



**Hospital in Europe
Link for Infection Control through
Surveillance**

Prevalence Surveys of Nosocomial Infections

Protocol
Version 7.0 (Final)
May 2004



PROJECT COMMISSIONED BY THE EC / DG SANCO/ F/ 4
Agreement Reference number : VS/1999/5235 (99CVF4-025)

MASTER PROTOCOL FOR PREVALENCE SURVEYS

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1 Rationale and objectives of prevalence surveys of nosocomial infections

During the last two decades, national prevalence surveys of healthcare-associated infection (HAI) have been performed in several European countries. The results of these studies have shown similarities and also discrepancies in methods, definitions and strategy of analysis. Despite this situation, these European studies, as well as others performed worldwide, have inevitably been compared even though standardized methods among countries were not used. The lack of consensus regarding many aspects of HAI has led to the promotion of initiatives to reach some standards in the European Union. Based on this common need for uniform methodologies, one of the aims of the HELICS Project was to address this issue by creating a consensus protocol.

The general objective of the working group was to create a European protocol for prevalence surveys of nosocomial infections based on the consensus reached by a multinational group formed on an ad hoc basis. The intention was to develop a protocol with wide validity, acceptance and applicability allowing data collection at local as well as national or European level.

There are clear methodological differences between prevalence and incidence. While incidence databases are continuously fed with data obtained by a continuous surveillance system, a database for prevalence data should collect all data obtained by the application of a common protocol, once the prevalence survey is carried out. Taking into account the need for European databases, and that a prevalence database is perfectly feasible and of great interest, the proposals for the next phase of HELICS co-operation will be the following:

As a consequence of the particular features of prevalence surveys, it is possible that nationwide or regional prevalence surveys will not be performed at the same time in all European countries. What is more important is that prevalence surveys are carried out in the same way, with the same methodology, in order to make comparisons possible. So, once one national or regional prevalence survey is performed, their data will feed a general database, leading to *The European Database on Prevalence Surveys*, the creation of which is a key objective.

OBJECTIVES

The database will be used to:

- gather data on all prevalence surveys (regional or national) carried out on the basis of the consensus method.
- adjust prevalence for the most relevant and known risk factors.
- describe the trends in prevalence of the most frequent NI, the differences in types and levels of exposure to risk factors, and antibiotic use in different countries.
- analyse prevalence surveys in their role in adding value to the general approach in surveillance, as an aid for needs-assessment in the field of NI prevention and control, in evaluation purposes before and after infection control interventions, and in educational purposes.
- study the effect of the use of a common protocol on the comparability of results among countries.
- improve our knowledge about the relationship between prevalence and incidence-based HELICS and national database results between and within countries. In this sense, prevalence can be also used as a validation tool for the SSI and ICU incidence components.

2 Elaboration of the HELICS protocol for prevalence surveys

The first step was to constitute the working group and to contract a research consultant for the project. Once the working group was constituted, email was used to exchange information, opinions, and the different contributions to the draft. The specific topics to discuss in order to reach an agreement were those related to study design, type of hospitals involved, the target population, definitions, infections and risk factors to be surveyed, the system for data collection, questionnaires, the protocol, the approach for analysis, validation and basic reporting of results. Members of working party provided the coordinating center with protocols and data collection forms from their respective countries, along with their wide experience in the field.

One of the tasks of the coordinating center (Barcelona) was to perform a literature search in order to analyse all scientific papers regarding prevalence surveys. The search strategy was twofold: a computerized search using the Medline database, with the keywords 'prevalence' and 'cross-infection', and a handsearch that included references cited in the most relevant papers, and the last ten years of the Journal of Hospital Infection, and Infection Control and Hospital Epidemiology.

On June 1st 2001 a WP3 workshop was held in Barcelona, and on this occasion, a consensus for the definition of a master protocol of prevalence surveys on nosocomial infections in the European Union countries was reached. This covered all relevant components of design and analysis, making it feasible to be applied at a local, regional or national level in Europe. These comprised: common definitions for nosocomial infections, a set of selected intrinsic and extrinsic risk factors to be surveyed, inclusion and exclusion criteria for inpatients and hospitals, the methods for data collection and analysis, and a description of the main results which would be obtained.

3 Indicators to be produced at European level on the prevalence of nosocomial infections

The indicators produced at European level will take into account the main variables collected regarding nosocomial infections, the burden of risk factors, and the use of antimicrobials. Both the number of active infections and the number of patients with one or more active infections will be used as numerators to calculate infection prevalences. All prevalences will be expressed as per 100 surveyed patients.

In general terms, the database analysis will provide major prevalences of nosocomial infections, stratified or adjusted for the main risk factors, at European level, by countries, and by characteristics of hospitals.

Infections:

Prevalence of nosocomial infections: Number of infections / Number of surveyed patients.

Prevalence of patients with nosocomial infection: Number of patients with infection / Number of surveyed patients.

Prevalence of nosocomial infections by the main hospital areas (Medicine, Surgery, Paediatrics, Gynecology and Obstetrics, Other services).

Prevalence of nosocomial infections by type of hospital and by hospital size.

Prevalence of nosocomial infections by the main infection sites.

Prevalence of surgical site infections by NNIS risk index.

Prevalence of nosocomial infections by the main diagnostics declared at the time of the survey.

The calculated prevalences will be also adjusted by the selected intrinsic and extrinsic risk factors, along with the prevalence length of stay.

Distribution of the microorganisms isolated as the agents of nosocomial infections, by infection site.

Percentage of resistance for the selected microorganisms.

Burden of risk factors at the European level:

Prevalence of the intrinsic risk factors.

Prevalence of use of extrinsic risk factors.

Antimicrobials:

Prevalence of use of antimicrobials.

Prevalence of use of antimicrobials by infection site.

Prevalence of use of antimicrobials by indication, indication and infection site.

4 Definitions of nosocomial infections

The great majority of prevalence surveys performed at national level, both in European and non-european countries, have used the CDC criteria for diagnosing nosocomial infections. In order to sustain the possibility of making useful comparisons among surveys, and adding up all the surveys in a common database, the working group made the decision that in the HELICS collaboration nosocomial infections will be defined according to the CDC definitions, except for the case of asymptomatic bacteriuria, which will not be recorded as infection.

Having different definitions for the same infection sites in the framework of HELICS cooperation would not make sense. Therefore, the definitions used in the protocol of surgical site infections and in the protocol of infections in the intensive care units have been compared to the CDC definitions.

- Regarding surgical site infections, the definitions used in the SSI HELICS protocol are the same as for the prevalence protocol.
- With respect to definitions used in the ICU HELICS protocol: bloodstream infections used CDC, urinary tract infection used CDC, CVC-related infection is not contemplated as a category in prevalence protocol, ICU-acquired pneumonia is not CDC, but is very similar.

Given these results, there is no rationale for not using CDC definitions in the prevalence surveys protocol, while the reasons in favour are clear.

5 Procedures for participation

The partners of the European network of networks will sign an agreement with the HELICS programme. The conditions for a partnership are presented in the Operating Manual: existence of a network co-ordination team, agreement on the protocol, on the quality check procedures, on the management of national codes and on modalities of data transfer, official agreement by national health authorities and designation of official representatives to HELICS.

They are expected to report data obtained by a prevalence survey, in the format described below. Only networks coordinated by officially mandated centres should participate. The institutions in charge of official networks and receiving data from the hospitals must validate the system and the quality of the data before data are transmitted to the EU database. Data will not be transmitted directly from the hospitals to the project database.

6 Data collection

This protocol has been designed to carry out a point prevalence survey. This means that, ideally, the information should be completed for the whole hospital on a single day. The main advantage of this type of survey is therefore rapidity, because important information can be collected by just one-day survey, avoiding the important economic and practical consequences derived from longer surveys. The objective of completing the survey on a single day is feasible for the smallest and medium-sized centres but it might not be possible for the larger ones. Hence, in these cases, at least each ward should be completed on a single day, and the overall hospital as soon as possible. There is supporting evidence that there can be differences in prevalence depending on the day of the week the survey is performed. So, when the prevalence survey lasts more than one day, specifically Saturdays, Sundays and Mondays should be avoided for data collection.

Each bed will be surveyed just once. Those beds that are not occupied at the time of the survey will be considered as surveyed. Only the bed allocated to a patient that transiently is not in the ward, at the moment of the survey (because the patient is undergoing surgery, a diagnostic test or any other procedure), will be surveyed again, once the patient's chart is in the ward. In these cases, the information will be collected (including risk factors) after the return of the patient. Non-occupied beds will not contribute to the denominators.

The way to collect information involves consulting the medical records (and nursing and laboratory records if necessary) of all the patients in hospital at the time of the survey. When the information is not clear or there are doubts on whether the patient has or has not an infection, the physician in charge of the patient should be consulted. The importance of routine bedside examination should be emphasized, and especially when doubts arise about the presence of some risk factors such as the presence of vascular or urinary catheters.

The composition of the team responsible for data collection may vary from one hospital to another. Nonetheless, the infection control personnel of the hospital should be involved and participate actively and predominantly in this study, due to their experience in recognising NI. The role of the team in charge of the patients should also be emphasized, as well as the participation of those who have experience in developing and implementing surveillance programmes.

6.1 Population under surveillance

PATIENTS

Inclusion criteria: All patients in hospital at the time of the survey, whatever age, days of admission or diagnostics. Psychiatric, geriatric, pediatric and patients undergoing haemodialysis will also be included in the survey.

Exclusion criteria: Patients admitted for on day diagnostic procedures or therapeutic purposes and discharged on the same day.

HOSPITALS

All kind of hospitals can participate in the survey, regardless of size. This includes acute-care, teaching or non-teaching, public or private, psychiatric or long-term hospitals.

6.2 Type of infections under surveillance

All nosocomial infections acquired during the current admission which are active at the time of the survey will be recorded.

6.3 Information to be collected (minimum data set)

The selection process of the minimum data set focused on the most significant variables for the analysis of prevalence data, and the capability of basic risk stratification or a more advanced analysis taking into account the joint effect of selected risk factors.

The variables are classified according to 3 levels:

- M=Mandatory:** data will be rejected if this variable is missing
R=Required: these variables are required for the correct interpretation of the results and/or for routine analysis
O=Optional: data used for additional analysis

6.3.1 Data at the Network level

Information at the level of the national or regional nosocomial infection surveillance network should be collected once per year.

A surveillance network is uniquely identified by three variables: the country code, a code for the surveillance network if different networks exist within a same country (if applicable, e.g. C.Clin networks in France or the different “countries” of the United Kingdom) and a code for the surveillance component, which is always 3 in the case of prevalence. These data are generated at the level of the surveillance network coordination and they should not be collected at the hospital level.

Data table helics_n: Network data table (one record per network and per year)

Attr.*	Variable Label	Variable Name	Format	Length
M	¹ Country code	country_id	Text	2
M	² Identification code of Surveillance Network	net_id	Text	2
M	³ Identification code of Surveillance component	sur_id	number	1
M	⁴ Year	year	number	4

* Attr.: field attribute: M=mandatory, R=required, O=optional
Unique key=country+network code+surveillance component+date

- Country code:** for country codes the ISO (International Organization for Standardization) country codes are used; AT=Austria; BE=Belgium; BG=Bulgaria; HR=Croatia; CZ=Czech Republic; DK=Denmark; EE=Estonia; FI= Finland; FR=France; DE=Germany; GR=Greece; HU=Hungary; IS=Iceland; IE=Ireland; IL=Israel; IT=Italy; LU=Luxembourg; MT=Malta; NL=Netherlands; NO=Norway; PL=Poland; PT= Portugal; RO= Romania; RU=Russia; SK=Slovakia; SI=Slovenia; ES=Spain; SE=Sweden; CH=Switzerland; UK=United Kingdom
- Network code:** internal code given by the national coordinator to each sub-network in the country, e.g. different C.Clin networks in France; 00 if not applicable; EN,SC,WA,NI designate respectively England, Scotland, Wales and Northern-Ireland

3. **Surveillance component code:** always 3 for prevalence survey (1=ICU surveillance, 2=SSI surveillance)
4. **Year for which data apply (yyyy).**

6.3.2 Data at the Hospital level

Data at the level of the hospital should be collected once per year.

Data table prev_h: Hospital characteristics (one record per hospital and per survey)

Attr.*	Variable Label	Variable Name	Format	Length
M	¹ Country code	country_id	text	2
M	² Identification code of Surveillance Network	net_id	text	2
M	³ Identification code of Surveillance component	sur_id	number	1
M	⁴ Year	year	number	4
M	⁵ Date			
M	⁶ Hospital code	h_code	number	4
R	⁷ Hospital size (n of beds in categories)	h_size	number	2
R	⁸ Hospital type	h_type	number	1
O	⁸⁹ Hospital location	h_region	text	2

* Attr.: field attribute: M=mandatory, R=required, O=optional

Unique key=country+network code+surveillance component+hospital code+year

1. **Country code:** see 6.3.1
2. **Network code:** see 6.3.1
3. **Surveillance component code:** see 6.3.1
4. **Year:** see 6.3.1
5. **Date:** designed date for the prevalence survey (dd/mm/yyyy). In the case of prevalence surveys, as they can be carried out more than once per year, it is necessary to define the data in order to differentiate each other within the same year.
6. **Hospital code:** hospital codes should be anonymized at the level of the surveillance network. Hospital names or codes used within a network should be converted to a new numeric code before sending data to Helics and the resulting code table (mapping of usual hospital ID's to new Helics hospital code) should be available at the level of the surveillance network only.
7. **Hospital size (n of beds, in categories):** 0=0-99, 1=100-199, 2=200-299, 3=300-399, 4=400-499,5=500-599,..., 99=unknown
8. **Hospital type:** 1=teaching, public, acute-care hospital; 2= non-teaching, public, acute-care hospital; 3= teaching, private, acute-care hospital; 4= non-teaching, private, acute-care hospital; 5=teaching, public, long term-care hospital; 6= non-teaching, public, long term-care hospital; 7= teaching, private, long term-care hospital; 8= non-teaching, private, long term-care hospital; 9=unknown
9. **Hospital location:** optional; region or area within a country where hospital is located; geographical code defined by the national coordination and used for mapping at EU level (e.g. pathogen-specific infection rates); may coincide with network code (e.g. C.Clin); 00 if not applicable

These hospital data represent the minimal data set that will be used for stratification of reference data.

6.3.3 Data at the Patient level

These are the data to be obtained from each single patient included in the prevalence survey. Yes/No questions are encoded 1=YES, 0=NO and 9=NOT APPLICABLE/UNKNOWN.

Data table prev_p: Patient data (one record per patient per survey)

Attr.*	Variable label	Variable Name	Format	Length
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M	² Country code	country_id	text	2
M	Identification code of Surveillance Network	net_id	text	2
M	Identification code of Surveillance component	sur_id	number	1
M	Year	year	number	4
M	⁴ Date	date	date	10
M	³ Hospital code	h_code	number	4
M	¹ Questionnaire Number	questnum	number	4
O	⁵ Service	serv	number	3
M	⁷ Age	age	number	3
M	⁷ Days / Months	daymon	text	1
M	⁸ Date of admission	admdate	date	10
R	⁹ Gender	gender	number	1
O	¹⁰ Immunodeficiency	immdef	number	1
O	¹¹ Neutropenia	neutpeny	number	1
R	¹² Urinary catheter	uricat	number	1
O	¹² Open urinary system	opuricat	number	1
O	¹² Closed urinary system	cluricat	number	1
R	¹³ Peripheral vascular cath.	pervscat	number	1
R	¹⁴ Central vascular catheter	cenvscat	number	1
R	¹⁵ Parenteral nutrition	pnt	number	1
R	¹⁶ Mechanical ventilation	mechvent	number	1
R	¹⁷ Gestational age (weeks)	gestage	number	2
R	¹⁸ Birthweight	birthw	number	4
M	¹⁹ Date of surgery	surgdate	date	10
M	²⁰ NNIS procedure code	nnis	number	2
M	²¹ ASA score	asa	number	1
M	²² Duration of surgery (min)	surgdur	number	3
M	²³ Wound contamination	surgclas	number	1
O	²⁴ Urgent/elective surgery	elective	number	1
R	²⁵ Endoscopic surgery	endoscop	number	1
R	²⁶ Infection site 1	inf1	number	2
R	²⁷ Date of onset inf. 1	inf1date	date	10
R	²⁸ Culture result inf. 1	inf1cult	number	1
R	²⁹ Micro-organism 1, inf. 1	inf1org1	number	3
O	³⁰ Resistance code M1 I1	rm1i1	number	2
R	²⁹ Micro-organism 2, inf. 1	inf1org2	number	3
O	³⁰ Resistance code M2 I1	rm2i1	number	2
R	²⁹ Micro-organism 3, inf. 1	inf1org3	number	3
O	³⁰ Resistance code M3 I1	rm3i1	number	2
R	²⁶ Infection site 2	inf2	number	2
R	²⁷ Date of onset inf. 2	inf2date	date	10
R	²⁸ Culture result inf. 2	inf2cult	number	1
R	²⁹ Micro-organism 1, inf. 2	inf2org1	number	3
O	³⁰ Resistance code M1 I2	rm1i2	number	2
R	²⁹ Micro-organism 2, inf. 2	inf2org2	number	3
O	³⁰ Resistance code M2 I2	rm2i2	number	2
R	²⁹ Micro-organism 3, inf. 2	inf2org3	number	3
O	³⁰ Resistance code M3 I2	rm3i2	number	2

R	²⁶ Infection site 3	inf3	number	2
R	²⁷ Date of onset inf. 3	inf3date	date	10
R	²⁸ Culture result inf. 3	inf3cult	number	1
R	²⁹ Micro-organism 1, inf. 3	inf3org1	number	3
O	³⁰ Resistance code M1 I3	rm1i3	number	2
R	²⁹ Micro-organism 2, inf. 3	inf3org2	number	3
O	³⁰ Resistance code M2 I3	rm2i3	number	2
R	²⁹ Micro-organism 3, inf. 3	inf3org3	number	3
O	³⁰ Resistance code M3 I3	rm3i3	number	2
R	²⁶ Infection site 4	inf4	number	2
R	²⁷ Date of onset inf. 4	inf4date	date	10
R	²⁸ Culture result inf. 4	inf4cult	number	1
R	²⁹ Micro-organism 1, inf. 4	inf4org1	number	3
O	³⁰ Resistance code M1 I4	rm1i4	number	2
R	²⁹ Micro-organism 2, inf. 4	inf4org2	number	3
O	³⁰ Resistance code M2 I4	rm2i4	number	2
R	²⁹ Micro-organism 3, inf. 4	inf4org3	number	3
O	³⁰ Resistance code M3 I4	rm3i4	number	2
R	³¹ Antimicrobial 1	antmic1	text	7
R	³² Indication 1	indic1	number	1
R	³¹ Antimicrobial 2	antmic2	text	7
R	³² Indication 2	indic2	number	1
R	³¹ Antimicrobial 3	antmic3	text	7
R	³² Indication 3	indic3	number	1
R	³¹ Antimicrobial 4	antmic4	text	7
R	³² Indication 4	indic4	number	1
O	³³ Main Diagnostic	maindiag	number	2

* Attr.: field attribute: M=mandatory, R=required, O=optional

Unique key = country + network code +surveillance component + year + date + hospital code + questionnaire number

6.4 Definition of key terms

Reference is made to Annex 8 Data Collection Form.

Patient hospital identification. It is important in order to verify or complete some data such as microbiology reports that were not ready at the time of the survey.

1. **Questionnaire num.** The team responsible of the survey in each hospital will assign an internal code (numerals) to the questionnaires. This might help to control several parameters such as the total number of beds surveyed within the hospital; this information can also be used to know the occupation beds rate in that particular day.
2. **Country code.** For country codes the ISO (International Organization for Standardization) country codes are used; AT=Austria; BE=Belgium; BG=Bulgaria; HR=Croatia; CZ=Czech Republic; DK=Denmark; EE=Estonia, FI= Finland; FR=France; DE=Germany; GR=Greece; HU=Hungary; IS=Iceland; IE=Ireland; IL=Israel; IT=Italy; LU=Luxembourg; MT=Malta; NL=Netherlands; NO=Norway; PL=Poland; PT= Portugal; RO= Romania; RU=Russia; SK=Slovakia; SI=Slovenia; ES=Spain; SE=Sweden; CH=Switzerland; UK=United Kingdom.

3. **Centre (hospital code)**. Unique hospital numeric code.
4. **Date of the survey**. Date in which the survey is carried out (dd/mm/yyyy).
5. **Service/Unit/Ward**. According to **Annex 1**.
6. **Bed number**. It is important because it helps to ensure that every single bed has been surveyed just one time.
7. **Age**. Write age in years, days or months. If patient is younger than one month old write the age in days and add the letter D in Days/Months. If patient is younger than one year old and older than one month old write the age in months and add the letter M in Days/Months. If patient is older than one year old write the age in years and do not write anything in Days/Months.
8. **Date of hospital admission**. Date of admission of the patient in hospital (dd/mm/yyyy).
9. **Gender**. Gender of the patient (man: 1; woman: 2).

INTRINSIC RISK FACTORS.

Answer by marking an "X" inside the appropriate boxes:

YES (first box), if the patient has the factor at the time of the survey, or NO (second box) if the patient has not the factor.

In those exceptional cases with doubts regarding the presence or absence of these factors do not fill in the blanks.

10. **Immunodeficiency**. Patients with this risk factor are those with the diagnosis of any kind of immune disease regardless of whether it is a primary or secondary. The diseases to be included are: leukaemia, lymphoma, AIDS, HIV positive with a CD4 account of equal or less than 500, among other diseases.
11. **Neutropenia**. Defined as the total number of neutrophils $< 1000/\text{mm}^3$ obtained in the last haematology account.

EXTRINSIC RISK FACTORS.

The following risk factors will be recorded if they are present on the day of the survey. These questions should be answered by marking an "X" inside the appropriate boxes (Yes/No). YES (first box), if the patient has the factor at the time of the survey, or NO (second box) if the patient has not the factor.

In those exceptional cases with doubts regarding the presence or absence of these factors do not fill in the blanks.

12. **Urinary catheter**. The presence of any kind of catheter in the urinary tract to drain urine will be collected. The identification of the drainage system as open or closed is optional. An open urinary system is an urinary catheter connected to a collecting container, so the sterile drainage is not maintained when the drainage bag is removed. A closed system is considered when it has one-way-valve to prevent the reflux of urine, a urine sampling port in the drainage tubing and a tap at the bottom of the collecting container which permits to empty the bag without opening the system.
13. **Peripheral vascular catheter**. Report in the appropriate box (YES/NO) any catheter inserted by peripheral access.
14. **Central vascular catheter**. Report in the appropriate box (YES/NO) any kind of central catheter (subclavian, jugular, femoral) including the umbilical catheter with this use.
15. **Parenteral nutrition**. Report in the appropriate box (YES/NO) if the surveyed patient is undergoing parenteral nutrition.
16. **Mechanical ventilation**. Report in the appropriate box (YES/NO) if the patient is or is not under mechanical ventilation.

BASELINE RISK ASSESSMENT

17. **Gestational age**. Report in weeks, only for paediatric patients younger than a month.
18. **Birth weight**. Report weight in grams, only for paediatric patients younger than a month.

SURGICAL PROCEDURE

To be reported if the operation has been performed during the current admission.

19. **Date of surgical intervention**. Date the operative procedure was carried out (dd/mm/yyyy).
20. **NISS procedure category**. The specific procedure, with their corresponding codes are shown in **Annex 2**.
21. **ASA score**. This is a pre-operative assessment score according to the classification of the American Society of Anesthesiologists (ASA). This will be the score made by the anaesthesiologist prior to the operative procedure, which appears in the anaesthetic chart, if the patient has been submitted to a surgical intervention. If the patient were not undergoing surgery or this score was not recorded for whatever reason, the survey team would calculate it.

The five categories are:

Code	ASA code	Definitions
1	I	Previously healthy patient
2	II	Mild systemic disease; no functional limitations
3	III	Severe systemic disease; definite functional limitation
4	IV	Severe systemic disease that is constant threat to life
5	V	Moribund patient: unlikely to survive 24 hrs, with or without operation

22. **Duration in minutes**. Report the duration of surgery, from the time of incision to closure skin to skin, in minutes. Report the real time if possible, for example 122 (minutes). Avoid procedure-specific cut-point for duration of surgery: in the former example would be 120 or 125 (minutes).
23. **Class of operation or wound class**. Wounds are classified according to the likelihood and degree of wound contamination at the time of operation, following the CDC definitions:
Clean = 1. These are uninfected operative wounds in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tracts are not entered. In addition, clean wounds are primarily closed, and if necessary, drained with closed drainage. Operative incisional wounds that follow no penetrating (blunt) trauma should be included in this category if they meet the criteria. It is an elective surgery.
Clean contaminated = 2. These are operative wounds in which the respiratory, alimentary, genital, or urinary tract is entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered.
Contaminated = 3. These include open, fresh, accidental wounds, operations with major breaks in sterile technique or gross spillage from the gastrointestinal tract, and incisions in which acute, non-purulent inflammation is encountered.
Dirty = 4. These include old traumatic wounds with retained devitalised tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.
24. **Urgent / Elective surgery**. 1 = YES, 0 = NO. Enter "yes" if the entire operation was performed using an endoscopic/laparoscopic approach.
25. **Endoscopic surgery**. 1 = YES, 0 = NO.

ACTIVE INFECTION

It is defined as the infection that the patient has on the day of the survey or as the infection for which the patient is undergoing antimicrobial treatment on the day of the survey. Antimicrobial use for prophylaxis is not considered as treatment for this purpose. In case of doubts about whether or not the patient is having an active infection, the opinion of the physician in charge of the patient would be decisive. Up to 4 active infections might be reported.

26. **Infection site.** The location of the active infection will be reported with the corresponding code according to the CDC list (**Annex 3**). Again, in case of doubts about the exact location of the active infection, the opinion of the physician in charge of the patient would be decisive.
27. **Day of onset of infection.** It refers to the date when the symptoms related to the NI started. If this information is not available, fulfil with the day of sample withdraw. Still if this information is not available fulfil with the date of onset of antibiotic therapy for the NI (no matter whether it was empirical or specific treatment), (dd/mm/yyyy).
28. **Culture.** Four possibilities/options are contemplated. Positive culture (code 1), negative culture (code 2), culture not done (code 3), others -antigen or antibody tests- (code 4). If the microbiology result is not available at the moment of the survey, and the sample was really drawn, this information should be collected in further visit.
29. **Microbiology result.** Up to 3 micro-organisms will be reported for each infection site, if this information is available. The list of micro-organisms code is in **Annex 4**.
30. **Resistance pattern.** For highly resistant bacteria, the resistance pattern should be collected with the corresponding resistance code (**Annex 5**).

ANTIMICROBIALS

31. **Antimicrobials.** Up to four antimicrobials would be reported, with the codes listed on **Annex 6**.
32. **Indication.** Each antimicrobial should have its indication. Write 1 if it is an specific indication (for example through antibiogram), 2 if it is an empirical indication, 3 if it is a surgical prophylaxis indication and 4 if it is other prophylaxis.

DIAGNOSTICS

33. **Main diagnostic.** The main admission diagnostic or the main diagnostic at the time of the survey will be reported according to ICD-9 CM (**Annex 7**).

7 Control of the quality and validation of data

Some authors make a distinction between *quality assurance* procedures (activities undertaken before data collection, to ensure that the data are of the highest possible quality at the time of data collection), and *quality control* procedures (aimed at identifying and correcting sources of data errors. Based on experiences described in the literature, there are a series of procedures for quality assurance and control that can be placed in a framework in which these procedures can be divided into 'central' (network) and 'local' (hospital collecting data) procedures. Both central and local procedures can be further subdivided into three phases: 1) the prevention of insufficient data quality, 2) the detection of inaccurate or incomplete data and their causes, and 3) corrections or actions to be taken to improve data quality.

7.1 Role of the official network

The official networks in the countries are responsible for the quality of the data, for validation and for data checks. They will be asked to provide an indication of the kind of selection in their data so that

the European centre can judge its representativeness. The official centres will be also be asked to describe their procedures to guarantee the quality of the data.

7.2 Identifying infections

An appropriate sensitivity and specificity of the instruments used to identify nosocomial infections must be assured. At the local level, the persons in charge of carrying out the survey should test the data collection protocol, check developed software for data entry, check reliability and completeness of extraction sources of information, and standardise correction of data items. The medical record and consultation with the personnel in charge of the patient will be used as a gold standard.

7.3 Validating the quality of clinical surveillance data

As occurs in the case for the identification of infections, data items that need to be collected should be provided with clear data definitions, and standardized guidelines for data collection methods must be designed. This is the aim of the present protocol.

When possible, clinical data should be entered by a trained person or obtained directly from the relevant electronic data source (e.g., a laboratory system).

7.4 Role of the HELICS management team

When receiving the data, the HELICS data manager will realise a new check of the quality of data for completeness of information and consistency. Records with missing or erroneous information will be excluded from data entry into the HELICS database. Deleted records or records with other kind of problems will be notified to the National network co-ordinator.

8 Data transfer

Methods for data transfer to the HELICS management team are presented in the Operating Manual. It will evolve according to IT development supporting the HELICS programme.

9 Confidentiality

9.1 Patient confidentiality

It will not be possible to identify individual patients in the European database on NI by coding patient information at the hospital level or at the level of the official networks in the countries. However, for validation purposes, the hospitals should be able to trace back patients based on anonymous unique patient numbers.

9.2 Hospital information

A unique code is assigned to each hospital by the national surveillance system. The key linking each hospital to its HELICS code remains strictly within the national surveillance system to secure

confidentiality. It is not to be transmitted to any other organization under any circumstance. This number will be used for correspondence and feedback.

9.3 Publication policy

The data will be used to generate European reports on nosocomial infections, reference tables on the internet, mapping of pathogen-specific prevalence of nosocomial infections in European countries, and scientific publications. Official networks in the countries have to provide written consent with any publication before publication. Authorships will be dealt with according to the authorship regulations used by the British Medical Journal; in any publication reference will be made to the official networks in the countries, including their acronym and contact information, if desired by the networks.

10. Data storage and accessibility

10.1 Data storage

Data will be stored in the European HELICS database until the end of the HELICS programme with a maximum of 10 years, under the responsibility of the Programme co-ordinator. The data will be stored safely, so that data cannot be approached by third parties and that data loss through fire, flooding, etc. is virtually impossible. When the database is shared between different members of the HELICS management team, the same rules apply even if they are not working in the same place.

10.2 Data accessibility

The access to the data is strictly limited to the HELICS management team, which is responsible for the security of the data and the production of analysis.

European and National health authorities and scientific bodies, or even individual scientists could request specific analysis. The procedure to obtain specific analysis is presented in the Operating Manual, but the data will never be transferred to a person out of the HELICS management team.

11. Annexes

11.1 Annex 1. Code list of services / units

Medical Services

Code	Ward/Service/Unit
10	Internal medicine
11	Infectious diseases
12	Hematology
13	Gastroenterology
14	Cardiology
15	Pulmonar diseases
16	Endocrionology

Code	Ward/Service/Unit
17	Oncology (Medical oncology)
18	Neurology
19	Nephrology
20	Rehabilitation
21	Dermatology
22	Rheumatology

Surgical Services

Code	Ward/Service/Unit
30	General surgery
31	Digestive surgery, colorectal surgery
32	Maxillofacial surgery
33	Vascular surgery
34	Thoracic surgery
35	Cardiac surgery
36	Plastic surgery

Code	Ward/Service/Unit
37	Burns unit
38	Neurosurgery
39	Urology
42	Traumatology
43	Orthopedics
45	Otolaringology
47	Ophtalmology

Intensive care services

Code	Ward/Service/Unit
50	Intensive care unit (ICU)
51	Coronary care unit (CCU)
52	ICU and CCU (mixed unit)

Code	Ward/Service/Unit
55	Kidney transplantation unit
56	Another transplantation unit

Gynecology and obstetrics

Code	Ward/Service/Unit
60	Gynecology
65	Obstetrics

Code	Ward/Service/Unit
66	Gynecology and obstetrics (mixed unit)

Paediatrics

Code	Ward/Service/Unit
70	Paediatrics (in general)
71	Neonatology
72	Perinatology
73	Scholar pathology
75	Paediatric hematology
76	Paediatric nephrology and kidney transplantation

Code	Ward/Service/Unit
77	Paediatric oncology
78	Paediatric burns unit
80	Paediatric ICU
81	Paediatric surgery (in general)
82	Cardiovascular surgery
83	Paediatric urological surgery
84	Another paediatric transplantation unit

Other services

Code	Ward/Service/Unit
93	Psychiatry and paediatric psychiatry
95	Geriatric and ortho-geriatric

Code	Ward/Service/Unit
99	Another service

11.2 Annex 2. NNIS surgical procedure code list

Code	Operative Procedure Category (NNIS)
01	Cardiac Surgery
02	CABG-Chest & Leg (Coronary artery bypass graft, chest and leg (donor) incisions).
03	CABG-Chest only (Coronary artery bypass graft, chest incision only; example: internal mammary artery).
04	Vascular Surgery
09	Other Cardiovascular Surgery
11	Thoracic Surgery
19	Other Respiratory System Surgery
21	Small Bowel Surgery
22	Colon Surgery
23	Appendectomy
24	Cholecistectomy
25	Liver/Pancreas
26	Gastric Surgery
29	Other Digestive Surgery
31	Nephrectomy
32	Prostatectomy
39	Other Genitourinary Surgery
41	Mastectomy
42	Vaginal Hysterectomy
43	Abdominal Hysterectomy
44	Cesarean Section
49	Other Obstetrical Procedures
51	Head and Neck
55	Other ENT (E: ear; N: nose; T: throat)
56	Skin Graft
59	Other Integumentary System
20	Laparotomy
70	Herniorrhaphy
61	Craniotomy
62	Ventricular Shunt
69	Other Nervous System
71	Limb Amputation
72	Spinal Fusion
73	Laminectomy
74	Open reduction Fracture
76	Hip Prosthesis
77	Knee Prosthesis
79	Other Musculoskeletal
81	Splenectomy
89	Other Hem/Lymph System
90	Organ Transplant
91	Other Endocrine System
95	Other Eye
97	Other Prosthesis
99	Any other procedure/intervention

11.3 Annex 3. Code list for infection sites

Code	Infection
	Urinary tract infection:
01	Symptomatic urinary tract infection
02	Other infections of the urinary tract
	Surgical site infection
10	Superficial incisional site infection
11	Deep incisional site infection
12	Organ/Space surgical site infection
	Respiratory tract infection (except upper respiratory tract infection)
20	Pneumonia
21	Lower respiratory tract infection (bronchitis, tracheobronchitis, tracheitis) and other infections of the lower respiratory tract (lung abscess, empyema)
	Bloodstream infection
30	Laboratory-confirmed bloodstream infection.
31	Clinical sepsis
	Gastrointestinal system infection
40	Gastrointestinal tract: esophagus, stomach, small and large bowel and rectum
40	Gastroenteritis
40	Necrotizing enterocolitis
40	Other Intraabdominal infections not surgery-associated
45	Acute hepatitis
	Reproductive tract infection
50	Endometritis
50	Episiotomy
50	Vaginal cuff
50	Other infections of the male or female reproductive tract
	Skin and soft tissue infection
60	Skin
60	Soft tissue
60	Decubitus ulcer
60	Burn
60	Breast abscess or mastitis
60	Omphalitis
60	Infant pustulosis
	Bone and joint infection.
70	Osteomyelitis
70	Joint or bursa
70	Disc space

Code	Infection
	Eye, Ear, Nose, Throat, or Mouth infection
75	Eye: conjunctivitis and other eye infection
76	Ear: otitis externa, otitis media, otitis interna
76	Mastoiditis
77	Upper respiratory tract, pharyngitis, laryngitis, epiglottitis
79	Oral cavity: mouth, tongue, or gums
79	Sinusitis
	Cardiovascular system infection
81	Arterial or venous infection
82	Endocarditis
83	Myocarditis or pericarditis
84	Mediastinitis
	Central nervous system infection
86	Intracranial infection: brain abscess, subdural or epidural infection, encephalitis
86	Meningitis or ventriculitis
86	Spinal abscess without meningitis
90	Systemic Infection

All the definitions of the different types of nosocomial infection (NI) are included in www.apic.org/pdf/cdcdefs.pdf .

11.4 Annex 4. Code list of micro-organisms

Note: The code list is adapted from the original WHOCARE coding system. The current list is a selection of micro-organisms based on their frequency of occurrence in nosocomial infections in different EU networks and infection types and/or on their public health importance. The minimal list represents the minimal level of detail that should be provided by every network. Networks/countries preferring to use the complete WHOCARE list may obtain the database from the HELICS coordination centre.

Micro-organism selection and minimal list

Microorganism	Code	Minimal list
Gram + cocci <i>Staphylococcus aureus</i> <i>Staphylococcus epidermidis</i> <i>Staphylococcus haemolyticus</i> Other coagulase-negative staphylococci (CNS) <i>Staphylococcus sp.</i> , not specified <i>Streptococcus pneumoniae</i> <i>Streptococcus agalactiae</i> (B) <i>Streptococcus pyogenes</i> (A) Other haemol. Streptococcae (C, G) <i>Streptococcus sp.</i> , other <i>Streptococcus sp.</i> , not specified <i>Enterococcus faecalis</i> <i>Enterococcus faecium</i> <i>Enterococcus sp.</i> , other <i>Enterococcus sp.</i> , not specified Other Gram-positive cocci	STAAUR	STAAUR
	STAEP	STACNS
	STAHAE	
	STAOH	
	STANSP	GPCOTH
	STRPNE	STRSPP
	STRAGA	
	STRPYO	
	STRHCG	
	STROTH	
	STRNSP	ENCSP
	ENCFAE	
	ENCFAC	
	ENCOTH	
ENCNSP	GPCOTH	
GPCOTH		
Gram - cocci <i>Moraxella catharralis</i> <i>Moraxella sp.</i> , other <i>Moraxella sp.</i> , not specified <i>Neisseria meningitidis</i> <i>Neisseria sp.</i> , other <i>Neisseria sp.</i> , not specified Other Gram-negative cocci	MORCAT	GNCTOT
	MOROTH	
	MORNSP	
	NEIMEN	GNCTOT
	NEIOTH	
	NEINSP	
	GNCOTH	
Gram + bacilli <i>Corynebacterium sp.</i> <i>Bacillus sp.</i> <i>Lactobacillus sp.</i> <i>Listeria monocytogenes</i> Other Gram-positive bacilli	CORSPP	GPBTOT
	BACSPP	
	LACSPP	
	LISMON	
	GPBOTH	
Enterobacteriaceae <i>Citrobacter freundii</i> <i>Citrobacter koseri</i> (e.g. <i>diversus</i>) <i>Citrobacter sp.</i> , other <i>Citrobacter sp.</i> , not specified <i>Enterobacter cloacae</i> <i>Enterobacter aerogenes</i> <i>Enterobacter agglomerans</i> <i>Enterobacter sakazakii</i> <i>Enterobacter gergoviae</i> <i>Enterobacter sp.</i> , other <i>Enterobacter sp.</i> , not specified	CITFRE	CITSPP
	CITDIV	
	CITOTH	
	CITNSP	
	ENBCLO	ENBSPP
	ENBAER	
	ENBAGG	
	ENBSAK	
	ENBGER	
	ENBOTH	
	ENBNSP	
	ENBNSP	

	<i>Escherichia coli</i>	ESCCOL	ESCCOL	
	<i>Klebsiella pneumoniae</i>	KLEPNE	KLESPP	
	<i>Klebsiella oxytoca</i>	KLEOXY		
	<i>Klebsiella sp., other</i>	KLEOTH		
	<i>Klebsiella sp., not specified</i>	KLENSP		
	<i>Proteus mirabilis</i>	PRTMIR	PRTSPP	
	<i>Proteus vulgaris</i>	PRTVUL		
	<i>Proteus sp., other</i>	PRTOTH		
	<i>Proteus sp., not specified</i>	PRTNSP		
	<i>Serratia marcescens</i>	SERMAR	SERSPP	
	<i>Serratia liquefaciens</i>	SERLIQ		
	<i>Serratia sp., other</i>	SEROTH		
	<i>Serratia sp., not specified</i>	SERNSP		
	<i>Hafnia sp.</i>	HAFSPP	ETBSPP	
	<i>Morganella sp.</i>	MOGSPP		
	<i>Providencia sp.</i>	PRVSPP		
	<i>Salmonella enteritidis</i>	SALENT		
	<i>Salmonella typhi</i> or <i>paratyphi</i>	SALTYP		
	<i>Salmonella typhimurium</i>	SALTYM		
	<i>Salmonella sp., not specified</i>	SALSPP		
	<i>Salmonella sp., other</i>	SALOTH		
	<i>Shigella sp.</i>	SHISPP		
	<i>Yersinia sp.</i>	YERSPP		
	Other enterobacteriaceae	ETBOTH		
	Enterobacteriaceae, not specified	ETBNSP		
Gram - bacilli	<i>Acinetobacter baumannii</i>	ACIBAU		ACISPP
	<i>Acinetobacter calcoaceticus</i>	ACICAL		
	<i>Acinetobacter haemolyticus</i>	ACIHAE		
	<i>Acinetobacter lwoffii</i>	ACILWO		
	<i>Acinetobacter sp., other</i>	ACIOTH		
	<i>Acinetobacter sp., not specified</i>	ACINSP		
	<i>Pseudomonas aeruginosa</i>	PSEAER	PSEAER	
	<i>Stenotrophomonas maltophilia</i>	STEMAL	STEMAL	
	<i>Burkholderia cepacia</i>	BURCEP	PSETOT	
	<i>Pseudomonadaceae family, other</i>	PSEOTH		
	<i>Pseudomonadaceae family, not specified</i>	PSENSP		
	<i>Haemophilus influenzae</i>	HAEINF	HAESPP	
	<i>Haemophilus parainfluenzae</i>	HAEPAI		
	<i>Haemophilus sp., other</i>	HAEOTH		
	<i>Haemophilus sp., not specified</i>	HAENSP		
	<i>Legionella sp.</i>	LEGSPP	LEGSPP	
	<i>Achromobacter sp.</i>	ACHSPP	GNBTOT	
	<i>Aeromonas sp.</i>	AEMSPP		
	<i>Agrobacterium sp.</i>	AGRSPP		
	<i>Alcaligenes sp.</i>	ALCSPP		
	<i>Campylobacter sp.</i>	CAMSPP		
	<i>Flavobacterium sp.</i>	FLASPP		
<i>Gardnerella sp.</i>	GARSPP			
<i>Helicobacter pylori</i>	HELPYL			
<i>Pasteurella sp.</i>	PASSPP			

	Other Gram-neg Bacilli, non enterobacteriaceae	GNBOTH		
Anaerobic bacilli	<i>Bacteroides fragilis</i>	BATFRA	BATSPP	
	<i>Bacteroides</i> other	BATOTH		
	<i>Clostridium difficile</i>	CLODIF	ANATOT	
	<i>Clostridium</i> other	CLOOTH		
	<i>Propionibacterium sp.</i>	PROSPP		
	<i>Prevotella sp.</i>	PRESPP		
	Other anaerobes	ANAOTH		
Other bacteria	Mycobacterium, atypical	MYCATY	BCTTOT	
	<i>Mycobacterium tuberculosis</i> complex	MYCTUB		
	<i>Chlamydia sp.</i>	CHLSPP		
	<i>Mycoplasma sp.</i>	MYPSP		
	<i>Actinomyces sp.</i>	ACTSPP		
	<i>Nocardia sp.</i>	NOCSPP		
	Other bacteria	BCTOTH		
Fungi	<i>Candida albicans</i>	CANALB	CANSPP	
	<i>Candida glabrata</i>	CANGLA		
	<i>Candida tropicalis</i>	CANTRO		
	<i>Candida parapsilosis</i>	CANPAR		
	<i>Candida sp.</i> , other	CANOTH		
	<i>Candida sp.</i> , not specified	CANNSP		
	<i>Aspergillus fumigatus</i>	<i>Aspergillus niger</i>	ASPFUM	ASPSPP
		<i>Aspergillus sp.</i> , other	ASPNIG	
		<i>Aspergillus sp.</i> , not specified	ASPOTH	
		Other yeasts	ASPNSP	
		Filaments other	YEAOTH	PARTOT
		Other parasites	FILOTH	
		PAROTH		
Virus	Adenovirus	VIRADV	VIRTOT	
	Cytomegalovirus (CMV)	VIRCMV		
	Enterovirus (polio, coxsackie, echo)	VIRENT		
	Hepatitis A virus	VIRHAV		
	Hepatitis B virus	VIRHBV		
	Hepatitis C virus	VIRHCV		
	Herpes simplex virus	VIRHSV		
	Human immunodeficiency virus (HIV)	VIRHIV		
	Influenza A virus	VIRINA		
	Influenza B virus	VIRINB		
	Influenza C virus	VIRINC		
	Parainfluenzavirus	VIRPIV		
	Respiratory syncytial virus (RSV)	VIRRSV		
	Rhinovirus	VIRRHI		
	Rotavirus	VIRROT		
	SARS virus	VIRSAR		
	Varicella-zoster virus	VIRVZV		
	Other virus	VIROTH		
	Micro-organism not identified or not found	_NONID		_NONID
Examination not done	_NOEXA	_NOEXA		
Sterile examination	_STERI	_STERI		

11.5 Annex 5. Antimicrobial resistance list

Antimicrobial resistance

Tracer antimicrobial resistance phenotypes for nosocomial pathogens

The surveillance of tracer antibiotic resistance phenotypes is optional and the proposed list is subject to adaptation in the future. Only for *S.aureus*, hospitals are requested to record resistance to methicillin/oxacillin.

	0	1	2	3	9
<i>S. aureus</i> *	oxa-S	oxa-R		GISA	unk
<i>Enterococcus faecalis</i> and <i>faecium</i>	ampi-S	ampi-R	vanco-R	-	unk
Enterobacteriaceae	ampi-S	ampi-R & C3-S	C3-R	-	unk
<i>Acinetobacter baumannii</i>	-	CAZ-S	CAZ-R	-	unk
<i>Pseudomonas aeruginosa</i>	ticar-S	ticar-R & CAZ-S	CAZ-R	-	unk

*minimal data=*S.aureus*, code STAAUR/0 for MSSA, STAAUR/1 for MRSA, STAAUR/9 if unknown

R = intermediate or resistant

Note : an I strain is coded as resistant (I = R)

S = sensitive

oxa = oxacillin

GISA = intermediate or resistant to glycopeptides (MIC vancomycin or teicoplanin)

vanco = vancomycin

ampi = penicillin A or amoxicillin

C3 = cefotaxim or ceftazidim

ESBL = Extended spectrum beta-lactamase producer

ticar = ticarcillin or piperacillin

CAZ = ceftazidime

unk = unknown

11.6 Annex 6. Code list of antimicrobials

List of antimicrobials (from ABC Calc 1.91)

ATC_cl	ATC_cl_label	Included antibacterials (+ ATC code)
J01A	Tetracyclines	Demeclocycline (J01AA01), Doxycycline (J01AA02), Chlortetracycline (J01AA03), Lymecycline (J01AA04), Metacycline (J01AA05), Oxytetracycline (J01AA06), Tetracycline (J01AA07), Minocycline (J01AA08), Rolitetracycline (J01AA09), Penimepicycline (J01AA10), Clomocycline (J01AA11), Tet.+chlor.+demecl. (J01AA20), Other comb. of tetracyclines (J01AA20), Oxytetracycline combinations (J01AA56)
J01B	Amphenicols	Chloramphenicol (J01BA01), Thiamphenicol (J01BA02)
J01CA_1	Penicillins, extended spectrum without anti-pseudomonal activity	Ampicillin (J01CA01), Pivampicillin (J01CA02), Amoxicillin (J01CA04), Bacampicillin (J01CA06), Epicillin (J01CA07), Pivmecillinam (J01CA08), Mecillinam (J01CA11), Metampicillin (J01CA14), Talampicillin (J01CA15), Temocillin (J01CA17), Hetacillin (J01CA18), Pivampi. + pivmecillinam (J01CA20), Other combinations (J01CA20), Ampicillin combinations (J01CA51)
J01CA_2	Penicillins, extended spectrum with anti-pseudomonal activity	Carbenicillin (J01CA03), Carindacillin (J01CA05), Azlocillin (J01CA09), Mezlocillin (J01CA10), Piperacillin (J01CA12), Ticarcillin (J01CA13), Sulbenicillin (J01CA16), Combinations (J01CA20)
J01CE	Beta-lactamase sensitive penicillins	Benzylpenicillin (J01CE01), Phenoxymethylpenicillin (J01CE02), Propicillin (J01CE03), Azidocillin (J01CE04), Pheneticillin (J01CE05), Penamecillin (J01CE06), Clometocillin (J01CE07), Benzathine benzylpenicillin (J01CE08), Procaine penicillin (J01CE09), Benzathine phenoxymethylpenicillin (J01CE10), Procaine pen.+benzylpen.(1800:360) (J01CE30), Combinations (other) (J01CE30)
J01CF	Beta-lactamase resistant penicillins	Dicloxacillin (J01CF01), Cloxacillin (J01CF02), Methicillin (J01CF03), Oxacillin (J01CF04), Flucloxacillin (J01CF05)
J01CG	Beta-lactamase inhibitors	Sulbactam (J01CG01), Tazobactam (J01CG02)
J01CR_1	Comb. of penicillins, incl. beta-lactamase inhib., without anti-pseud. activity	Ampicillin and enzyme inhibitor (J01CR01), Amoxicillin and enzyme inhibitor (J01CR02), Sultamicillin (J01CR04)
J01CR_2	Comb. of penicillins, incl. beta-lactamase inhib., with anti-pseud. activity	Ticarcillin and enzyme inhibitor (J01CR03), Piperacillin and enzyme inhibitor (J01CR05)
J01CR_3	Other combinations of penicillins	Ampicillin + cloxacillin (J01CR50), Ampicillin + flucloxacillin (J01CR50), Other combinations of penicillins (J01CR50)

J01DA_1	First generation cephalosporins	Cefalexin (J01DA01), Cefaloridine (J01DA02), Cefalotin (J01DA03), Cefazolin (J01DA04), Cefadroxil (J01DA09), Cefazedone (J01DA15), Cefatrizine (J01DA21), Cefapirin (J01DA30), Cefradine (J01DA31), Cefacetrile (J01DA34), Cefroxadine (J01DA35), Ceftezole (J01DA36)
J01DA_2	Second generation cephalosporins	Cefoxitin (J01DA05), Cefuroxime (Oral) (J01DA06), Cefuroxime (Parenteral) (J01DA06), Cefamandole (J01DA07), Cefaclor (J01DA08), Cefotetan (J01DA14), Cefonicide (J01DA17), Cefotiam (J01DA19), Loracarbef (J01DA38), Cefmetazole (J01DA40), Cefprozil (J01DA41)

11.7 Annex 7. ICD-9 CM code list for main diagnostics

Code	Main ICD-9 CM Diagnoses
01	Infectious and parasitic diseases
02	Neoplasms
03	Endocrine, nutritional and metabolic diseases, and immunity disorders
04	Diseases of the blood and blood-forming organs
05	Mental disorders
06	Diseases of the nervous system and sense organs
07	Diseases of the circulatory system
08	Diseases of the respiratory system
09	Diseases of the digestive system
10	Diseases of the genitourinary system
11	Complications of pregnancy, childbirth, and the puerperium
12	Diseases of the skin and subcutaneous tissue
13	Diseases of the musculoskeletal system and connective tissue
14	Congenital anomalies
15	Certain conditions originating in the perinatal period
16	Symptoms, signs, and ill-defined conditions
17	Injury and poisoning

11.8 Annex 8. Data collection form

Questionnaire num.

PATIENT IDENTIFICATION

Questionnaire num. Country Centre Date of the survey

GENERAL INFORMATION	
SERVICE/UNIT/WARD	<input type="text"/>
BED NUMBER	<input type="text"/>
AGE <input type="text"/> (Days=D; Months=M)	<input type="text"/>
DATE OF ADMISSION	<input type="text"/>
GENDER (Man=1; Woman=2)	<input type="text"/>

INTRINSIC RISK FACTORS	Yes	No
Immunodeficiency	<input type="checkbox"/>	<input type="checkbox"/>
Neutropenia	<input type="checkbox"/>	<input type="checkbox"/>

EXTRINSIC RISK FACTORS	Yes	No
Urinary catheter	<input type="checkbox"/>	<input type="checkbox"/>
OPEN urinary drainage	<input type="checkbox"/>	<input type="checkbox"/>
CLOSED urinary drainage	<input type="checkbox"/>	<input type="checkbox"/>
Peripheral vascular catheters	<input type="checkbox"/>	<input type="checkbox"/>
Central vascular catheters	<input type="checkbox"/>	<input type="checkbox"/>
Parenteral nutrition	<input type="checkbox"/>	<input type="checkbox"/>
Mechanical ventilation	<input type="checkbox"/>	<input type="checkbox"/>

BASELINE RISK ASSESSMENT	
Birthweight (grams; only patients =1month)	<input type="text"/>
Gestational age (weeks; only patients = 1month)	<input type="text"/>

SURGICAL PROCEDURE	
Date of surgical intervention	<input type="text"/>
NNIS procedure category	<input type="text"/>
ASA score	<input type="text"/>
Duration in minutes	<input type="text"/>
Class of operation (clean=1; clean-contaminated=2; contaminated=3; dirty=4)	<input type="text"/>
	Yes No
Elective	<input type="checkbox"/> <input type="checkbox"/>
Endoscopic	<input type="checkbox"/> <input type="checkbox"/>

ACTIVE INFECTIONS (only nosocomial infections)

Infection site 1

Date of onset

Culture (positive=1; negative=2; not done=3; other test=4)

Micro organism 1 Resist.

Micro organism 2 Resist.

Micro organism 3 Resist.

Infection site 2

Date of onset

Culture (positive=1; negative=2; not done=3; other test=4)

Micro organism 1 Resist.

Micro organism 2 Resist.

Micro organism 3 Resist.

Infection site 3

Date of onset

Culture (positive=1; negative=2; not done=3; other test=4)

Micro organism 1 Resist.

Micro organism 2 Resist.

Micro organism 3 Resist.

Infection site 4

Date of onset

Culture (positive=1; negative=2; not done=3; other test=4)

Micro organism 1 Resist.

Micro organism 2 Resist.

Micro organism 3 Resist.

ANTIMICROBIALS
Antimicrobial 1 <input type="text"/> Indication <input type="checkbox"/>
Antimicrobial 2 <input type="text"/> Indication <input type="checkbox"/>
Antimicrobial 3 <input type="text"/> Indication <input type="checkbox"/>
Antimicrobial 4 <input type="text"/> Indication <input type="checkbox"/>

Main diagnostic

11.9 Annex 9. List of participants to the working group

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