



Operating Manual 2003

V12 (Final)



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Summary

- Reported rates of nosocomial infections (NI) show large variations across the Member states of the European Union (EU). This variability reflects differences in surveillance methodology, in the functioning of the health services and in the adoption of policies, guidelines and technologies which could reduce the level of risk. The availability of European standardised comparable data has been recognised as a considerable support to evaluation, risk assessment and control activities to reduce the burden of these infections.
- The HELICS programme is an international network aiming at the collection, analysis and dissemination of valid data on the risks of nosocomial infections in European hospitals. It is dependent upon the co-operation of the surveillance systems established by the national health authorities of the EU, Candidate and Associated countries. Eligible surveillance systems may have a national or a regional coverage.
- The main objective of the HELICS programme is to establish a large reference data set required to mirror national data to guide preventive activities and stimulate comparative and evaluative approaches.
- HELICS will monitor variations in the risks of nosocomial infections over time and between the different countries, and according to the characteristics of healthcare organisations.
- HELICS will also support the implementation of new surveillance networks, improve the quality and comparability of data and extend the capacity of data exchange between the existing European national or regional networks. Taking advantage of a large European network and database, it will stimulate applied research and evaluation.
- The primary targets of the HELICS programme are (1) the surveillance of the incidence of surgical site infections, (2) the surveillance of the incidence of infections in intensive care units, and (3) the harmonisation of prevalence hospital-wide surveys. A consensus has been established on the three corresponding Master Protocols which have been agreed upon by the professionals in charge of the national surveillance networks.
- Analyses will be permanently accessible through the HELICS internet site. A widely disseminated Annual Report will provide feedback on the major variations and trends.
- The HELICS networks will also harmonise their early warning systems so that there can be rapid dissemination of any information on new, important or threatening events and facilitating the implementation of interventions and preventive measures.

The HELICS Operating Manual was prepared by the Co-ordination Team¹ in Université Claude Bernard Lyon (France) in close collaboration with the other members of the HELICS Management Team². It was validated on May 17, 2003 by the Networks meeting.

¹ Jacques Fabry, Ian Russell, Sylvie Fayolle

² Barry Cookson, Annette De Boer, Petra Gastmeier, José Rossello, Carl Suetens

LIST OF ABBREVIATIONS

CNIL	Commission Nationale Informatique et Liberté (France)
DG SANCO	Directorate General Health and Consumer protection
EARSS	European Antimicrobial Resistance Surveillance System
EC	European Commission
ECDPC	European Centre for Diseases Prevention and Control
ESCMID	European Society of Clinical Microbiology and Infectious Disease
ESGNI	European Study Group on Nosocomial Infections
EU	European Union
EUPHIN	European public health information network
HELICS	Hospital in Europe Link for Infection Control through Surveillance
HICAB	Hospital Infection Control Advisory Committee
HIS	Hospital Infection Society
HISC	Health Information Standards Council
HSSCD	Health Surveillance System for Communicable Diseases
ICU	Intensive Care Unit
ICNA	Infection Control Nurses Association
KISS	Krankenhaus Infektions Surveillance System
NI	Nosocomial Infection
NINSS	Nosocomial Infection National Surveillance Service
NSIH	National Surveillance of Hospital Infections
PREZIES	PREventie van ZIEkenhuisinfecties door Surveillance
RAISIN	Réseau d'Alerte, d'Investigation et de Surveillance des Infections Nosocomiales
SIRO	Sairaalainfektio-ohjelma (Finnish Hospital Infection Program)
SSI	Surgical Site Infection
WHO	World Health Organisation

➤ **HELICS MANAGEMENT TEAM**

**Project Co-ordinator
Assistant - Data manager
Epidemiologist / IC specialists**

**Jacques FABRY
Ian RUSSELL
Carl SUETENS
Annette De BOER
Petra GASTMEIER
José ROSSELLO
Barry COOKSON**

**Microbiology & IC specialist
Assistant epidemiologist
Administrative assistant**

**-
Sylvy FAYOLLE**

*Mail: Laboratoire d'épidémiologie et Santé publique
Université Claude Bernard Lyon 1
8, avenue Rockefeller
69373 LYON Cedex 08 - France*

E-mail: helics@adm.univ-lyon1.fr

Tel : +33 4 78 77 75 99

Fax: +33 4 78 00 93 86

➤ **EXPERT ADVISORY BOARD (to be designated)**

➤ **NATIONAL [REGIONAL] NETWORKS CO-ORDINATORS**

Michael HIESMAYR, Walter KOLLER (Wien), Carl SUETENS, Ingrid MORALES, Hedwig CARSAW (Brussels), Ole B. JEPSEN (Copenhagen), Jennie WILSON (London), Outi LYYTIKAINEN (Helsinki), Anne SAVEY (Lyon), Pascal ASTAGNEAU (Paris), Petra GASTMEIER, Christine GEFFERS, Christian BRANDT (Berlin), Jean-Claude SMITH, Margaret HEMMER (Luxembourg), Jan WILLE (Utrecht), Annette De BOER (Bilthoven), Edward SMYTH (Belfast), Bjorn IVERSEN, Nina SORKNESS (Oslo), Eduardo GOMES DA SILVA, Elaine PINA (Lisbon), Mercedes PALOMAR, José ROSSELLO (Barcelona), Angel ASENSIO (Madrid), Piotr B. HECZKO (Krakow), Michael BORG (Malta), Irena KLAVS, (Ljubljana), Jacqui REILLY (Glasgow), Nick LOOKER (Cardiff)

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1. INTRODUCTION

Nosocomial Infections (NI) present particular challenges compared to the surveillance of other infections. Their clinical, microbiological, epidemiological and even physio-pathological features are heterogeneous. National initiatives to foster NI surveillance and control activities have varied from a complete absence to their being considered high-level public health priorities. However, European health systems in many countries are increasing the priority and resources for such initiatives. This is because they realise that valid outcome data have the potential to make a major contribution to the improvement in the quality of patient care by optimising patient management systems and informing the adoption of valid evidence-based healthcare guidelines, policies and practices. Furthermore, important nosocomial events such as epidemics, particularly virulent infections and preventive failures, could benefit from an early warning and alert system involving the public health national authorities. To take these specific aspects into account, the HELICS group adopted a “bottom-up” consensual approach to the preparation of the NI component of the EU network on communicable diseases.

Commissioned before the decision 2119/98/EC, an initial work of the HELICS group proposed a global strategy for the implementation of a European network on Nosocomial Infections, comprising surveillance, control, training and research. A first implementation phase (HELICS Programme Phase I: Jan. 2000 – June 2002) then proceeded within the context created by decision 2119/98/EC. It focused on the harmonisation of existing European networks and the solution of the technical problems of producing epidemiological data and other relevant information for these infections. After a further stage of adaptation of national protocols, the production of NI indicators at a European level is now proposed, the main ones being as follows:

Table 1 – Main indicators produced by the HELICS programme

Population	Main Indicators	Analysis
ICU Patients (with lengths of stay >2 days)	level 1: Incidence rates (all, major sites) per 100 patients, per 1000 patient-days [Unit- or Patient based] Bloodstream infections (origin and micro-organisms) <i>Optionally:</i> Incidence rates (major sites) per 1000 patient-days of device-exposures	EU Countries Networks Inter-unit variations
	level 2: Stratified Incidence rates (major sites) per 1000 patient-days of device-exposures [Patient-based] Standardised Infection Ratio (SIR 1)	
	level 3: Standardised Infection Ratio (SIR 2) [Patient-based]	Micro-organisms and antimicrobial susceptibilities
Surgical patients (specific interventions)	Incidence rates of Surgical Site Infections (superficial, deep, organ-space) per 100 patients, per 1000 post-operative patient-days Antibiotic prophylactic use	
All hospitalised patients (one-day prevalence)	Prevalence rates (all, major sites) per 100 hospitalised patients	Countries or regions Surveys
	Antibiotic use	Variations according to the hospital characteristics

These achievements required

- the commitment of a large number of experts involved in seven working groups;
- the creation and analysis of two databases (on surgical and ICU infections);
- the testing of two data collection mechanisms (on surgical infections and for immuno-compromised patients);
- the preparation, extensive and in-depth discussions of three master protocols (on ICU and surgical infections and the prevalence survey);
- the evaluation of a procedure for the production of European evidence-based technical guidelines;
- and an inventory of a European training programme on NI surveillance methods (plus the proposal of a core teaching curriculum).

Three targets attained a high level of consensus for the implementation of the European network:

- infections in ICU patients (with three optional levels of comprehensiveness in data collection and analysis);
- infections in surgical patients;
- hospital-wide prevalence studies of nosocomial infections with clearly-defined case definitions and denominator data.

The present challenges to the HELICS programme are to organise the routine production and dissemination of analyses, and extend the coverage of the programme progressively to countries or regions with little or no experience of surveillance. Some actions are critical at this stage:

- assisting the national [regional] networks in adopting the harmonised HELICS master protocols,
- assisting countries [regions] not covered by a surveillance network in developing their own organisation within the HELICS partnership,
- developing a set of hospital and quality of care parameters to complete the indicators and allow cross-analysis of resources, procedures and outcome indicators,
- developing common surveillance methodologies and tools through reflection and sharing of expertise for the current HELICS network trainers and others that join it from current, candidate and associated member states,
- creating tools for collection, quality control, transfer, analysis and dissemination of electronic data which are conducive to their supporting the use of the HELICS internet database-site and EUPHIN-HSSCD.

The HELICS co-operation has clearly demonstrated the willingness and ability of its participants to work productively and efficiently in the effort to rationalise approaches and ensure that significant progress can be made in the control of this important health issue. The participants are now ready to implement and extend a harmonised surveillance scheme within the framework of the EU policy on communicable diseases.

2.1 The General Structure

The HELICS programme functions as a “Network of Networks”, in agreement with the philosophy of the Decision 2119/98/CE on December 22 1999. The HELICS-associated participating networks will collect NI data according to standardised, or HELICS-compatible, protocols. The data will then be transferred to the HELICS Management Team for entry into the HELICS database for analysis, feedback and dissemination.

The co-ordinators of each HELICS-associated network will participate in the definition of harmonised procedures and data management and analysis, which is under the responsibility of the HELICS Management Team. Designated by all participating countries, an Expert Advisory Board of will review and evaluate the functioning of the programme.

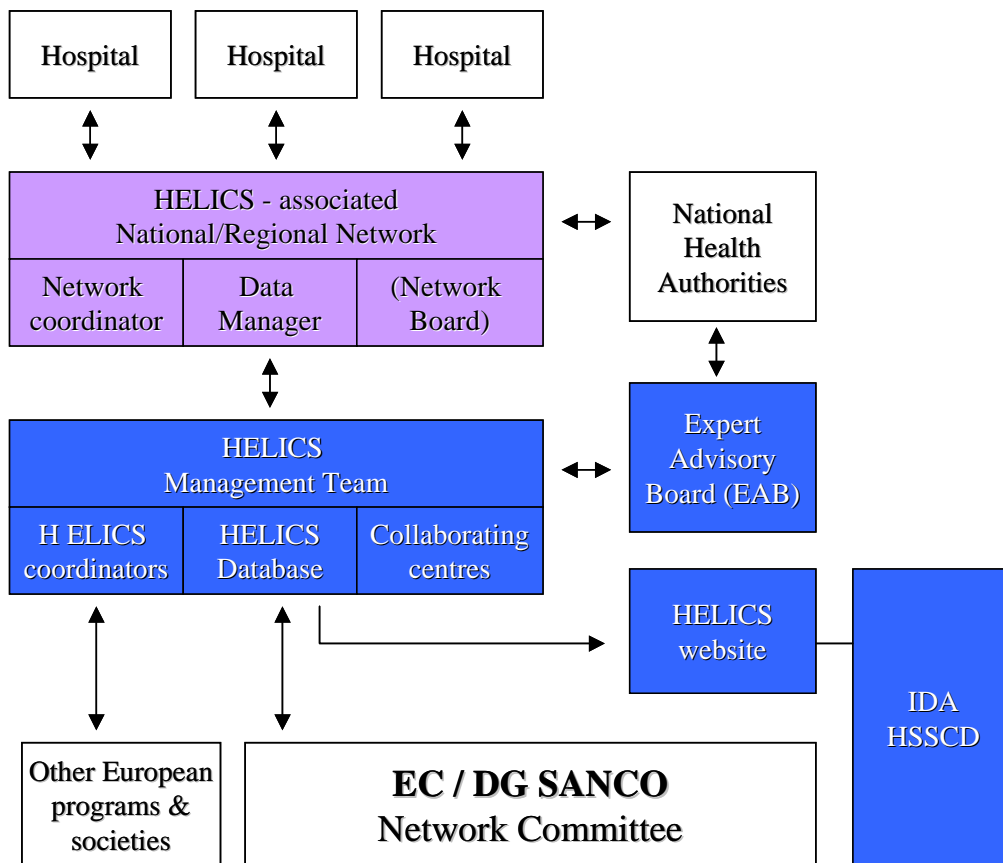


Fig.1-The HELICS programme: general structure

2.2 The Expert Advisory Board (EAB)

2.2.1 Mission

The Expert Advisory Board functions are:

- overseeing the advancement of the programme and proposing improvements in organisation,
- agreeing the way HELICS data and analyses are to be circulated to appropriate organisations in the participating countries and advising the Programme Management Team about the best ways to involve national [regional] bodies in the co-operation,
- facilitating links with other European projects and relevant Professional Societies and avoiding duplication and overlap,
- preparing future developments of the HELICS programme, by constituting a forum for discussion regarding NI control activities and priorities in Europe.

The HELICS programme will also call on other experts for technical advice, particularly those who contributed in 2000-2002 to the working parties of HELICS Phase 1³ (see Appendix 1).

2.2.2 Membership⁴

The EAB regroups national representatives from the member states, designated by the competent health authorities. Optimally, the designated individuals should be the person in their national public health system who is responsible and familiar with the practical and scientific challenges of nosocomial infection control. Representatives from concerned European organisations and projects can also be invited as ad hoc participants, particularly the following:

1. European Society for Intensive Care Medicine (ESICM)
2. European Society for Clinical Microbiology and Infectious Diseases (ESCMID) and Study Group on Nosocomial Infection (ESGNI)
3. Surgical Infection Society (SIS) - Europe
4. European Antimicrobial Resistance Surveillance System (EARRS)
5. Hospital Infection Society (HIS)
6. Infection Control Nurses Association (ICNA)

The designated members by April 2003 are listed in Appendix 1.

2.2.3 Procedures

- The HELICS Management Team solicits designation or confirmation of membership at each phase of the project, with the competent health authorities.
- The EAB meets once every two years, preferably on an occasion which will facilitate contact with the HELICS co-ordinators and experts, and with the co-ordinators of the HELICS-associated networks (for example the HELICS Biennial Conference).
- The EAB designates a chairman from within its members, who approves the EAB agenda with the Programme Co-ordinator.
- The relevant documentation is sent or made available at least one month before the EAB meeting.

³ During the HELICS Implementation phase I, experts met together and in specific Working Parties to exchange experience and opinions and to agree protocols including details of the information that will be collected for the different types of infection. They have also performed preliminary studies on the surveillance of NI.

⁴ The members of the Expert Advisory Committee (formerly HICAB) designated in 2001 by National Health Authorities was: Austria: **Maria Woschitz-Merkac**, Belgium: **Bart Gordts**, Denmark: **Ole Bent Jepsen**, France: **Jean Carlet**, Finland: **Petri Ruutu**, Germany: **H. Rüden**, Greece: **Nicholas J. Legakis**, Italy: **Maria Luisa Moro**, Luxembourg: **Elisabeth Heisbourg**, Norway: **Bjorn Iversen**, Spain: **J.-L. Arribas-Llorente**, Portugal : **Elaine Pina**, The Netherlands: **M.A.J. Bilkert-Mooiman**, Sweden: **Peet J. Tüll**, United Kingdom: **Susan Macqueen**, **Gary French**

- The HELICS Management Team presents to EAB the work conducted during the preceding period.
- The minutes of the EAB meeting are accessible through the HELICS site.

2.3 The Co-ordinators of the HELICS-associated National [Regional] Networks

2.3.1 Mission

The National Co-ordinators are responsible to:

- Organise data collection directly in the participating hospitals/wards,
- Pool the hospital data and check their quality, particularly the consistency with the HELICS protocols,
- Format the data using the HELICS transfer format,
- Transfer these data to the HELICS Management Team,
- Collect additional information about participating hospitals/wards and transfer it to the HELICS Management Team.

Furthermore it will be the responsibility of the Network Co-ordinator to disseminate the information produced by the HELICS database to the participating hospitals or wards.

2.3.2 Identification of the participating networks

The participating national or regional networks and their co-ordinators are identified through contact with the relevant health authorities.

2.3.3 Participation in the programme

The National Co-ordinators will be involved in the functioning of the programme by:

- Participating, if necessary with their Data Manager and/or IT technician, in the Plenary Networks Meetings which are convened at least annually,
- Exchanging data and relevant information regularly through the Internet.
- Directly contacting members of the HELICS Management Team during site field visits.

2.4 The HELICS Management Team

2.4.1 Mission

Under the guidance of the HELICS Programme Co-ordinator, the members of the HELICS Management Team share the responsibility of the programme management, as:

- scientists in charge of the development of a particular technical aspect by leading a Collaborative Team (see below 2.4.3),
- professionals in charge of data management and analysis,
- members of the management staff

2.4.2 Membership

The members of the HELICS Management Team (see p.4 and Appendix 1) are:

- the people who have signed contracts with the European commission and have taken a defined responsibility in the programme management,
- the professionals recruited on the project's budget.

2.4.3 Procedures

- They will work in permanent or regular contact.
- They will report their activities to the EAB, and then to the European Commission (DG SANCO) through the annual HELICS reports.

2.4.4 The Co-ordination Team

The Co-ordination Team in Lyon co-ordinates the activities of the project from an administrative and process standpoint:

- *Administration*
 - handles the financial management,
 - organises the EAB and Networks meetings,
 - prepares and distributes the minutes and meeting decisions,
 - co-ordinates the writing of DG SANCO reports.
- *Process*
 - updates the project stakeholders regularly on its progress,
 - publishes and updates the Operating Manual,
 - explores and evaluates best practice and proposes, implements and monitors procedure improvements as discussed and agreed with the HELICS Management Team.
 - manages the HELICS site and disseminates new and revised documentation.

The team also is the focal point of contact with the National [Regional] Networks. As described further in Part 4. [Organisation of Data Flow], the Co-ordination Team will be responsible for the maintenance and management of access to the database and the dissemination of the data analyses produced by the Collaborative Teams.

2.4.5 The Collaborative Teams

The Collaborative Teams share the responsibility for the technical functioning by taking charge of a specific duty e.g. data collection and analysis, publication, training of the participating networks. There are currently four collaborating teams:

- *Brussels – Data analysis*

The epidemiologist will be responsible for the analysis of the data collected by the Co-ordination Team on Surgical Site Infections and Infections in ICU patients. As such, the Co-ordination Team and the Epidemiologist will work in close collaboration to define the analysis needs, methods and publication format.

- *Barcelona – Prevalence Surveys*

This team will supervise the dissemination and use of the HELICS Master protocol for Prevalence Surveys. This will include the organisation of data collection and their entry into a specific Prevalence database, and propose a strategy and initiatives to develop a European co-ordinated approach.

- *Berlin – Complementary studies*

This team has the responsibility to define and collect the additional information (on hospitals, wards, units and procedures) to allow evaluation of the representativeness of the HELICS network, and design complementary studies and evaluations linking level of risks, organisation of care and adoption of preventive procedures.

- *London – Training*

This team will define and organise training to support the project needs which will also serve to inform new network members. The current requirements are to produce a “Training the Trainers” module which will cover definitions, data collection, validation and central and local analysis.

This chapter presents the minimal organisational conditions required for the integration of a surveillance network in the HELICS group.

3.1 Administrative Requirements

- *Agreement of the competent National Public Health Authorities.* The involvement of policy-makers is an absolute requirement for participating in the HELICS programme, as the production and use of data at local, regional or national will necessitate significant allocation of resources.
- *Designation of the National Representative and the Network Co-ordinator(s).* The National Representative is, in principle, the official contact person for the HELICS project and the representative at EAB, whereas the Network Co-ordinator is in charge of the management of one or several networks. These positions can be occupied by the same individual. They are invited to all Plenary Network meetings.
- *Exchange of letters of agreement* between the competent National Public Health Authorities and the HELICS Programme Co-ordinator, with the official Attestation of Partnership.

3.2 Technical requirements

- *Existence of a National [Regional] Co-ordination Team.* A technical co-ordination team with trained professionals is managing the participating network with at least a Network Co-ordinator and preferably a Data Manager and/or IT Technician, and a Network Board. Participation of the Team in the HELICS Training Module is desirable.
- *Existence of surveillance protocols which must comply with the relevant HELICS protocols.* Mandatory and required items are included in the national surveillance protocols. In some situations, however, aggregated data collected by a unit-based methodology can be transferred and contribute to some of the standardised tables of results.
- *Existence of a procedure to check the quality of data* (see Section 4.2.3)
- *The management of a list of anonymous codes for hospitals and wards/units.* The use of these codes is essential for the analysis of trends and must be maintained permanently. However, the names of hospital and of wards/units will not be transferred to the HELICS database.
- *Agreement on the collection of additional data on each participating hospitals and wards/units.* This information will be used to estimate the representativeness of the HELICS network and for complementary data analysis.
- *Agreement on the conditions of data transfer to the HELICS team.* After validity checks and formatting (standard formats, see Section 4.2.2) the data will be transferred every six months.

4.1 Global system architecture

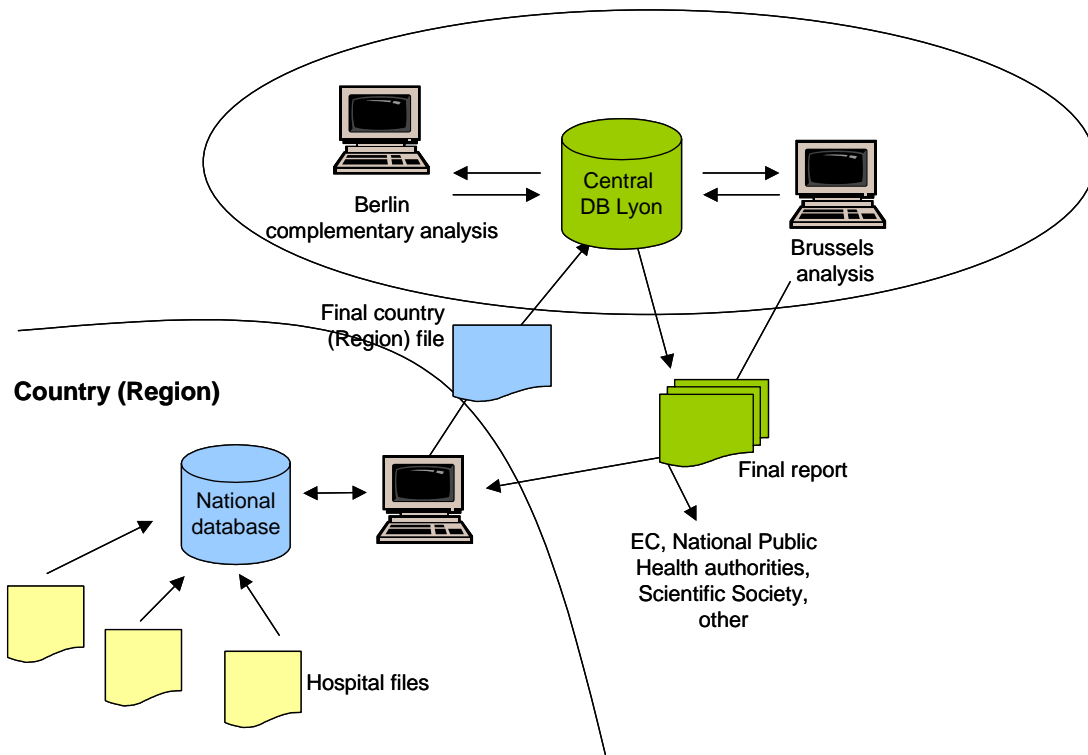


Fig.2-The HELICS Information System architecture

The HELICS Management team is responsible for management of the data which is transferred from the National [Regional] HELICS-associated networks. The HELICS Database Management Software that is being developed will also be offered to the HELICS-associated networks so that they can use the same format to gather and analyse their own data, and to transfer them to HELICS. Using the existing HELICS Database Management Software as a framework will therefore enable maximum leverage of existing efforts and avoid duplication. The development of this software will rely upon the experience gained by National networks in Belgium, France, the Netherlands and England.

4.2 Data collection and analysis process

The following chart illustrates the different steps involved in the collection, pooling and analysis of the data gathered from the National [Regional] Networks.

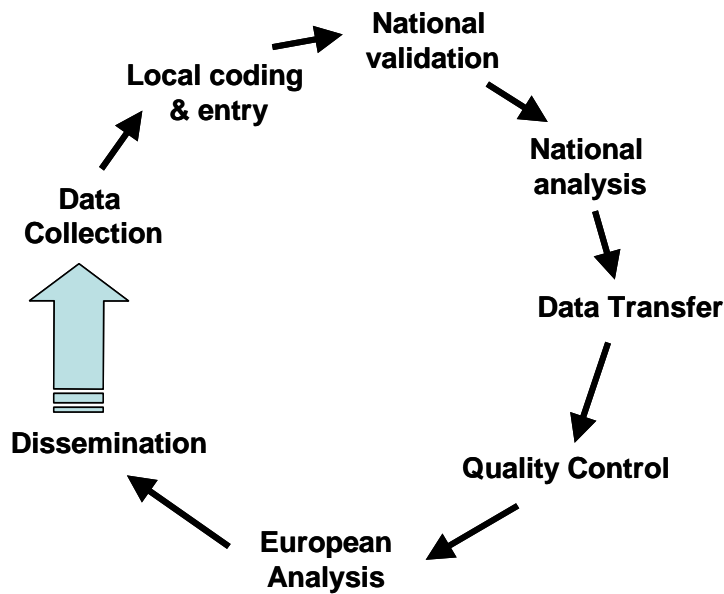


Fig.3-The HELICS data collection and analysis process

4.2.1 Data Collection at hospital/wards level

The review and improvement of data collection methods at a local level should be carried out with a view to reducing workloads and improving data quality. Because of varying local hospital organisations across Europe, methods of data collection have not been prescribed in a standardised way. However, surveillance is best carried out by well motivated personnel who have the experience and training to meet the requirements of the job and are aware of the benefits of surveillance. Format of data is defined in the SSI, ICU and Prevalence Master Protocols.

4.2.2 Coding

The Coding Scheme for HELICS is presented in Appendix 4. This presently covers ICU and SSI surveillance.

To comply with confidentiality, codes for hospitals, wards/units and patient identifiers must be anonymous.

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 the usual hospital ID's to the new HELICS code) should be available at the level of the surveillance network only.

Patient ID's should be a unique patient code. This code should be anonymous and prevent the network coordination from tracing back the patient. However a patient who is admitted or infected several times should keep the same number. Since this number will also be used for validation studies, (only) the hospital should be able to link the number to the patient's file.

The variables are classified as follows :

- M : Mandatory data items must be answered according to specification before the record can be included in the HELICS database.
- R : Required data items must be answered according to specification before the record can be included in comparable data. A 'null' response will prevent the record being included in comparable data.
- O : Optional data items are used for additional analysis. A 'null' response will prevent the record being included in additional analysis.
- M/O : Conditionally mandatory data items must be answered according to specification, dependant on the value of another data item, before the record can be included in the HELICS database. Where the dependency does not exist, a 'null' response is required.
- R/O : Conditionally required data items must be answered according to specification, dependant on the value of another data item, before the record can be included in comparable data. Where the dependency does not exist, a 'null' response is required. Also, where the dependency does exist, a 'null' response will prevent the record being included in comparable data.

The HELICS Coding Scheme contains the following tables of data :

<u>Table Name</u>	<u>Description</u>
Helics_n	Network Data Table
icu_h	ICU Hospital Characteristics Data Table
ssi_h	SSI Hospital Characteristics Data Table
icu_u	ICU Unit Characteristics Data Table
ssi_u	SSI Surgical Unit Characteristics Data Table
icu_d	ICU Level 1 Denominator Data Table
icu_i	ICU Level 1 Numerator (Infection) Data Table
icu_p	ICU Level 2 Patient Data Table
icu_e	ICU Level 2 Day-by-Day Exposure Data Table
icu_c	ICU Level 2 CVC Option Data Table
icu_a	ICU Level 2 Antimicrobial Consumption Option Data Table
icu_i	ICU Level 2 Infection Data Table
icu_inf	ICU Infection Data Table (Optional)
icu_res	ICU Micro-organism & Antimicrobial Resistance Data Table
ssi_o	SSI Patient and Operative Procedure Characteristics Data Table
ssi_i	SSI Surgical Site Infection Data Table

Data on participating networks, hospitals and wards/units are collected in the helics_n, icu_h, ssi_h, icu_u and ssi_u tables. These tables will be documented once a year only. The 'Standard questionnaire on HELICS-associated networks' (Appendix 2) and 'Standard questionnaire on participating hospitals/wards' (Appendix3) will be issued to participating networks at the beginning of each year. These questionnaires will be used to collect the necessary data on participating networks, hospitals and wards/units and also for the collection of other data (see later).

4.2.3 Data Validation at National [Regional] level

The National [Regional] Co-ordinators are responsible for data quality. Performing quality checks and validation are essential tasks, as they ensure the quality of the data, the credibility of the final analyses and their ability to inform and monitor prevention and control activities. Participating centres will be asked to describe their procedures to guarantee the quality of the data. The minimal procedures are:

- (a) a systematic review of the completeness of information,
- (b) a systematic check of the consistency of data:
 - data set within predefined limits
 - "impossible" or inconsistent data

Easy communication between the hospitals and the National [Regional] Data Managers is essential at this stage of the process to complete or rectify or discuss possible issues such as invalid or missing data.

National Co-ordinators will also provide information regarding the method used to select their data so that the European data analysis team can evaluate its representativeness. A limited set of data describing the participating hospitals and wards/units will make it possible to follow-up on issues of data representativeness and to propose possible ways to improve it (Tables helics_n, ssi_h, icu_h, ssi_u and icu_u).

4.2.4 Data transfer

Each participating network is responsible for the data input and transmission to the HELICS Management Team. The HELICS Database Management Software, shared by participants in the HELICS programme, will enable this to be carried out by facilitating data formatting and exchange. While the software is under development and is unavailable, data may be transferred using appropriate support such as CD-R, disk or Internet transmission, as agreed between the HELICS Management Team and the network.

4.2.5 Data control and storage

Data control and entry into the HELICS database will be carried out by the Data Manager based in Lyon, France. Before entry into HELICS database, a quality check will be carried out. Data items must be answered according to specification before the records can be included. Mandatory data items which have not been answered will prevent the record being included and the National [Regional] Coordinator will be informed accordingly. A summary of the data input into the HELICS database will be sent to the National [Regional] Coordinator.

4.2.6 European data analysis

Analysis will be performed using the “mandatory” and “required” variables which will allow the production of comparable figures on risks and trends. If a “required” variable is missing in a record which has been accepted in the database, this record will be excluded from the specific analysis for which this variable is required without excluding the records of other analyses. Optional variables will be used for complementary analysis.

The principal tables and figures presenting the indicators of Table 1 will be:

- major rates of nosocomial infections stratified or adjusted for the main risk factors,
 - at European level
 - by countries (and networks) (+ map)
 - by characteristics of hospitals
 - by countries and characteristics of hospitals (+ map)
 - according to the available information on structures and processes.
- trends of the major stratified or adjusted rates over time.

A complementary study will also be carried out by the Collaborating Centre in Berlin to establish the association between nosocomial infection rates and patient care quality parameters.

The “standard questionnaire on HELICS on participating hospitals/wards” Appendix 3 will contain optional questions for the complementary Study. As mentioned previously, the questionnaire will be issued to participating networks for completion at the beginning of each year.

Timeline. Data analysis will be performed each year and presented in the HELICS annual report. Assuming the finalisation of national [regional] data collection takes six months after the end of each semester, and that four to five months are needed for the completion of the analysis, the results for any year will be made available for dissemination at the end of the following year. An intermediate data analysis will be performed in the middle of each year on the data of the first semester of the preceding year. Its results will be available only on the HELICS site.

Ownership. Data analysis will be carried out by the epidemiologist in charge of the SSI and ICU components based in Brussels, and by the epidemiologist in charge of the complementary analysis based in Berlin. When another component is created, for example for prevalence data, data analysis will be carried out by an epidemiologist based for example in Barcelona.

Communication. Communication between the countries and the analyst in Brussels is essential to the timeliness and appropriateness of the analysis. The analyst will transmit preliminary results to the different countries, will request their comments on the comparative results, and will request their support and approval for the final report write-up.

The data will be used to generate European annual reports on NI in Europe, scientific publications and reference tables on the Internet.

5.1 Outline of the annual report

Its purpose will be to show a comparative analysis of data across countries. Results will therefore be presented by countries, type of hospital/unit, type of patients or surgical interventions, levels of risk, etc ..., as mentioned in Section 4.2.6.

A high-level outline of the annual report will be:

1. Summary
2. Nosocomial Infection Control in Europe: progress of surveillance systems
3. Surveillance of SSI: facts and trends
4. Surveillance of ICU patients: facts and trends
5. Prevalence surveys in Europe
6. Other activities of the HELICS programme
7. Comments of the EAB

The final report will be submitted for comments, review and approval to the different networks. The networks will have 15 days to formulate comments on the document. If the networks haven't responded within that timeframe, it will be considered that they have given their consent to its publication.

The annual report will be published and distributed in a paper format. An electronic copy will also be made available on the Internet on the HELICS website.

5.2 Diffusion of the HELICS annual report

The HELICS annual report will be distributed to the main stakeholders in the project, including :

- DG SANCO,
- The National Health Authorities in charge of Nosocomial Infection control,
- HELICS associated networks.

The report will also be publicised widely and the information from the report will be widely disseminated via the Internet, conference presentations and via Professional Associations in Infection Control.

5.3 Scientific publications: rules of authorship

The HELICS Management Team and each of the HELICS-associated Network Co-ordinators must provide written consent prior to any publication. Authorship will be dealt with according to the authorship regulations used by the British Medical Journal (order of authorship in the publication will be based on every author's contribution to the paper); in any publication reference will be made to the HELICS programme and to the official networks in the countries, including their acronym and contact information, if desired by the networks.

The HELICS Management Team and each of the HELICS-associated network co-ordinators will approve the order of authorship as part of the process to authorise the overall publication.

6.1 Overview of general policy

The policies that cover the issues of data confidentiality and database protection are both the European guidelines used for the HELICS database as well as the local rules of the country which will be hosting this database.

The Directive 95/46/EC of the European Parliament (24 October 1995) clarifies the rules regarding the protection of individuals with regard to the processing of personal data. It defines “personal data” as “any information related to an identified or identifiable natural person. An identifiable person is one who can be identified, **directly** or **indirectly**, in particular by reference to an identification number.”

To ensure that records in HELICS database cannot be directly or indirectly accessed, a number of guidelines have been proposed in the next section. More detailed database access guidelines have also been defined to ensure its security (see Section 6.2). Finally, guidelines have been established in order to provide a framework for access to HELICS data by third-parties (external entities which do not participate in the HELICS programme).

6.2 Data confidentiality policies

All measures necessary to prevent access to nominative data will be applied. The following guidelines will ensure that these nominative data are coded to prevent direct identification of patients and hospitals.

6.2.1 Protection of patient information

Coding patient information at the hospital level or at the level of the official networks in the countries will prevent identification of individual patients in the HELICS database. The key linking each hospital/unit to its code remains strictly within the national surveillance system to secure maximum confidentiality.

6.2.2 Protection of hospital data

Coding hospital information at the hospital level or at the level of the official networks in the countries will prevent identification of hospital information or of individual hospitals. When presenting the results of surveillance, the necessary measures to ensure that individual hospital can be recognised will be taken.

6.3 Physical and electronic Database protection

6.3.1 Data storage

Data will be stored in the HELICS database until the end of the HELICS co-operation for up to 10 years. 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.

6.3.2 Data accessibility

Access to the data will be limited to the HELICS Management Team members who are responsible for the production of analysis: the Data Manager in Lyon, the Epidemiologist in Brussels for analysis of SSI and ICU infections, the Epidemiologist in Berlin for complementary analysis. They will access the data according to the work plan established by the HELICS Management Team.

Data encryption will be used to ensure the security of data during transmission.

6.3.3 Access to the Database through a computer

- Computer access will be protected by a password. Passwords will not be easily identifiable, will not be written on the computer and will be changed regularly.
- Backup copies will be made regularly and kept in a locked place.
- External maintenance will be carried out in the presence of the computer user.
- The computer will be switched off or a password-protected screen saver will be activated when the computer is left unattended.

6.3.4 Database access

- Access to the data will be protected according to the user authorization level.
- Copying of data on external peripherals will be controlled.
- Database and data access will be protected by a password (see above for password guidelines). Additionally, the application access password will be different from the computer password.
- It must be impossible for users to connect simultaneously using the same username and password.
- Connections to the server and the database must be logged on a file.
- In the case of repetitive incorrect input of username/password, the connection must be blocked to the user and the user must be requested to contact the database administrator.
- When the database is not accessed during a certain length of time while the user is logged on, the user must be logged off.
- As much as possible, usage of smart-card protected access is recommended

6.3.5 Network access and data transfer (between members of the Management Team)

To ensure maximum confidentiality of the data, the overall system architecture will take into account the risk of fraudulent data access through the Internet or the computer network. For that purpose, the database will not be connected to a network and will be protected from the Internet by a firewall.

Furthermore, all file exchanges of raw data between members of the HELICS Management Team will be encrypted. The number of files and volume of data exchanged will be limited as much as possible,

6.4 Access policies to data and analyses for HELICS non-members

6.4.1 General guidelines

- Network data belong to those providing them, i.e. the National [Regional] networks.
- No data will be provided to third parties for commercial purposes.
- The HELICS project aims to encourage research on Nosocomial Infections. With this objective in mind, when European and National health authorities, scientific bodies, or individual scientists request specific analyses, the procedure for obtaining these is outlined below. However, the data will never be transferred to a person outside the HELICS Management Team.

6.4.2 Procedure for external access

An application (~ 2/3 pages) must be made to request HELICS data analysis to the PMG presenting:

- The list of authors and co-authors
- The objective and aims of the study
- An introduction
- A description of the methodology (patients clinical diagnostic, microbiological diagnostic, forecasted statistical analysis)
- The expected results of the study
- Conclusion
- Proposed timetable

The PMG will seek clarification where necessary and agree on a timeline for the data analysis. The data analysis will be performed in Brussels.

Once the analysis is completed, the requestor agrees to write a scientific article within 3 months.

APPENDIXES

1. Participants (detailed tables).
2. Standard questionnaire on HELICS-associated networks
3. Standard questionnaire on participating hospitals/wards – (Draft Version)
4. HELICS common codification scheme.
5. Attestation of Partnership