



HALT Project

European Point Prevalence Survey of Healthcare Associated Infections and Antibiotic use in Long-Term Care Facilities

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LIST OF ABBREVIATIONS

AB	Antibiotic/Antimicrobial therapy
ADB	Advisory board
ASSR	Agenzia Sanitaria e Sociale Regionale
AMR	Antimicrobial resistance/resistant organisms
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EFTA	European Free Trade Association
ESAC	European Surveillance of Antimicrobial Consumption
EU	European Union
GP	General Practitioner
HALT	Healthcare Associated infections in Long-Term care facilities
HCAI	Healthcare associated infections
HPA	Health Protection Agency
IC	Infection Control
IT	Information Technology
IPH	Institute of Public Health Brussels
IPSE	Improving Patient Safety in Europe
LTC	Long-Term Care
LTCF	Long-Term Care Facilities
LRTI	Lower Respiratory Tract Infections
MRSA	Methicillin Resistant <i>Staphylococcus aureus</i>
MT	Management Team
NH	Nursing Home
NN	National Network
NR	National Representative
OCR	Optical Character Recognition
rPPS	Repeated Point Prevalence Survey
RTI	Respiratory Tract Infection
UCBL	Université Claude Bernard Lyon 1
UTI	Urinary Tract Infection
WA	Work area
WHO	World Health Organisation
WP	Work Package

1 INTRODUCTION

In 2008 ECDC (European Centre for Disease Prevention and Control) funded the HALT (Healthcare Associated infections in Long-Term care facilities) project with the aim of supporting the control of Healthcare Associated Infection (HCAI), Antimicrobial Resistant organisms (AMR), AB-use and to process indicators for infection control (IC) practices in LTCFs in Europe.

The HALT Project is partially based on former work achieved by the IPSE-NH (WP7) and ESAC-NH-project and combines the experience and methodologies of these two complementary European projects.

The project 'Improving Patient Safety in Europe (IPSE, 2006-2008, Co-ordinator WP7: Maria Luisa Moro, Italy) carried out a feasibility study looking at the availability of necessary data for HCAI surveys in the different EU LTCF settings. This project highlighted that, despite increasing evidence in the scientific literature, LTCF comprised a sadly neglected frontier for IC with very few EU countries having given sufficient attention to the issue of LTCF HCAI. Resources available for infection control were often sparse and there was little experience of national infection surveillance systems.

Facing the lack of data on antimicrobial use in LTCF, the ESAC-3 Nursing-Home subproject (2008-2010, NH-sub-project, co-ordinated by Béatrice Jans, Belgium) worked out a methodology for the measurement of the prevalence and the characteristics of antibiotic prescriptions in European High skilled Nursing Homes. In order to better understand the global background of these facilities in the different participating countries, a national survey was organised in September 2008, collecting information about institutional characteristics, medical- and nursing care organisation, infection prevention and control structures, antibiotic policy and available infrastructure for installing survey systems in these facilities. In April and in November 2009 two consecutive point prevalence surveys took place and investigated AB-prescriptions, their indications and determinants of AB-use both at resident level (indications for treatment, underlying conditions, etc.) and at an institutional level (AB and IC policies, medical- and nursing care plans, etc.).

The results of this project will be reported to local, regional and national policy makers and ECDC and the methods and tools will be transferred to ECDC for a sustainable implementation as a European programme.

2 AIMS OF THE HALT PROJECT

The overall aim of the project is to support the control of HCAI, AB use and AMR by implementing a EU wide network of networks in LTCF in the 27 European Member States, 3 EEA/EFTA and 3 candidate countries (Croatia, former Yugoslavian Republic of Macedonia and Turkey) for collecting repeated point prevalence studies (rPPS) data of HCAI and current IC practices/resources in a well defined group of LTCF by means of a standardised sustainable methodology partially based on former work achieved by the IPSE-NH (Work Area WP7) and ESAC-NH-project.

The obtained data will be useful to:

- Quantify the prevalence of infections and AB use in institutions, countries and European regions;
- Follow trends;
- Identify needs for intervention, training and/or additional IC resources;
- Design policies to cope in a timely way with HCAI problems which might arise in LTCF or have impact on other closely or more remotely related health care sectors; and
- Foster the safety of health care for residents in LTCF and indeed the ageing population in general. The results will be reported to local, regional and national policy makers and ECDC.

More specifically, the HALT project will:

- Develop a comprehensive European network of networks
- Promote a European rPPS designed to study:
 - The prevalence of HCAI and antimicrobial use in European LTCF
 - The related IC process and structure indicators in the same group of LTCF
- To develop and implement a sustainable methodology to estimate the prevalence of HCAI and AB-use in LTCF in Europe

3 ORGANISATION OF THE PROJECT

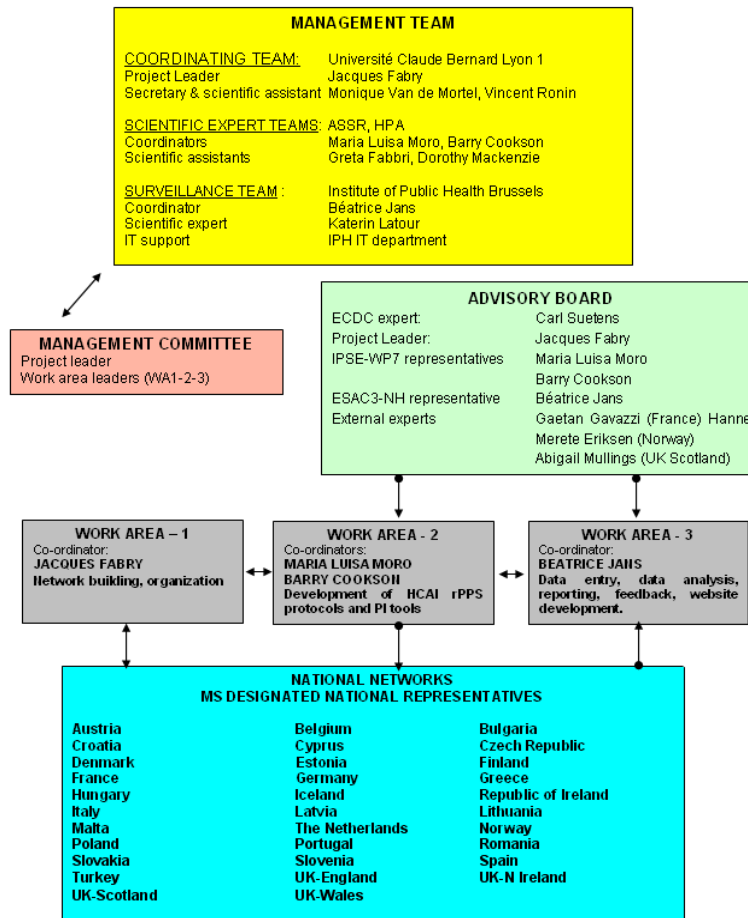


Figure 1: organization of the project

3.1 The HALT Management team

A consortium of four institutions (UCBL, ASSR, HPA and IPH) will provide the project staff to compose the HALT management team (MT) as well as the necessary infrastructure and functional support.

- The project will be administered by the central co-ordinating team who will be also the project leader.

It is composed of:

Project leader:	Jacques Fabry, [Lyon, UCBL]
Secretary:	Monique Van de Mortel
Scientific assistant:	Vincent Ronin

- Two scientific expert teams that will develop the protocol and methodology for the rPPS of HCAI and AB-use in LTCF (ASSR team) and for the monitoring of indicators on AMR, infection control process and structure indicators (HPA team) relevant for use at the level of the LTCF itself and at a national or regional level. The

ASSR and HPA team will jointly work out methods for the data collection taking into account work previously done by IPSE and ESAC, in collaboration with the advisory board and ECDC. This activity comprises the development of the protocol and its revision in function of the pre-test experience.

They are composed of:

Expert team 1: protocol and methodology for the rPPS of HCAI and related variables and indicators.

Co-ordinator: Maria Luisa Moro [Bologna, ASSR]

Expert team 2: protocol and methodology for monitoring structures and practices for controlling infections.

Co-ordinator: Barry Cookson [London, HPA]

Scientific assistant: Dorothy Mackenzie

- The rPPS team will implement the data collection, analyse epidemiologically the data and assure feedback to participants during both the pre-test and the EU wide phase of the project. This team also supervises, in co-ordination with ECDC, the IT department of the IPH which will be responsible for designing the database, managing the data, developing the website and project related IT tools and transferring the developed IT solutions to ECDC.

Epidemiological activities:

Co-ordinator: Béatrice Jans [Brussels, IPH]

Scientific assistant: Katrien Latour

3.2 The advisory board

The advisory board is composed of the four HALT team leaders, a HCAI/AMR surveillance expert of the ECDC (Carl Suetens) and five national experts (to be designated by WA-1, for the duration of 2 years):

- Gaetan Gavazzi Clinique de Médecine Gériatrique, France
- Hanne Merete Eriksen Institute of Public Health Department, Norway
- Abigail Mullings Health Protection Scotland, UK Scotland
- Constanze Wendt Hygiene Institut, Germany
- Rolanda Valinteliene Institute of Hygiene, Lithuania

3.3 The national representatives (NR) of the national surveillance networks (NN)

The national representatives (NR) of the national rPPS networks (NN) (one per participating EU MS, EEA/EFTA and candidate countries) will be nominated by the Competent Bodies of surveillance. They will represent their national or regional coordinating centre in charge of surveillance of HCAI in LTCF where these exist and/or be key experts or professionals in this area able to facilitate the set up of a national/regional network for HCAI surveillance and monitoring in LTCF in their country.

Their main responsibilities will be the organisation of data collection in LTCF in their country, according to the proposed rPPS protocol and tools, the transmission of data to the WA 3 coordinator and to act as the liaison person between the project and their competent body for surveillance.

4 STUDY DESIGN

The study has been designed as a point prevalence survey. Data will be collected on all active HCAs and on currently prescribed systemic antibiotics present on the day of the survey.

4.1 Time schedule for the rPPS

Two consecutive PPS are organized in the participating facilities.

The Pilot PPS was performed in November 2009 (between 1/11/2009 and 30/11/2009) in a limited number of nursing homes.

In May 2010 (between 1/05/2010 and 31/05/2010) a European PPS in a wide range of long-term care facilities in European countries will be held.

Data are preferably collected during one single day, depending on the total number of beds in the facility and taking into account the extra workload that the PPS will cause. It is recommended to involve extra staff during this period. In large settings data collection can be spread over two or more consecutive days during the PPS period. It is important that all beds in the ward are surveyed during one single day (closing data collection for the ward during the same day).

4.2 Study population

4.2.1 Countries

All the countries among the 27 European Member States, 3 EEA/EFTA and 3 candidate countries (Croatia, former Yugoslavian Republic of Macedonia and Turkey) will be invited to participate in the European HALT point prevalence survey of May 2010.

4.2.2 Eligibility criteria for Long-Term Care Facilities (LTCF)

Many different types of Long-Term Care Facilities exist in European countries. The following inclusion criteria will be applied:

Institutions where elderly are staying temporary (long or short) or permanently.

The **residents** in these institutions:

- Need constant supervision (24/24h),
- Need 'high-skilled nursing care' = more than 'basic' nursing care and ADL-assistance (= Activities of daily living),
- Are medically stable and don't need constant 'specialised medical care' (= care administered by specialised physicians),
- Don't need invasive medical procedures¹ (ex. ventilation) .

In these institutions

- Mostly, registered nursing staff is present 24/24h,
- Different types of residents are treated in the facility, even if some of the wards could be more specialised e.g. in dementia care or in revalidation.

¹ **Invasive medical procedures:** In this project, ambulatory treatments (e.g. haemodialysis, peritoneal dialysis and chemotherapy) are not considered to be invasive medical procedures.

Exclusion criteria:

- Hospital Long-Term Care wards
- Residential care (hotel), sheltered care houses, day centers, home-based centers, resident flat, protected living.

Even with specific inclusion and exclusion criteria, the characteristics of the facilities will probably be different in the participating EU countries. Therefore characteristics (e.g. turn over rate) and aggregated resident characteristics (e.g. total number of residents with wounds, catheter, etc on the PPS day) for the whole LTCF population will be collected on institutional level using an institutional questionnaire. Afterwards, this information will allow categorization of LTCFs and its residents.

4.2.3 Eligible residents

All residents living 24h/24h in the institution should be included in the survey unless they refuse to participate or are absent the day of the survey. Each resident present at 8 AM in the selected LTCF on the day of the PPS and at least resident for > 24 hours is eligible for inclusion in the study. Newly admitted residents on the PPS day are excluded, because their medical history is often not well known and important data could sometimes not be available the day after admission (they are admitted, but the GP has to visit the resident and install treatment, this is not always done on the first day of stay).

Residents receiving chronic ambulatory care on regular basis in the acute care hospital (e.g. haemodialysis, chemotherapy, etc.) are included in the PPS study as long as they are not hospitalized (= inpatient in an acute care hospital with hospital stay for at least 24 h.) on the day of the PPS and during the previous 24h.

4.3 Participation options for the PPS

Countries can participate by collecting PPS data in facilities spread all over the country (national data) or limit data collection to settings from one country region (regional data).

For the May 2010 PPS each country will try to participate with a large number of LTCFs. The characteristics of LTCFs existing in European countries will be explored.

4.4 Type of surveyor

Data can be collected, depending on the resources available, by local surveyors (designated physician, infection control doctor/nurse, head nurse, of the LTCF) or local surveyors supported by an external surveyor (infection control nurse of the Local Health Authority).

Both local and external trained surveyor will visit the facility the day of the survey and review each resident with the nurse in charge, nurses' aide and healthcare workers of the LTCF, looking for recent symptoms suggestive of infection, examining charts, case notes and drug charts. Possible infected patients will be reviewed and if possible discussed with the attending physician.

This methodology is required to ensure that all patients with signs and/or symptoms of infection are identified and included in the surveillance. Ward staff should be fully aware of which residents present symptoms, making use of the list of signs and symptoms included in the Resident Questionnaire. The survey could be conducted in one of the days in the defined week the attending medical doctor or the attending general practitioners is/are visiting the institution. Written instructions and a PowerPoint presentation will be developed and used for training of the identified surveyors before the survey.

Type of surveyor for PPS- data collection:

Local surveyor:

Works in the participating LTCF, will perform the survey in the own institution

e.g. a general practitioner, coordinating/ designated physician, trained head-nurse, IC nurse/doctor

External surveyor:

Recruited by national representative, will perform survey in the participating LTCFs

Familiar with medicines, treatment sheets and resident data

e.g. a medical doctor or a nurse (professional confidentiality)

5 METHODOLOGY

The project contains 2 components:

Component 1: A national questionnaire per participating country

Component 2: An institutional questionnaire per participating LTCF and one resident questionnaire for each resident using antibiotics and/or presenting signs and symptoms of infection on the PPS day.

5.1 Component 1: National survey on characteristics & regulating mechanisms for AB use and Infection Control in EU LTCF

The aims of this component are to collect national information on:

- The availability of national programs such as a national HCAI prevention and control program or national Antimicrobial Resistance/Stewardship (ASt) Program;
- Guidelines for infection control (IC) and antimicrobial Stewardship specific for or including LTCF;
- The availability of expert advice on IC or antibiotic treatment;
- Structural resources for infection prevention and control;
- The availability of national/regional programs for surveillance of HCAs, AB usage and AMR
- The availability of national program indicators such as clinical training programs, designated reference laboratories, research and development programs and campaigns on hand hygiene or antimicrobial stewardship.

5.2 Component 2: Data collection on infections, antibiotic use and antibiotic resistance in high-skilled EU LTCFs

A European *point prevalence surveys* (PPS) will be organized measuring the prevalence of HCAs and AB use among residents in participating EU high-skilled LTCFs.

5.2.1 Facility and patient case mix description

Facilities have different experiences with infections and different approaches to infection control depending on the resident case-mix and institution profile which need to be described for the full spectrum of LTCFs participating to HALT project.

In addition, appropriate adjustments for case-mix will be critical to compare infection rates in different type of facilities, nationally and at European level.

A collection of tools, developed by ESAC3-NH subproject and modified by HALT are available to describe residents, to collect data on infection, antibiotic consumption and microorganism resistance, and to describe institutional profile and process indicators:

- On institutional level:
 - o General data (ownership, turn-over rate, qualified nurse-presence)

- Denominator data: total number of available and occupied beds, of hospitalised patients, of residents with signs/symptoms of infection, of AB-users, residents with urinary-catheter, vascular-catheter, incontinent, pressure sores, wounds, disoriented, impaired mobility
 - Specific questions on medical care coordination, infection control structure, antibiotic policy.
- On resident level (for each infected resident or resident receiving AB treatment only):
- Antimicrobials data (name, date of treatment start, daily dosage, administration route, indications, sample taken, microorganism isolated, prescribed by whom)
 - Signs and symptoms of infection
 - Seven case-mix factors (urinary-catheter, vascular-catheter, pressure sores, wounds, incontinent, disoriented, impaired mobility) as resident profile
 - General data (birth year, sex, admission-date, previous admission to hospital)

5.2.2 Infection data

In LTCFs, the first line of infection detection more often than not is a nurses' aide, who must determine that there is a problem with the resident and then promptly reports it to the charge nurse. Moreover, physician visits are infrequent, and on-site diagnostic testing is uncommon. For the above reasons, diagnosis of infection in nursing homes needs to be based mainly on clinical ground.

It has been decided to identify infections through checklists of signs and symptom by signs and symptoms rather than simply record the occurrence of an infection. This checklist may be completed by the surveyor, in collaboration with a nurse and nurses' aide, as a screening tool to identify possible infected residents to be discussed with the attending physicians.

HALT collects information on the occurrence of all healthcare-associated infections, according to the following infection sites:

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. Respiratory tract infection <ul style="list-style-type: none"> Common cold syndromes/pharyngitis Influenza-like illness Pneumonia Other lower respiratory tract infection 2. Urinary tract infection 3. Skin infection <ul style="list-style-type: none"> Wound/soft tissue infection Fungal infection Herpes infection Scabies 4. Gastrointestinal tract infection | <ol style="list-style-type: none"> 5. Eye, Ear, Nose and Mouth infection <ul style="list-style-type: none"> Conjunctivitis Ear infection Mouth and perioral infection Sinusitis 6. Systemic infection 7. Unexplained febrile episode 8. Other |
|---|--|

This infection list is based on definitions developed by McGeer¹, which have been widely used for the surveillance of infection in nursing home. Published in 1991, these criteria were developed by infectious disease experts for purposes of surveillance and outcome assessment in nursing homes.

Three important conditions apply to all of the definitions:

1. All symptoms must be new or acutely worse. Many residents have chronic symptoms, such as cough or urinary urgency that are not associated with infection. However, a change in the resident's status is an important indication that an infection may be developing.
2. Non-infectious causes of signs and symptoms should always be considered before a diagnosis of infection is made.
3. Identification of infection should not be based on a single piece of evidence. Microbiological and radiological findings should be used only to confirm clinical evidence of infection. Similarly, physician diagnosis should be accompanied by compatible signs and symptoms of infection.

Diagnosis of infection in the LTCF is not a clear-cut matter and infection surveillance based on the McGeer criteria may therefore underestimate the infection rate. In order to evaluate the proportion of residents who do not meet all McGeer criteria for infections, but are nevertheless considered to be infected by the attending physician, an additional criterion ("diagnosed by the attending physician") has been added.

Afterwards, based on selected symptoms and signs from the checklist, a decision algorithm will be used during data analysis to identify "confirmed" infected residents according to McGeer (*cf. Appendix 1*) and "probable" infected residents if McGeer criteria have not been fully met.

To define "NH/LTCF-acquired" infections, McGeer criteria consider only infections not already present or in incubation at the time of admission or readmission (after hospitalization or community visit) to the nursing home. Sometimes, for residents who develop signs and symptoms having been admitted or readmitted to the facility recently (within the last few days) it could be difficult to judge if the infection has been acquired or not before admission. In these cases, the decision should rely on the type of infection and the expected incubation period.

5.2.3 Antibiotic consumption

Using the ESAC-NH3 data collection questionnaire frequency and characteristics of antimicrobial consumption in LTCFs will be monitored.

An "Antibiotic using resident" is each resident present on the day of the PPS who has been resident for > 24 hours and receiving an antibiotic for systemic use on the PPS day.

In this study we include:

¹McGeer A, Campbell B, Emori TG, et al. (1991) Definitions of infection for surveillance in long-term care facilities. *Am J Infect Control.* **19** :1-7

- all oral, rectal, intramuscular (IM) and intravenous (IV) treatment with:
 - antibacterials for systemic use (ATC-class J01 but also vancomycin for intestinal use ATC A07AA09)
 - antimycotics for systemic use (ATC-class J02 and also nitroimidazole derivates, e.g. metronidazole, from the ATC-class P01AB).
 - drugs for systemic treatment of tuberculosis (antimycobacterials) (ATC-class J04)
- antibiotic treatment by inhalation (aerosol therapy)
- topical (local) use of mupirocin (nasal ointment) for MRSA decolonization (ATC code R01AX06, but in some countries there seems to be only dermatological mupirocin, ATC code D06AX09)

In this study we exclude:

- antivirals for systemic use (ATC-class J05)
- antimicrobials for topical use (other than mupirocin)
- antiseptics

Only antibiotics for oral, rectal, intramuscular or intravenous administration are registered.

Among topical antibiotics, only the nasal application of mupirocin for decontamination of MRSA-carriers is registered.

We include also the antibiotic use by inhalation (aerosol therapy) because this type of antimicrobial consumption could be relatively important in these chronic care facilities.

5.2.4 Antimicrobial resistance (optional)

Recording antimicrobial resistance data in LTCFs is hampered by the low frequency of laboratory testing and by differences in antimicrobial susceptibility testing across Europe. Nevertheless, it has been decided to collect antimicrobial resistance data in the Resident Questionnaire.

Data recording on antimicrobial resistance is optional, but if completed for one resident, must be completed for all AB-using residents

<i>Acinetobacter baumannii</i>	- Amikacin and/or Carbapenem Resistant
<i>Enterococcus</i>	- Vancomycin Resistant
<i>Escherichia coli</i>	- 3rd-Generation Cephalosporin Resistant
<i>Klebsiella pneumoniae</i>	- 3rd-Generation Cephalosporin Resistant
<i>Proteus mirabilis</i>	- 3rd-Generation Cephalosporin Resistant
<i>Pseudomonas aeruginosa</i>	- Amikacin and/or Carbapenem Resistant
<i>Staphylococcus aureus</i>	- Methicillin resistant

6 DATA COLLECTION: TOOLS AND VARIABLES

6.1 Questionnaires

For the PPS data collection 3 forms will be used:

- **The Ward List** On the PPS day, the surveyor completes for each ward a WARD LIST. It is a form describing the ward type and summarising denominator data collected on the day of the PPS. This list is for internal use only and is not mandatory but created in order to make the denominator data collection easier. When completed for each ward, the surveyor has already collected denominator data required for the institutional questionnaire. He just has to add up the denominators from each ward and to fill in the totals in the institutional questionnaire.

- **The Resident Questionnaire** This questionnaire has to be filled in only for residents with signs/symptoms of an infection and/or using an antibiotic on the day of the survey.

- **The Institutional Questionnaire** Each participating LTCF has to complete the institutional questionnaire. Response to this questionnaire is essential for the study since this document is collecting important structural & functional characteristics, denominator data and information about AB policy and infection control resources in the participating LTCFs.

6.2 Data entry options

During the first European HALT PPS (May 2010) a software program, developed by the HALT IT-team, will be used to enter data at local level. The surveyor or a person designated in the LTCF will enter the data in the software. When data collection for the LTCF is complete, data will be exported to the National Representative who will check and clean the data and generate an automatic feedback report for each participating LTCF, before exporting the national data to the IPH, where data will be added to the European HALT database. A detailed user guide will be provided and National Representatives will have the opportunity to attend a HALT software workshop during the HALT mid-term meeting on the 31st of March 2010.

6.3 Data analysis and feedback

The national representative from each country will generate (using the national IT software module) an automatic feedback report and address this report to the participating LTCFs after the first European HALT PPS. A study report with the aggregated results for all participating LTCFs in the project will be developed by the IPH and send to the National Representative from each country. An electronic version will be available on the HALT web site which will be hosted on the ECDC web site.

6.4 Role of the national representative

The role of the national representative is very important and is a determinant for the success of this innovating project.

Before the PPS data collection, his/her role is to:

- Translate PPS data collection tools and letters in local language
- Make a list of all LTCFs with number of beds and type of LTCF
- Select LTCFs which want to participate on voluntary basis
- Organize information and training of participating LTCFs
- Distribute the data collection tools (e.g. HALT software).
- Send reminder to participating LTCFs approximately 1 month before each PPS
- Assist LTCFs during data collection (helpdesk)

After the PPS data collection:

- Collect and clean the data base of their country
- Generate an automatic feedback rapport with the HALT software and send it to all the participating LTCFs
- Export of the national data base to IPH, Brussels
- Distribution of the national feedback (produced by the IPH) to participating LTCF
- Communication of national results, e.g. at national scientific meetings
- Participate in intermediate meetings to discuss study results
- Discuss the final results at the final HALT Annual Meeting

6.5 Ethical considerations

The ethical requirements are different depending on the countries. HALT will provide a standard letter for local ethical committees.

The study is not an experiment, but study of medical/nursing records in order to collect data on antibiotic use and the occurrence of signs/symptoms of infections in long-term care facilities. No medical examinations or manipulations will be applied.

Depending on local legislation, ethical committees could require a written consent at least those residents for whom a resident questionnaire needs to be completed (each resident with signs/symptoms of infection or using an AB on the day of the study). If the resident is cognitively impaired, consent of his proxy (family, GP or friend) should be acquired. Participation to this project can be refused. In that case, their data will be excluded for the survey.

The HALT management team will provide a standardized letter informing residents and participating LTCFs about the aims of the project to the NR of participating countries (for local use).

In the institutional questionnaire only aggregated risk factors should be recorded for the total population of the LTCF (number of residents with a urinary/vascular catheter, with wounds, incontinence, disorientation or impaired mobility). No names or individual resident characteristics are asked. To help the investigators with

calculating these aggregated data, a ward list was designed. This (optional) document which contains a name box, is for internal use only and should be kept in a secure and secret place in the LTCF and destroyed at the end of the project.

To secure confidentiality in this project, study numbers will be used:

- a LTCF study number will be attributed by the HALT Management team to each participating LTCF in the country. The participating facilities will not be identifiable by others since reports and presentations of results will only use LTCF study numbers, never institution names.
- the resident questionnaire is anonymous: a unique resident study number will be used instead of the resident name. This study number will be allotted by the local or external surveyor. This information will not be transmitted the HALT Management Team.

The collected data should be entered in the HALT software, which allows export of the data via e-mail or by the use of a USB stick or CD. This data base will only contain the study numbers.

Facilities only have access to their own data. Exchange of data between institutions is only possible after written and mutual consent.

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

6.6 Estimation of the workload for local surveyors / study coordinators

Information sessions are to be organized for the staff and if required by national regulations, written consent forms have to be completed for residents with signs/symptoms of an infection or AB-using residents. However, if the PPS is correctly prepared and the ward list is completed by a nursing staff member from each ward, data collection can be very fast.

The data collection for the resident questionnaires requires the largest efforts. However, resident questionnaires have to be completed only for residents with signs/symptoms of an infection and AB-using residents. If the prevalence of AB use in your LTCF is comparable to the one observed during the pilot study of ESAC (+/- 7.7%) it means that in a LTCF with 100 beds a maximum of +/- 8 residents questionnaires should be completed. Moreover AB using residents and residents with signs/symptoms of an infection are mostly the same individuals. If the medical and nursing records and/or medication files from the residents are complete, it will be reasonably easy to find the required information.

Filling in the institutional questionnaire should be straightforward if the ward lists are rigorously completed. Moreover, the institutional questionnaire can be completed the day after the PPS.

If a nurse is responsible for data collection, data on infected and/or treated residents should be preferably discussed and shared with the attending GPs or the coordinating physician. Full assistance (by the use of code-lists) is available for the indications, microorganisms and antibiotic names.

6.7 Financial aspects

There is no financial support provided for participation in the data collection. Only for the translation of the questionnaires a small financial compensation will be given.

6.8 Data ownership

The national data providers are the owners of the data submitted to the project. The HALT project is the owner of the processed data.

All analysis and outputs are done in consultation and in the agreement with the HALT MT. The results will be published on the HALT website. Participants will disseminate the results to their LTCFs and local authorities. Publications in international peer-reviewed journals and communications at international conferences will be prepared throughout the project. The HALT project group should be acknowledged in all scientific publications whereas ECDC should be acknowledged for their financial support. HALT LNR and NR will co-author on a case-by-case basis. Authorship of LNR and NR will be judged by how honestly they reflect actual contributions to the final product. The whole anonymous database provided by the HALT project will be transferred to the ECDC and data will be included in the European Surveillance System (**TESSy**) database - the new integrated European communicable disease surveillance system. TESSy aims to collect, store, analyse and disseminate anonymous information on infectious diseases in Europe. The data are mainly provided by the national surveillance institutes in the EU Member States and EEA countries. An integrated EU database (TESSy) at ECDC for all the diseases under EU-wide surveillance should ensure that a stronger database is available for the analysis.

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APPENDIX 1 - McGeer definitions of infection in LTCF

Introduction

Consensus definitions for surveillance of infection in LTCFs [14] have been developed and are widely used in Europe [15-16], USA [17] and Canada [18-19]. These uniform definitions for infections for the elderly rely less on diagnostic studies and more on patient symptoms and signs and have been widely used but not validated.

The McGeer criteria recognize that few LTCFs have ready access to laboratory or diagnostic facilities and that diagnosis of infection should rely primarily on new or acutely worse signs and symptoms. In addition, these criteria recognize the importance of acute change in functional status as a symptom of infection.

Diagnosis of infection in the LTCF is not a clear-cut matter and infection surveillance based on the McGeer criteria may therefore underestimate the infection rate.

For this reason a decision algorithm, based on selected symptoms and signs from the checklist, will be used during the data analysis to identify “confirmed” infected residents according to McGeer and “probable” infected residents if McGeer criteria have not been fully met.

General Information

Three important conditions apply to all of the definitions:

4. All symptoms must be new or acutely worse. Many residents have chronic symptoms, such as cough or urinary urgency that are not associated with infection. However, a change in the resident's status is an important indication that an infection may be developing.
5. Non-infectious causes of signs and symptoms should always be considered before a diagnosis of infection is made.
6. Identification of infection should not be based on a single piece of evidence. Microbiological and radiological findings should be used only to confirm clinical evidence of infection. Similarly, physician diagnosis should be accompanied by compatible signs and symptoms of infection.

URINARY TRACT INFECTIONS (*only symptomatic*)

DEFINITION: Urinary tract infections (only symptomatic) must meet at least one the following criteria:

Criterion 1:

- Resident does not have an indwelling urinary catheter
and
has at least *three* of the following signs and symptoms:
- a. fever ($\geq 38^{\circ}$ C) or chills
 - b. new or increased burning pain on urination
 - c. new or increased frequency or urgency
 - d. recent or increased incontinence
 - e. new flank or suprapubic pain or tenderness
 - f. change in character of urine †

- g. worsening of mental or functional status

Criterion 2:

Resident has an indwelling catheter

and

has at least *two* of the following signs or symptoms:

- a. fever ($\geq 38^{\circ}$ C) or chills
- b. new flank or suprapubic pain or tenderness
- c. change in character of urine †
- d. worsening of mental or functional status.

† Change in character may be clinical (e.g., new bloody urine, foul smell, or amount of sediment) or as reported by the laboratory (new pyuria or microscopic hematuria). For laboratory changes, this means that a previous urinalysis must have been negative.

COMMENT:

It should be noted that urine culture results are not included in the criteria because of the high prevalence of asymptomatic bacteriuria in elderly nursing home residents. However, if an appropriately collected and processed urine specimen was sent and if the resident was not taking antibiotics at the time, then the culture must be reported as either positive or contaminated.

Because the most common occult infectious source of fever in catheterized residents is the urinary tract, the combination of fever and worsening mental or functional status in such residents meets the criteria for a urinary tract infection. However, particular care should be taken to rule out other causes of these symptoms. If a catheterized resident with only fever and worsening mental or functional status meets the criteria for infection at a site other than the urinary tract, only the diagnosis of infection at this other site should be made.

RESPIRATORY TRACT INFECTIONS

DEFINITION: Common cold syndromes/pharyngitis must meet at least two of the following signs or symptoms:

- a. runny nose or sneezing
- b. stuffy nose (i.e., congestion)
- c. sore throat or hoarseness or difficulty in swallowing
- d. dry cough
- e. swollen or tender glands in the neck (cervical lymphadenopathy)

COMMENT:

- Fever may or may not be present.
- Symptoms must be new, and care must be taken to ensure that they are not caused by allergies.

DEFINITION: Influenza-like illness must meet *both* of the following criteria:

1. Fever ($\geq 38^{\circ}\text{C}$)
2. The resident must have at least *three* of the following signs and symptoms
 - a. chills
 - b. new headache or eye pain
 - c. myalgias
 - d. malaise or loss of appetite
 - e. sore throat
 - f. new or increased dry cough

COMMENT:

This diagnosis can be made only during influenza season (October to April). If criteria for influenza-like illness and another upper or lower respiratory tract infection are met at the same time, only the diagnosis of influenza-like illness should be recorded.

DEFINITION: Pneumonia. *Both* of the following criteria must be met:

1. Interpretation of a chest radiograph as demonstrating pneumonia, probable pneumonia, or the presence of an infiltrate. If a previous radiograph exists for comparison, the infiltrate should be new.
2. The resident must have at least *two* of the signs and symptoms described under “other lower respiratory tract infections”.

COMMENT:

Non infectious causes of symptoms must ruled out. In particular, congestive heart failure may produce symptoms and signs similar to those of respiratory infections.

DEFINITION: Other lower respiratory tract infection (bronchitis, tracheobronchitis). The resident must have at least *three* of the following signs and symptoms:

- a. new or increased cough
- b. new or increased sputum production
- c. fever ($\geq 38^{\circ}\text{C}$)
- d. pleuritic chest pain
- e. new or increased physical findings on chest examination (rales, rhonchi, wheezes, bronchial breathing)
- f. one of the following indications of change in status or breathing difficulty:
 - new/increased shortness of breath
 - respiratory rate >25 per minute
 - worsening mental or functional status

COMMENT:

This diagnosis can be made only if no chest film was obtained or if a radiograph failed to confirm the presence of pneumonia.

SKIN INFECTIONS

DEFINITION: Cellulitis/ soft tissue/ wound infection must meet at least *one* of the following

Criteria:

Criterion 1: Pus present at a wound, skin, or soft tissue site

Criterion 2: The resident must have *four* or more of the following signs and symptoms

- a. fever ($\geq 38^{\circ}\text{C}$) or worsening mental/ functional status;
and/or, at the affected site, the presence of new or increasing
- b. heat
- c. redness
- d. swelling
- e. tenderness or pain
- f. serous drainage

DEFINITION: Fungal skin infection The resident must have *both*:

- a. a maculopapular rash
- AND
- b. either physician diagnosis or laboratory confirmation

DEFINITION: Herpes simplex and herpes zoster infection. For a diagnosis of cold sores or shingles, the resident must have *both*:

- a. a vesicular rash
- AND
- b. either physician diagnosis or laboratory confirmation

DEFINITION: Scabies. The resident must have *both*:

- a. a maculopapular and /or itching rash
- AND
- b. either physician diagnosis or laboratory confirmation

COMMENT:

Care must be taken to ensure that a rash is not allergic or secondary to skin irritation

GATROINTESTINAL TRACT INFECTIONS

DEFINITION: Gastroenteritis must meet at least *one* of the following criteria:

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- Criterion 1: Two or more loose or watery stools above what is normal for the resident within a 24-hour period
- Criterion 2: Two or more episodes of vomiting in a 24-hour period
- Criterion 3: *Both* of the following:
- a stool culture positive for a pathogen (*Salmonella*, *Shigella*, *E. coli* O157:H7, *Campylobacter*) or a toxin assay positive for *C. difficile* toxin
- AND
- at least one symptom or sign compatible with gastrointestinal tract infection (nausea, vomiting, abdominal pain or tenderness, diarrhoea).

COMMENT:

Care must be taken to rule out non-infectious causes of symptoms. For instance, new medications may cause both diarrhoea and vomiting; vomiting may be associated with gallbladder disease.

SYSTEMIC INFECTIONS

DEFINITION: Primary blood infection must meet at least *one* of the following criteria:

- Criterion 1: Two or more blood cultures positive for the same organism
- Criterion 2: A single blood culture documented with an organism thought not to be a contaminant and at least *one* of the following:
- fever ($\geq 38^{\circ}\text{C}$)
 - new hypothermia ($< 34.5^{\circ}\text{C}$, or does not register on the thermometer being used)
 - a drop in systolic blood pressure of > 30 mm Hg from baseline
 - worsening mental or functional status.

COMMENT:

Bloodstream infections related to infection at another site are reported as secondary bloodstream infections and are not included as separate infections

EYE, EAR, NOSE and MOUTH INFECTION

DEFINITION: Conjunctivitis must meet at least *one* of the following criteria:

- Criterion 1: Pus appearing from one or both eyes, present for at least 24 hours
- Criterion 2: New or increased conjunctival redness, with or without itching or pain, present for at least 24 hours (also known as “pink eye”)

COMMENT:

Symptoms must not be due to allergy or trauma to the conjunctiva.

DEFINITION: Ear infection must meet at least *one* of the following criteria:

Criterion 1: Diagnosis by a physician of any ear infection.

Criterion 2: New drainage from one or both ears. (Non-purulent drainage must be accompanied by additional symptoms, such as ear pain or redness.)

DEFINITION: Mouth and perioral infection

Oral and perioral infections, including oral candidiasis, must be diagnosed by a physician or a dentist.

DEFINITION: Sinusitis

The diagnosis of sinusitis must be made by a physician.

UNEXPLAINED FEBRILE EPISODE

DEFINITION: Unexplained febrile episodes. The resident must have documentation in the medical record of fever ($\geq 38^{\circ}$ C) on two or more occasions at least 12 hours apart in any 3-day period, with no known infectious or non-infectious cause.

COMMENT:

The fever source is considered unknown if the episode failed to meet the criteria for infection at a specific site using information available from history, physical examination, and laboratory investigation or if the information is consistent with more than one potential site of infection.