4.3.3, 'Infection data').

The form's questions are grouped into three sections: 'Resident data', 'Part A: Antimicrobial use' and 'Part B: Healthcare-associated infections'.

4.3.1 Resident data

Variable	Description/definition
Resident study number	Unique code assigned to the resident by the local data collectors.
Gender	Gender of the resident: Male or Female.
Birth year	Year the resident was born (YYYY).
Length of stay in the facility	The resident has already lived in the facility for EITHER less than one year OR one year or longer.
Admission to a hospital in the last three months	Was the resident admitted to a hospital in the three months preceding the date of the PPS? Only admissions to hospitals – i.e. hospitals with at least one medical or surgical ward – for at least one night should be considered.
Surgery in the previous 30 days	Did the resident undergo surgery in the 30 days preceding the PPS? Surgery is defined as a procedure where an incision is made (not just a needle puncture), with breach of mucosa and/or skin (including laparoscopic approaches). The procedure does not necessarily have to take place in operating theatres/rooms, but can also take place in interventional radiology rooms, cardiac catheterisation rooms, endoscopic rooms, etc.
Urinary catheter	Any tube system placed in the body to drain and collect urine from the bladder, e.g. an indwelling urinary catheter, suprapubic or abdominal wall catheter, or a cystostomy. External catheters not draining urine directly from the bladder (e.g. condom catheters) should not be included.
Vascular catheter	Any tube system placed in the body to access the vascular (venous, arterial) system, e.g. a peripheral intravenous catheter, an implanted vascular access system or any other intravascular access system (including arteriovenous fistulae).
Urinary and/or faecal incontinence	Lack of control of the bladder or bowel sphincters resulting in an uncontrolled loss of urine or faeces, and necessitating the use of diapers (during the day and/or night). A resident with a urinary catheter should not be considered as incontinent for urine.
Pressure sores	All grades of pressure sores should be considered, even the lowest grade, non-blanchable erythema, characterised by discolouration of intact skin not affected by light finger pressure.
Other wounds	All wounds other than a pressure sore, including leg ulcers, traumatic or surgical wounds and insertion sites for percutaneous endoscopic gastrostomy (PEG), tracheostomy, urostomy, colostomy or suprapubic and peritoneal dialysis catheters.
Disoriented in time and/or space	Residents who suffer from periods of confusion especially as to time, place or identification of persons (e.g. cognitive impairment).
Mobility	In general, is the resident ambulant (they can walk alone with or without canes, crutches, walkers, etc.)? Do they need a wheelchair for their movement or are they bedridden?

Figure 8. HALT-4 resident questionnaire: resident data

RESIDENT STUDY NUMBER ☐☐☐☐

Healthcare-associated infections and antimicrobial use in European long-term care facilities (HALT-4)

RESIDENT QUESTIONNAIRE

RESIDENT DATA

GENDER	☐	*Male*	☐	*Female*	
BIRTH YEAR	☐☐☐☐	*(YYYY)*			
LENGTH OF STAY IN THE FACILITY	☐	*Less than one year*	☐	*One year or longer*	
ADMISSION TO A HOSPITAL IN THE LAST 3 MONTHS	☐	*Yes*	☐	*No*	
SURGERY IN THE PREVIOUS 30 DAYS	☐	*Yes*	☐	*No*	
PRESENCE OF:					
URINARY CATHETER	☐	*Yes*	☐	*No*	
VASCULAR CATHETER	☐	*Yes*	☐	*No*	
INCONTINENCE (URINARY AND/OR FAECAL)	☐	*Yes*	☐	*No*	
WOUNDS					
- PRESSURE SORE	☐	*Yes*	☐	*No*	
- OTHER WOUNDS	☐	*Yes*	☐	*No*	
DISORIENTATION (IN TIME AND/OR SPACE)	☐	*Yes*	☐	*No*	
MOBILITY	☐	*Ambulant*	☐	*Wheelchair*	☐ *Bedridden*

4.3.2 Antimicrobial use data

The following antimicrobial agents should be included if their route of administration is oral, parenteral (intravenous), intramuscular, subcutaneous, inhalation or rectal:

- antibacterials (ATC level J01), antimycotics (J02) and antifungals (D01BA) for systemic use;
- antibiotics used as intestinal anti-infectives (A07AA)
- nitroimidazole-derived antiprotozoals (P01AB)
- antimycobacterials (J04) when used for the treatment of mycobacteria, including tuberculosis or as reserve treatment for multidrug-resistant bacteria;
- Antivirals for COVID-19: PF-07321332/ritonavir/nirmatrelvir (Paxlovid™), regdanvimab (Regkirona™), casirivimab/imdevimab (Ronapreve™), remdesivir (Veklury™), sotrovimab (Xevudy™), molnupiravir (Lagevrio™), tixagevimab/cilgavimab (Evusheld™).

The following antimicrobial agents should be excluded:

- Antiviral agents for systemic use (J05) (other than for COVID-19);
- Preparations of antimicrobial agents for topical use;
- Antiseptic agents.

Collect the following information for each antimicrobial agent the resident receives on the day of the survey.

Variable	Description/definition
Antimicrobial name	Generic or brand name of the antimicrobial agent. These names should be converted to ATC5 codes at the time of data entry to HelicsWin.Net.
Administration route	Route of administration of the antimicrobial agent; oral, parenteral (intravenous (IV), intramuscular (IM) or subcutaneous (SC)) or other (e.g. rectal, inhalation).
End date/review date of treatment	The resident's medical or nursing records clearly state the final date when the antimicrobial agents should be given (end date), or when the treatment using antimicrobial agent(s) should be revised by the prescriber (review date).
Type of treatment	Indication for antimicrobial use.
Prophylactic	Antimicrobial agents prescribed to prevent an infection. The resident presented no signs/symptoms of an infection when the antimicrobial agent(s) was prescribed.
Therapeutic	Antimicrobial agents prescribed to treat an infection. The resident presented signs/symptoms of an infection when the treatment was prescribed. Both empirical treatments (i.e. initiation of treatment before the causative pathogen is known), and microbiologically documented treatments (i.e. with knowledge of causative pathogen) should be considered.
Antimicrobial given for	Diagnosis group by anatomical site.
Where prescribed	Place where the antimicrobial was prescribed: in this facility (LTCF), in the hospital or elsewhere.

4.3.3 Infection data

The following information should be recorded for each identified infection using the decision algorithm (see Section 4.3.3.1, 'Active healthcare-associated infections', Section 4.3.3.2, 'Identifying the infection code using the decision algorithms', and Annex 4).

Variable	Description/definition
Infection code	See Sections 4.3.3.1, 'Active healthcare-associated infections' and 4.3.3.2, 'Identifying the infection code using the decision algorithms'.
If 'OTHER', please specify	If infection code = 'OTHER', please provide more information on the type of infection.
Date of onset	Date of onset of the infection (dd/mm/yyyy). Record the date of first signs or symptoms of the infection. If unknown, record the date on which treatment was started for this infection, or the date on which the first diagnostic sample was taken. If no treatment has been started or samples taken, please estimate the approximate date of onset with the available information.

Figure 9. HALT-4 resident questionnaire: Part A – Antimicrobial use

RESIDENT STUDY NUMBER

PART A: ANTIMICROBIAL USE				
	ANTIMICROBIAL 1	ANTIMICROBIAL 2	ANTIMICROBIAL 3	ANTIMICROBIAL 4
ANTIMICROBIAL NAME	....	....	....	....
ADMINISTRATION ROUTE *PARENTERAL = IM, IV OR SC*	☐ *Oral* ☐ *Parenteral* ☐ *Other*	☐ *Oral* ☐ *Parenteral* ☐ *Other*	☐ *Oral* ☐ *Parenteral* ☐ *Other*	☐ *Oral* ☐ *Parenteral* ☐ *Other*
END DATE / REVIEW DATE OF TREATMENT KNOWN?	☐ *No* ☐ *Yes*	☐ *No* ☐ *Yes*	☐ *No* ☐ *Yes*	☐ *No* ☐ *Yes*
TYPE OF TREATMENT	☐ *Prophylactic* ☐ *Therapeutic*	☐ *Prophylactic* ☐ *Therapeutic*	☐ *Prophylactic* ☐ *Therapeutic*	☐ *Prophylactic* ☐ *Therapeutic*
ANTIMICROBIAL GIVEN FOR	☐ *Urinary tract* ☐ *Genital tract* ☐ *Skin or wound* ☐ *Respiratory tract* ☐ *Gastrointestinal* ☐ *Eye* ☐ *Ear, nose, mouth* ☐ *Surgical site* ☐ *Tuberculosis* ☐ *Systemic infection* ☐ *Unexplained fever* ☐ *Other (specify)*	☐ *Urinary tract* ☐ *Genital tract* ☐ *Skin or wound* ☐ *Respiratory tract* ☐ *Gastrointestinal* ☐ *Eye* ☐ *Ear, nose, mouth* ☐ *Surgical site* ☐ *Tuberculosis* ☐ *Systemic infection* ☐ *Unexplained fever* ☐ *Other (specify)*	☐ *Urinary tract* ☐ *Genital tract* ☐ *Skin or wound* ☐ *Respiratory tract* ☐ *Gastrointestinal* ☐ *Eye* ☐ *Ear, nose, mouth* ☐ *Surgical site* ☐ *Tuberculosis* ☐ *Systemic infection* ☐ *Unexplained fever* ☐ *Other (specify)*	☐ *Urinary tract* ☐ *Genital tract* ☐ *Skin or wound* ☐ *Respiratory tract* ☐ *Gastrointestinal* ☐ *Eye* ☐ *Ear, nose, mouth* ☐ *Surgical site* ☐ *Tuberculosis* ☐ *Systemic infection* ☐ *Unexplained fever* ☐ *Other (specify)* ....
WHERE PRESCRIBED?	☐ *In this facility* ☐ *In the hospital* ☐ *Elsewhere*	☐ *In this facility* ☐ *In the hospital* ☐ *Elsewhere*	☐ *In this facility* ☐ *In the hospital* ☐ *Elsewhere*	☐ *In this facility* ☐ *In the hospital* ☐ *Elsewhere*

Figure 10. HALT-4 resident questionnaire: Part B – Healthcare-associated infections

PART B: HEALTHCARE-ASSOCIATED INFECTIONS					
		INFECTION 1	INFECTION 2	INFECTION 3	INFECTION 4
INFECTION CODE					
IF 'OTHER', PLEASE SPECIFY		....	....	....	....
DATE OF ONSET (DD/MM/YY)		/ /	/ /	/ /	/ /
A. NAME OF ISOLATED MICROORGANISM (PLEASE USE CODE LIST) B. TESTED ANTIMICROBIAL(S)[1] AND RESISTANCE[2] ONLY FOR STAAUR, ENC***, ACIBAU, PSEAER OR *ENTEROBACTERALES* (CIT***, ENB***, ESCCOL, KLE***, MOGSPP, PRT***, SER***)	1. A				
	B				
	2. A				
	B				
	3. A				
	B				

[1] Tested antimicrobial(s): STAAUR: oxacillin (OXA) or glycopeptides (GLY); ENC***: GLY only; *Enterobacterales*: third-generation cephalosporins (C3G) or carbapenems (CAR); PSEAER and ACIBAU: CAR only.
[2] Resistance: S=susceptible, standard dosing regimen, I=susceptible, increased exposure, R=resistant, U=unknown

4.3.3.1 Active healthcare-associated infections

Data collectors must identify residents presenting signs and/or symptoms of an active HAI on the day of the PPS.

An infection is active when new or acutely worse signs/symptoms of the infection:

- are present on the survey date AND are new or acutely worse.[a]
  OR
- were present in the two weeks (14 days) prior to the PPS AND were new or acutely worse[a], AND the resident is (still) receiving treatment for that infection on the survey date[b].
  AND
- The onset of symptoms occurred more than 48 hours (i.e. day three onwards) after the resident was (re-)admitted to the current LTCF.
  OR
- The resident was diagnosed with COVID-19[c] and the onset of symptoms – or in the case of asymptomatic COVID-19, the first positive test was recorded within two weeks (14 days) prior to the PPS – occurred more than 48 hours (i.e. day three onwards) after the resident was (re-)admitted to the current LTCF.

Exceptions:

- When a resident presents signs/symptoms of a skin or wound infection on the day of the survey, it should be verified that these signs/symptoms of an infection are not the result of a prior surgery. Skin or wound infections occurring within 30 days after surgery without an implant or within 90 days after surgery with an implant are considered to be surgical site infections. Surgical site infections should be excluded from this study as they are hospital associated.
- *Clostridioides (Clostridium) difficile* infections should be excluded from this study if the onset of signs/symptoms happened within 28 days after a stay in another healthcare facility (e.g. hospital or other LTCF). In this situation, *C. difficile* infections are considered as acquired in another healthcare facility.

Notes:
a. Chronic symptoms, such as cough or urinary urgency, are commonly not associated with infection. Non-infectious causes should always be considered before a diagnosis of infection is made. A change in the resident's status is an important indication that an infection is in development.
b. If these signs/symptoms meet a case definition for an HAI, that HAI should be recorded on the resident form. Data collectors should investigate the signs/symptoms in the preceding two weeks, e.g. from patient records or by consulting the resident's physician, if practicable.
c. Diagnosis for COVID-19 is made on the sole confirmation of a documented laboratory test (viral RNA target or antigenic detection from an oropharyngeal or nasal swab, or any other appropriate clinical specimen), ***even in the absence of any clinical signs and symptoms****.*

4.3.3.2 Identifying the infection code using the decision algorithms (Annex 4)

Figure 11. HALT-4 infection decision algorithms (example)

Healthcare-associated infections and antimicrobial use in European long-term care facilities (HALT-4)

CASE DEFINITIONS OF INFECTIONS

IMPORTANT REMARK:

All **active healthcare-associated infections** present on the day of the survey should be reported.

An infection is active when new or acutely worse 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 onset of symptoms should occur more than 48 hours (i.e. day three onwards) after the resident was (re-)admitted to the current LTCF OR the resident was diagnosed with COVID-19 and the onset of symptoms (or first positive test, if asymptomatic) occurs more than 48 hours (i.e. day three onwards) of the current admission. The presence of symptoms and signs in the two weeks (14 days) preceding the day of the PPS should be verified in order to determine whether the treated infection matches one of the case definitions.

* **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°C over baseline from any site (oral, tympanic, axillary)

** **Leukocytosis**: 1) Neutrophilia > 14 000 leukocytes/mm³ or 2) Left shift (>6% bands or ≥ 1 500 bands/mm³)

§ **Acute change in mental status from baseline**: Acute onset + fluctuating course + inattention AND either disorganised thinking or altered level of consciousness

§§ **Acute functional decline**: New three-point increase in total ADL score (Range 0–28) from baseline based on seven ADL items (bed mobility, transfer, locomotion, dressing, toilet use, personal hygiene, eating) each scored from 0 (independent) to 4 (total dependence) OR increased dependency defined by scales other than ADL

URINARY TRACT INFECTIONS

❒ Resident without a urinary catheter

SIGNS/SYMPTOMS

*AT LEAST **ONE** 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 urgency
- ☐ New or marked increase in incontinence

❒ ③ Two or more (in the absence of fever or leukocytosis):
- ☐ Frequency (new/increased)
- ☐ Urgency (new/increased)
- ☐ Incontinence (new/increased)
- ☐ Suprapubic pain
- ☐ Gross hematuria

URINE CULTURE

❒ Not Done, negative or test results unknown
❒ Urine culture done **AND**
- ☐ At least 10^5 cfu/ml of no more than two species of microorganisms in a voided urine sample
  OR
- ☐ At least 10^2 cfu/ml of any number of organisms in a specimen collected by in-and-out catheter

❒ Resident with a urinary catheter

SIGNS/SYMPTOMS

*AT LEAST **ONE** OF THE FOLLOWING (①, ②, ③ or ④) CRITERIA:*

❒ ① Fever*, rigors, OR new onset of hypotension with NO alternate site of infection

❒ ② Acute change in mental status § OR acute functional decline §§ with NO alternate diagnosis AND leukocytosis**

❒ ③ New onset of suprapubic or costovertebral angle pain or tenderness

❒ ④ Purulent discharge around catheter or acute pain, swelling or tenderness of testes, epididymis, or prostate

URINE CULTURE

❒ Not done, negative or test results unknown
❒ Urine culture done **AND**
- ☐ At least 10^5 cfu/ml of any organism(s) in a urinary catheter specimen

INFECTION CONFIRMATION

❒ Signs/symptoms AND urine culture positive: *INFECTION **CONFIRMED** (= UTI-C)*
❒ Signs/symptoms AND urine culture not done, negative or results unknown: *INFECTION **PROBABLE** (= UTI-P)*

By comparing eligible residents' signs/symptoms with those listed in the decision algorithms (Annex 4), data collectors will see whether enough signs/symptoms are present to confirm an infection. They will subsequently enter the relevant code(s) in Part B of the resident questionnaire within infection code. Therefore, an exhaustive search for signs/symptoms present in residents is crucial.

The decision algorithms used in this survey are based on clinical criteria, i.e. US CDC/SHEA case definitions [5] which in turn are based on the McGeer criteria [6] for the surveillance of infections in LTCFs.

Only results of tests/examinations that are available on the survey date should be considered when establishing whether the case definition criteria are fulfilled. Those that are available after the day of the survey should not be considered. Although this will result in some underestimation of the true number of HAI cases, it will ensure comparability between all participating LTCFs and countries.

As European LTCFs have more limited access to microbiological and laboratory tests than institutions in Canada and the United States [7], the case definition for urinary tract infections has two levels: 'probable' and 'confirmed'.

Healthcare-associated infection codes

Infection	Level	Infection code
Urinary tract infections (UTIs) • Confirmed UTIs • Probable UTIs	Confirmed Probable	UTI-C UTI-P
COVID-19 • Asymptomatic • Mild/moderate • Severe	Confirmed Confirmed Confirmed	COV-ASY COV-MM COV-SEV
Respiratory tract infections (RTIs)[ix] • Common cold syndromes/pharyngitis • Influenza-like illness ('Flu') • Pneumonia • Other lower RTIs	Confirmed Confirmed Confirmed Confirmed	COLD-C FLU-C PNEU-C LRTI-C
Skin infections[x] • Cellulitis/soft tissue/wound infection • Scabies • Herpes simplex or zoster infection • Fungal infections	Confirmed Confirmed Confirmed Confirmed	SKIN-C SCAB-C HERP-C FUNG-C
Gastrointestinal tract infections • Gastroenteritis • *Clostridioides* (*Clostridium*) *difficile* infection	Confirmed Confirmed	GE-C CDI-C
Eye, ear, nose and mouth infections • Conjunctivitis • Ear infections • Sinusitis • Mouth infection or oral candidiasis	Confirmed Confirmed Confirmed Confirmed	CONJ-C EAR-C SINU-C ORAL-C
Bloodstream infections	Confirmed	BSI-C
Unexplained febrile episode	Confirmed	FUO-C
Other infection(s)		OTHER

[ix] Other than COVID-19.

[x] Surgical site infections should be excluded from this study if the onset of signs/symptoms took place within 30 days after surgery without an implant or within three months (90 days) in case of surgery involving an implant.

Definitions of key terms used in the decision algorithms (Annex 4)

Key terms	Description/definition
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°C over baseline from any site (oral, tympanic, axillary) * tympanic membrane: membrane that separates the external ear from the middle ear
Leukocytosis	1. Neutrophilia > 14 000 leukocytes/mm^3 OR 2. Left shift (>6% bands or ≥ 1 500 bands/mm^3)
Acute change in mental status from baseline	Acute onset + fluctuating course + inattention AND either disorganised thinking or altered level of consciousness
Acute functional decline	New three-point increase in total ADL score (Range 0–28) from baseline based on seven ADL items (bed mobility, transfer, locomotion, dressing, toilet use, personal hygiene, eating) each scored from 0 (independent) to 4 (total dependence) OR increased dependency defined by scales other than ADL
Urinary tract infection	Can be an infection of the kidney, ureter, bladder or urethra
Costovertebral angle pain	Pain in the area of the back overlying the kidney (between the 12th rib and the spine)
Suprapubic pain/tenderness	Pain or tenderness in the area above the pubis
Respiratory tract infection	Can be an infection of the upper or lower respiratory tract
Upper respiratory tract infection	Infection of the (naso-)pharynx: nasopharyngitis or tonsils (tonsillitis)
Lower respiratory tract infection	Infection of the trachea and bronchus (bronchitis), bronchiole (bronchiolitis) or lung and alveoli (pneumonia)
Lymphadenopathy	Disease of the lymph nodes (swollen or enlarged)
Infiltrate	Deposition of fluid (e.g. blood, pus, etc.) in tissues and cells
Sputum	Secretion expectorated from the lower respiratory tract (not to be confused with saliva)
Pleuritic chest pain	Pain in the chest during inhalation which can cause fast and superficial breathing to decrease the pain
Thoracic imaging	Imaging modalities for chest diseases including chest X-ray, computed tomography (CT) and nuclear medicine, including ventilation-perfusion lung scanning and positron emission tomography (PET), and ultrasound.
COVID-19	SARS-CoV-2 infection
Oxygen therapy	Use of oxygen as medical treatment, most commonly through a mask or nasal cannula.
Oxygen saturation	Blood oxygen saturation is commonly measured from the fingertip with pulse oximetry. Normal blood oxygen saturation levels for older adults are approximately 95% or above.
Skin infections	
Cellulitis	Infection of the connective tissue
Soft tissues	Tissues that connect, support or surround other structures or organs (muscles, tendons, ligaments, nerves, blood vessels, fat, fibrous tissues, fascia and membranes)
Maculopapular rash	Rash characterised by spots and bumps
Herpes simplex	Disease caused by a virus leading to a rash (often around the lips and nose) with groups of blisters containing fluid which soon dry out
Herpes zoster	Disease caused by a virus; mostly painful blister-shaped rash in areas where many sensory nerves are present (e.g. face, chest, shoulders and hip)
Scabies	Contagious and heavy itching disease of the skin caused by a mite
Gastrointestinal infection	Infection of the stomach and/or intestines
Clostridioides (*Clostridium*) *difficile* (CD)	*C. difficile* (gram-positive sporulating bacilli); can cause persistent diarrhoea and ulcero-haemorrhagic colitis
Toxic megacolon	Life-threatening complication that causes widening (dilation) of the large intestine and symptoms such as abdominal pain, distension, tenderness, fever, rapid heart rate and can even lead to shock
Pseudomembranous colitis	A condition of antibiotic-associated diarrhoea (often caused by *C. difficile*) characterised by abdominal cramps, bloody stools, fever and diarrhoea
Eye infection	
Conjunctival erythema	Redness of the conjunctiva (mucous membrane lining the eyelid)

4.3.4 Isolated microorganisms and antimicrobial resistance (see Annex 5)

Data on the isolated microorganisms and antimicrobial resistance are collected in 'Part B – Healthcare-associated infections' of the resident questionnaire (See Figure 10). It is recognised that there is a low frequency of laboratory testing of clinical samples from LTCFs in Europe, and that there are differences between the antimicrobial susceptibility testing protocols used by those laboratories.

Collect microbiological results available on the survey date (do not wait for results that are unavailable on the survey date). Specify up to three isolated microorganisms, using the microorganism code list (see Annex 5). If no microbiological result is available on the day of the PPS, one of the following options should be selected:

_NOEXA	EXAMINATION NOT DONE	No diagnostic sample taken, no microbiological examination done.
_NA	RESULTS NOT AVAILABLE	The results of the microbiological examination are not (yet) available or cannot be found.
_NONID	MICROORGANISM NOT IDENTIFIED	Evidence exists that a microbiological examination has been done, but the microorganism cannot be correctly classified.
_STERI	STERILE EXAMINATION	A microbiological examination has been done, but the result was negative (e.g. negative culture).

Five groups of selected bacteria (highlighted in red in the microorganism code list in Annex 5) should have their antimicrobial resistance reported according to their resistance profiles, as indicated in the table below.

Table 3. Antimicrobial resistance codes and profiles

Microorganism	Tested antibiotic[1]	Antimicrobial resistance			
Staphylococcus aureus (STAAUR)	Oxacillin (OXA)	Susceptible, standard dosing regimen (S)	–	Resistant (R)	Unknown (U)
	Glycopeptides (GLY)	Susceptible, standard dosing regimen (S)	Susceptible, increased exposure (I)	Resistant (R)	Unknown (U)
Enterococcus* species** (ENC)	Glycopeptides (GLY)	Susceptible, standard dosing regimen (S)	Susceptible, increased exposure (I)	Resistant (R)	Unknown (U)
Enterobacterales[2], including: *Escherichia coli (ESCCOL)* *Klebsiella* species (KLE***) *Enterobacter* species (ENB***) *Proteus* species (PRT***) *Citrobacter* species (CIT***) *Serratia* species (SER***) *Morganella* species (MOGSPP)	Third-generation cephalosporins (C3G)	Susceptible, standard dosing regimen (S)	Susceptible, increased exposure (I)	Resistant (R)	Unknown (U)
	Carbapenems (CAR)	Susceptible, standard dosing regimen (S)	Susceptible, increased exposure (I)	Resistant (R)	Unknown (U)
Pseudomonas aeruginosa (PSEAER)	Carbapenems (CAR)	Susceptible, standard dosing regimen (S)	Susceptible, increased exposure (I)	Resistant (R)	Unknown (U)
Acinetobacter baumannii (ACIBAU)	Carbapenems (CAR)	Susceptible, standard dosing regimen (S)	Susceptible, increased exposure (I)	Resistant (R)	Unknown (U)

[1] OXA: susceptibility to oxacillin, or other marker of MRSA, such as cefoxitin, cloxacillin, dicloxacillin, flucloxacillin, meticillin;
GLY: susceptibility to glycopeptides: vancomycin or teicoplanin;
C3G: susceptibility to third-generation cephalosporins: cefotaxime, ceftriaxone, ceftazidime;
CAR: susceptibility to carbapenems: imipenem, meropenem, doripenem.
[2] Antimicrobial resistance markers are not collected for other Enterobacterales (e.g. Hafnia spp., Salmonella spp., Shigella spp., Yersinia spp.).

5 Data delivery

5.1 Software

A stand-alone software programme, 'HelicsWin.Net' developed for the HALT-4 project may be used for data entry at the local (LTCF application) or national (NSC application) levels. National survey coordinators (NSCs) are encouraged to offer this software to LTCFs so they can enter their data into the software. A user guide (provided with the application) assists the local data collector or person designated in the LTCF during software installation and data entry.

All data are stored on the local computer rather than a central database. Therefore, the data needs to be exported. By clicking on this function in the menu, an MDB (Microsoft Access database) file will be created that can be sent to the NSC.

NSCs either merge all MDB files received from their participating LTCFs into the software, or enter the data into the application themselves. NSCs can use their application to check for errors. If needed, changes should be made using the software (rather than directly on the database file). Once all the data is checked, NSCs should create a national database using the software's export function – preferably a set of CSV (comma-separated values) files compatible with the European Surveillance System (TESSy.

The software can be translated into a language other than English. To achieve this, NSCs should contact ECDC at HAI-Net@ecdc.europa.eu and arrange the translation.

ECDC can be contacted at HAI-Net@ecdc.europa.eu regarding any problems encountered during the use of the software.

5.2 Deadline for data delivery

The national databases should, in each country, be sent to the country institution designated by the country's Coordinating Competent Body. These institutions are then requested to upload the data to TESSy at ECDC, according to the same methodology used for other communicable diseases and related special health issues within Decision 1082/2013/EU[xi]. The deadlines for data submission will be communicated to participating NSCs by ECDC.

5.3 Data analysis and feedback

The European database, containing data from all national databases, will be checked for errors and inconsistencies by ECDC. Individual feedback reports (in English) will be generated for each participating LTCF and sent to the NSC for further distribution (e.g. to each participating LTCF). ECDC can be contacted at HAI-Net@ecdc.europa.eu to request translated LTCF feedback reports, which will require the NSC to arrange a translation of the text in an Excel file.

A European report will be prepared using aggregated results, sent to the NSCs from each participating country for verification, and subsequently published on the ECDC website.

5.4 Data ownership

NSCs are encouraged to publish their data in international peer-reviewed journals and/or present their results at international conferences. The work done by the NSCs and the LTCFs should be acknowledged, e.g. by adding 'on behalf of the national networks' to the author list and/or by thanking all the NSCs by name in the acknowledgements section. ECDC should be acknowledged in all scientific publications (including posters and oral communications).

All analyses and outputs, including data other than their own country's data, should be performed in consultation and in agreement with ECDC. All scientific outputs should be communicated to ECDC in advance of publication; these may be referenced on the ECDC website, and/or in other public outputs.

[xi] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC Text with EEA relevance.

6 Training

Train-the-trainer sessions will be organised, and ECDC will provide training material for the local/external data collectors. It is recommended that national/regional survey coordinators organise at least a one-day information and training session for the LTCFs participating in the PPS, prior to the national/regional survey.

7 Role of the national survey coordinator

National survey coordinators (NSCs) are crucial determinants of the success of repeated PPSs.

Tasks to be undertaken by NSCs before the PPS data collection include the following:

- Select and invite LTCFs to participate.
- Make a list of all the participating LTCFs and group them by types of LTCF.
- Participate in the train-the-trainer workshop.
- Organise at least a one-day information and training session for LTCFs participating in the PPS.
- Distribute the data collection tools (e.g. HALT software).
- Assist LTCFs during the data collection process (helpdesk).
- Translate PPS data collection tools and letters into national languages (if required).

Tasks to be done by NSCs after the PPS data collection include the following:

- Collect and enter local LTCF data and check the national database.
- Export the national database and submit the data to ECDC. ECDC will convert the HALT data to the HAI-HALT and TESSy format. Data will be pre-uploaded in TESSy by ECDC, and EU/EEA countries will receive the converted national data in the TESSy format from ECDC to identify any necessary data updates/replacement.
- Distribute the feedback forms to the participating LTCFs; translation of these is possible if the national representative provides a translated Excel file.
- Communicate national results, e.g. at (inter)national scientific meetings.

8 Ethical considerations

Countries will have different requirements for the ethical approval of a PPS in LTCFs. The experience from the previous projects, HALT (2010), HALT-2 (2013) and HALT-3 (2016–2017) is that some countries required approval from an ethics committee. Some of the committees requested that written consent be obtained from each resident with an active HAI or receiving a systemic antimicrobial agent on the day of the PPS. If this was not possible (e.g. in case of cognitive impairment), consent had to be obtained from a 'proxy' such as a carer or a medical professional. Data collectors in these countries found that it was relatively feasible to acquire the signatures, by simply explaining the necessity of the PPS to the resident or their 'proxy', which sufficed.

Confidentiality of the LTCF 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 the names of LTCFs. ECDC will not be sent any key to the names of LTCFs linked to the LTCF survey number.
- 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 ward list (optional, for internal use) for the primary HALT-4 PPS protocol includes resident identifiers. This information must be kept in the LTCF in a secure and confidential manner, and should be destroyed at the end of the HALT-4 project, i.e. September 2024.

Data collected within the framework of the HALT-4 project should not be used for purposes other than those described in the objectives of the present protocol.

9 Contact information

For questions related to the use of this protocol, please contact the HALT-4 Management Team (HALT@sciensano.be) and/or the ECDC HAI-Net team (HAI-Net@ecdc.europa.eu).

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European Centre for Disease Prevention and Control (ECDC)

Gustav III:s Boulevard 40, 16973 Solna, Sweden

Tel. +46 858601000
Fax +46 858601001
www.ecdc.europa.eu

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