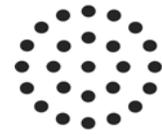




Scottish Intensive Care Society
Audit Group



Health
Protection
Scotland



Scottish Surveillance of Healthcare
Associated Infection Programme

Intensive Care Unit Associated Infection

A National Surveillance Programme

Protocol for Data Collection
Final Version
May 2009

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1. NATIONAL SURVEILLANCE OF INTENSIVE CARE UNIT ASSOCIATED INFECTIONS

1.1 Background to the programme

- Health Protection Scotland has been working with the Scottish Intensive Care Society Audit Group (SICSAG) over recent years to develop a national surveillance programme for Intensive Care Associated Infection (ICUAI).
- This collaboration secured funding from the Scottish Government to support the development of a national programme for ICUAI Surveillance.
- The funding has facilitated the development of the WardWatcher software to collect ICUAI surveillance data using the Hospitals in Europe Link for Infection Control through Surveillance (HELICS) methodology¹. The decision to collect surveillance data in WardWatcher was taken in an effort to minimise the burden of data collection for surveillance purposes.
- The ICUAI surveillance pages for WardWatcher were initially developed for a pilot project in 2005 and following a trial of these pages, it was decided by the National Healthcare Associated Infection Steering Group (NHAISG) that this work should be further developed and a national surveillance programme rolled out to all volunteer Intensive Care Units (ICUs) in Scotland.
- The pilot version of the HAI pages in WardWatcher required a number of refinements to ensure robust data and to facilitate data export. These refinements have now been carried out and the HAI pages are ready to use.
- More recently the Scottish Patient Safety Programme (SPSP) have requested HAI surveillance data from ICUs in Scotland and it is anticipated that the National Surveillance Programme for ICUAI fits alongside the Scottish Patient Safety Programme (SPSP). Data collection for ICUAI surveillance in WardWatcher fulfils the needs of both SPSP and national surveillance. HPS work closely with SPSP to ensure that the programmes are aligned and can complement each other.

1.2 Background to HAI surveillance in Scotland

- The requirement for national surveillance of HAI was set out in “A Framework for National Surveillance of Hospital Acquired Infection in Scotland” HDL (2001) 57 which required NHS Boards to implement surveillance of healthcare associated infection using standardised methodologies over a period of defined timescales.
- The NHS QIS standard for infection control (standard 9) monitors NHS board compliance with this.
- A revised framework for national surveillance of HAI in Scotland was issued to NHS Boards in July 2006; HDL (2006) 38. The revised framework reflects policy developments since the issue of HDL (2001) 57 and forms part of the work programme for the Ministerial HAI Task Force.
- This HDL states that “in addition to the mandatory requirements for surveillance, all infection control teams should also target local HAI surveillance to locally identified priority areas. Whenever possible, this surveillance should be carried out using Scottish Surveillance of Healthcare Associated Infection Programme surveillance protocols. Boards are encouraged to implement as many of the ‘voluntary’ list of surveillance topics as possible, and a minimum of two in addition to the compulsory elements.”
- ICUAI surveillance is one of the voluntary surveillance topics, therefore Boards are encouraged to participate in this surveillance programme wherever possible.

1.3 The objectives of the surveillance programme for ICUAI

1.3.1 At Unit Level

- To obtain infection rates and information on quality of care.
- To examine trends over time and evaluate changes in practice.

1.3.2 At Scottish Level

- Establish a national database of ICUAI surveillance data for Scotland. It is anticipated that once a sufficient amount of data have been collected that detailed epidemiological analysis of this dataset could be carried out.
- To provide a nationally agreed methodology for the collection of ICUAI data in Scotland and to support Divisions in setting up surveillance programmes locally.
- To provide training and protocols for data collection in participating units.
- To provide expertise to staff at local level in the form of staff at HPS with a detailed knowledge of the HELICS protocol, contacts at HELICS and experience with the epidemiological analysis and interpretation of HAI surveillance data.

1.3.3 At EU Level

- It is anticipated that the data collected from surveillance of ICUAI in Scotland will form part of the European ICUAI dataset. The time frames for contribution to the HELICS dataset have yet to be confirmed and will not take place prior to 2010.
- Further details of how the data will be used and the objectives of HELICS are available at <http://helics.univ-lyon1.fr/index.htm>.
- HELICS is part of the Improving Patient Safety in Europe (IPSE) network which operates through the European Centre for Disease Control (ECDC).

1.4 Reporting and Publications

1.4.1 Local Level

At local level staff can generate their own reports from the surveillance output and SICSAG will generate monthly reports of HAI data for units to satisfy the requirements of the Scottish Patient Safety Programme (SPSP).

HPS encourage regular reporting of surveillance data at local level and are willing to assist staff locally in getting the best from their data.

1.4.2 National Level

An annual report will be produced by Health Protection Scotland, with the first report due for publication in Autumn 2010.

This report will detail risk adjusted average Scottish infection rates by infection category. The annual report will be approved by SICSAG and the NHAISG prior to publication.

Whilst SICSAG and the NHAISG will agree the content of reports, it should however be noted that the surveillance data held at HPS will be subject to Freedom of Information

requests and as such data other than that published may enter the public domain, if requested.

1.4.3 International level

HELICS will produce epidemiological reports and Scottish data will be presented at country level. The timescales for submission of data to HELICS have yet to be agreed.

1.5 Validation of surveillance data

Validation of surveillance data is necessary to ensure its scientific credibility, to identify methodological problems within the surveillance programme, to help increase compliance and participation in the surveillance programme, and to identify data quality issues at local level.

The published literature states that the accuracy with which nosocomial infections are identified and reported varies considerably, and that experience, qualifications, training and awareness of surveillance staff affect the accuracy of infection reporting². This emphasises the need for staff to have a good working knowledge of a standard set of data definitions that are simple and easy to interpret. To achieve this, surveillance staff require training and access to these data definitions in a protocol, this is therefore the approach adopted by Health Protection Scotland (HPS). In addition, the WardWatcher system incorporates an algorithm which allows the definition to be applied with minimal input and knowledge from the data collector.

Validation is the independent determination of data accuracy, this is essential for aggregated data from multiple data collectors³. Validation of surveillance data is necessary to ensure its scientific credibility and to help identify methodological problems within the surveillance programme.

Validation assesses the accuracy of the data by determining the sensitivity, specificity and positive predictive value of infection case-finding by a trained independent observer³. The process of validation adds credibility to the surveillance system can also help to increase compliance and participation in the surveillance programme, and it may identify local problems and issues at hospital level^{4,5}.

The HPS methodology or data validation is based on an evaluation research approach. The evaluation research approach involves a range of investigative activities, aimed at judging the worth of programme or practice and measures the surveillance programme in terms of structure, process and outcome. The methodology relies on the approach taken by the Hospitals in Europe Link through Infection Control and Surveillance (HELICS) data validation study of the national surveillance of nosocomial infections in intensive care units (SIZ-IPH)⁴, which has validated data from nosocomial pneumonia and bacteraemia surveillance in intensive care units.

It is anticipated that data validation would follow the publication of the first annual report, providing sufficient data were available to support a validation study.

2. SURVEILLANCE METHODOLOGY

- Scotland has adopted the HELICS Level 2 ICU surveillance methodology. This surveillance methodology is patient based surveillance of:
 - Blood stream infection (BSI)
 - Central venous catheter related infection (CVCRI), [including CVC related BSI, Local CVCRI and General CVCRI]
 - Pneumonia (PN) [includes both ventilator associated PN (VAP) and non-VAP]
- Full details of the HELICS methodology can be found at <http://helics.univ-lyon1.fr/index.htm>. However, all the information required for surveillance of ICUAI in Scotland is detailed in this protocol.
- The case definitions and data definitions in this document are those specified by the HELICS protocol for Surveillance of Nosocomial Infections in Intensive Care Units.
- Risk factors are collected for every patient staying in the ICU, whether infected or not (patient-based surveillance). Demographic data, risk factor data to include both intrinsic and extrinsic risk factors and infection data will be collected. This will allow for stratification of ICUAI rates. For example, device-adjusted infection rates and other risk adjusted rates can be produced.
- In order to obtain a sufficient data set for statistical analysis, a minimum surveillance period of *six months* is recommended. However, continuous surveillance is ideal where resources will allow for this.

2.1 Data Collection for ICUAI surveillance

2.1.1 Data collection system

- Data collection for ICUAI surveillance data will be facilitated through the SICSAG WardWatcher audit system currently in place in ICUs throughout Scotland.
- Surveillance of ICUAI requires a number of additional data items to be collected in WardWatcher. These data will be captured by a series of new “HAI pages” within WardWatcher. All other data items required for surveillance purposes will be collected within the routine WardWatcher data set.
- The data items required for surveillance of ICUAI are given in Appendix I. The data fall into three categories
 - Demographic data.
 - Infection data e.g. details of infections, micro-organisms and antibiotic resistance data.
 - Daily exposure data e.g. presence of a central line, ventilator etc.
- Data will be accepted from units currently using the HELICSwin data collection system and where a unit has another system in place for the collection of ICUAI surveillance data, HPS will consider whether the data can be accepted for the National database.

2.1.2 Inclusion Criteria

The methodology states that only patients staying more than two calendar days are included in the surveillance. However, some data relating to the patient is required for days one and two of their stay (for example, the use of a ventilator and antibiotic use).

2.1.3 Diagnosis of ICUAI for surveillance purposes

(i) Interpretation of the data and case definitions

For the purposes of surveillance, infections will be diagnosed according to the HELICS infection definitions. *This should not influence any aspect of clinical diagnosis and clinical decision-making.*

The WardWatcher based data collection system comprises a criterion based infection diagnosis system.

- The system allows all signs, symptoms and laboratory findings for a suspected infection to be entered into the database.
- If the required combination of signs, symptoms and laboratory findings are present, WardWatcher will determine the presence or absence of an infection according to the HELICS definitions.
- This means that a detailed knowledge of the criteria required for a HELICS infection diagnosis are not required. However, a reasonable knowledge/understanding of the data definitions will ensure that robust and comparable data are collected.

(ii) Case Definitions

The HELICS protocol states that an infection is considered as ICU-acquired if it occurs later than 48 hours following admission to the ICU. Therefore, infection data are only collected from patients with a stay of more than two days in the ICU.

The HELICS case definitions for BSI, CVC-related infections and pneumonia are given in Appendix II.

- The HAI pages in WardWatcher have been designed to minimise the requirement for a detailed knowledge of the data definitions and it has an in-built algorithm to determine whether the case definition for an infection is or is not met.

It is anticipated that this will remove much opportunity for incorrect application of the definitions. However, an understanding and appreciation of the importance of these definitions is important for those collecting the data.

3. SETTING UP SURVEILLANCE

Prior to starting local surveillance it would be useful to consider the following:

(i) Identify a surveillance team which should be multi disciplinary (e.g. include infection control staff, clinicians, microbiologists, ward nurses and clinical effectiveness staff).

(ii) Identify key roles e.g.

Surveillance co-ordinator to facilitate the setting up of the surveillance locally, provide overall co-ordination, liaison with HPS and ensuring input from the multi-disciplinary team.

Data Collector(s) to collect HAI data and ensure completeness of data within WardWatcher.

4. DATA COLLECTION USING WARDWATCHER

4.1 Collecting data using WardWatcher

The data required for surveillance of ICUAI surveillance can be collected via the WardWatcher system. Infection data is captured within the “HAI” window in WardWatcher, other data items required for surveillance form part of the normal dataset for ICU audit purposes. All required data items are listed in Appendix I.

4.2 Entering the “HAI” Page



To enter the “HAI” window, select the “HAI” button at the bottom of the “Admission and Identity Data” window as shown in Figure 1.

Figure 1: Admission and Identity Data window

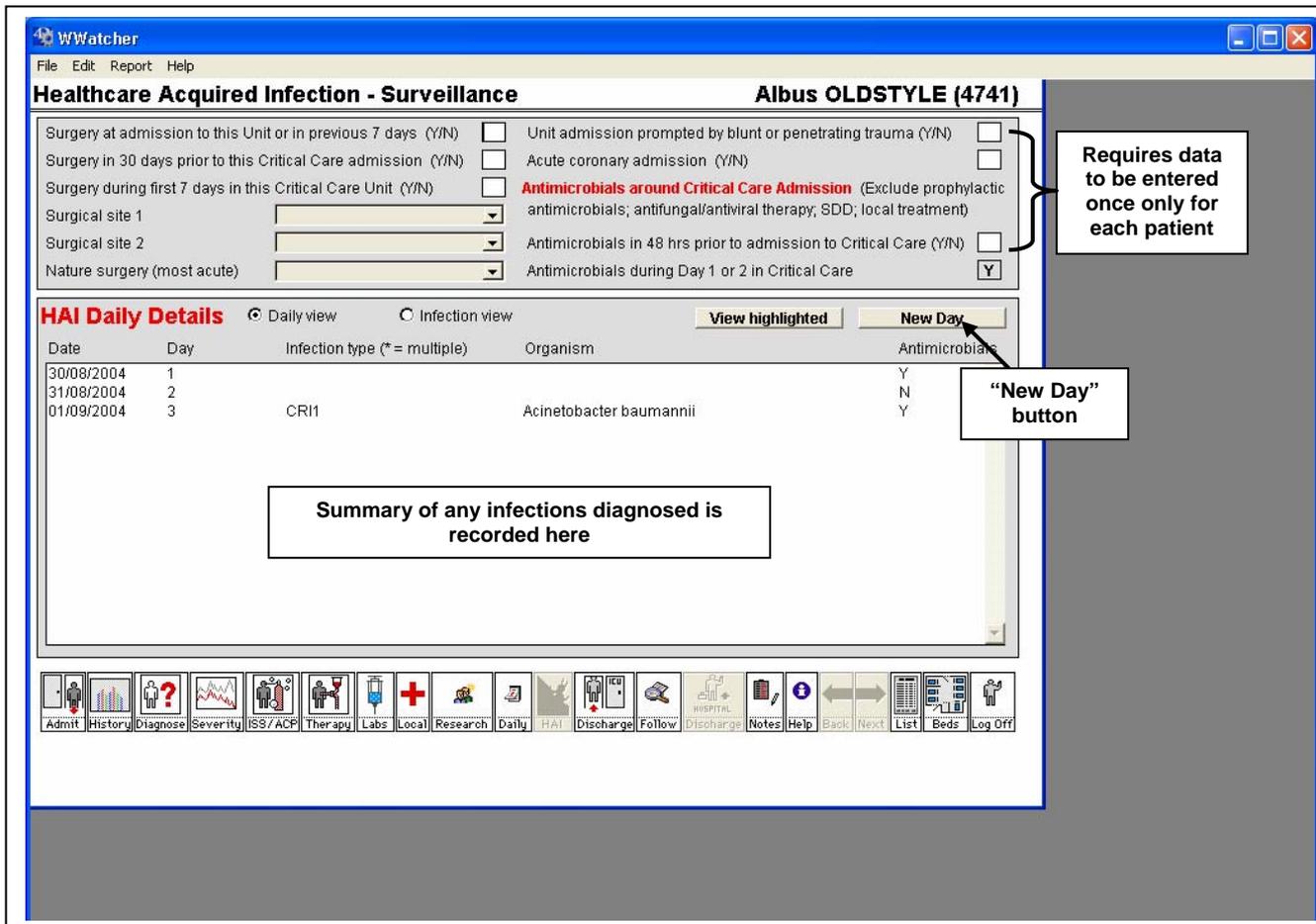
The screenshot shows the 'Admission & Identity Data' window in WardWatcher. The window title is 'WWatcher' and it has a menu bar with 'File', 'Edit', 'Report', and 'Help'. The main content area is titled 'Admission & Identity Data' and 'ICU'. It contains several data entry fields:

- Surname:** OLDSTYLE (Key: 4741)
- Date & time admitted to this Unit:** 30/08/2004 23:00
- Age:** 48
- Under care of:** Binning
- Forename:** Albus
- Sex:** M
- Admitted from (type):** 11. Other area in another hospital (not...)
- Also under (optional):** (empty)
- Hospital number:** H4329
- Date of Birth:** 21/05/1956
- Admitted from (name):** (empty)
- Date admitted this hospital:** 30/08/2004
- Days to Unit:** 0
- Patient's Address:** (empty)
- Next of Kin:** (empty)
- GP's Details:** Select
- GP details:** (empty)
- Post code:** XX1 1YY (DHA Telephone: 0123 456 789)
- Telephone:** 0123 456 789
- Post code:** ZZ1 1ZZ (Telephone: 0123 456 789)
- Admission comments:** Transfer by shock team from St Elsewhere post laparotomy (no ITU beds)
Blood loss 500mls and had 6 Ls of IV fluids
PMH of alcohol XS, smoker and multiple abdominal surgeries the first was last summer after which he was admitted to ITU for 50 days
Intubated and ventilated, on Metronidazole and Taz. and no inotropes.

At the bottom of the window is a toolbar with various icons. The 'HAI' icon, which is a green map of the UK with a red location marker, is circled in red. A callout box points to this icon with the text: 'HAI button' and 'Click on this button to enter the "Hospital Acquired Infection – Surveillance" window'. Other icons in the toolbar include 'Admit', 'History', 'Diagnose', 'Severity', 'ISS/ACF', 'Therapy', 'Labs', 'Local', 'Research', 'Daily', 'HAI', 'Discharge', 'Follow', 'Discharge', 'Notes', 'Help', 'Back', 'Next', 'List', 'Beds', and 'Log Off'.

On selecting the “HAI” button the “Healthcare Acquired Infection – Surveillance” window appears as shown in Figure 2.

Figure 2: Healthcare Acquired Infection – Surveillance window



4.3 Healthcare Acquired Infection – Surveillance window

The upper part of the Healthcare Acquired Infection-Surveillance window shown in Figure 2 requires data relating to admission, surgery and antibiotic use to be entered for each patient once only.

The lower part of the window in Figure 2 shows a summary of any infections diagnosed according to the HELICS infection definitions during the patient stay in ICU.

4.4 HAI Daily Details

Following the completion of the data in the “Healthcare Acquired Infection- Surveillance” window, the “New Day” button should be selected to open the “HAI Daily Details” window, shown in Figure 3.

“HAI Daily Details” should be completed *every day for all patients admitted to ICU for more than 48 hours (Day 3)*. The upper part of the window in Figure 3 requires data relating to re-intubation, naso or oro-gastric GI tube, antimicrobial use and new infections. These fields should be completed in the usual way with “Y” for yes and “N” for no. These data will be collected from day 1 to day of unit discharge.

The lower part of the window in Figure 3 summarises any infections diagnosed on that day only. If more than one infection has been diagnosed on a particular day an asterisk (*) appears beside the “Infection Type” listed in HAI Daily Details section on the surveillance page.

4.4.1 No infection is present/suspected

If no infection is present/suspected and “N” is entered for “New Infection diagnosed today”, the “Data Collected By” box should be completed and the OK button can be selected to leave this window. If the “Data Collected by” is *not* completed, a reminder box requesting this data to be entered will appear.

4.4.2 Infection is diagnosed/suspected

If an infection is diagnosed/suspected and “Y” is entered for “New Infection diagnosed today” the “New Infection” button becomes activated from day 3 onwards.

Figure 3: HAI Daily Details window

The screenshot shows the 'WWatcher' application window titled 'HAI Daily Details' for patient 'Albus OLDSTYLE (4741)'. The window has a menu bar with 'File', 'Edit', and 'Help'. The main content area is divided into several sections:

- Medical Procedures and Antibiotic Use:** A grid of checkboxes for 'Reintubated today (Y/N)', 'Naso- or oro-gastric GI tube in situ today (Y/N)', 'Antibiotic/antifungal/antiviral (NOT SDD) today (Y/N)', and 'New infection diagnosed today (Y/N)'. All are currently checked.
- Date and Collection Info:** 'Date' is set to '01/09/2004', 'Collected by' is 'jrn', and 'Day' is '3'.
- Infection Details:** A large text area for 'Infection type' and 'Microorganism (*=multiple)'. A 'View highlighted' button is present.
- Buttons:** 'New Infection', 'Delete', 'Cancel', and 'OK' buttons are visible.

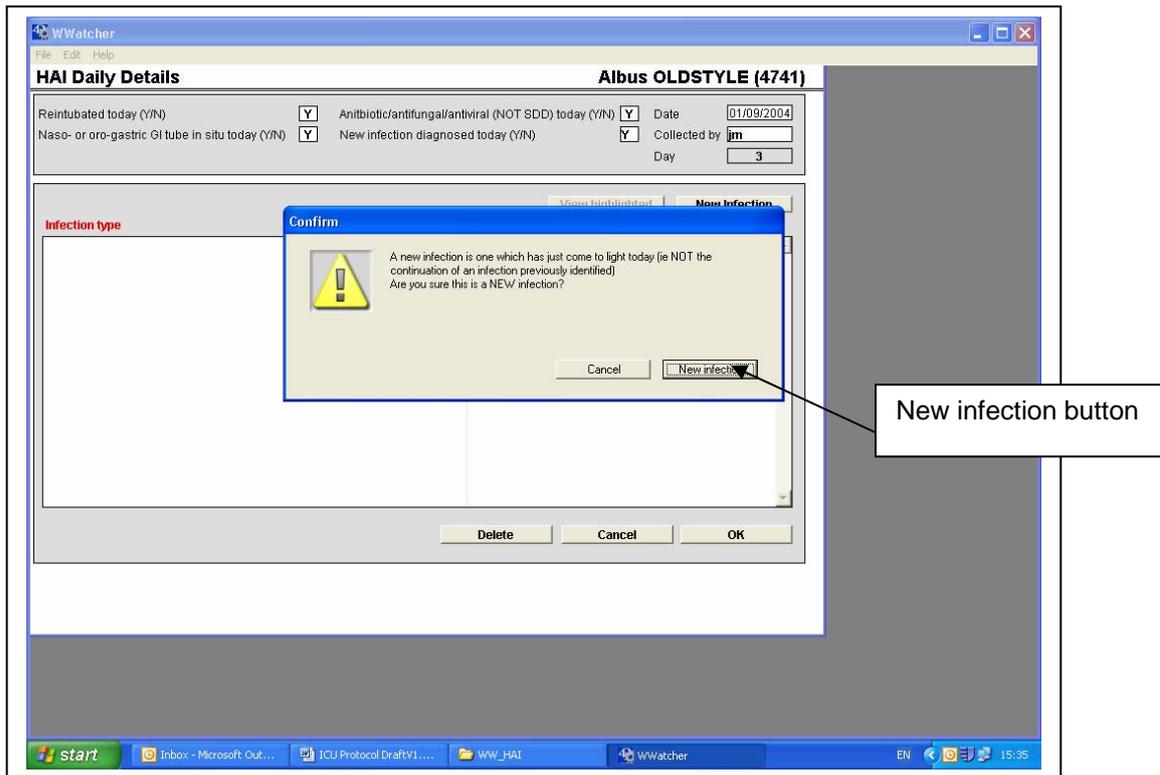
Callouts provide the following information:

- A callout pointing to the 'New Infection' button: "New infection button- this becomes active if a new infection is diagnosed on that day".
- A callout pointing to the 'OK' button: "If no infection is diagnosed click 'OK' to leave this window".
- A callout pointing to the top right area: "Data relating to medical procedures, antibiotic use and infection is recorded each day for each patient".

4.5. Entering Infection Details

When the “New Infection” button is selected a box appears on the screen asking for confirmation that this is a new infection - shown in Figure 4. If it is a new infection the user clicks the “New Infection” button to move on and if not the user clicks cancel to return to the HAI Daily Details Screen.

Figure 4: HAI Daily Details window- “New Infection” button



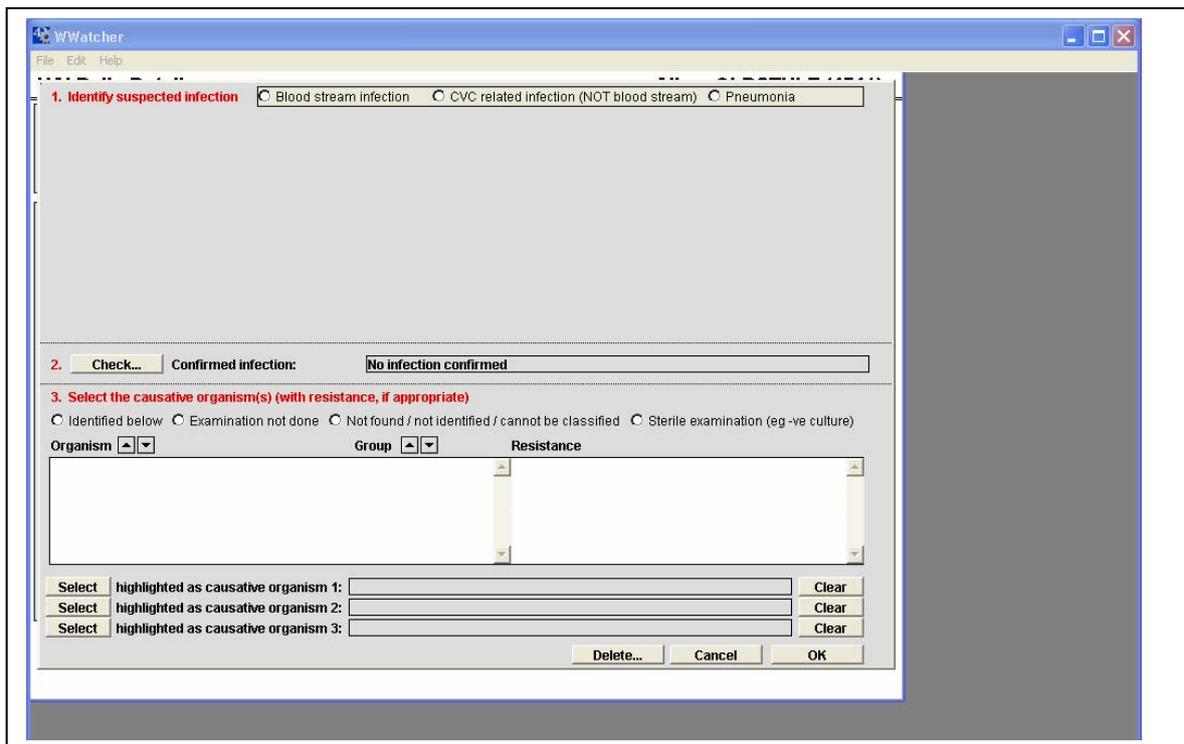
If the “New Infection” button is selected, a new window appears, as shown in Figure 5.

The infection type e.g. BSI, CVC related infection and Pneumonia can be selected at the top of the window in Figure 5.

***An infection should be recorded as the day it was first diagnosed clinically.**

NB: According to HELICS definitions a BSI and CVC related infection require positive microbiology, therefore these data will have to be entered retrospectively once lab results have been received. See Appendix II for case definitions.

Figure 5: Infection details window



On selecting the infection type suspected, a list of infection criteria required to make a diagnosis according to the HELICS protocol appear on screen. Details of the signs, symptoms and laboratory test results of the infection for the selected patient can be entered.

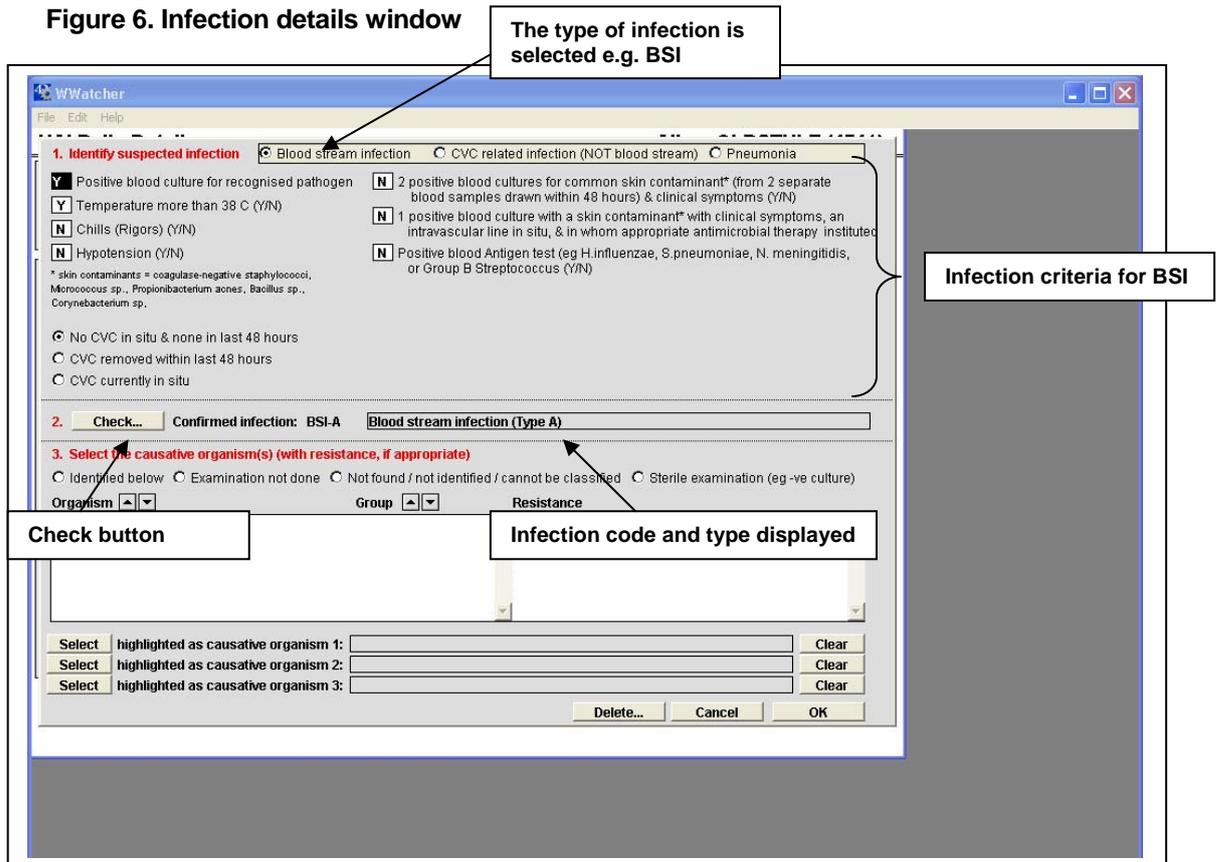
4.5.1 Recording a BSI

If a BSI is suspected the user ticks the “BSI” box and a list of possible infection criteria appear on the screen.

When all presenting signs and symptoms for the infection have been recorded the “Check” button shown in Figure 6 should be selected. On checking the infection criteria the “Confirmed Infection” is displayed.

The lower part of the infection detail window (3.) shown in Figure 6 allows the organism (and antimicrobial resistance for certain organisms) to be recorded.

Figure 6. Infection details window



N.B. For BSI, the user is asked to provide information on CVC status in order to determine whether the BSI is CVC related or not. If the required criteria are selected (CVC present within last 48hrs) a new set of criteria will appear on the screen and the user must complete these before selecting “Check”. This is shown in Figure 7.

Figure 7: Infection details window- CVC related BSI criteria

1. Identify suspected infection Blood stream infection CVC related infection (NOT blood stream) Pneumonia

Positive blood culture for recognised pathogen 2 positive blood cultures for common skin contaminant* (from 2 separate blood samples drawn within 48 hours) & clinical symptoms (Y/N)

Temperature more than 38 C (Y/N) 1 positive blood culture with a skin contaminant* with clinical symptoms, an intravascular line in situ, & in whom appropriate antimicrobial therapy instituted

Chills (Rigors) (Y/N) Positive blood Antigen test (eg H.influenzae, S.pneumoniae, N. meningitidis, or Group B Streptococcus (Y/N)

Hypotension (Y/N) Positive culture with the SAME ORGANISM:

No CVC in situ & none in last 48 hours Quantitative CVC culture $\geq 10^3$ CFU/ml or semi-quantitative CVC culture > 15 CFU

CVC removed within last 48 hours Quantitative blood culture ratio (CVC blood sample/peripheral blood sample) > 5

CVC currently in situ Differential delay of positivity of blood cultures (CVC blood sample culture positive 2 hrs or less before peripheral blood culture (blood samples drawn same time)

Positive culture with the SAME ORGANISM from pus from insertion site

2. Check... Confirmed infection: CR13

3. Select the causative organism(s) (with resistance, if appropriate)

Identified below Examination not done Not found / not identified / cannot be classified Sterile examination (eg -ve culture)

Organism	Group	Resistance

Select highlighted as causative organism 1: Clear

Select highlighted as causative organism 2: Clear

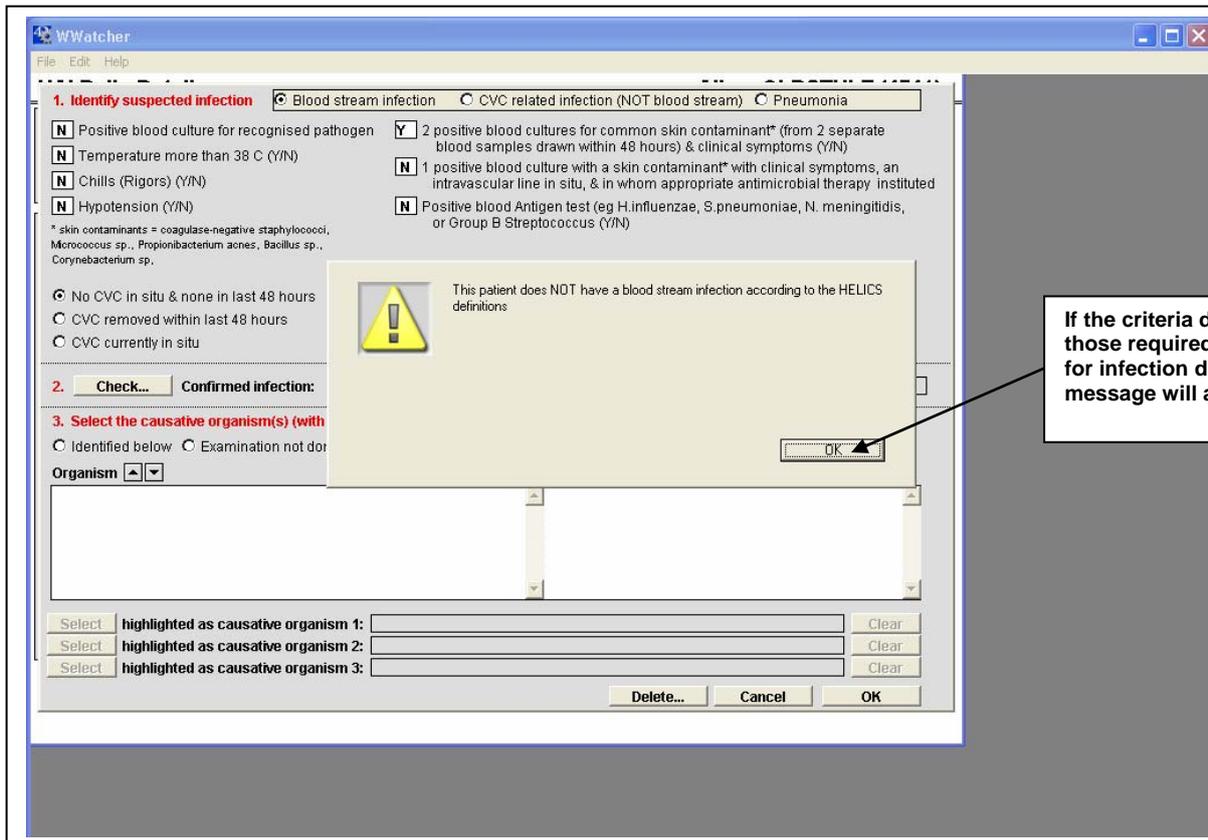
Select highlighted as causative organism 3: Clear

Delete... Cancel OK

Infection criteria for CVC related BSI

If the signs, symptoms and laboratory tests selected do not meet the criteria to diagnose a HELICS ICU acquired infection a box will appear and advise the user of this, as shown in Figure 8. Click on OK and then cancel to re-enter the HAI daily details page. Change Y to N for new infection diagnosed today and click ok. **REMEMBER: If no microbiology results yet received go back and enter infection criteria once results received.**

Figure 8: Infection Details window- criteria for infection not met



4.5.2 Diagnosing a pneumonia

Figure 9 shows criteria required for a **pneumonia** diagnosis. If criteria is met a window requesting details of microbiological tests appears, as shown in Figure 10.

Figure 9: Infection details window- Pneumonia

1. Identify suspected infection Blood stream infection CVC related infection (NOT blood stream) Pneumonia

Temperature more than 38 C with no other cause (Y/N)
 WBC less than 4.0 (10⁹/L) or more than 12.0 (10⁹/L) (Y/N)
 New onset of purulent sputum or change in character of sputum (colour, odour, quantity, consistency) (Y/N)
 Cough, dyspnoea, or tachypnoea (Y/N)
 Suggestive auscultation (rales or bronchial breath sounds), ronchi, wheezing (Y/N)
 Worsening gas exchange (eg O₂ desaturation, increased O₂ requirements, increased ventilation demand)
 Patient has underlying cardiac or pulmonary disease (Y/N)
 2 or more serial chest X-rays/CT scans with a suggestive image of pneumonia (Y/N)
 Single definitive chest X-ray/CT scan (Y/N)
 Invasive respiratory device present (even intermittently) in last 48 hours (Y/N)

2. Check... Confirmed infection:

3. Select the causative organism(s) (with resistance, if appropriate)
 Identified below Examination not done Not found / not identified / cannot be classified Sterile examination (eg -ve culture)

Organism	Group	Resistance
----------	-------	------------

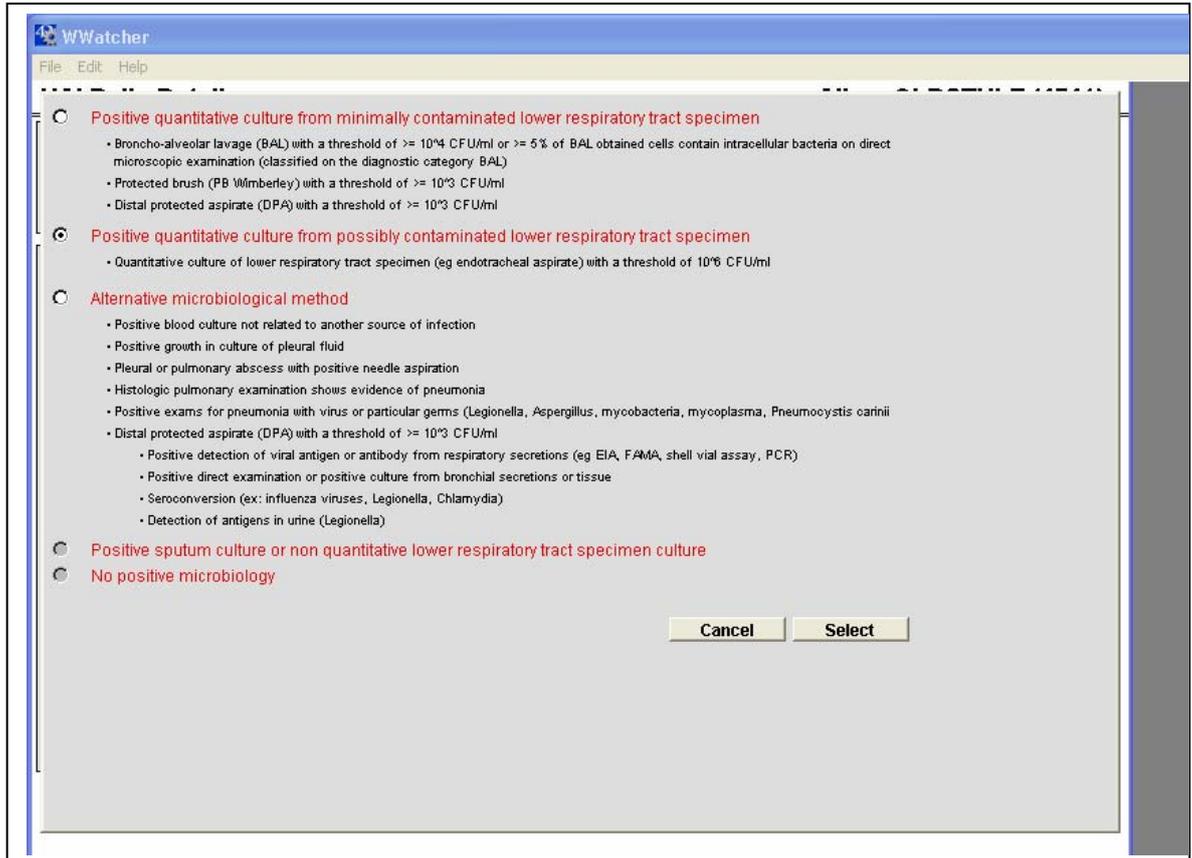
Select highlighted as causative organism 1: Clear
Select highlighted as causative organism 2: Clear
Select highlighted as causative organism 3: Clear

Delete... Cancel OK

The appropriate laboratory test should be selected followed by the Select button.

If no lab results received click on no positive microbiology but remember to go back and change this once results are received as this will alter the case definition.

Figure 10: Laboratory findings criteria for pneumonia



4.5.3 Diagnosing a CVC Related Infection (Local and General)

When all signs and symptoms for the infection have been recorded the “Check” button shown in Figure 11 should be selected. On checking the infection criteria the “Confirmed Infection” is displayed. The lower part of the infection detail window shown in Figure 12 allows the organism and where appropriate antimicrobial resistance to be entered.

Figure 11: Infection Details Window- CVC related Infection

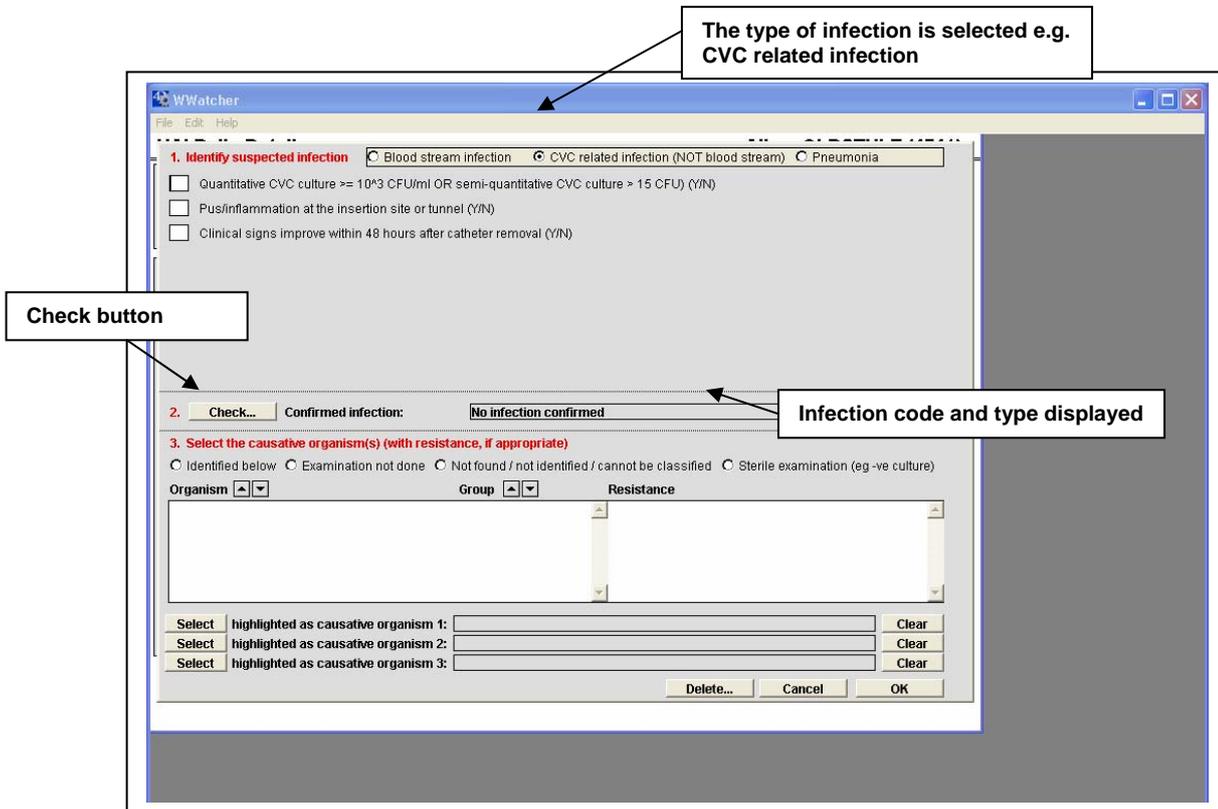


Figure 12: Infection Details Window - Local CVC Related Infection

1. Identify suspected infection Blood stream infection CVC related infection (NOT blood stream) Pneumonia

Quantitative CVC culture $\geq 10^3$ CFU/ml OR semi-quantitative CVC culture > 15 CFU) (Y/N)

Pus/inflammation at the insertion site or tunnel (Y/N)

Clinical signs improve within 48 hours after catheter removal (Y/N)

2. Check... Confirmed infection: CR1 Local CVC-related infection

3. Select the causative organism(s) (with resistance, if appropriate)

Identified below Examination not done Not found / not identified / cannot be classified Sterile examination (eg -ve culture)

Organism	Group	Resistance
Bacteroides fragilis	Anaerobic bacilli	
Burkholderia cepacia	Gram negative bacilli	
Campylobacter sp.	Gram negative bacilli	
Candida albicans	Fungi	
Candida glabrata	Fungi	
Candida parapsilosis	Fungi	
Candida sp. (Not specified)	Fungi	

Select highlighted as causative organism 1: Acinetobacter baumannii (Cefotaxin/Ceftazidim sensitive) Clear

Select highlighted as causative organism 2: Candida albicans Clear

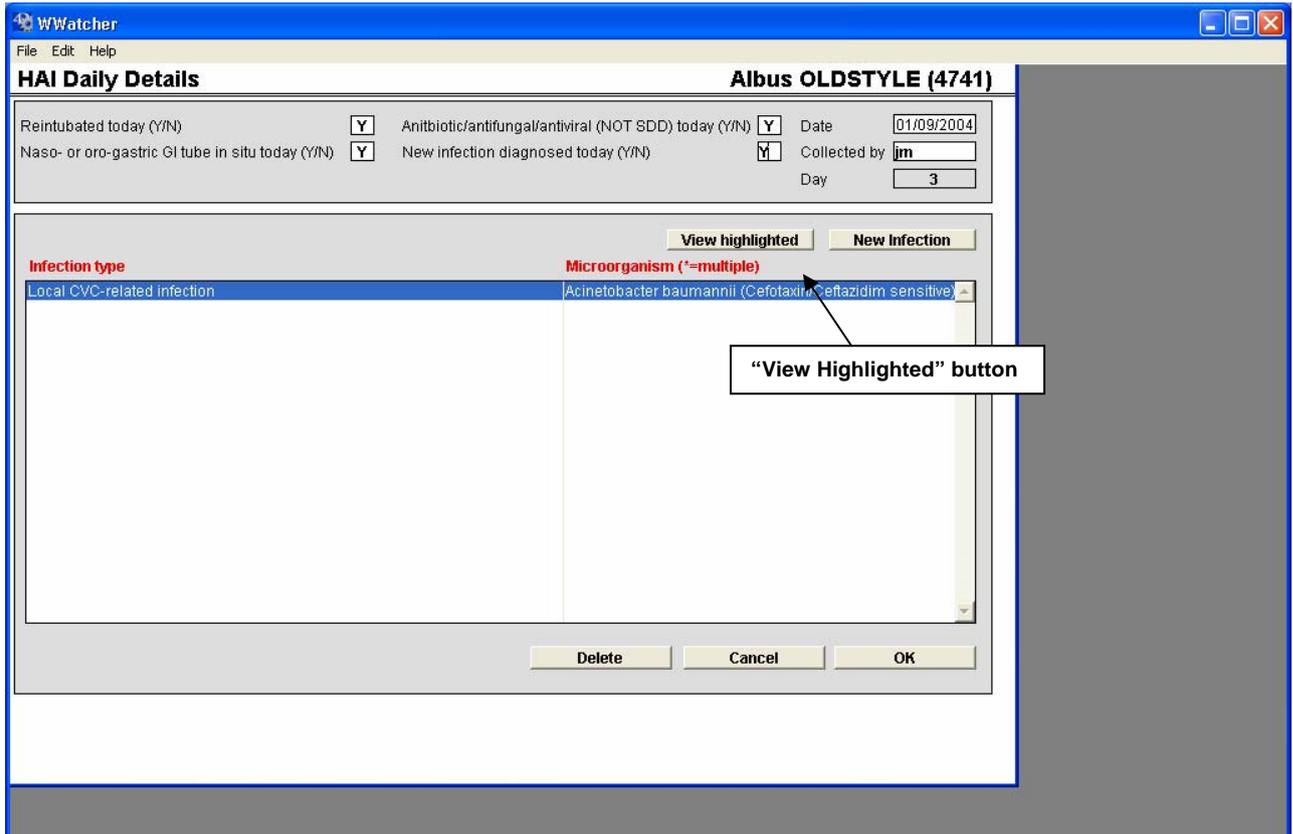
Select highlighted as causative organism 3: Clear

Delete... Cancel OK

4.6 To view details of an infection already recorded in WardWatcher

Go to the HAI Surveillance screen and select the infection of interest on the date of interest and then select the "View Highlighted" button. This will open the HAI daily details page. Again click on infection of interest and view highlighted button (figure 13). This will open the infection of interest details.

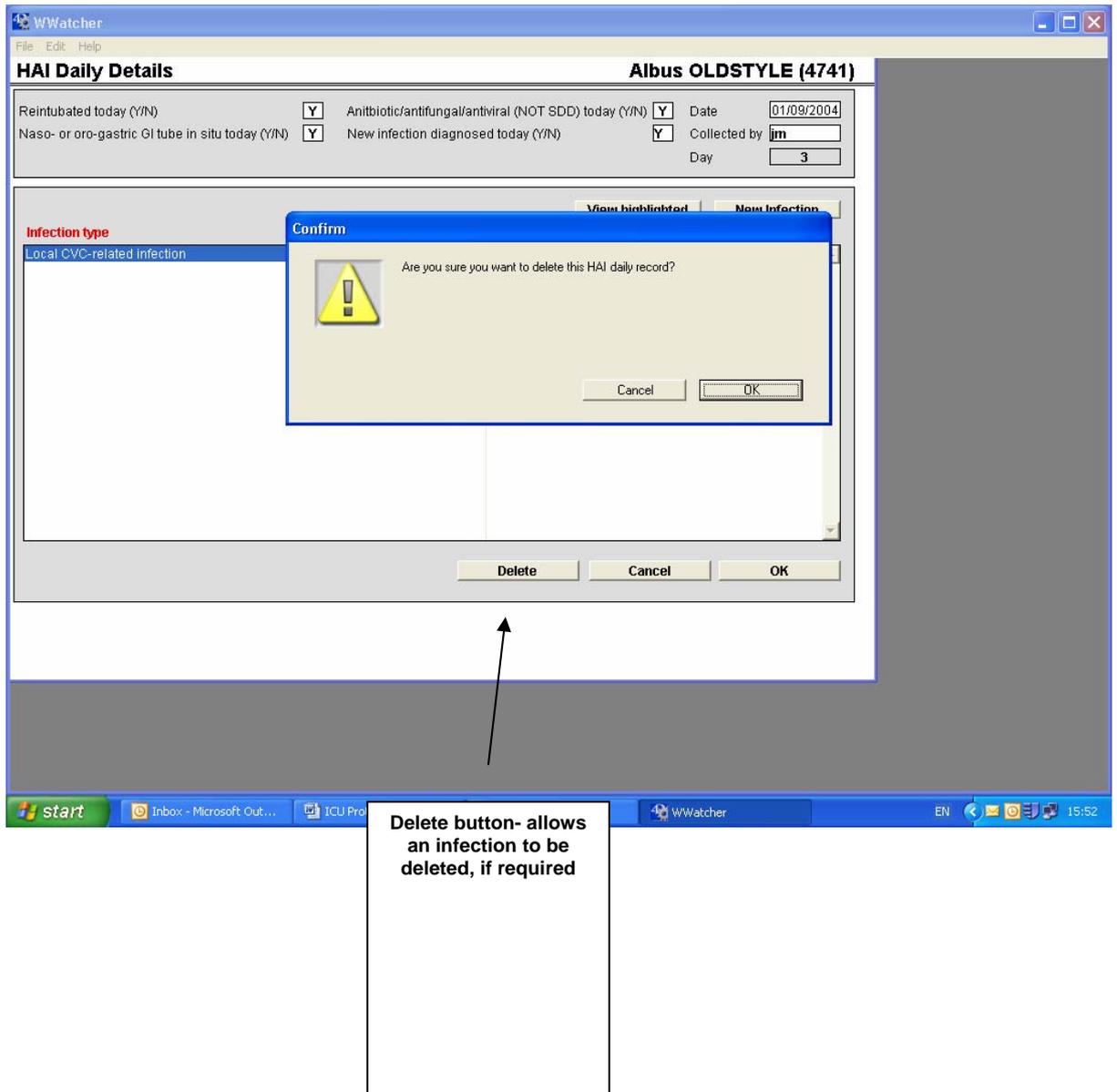
Figure 13: HAI Daily Details- List of infections by date



4.7 To delete an infection already recorded in WardWatcher

To delete a record in WardWatcher, highlight the record to be deleted and click delete. A message confirming the action will appear. The action can be confirmed or cancelled.

Figure 14: Deleting a record.



4.8 Entering an infection retrospectively (once microbiology has been received)

Go to HAI Surveillance page and click on the date (HAI Daily details) new infection was diagnosed clinically.

Click on view highlighted which will bring you into the daily page.

Change new infection question from N to Y, and then click on 'new infection' button to enter Infection details window.

See page 14 for details on entering infection data.

5. DATA CONFIDENTIALITY

5.2 The information obtained by HPS for the purposes of surveillance will:

- Be held in the strictest confidence.
- Be used only for the purposes stated.
- NHS Boards should note that “recorded” information held by HPS is subject to The Freedom of Information (Scotland) Act, 2002. This act gives a right of access to “recorded” information held by public authorities. Information received at HPS will be held in accordance with this act and may be subject to disclosure. Boards will be notified of any FOI request affecting their Board prior to release of information.

For further information:

<http://www.itspubliknowledge.info/home/ScottishInformationCommissioner.asp>

The data will be transferred from SICSAG to HPS and all transfer of data will be carried out in line with the Confidentiality and Security Advisory Group for Scotland (CSAGS) report:

- No patient named details will be sent to HPS.
- If e-mailing data they should be sent
 - (i) between two NHS.net e-mail addresses
 - or
 - (ii) the database should be encrypted using encryption software WinZip Version 9 or above.

5.2 National Confidentiality

- Where information is supplied to HPS as part of national surveillance activity, obtaining specific consent to pass the information to HPS should be addressed as part of the NHS Boards process for informing patients about the use of data. Patient information leaflets about data collection systems should now be available within NHS Boards in accordance with the Data Protection Act 1998 and the guidance for public sector organisations can be found at: <http://www.ico.gov.uk>
- Once received at HPS, the information will be held in accordance with this Act. All data held electronically is password protected with restricted access.
- The format of any national reporting will not commence until there is confidence that valid and reliable data are available and will be discussed with NHS Board staff, SICSAG and by the National HAI Steering Group to whom the SSHAIP Team are accountable.
- The information received from SICSAG will relate only to that data required for ICU surveillance purposes and will not be patient identifiable.

6. REFERENCES

1. Hospital in Europe Link for Infection Control through Surveillance (2004). Surveillance of Nosocomial Infections in Intensive Care Units Protocol Version 6.1. Available at: <http://helics.univ-lyon1.fr/helicshome.htm>
2. Gastmeier P, Kampf G et al (1998). Experience with two validation methods in a prevalence survey on nosocomial infection. *Infect Cont and Hosp Epidemiology* 19:668-673.
3. Gaynes RP and Horan TC (1999) Surveillance of Nosocomial Infections. In: Mayhall GC, Hospital Epidemiology and Infection Control. 2nd edn. Philadelphia: Lippincott Williams and Wilkins.
4. Scientific Institute of Public Health Epidemiology Unit, Belgian Society of Intensive Care Medicine and Emergency Medicine (2000). Data validation study of the National surveillance of nosocomial infections in intensive care units (SIZ-IPH).
5. Guidelines Working Group (2001). Updated guidelines for evaluating public health surveillance systems. *MMWR* 50, RR-13

APPENDIX I DATA ITEMS REQUIRED FOR ICU SURVEILLANCE

(i) Infection data:

For each infection episode with onset (infection date) within the start and end date of the surveillance period, following variables should be collected.

Data table icu_i:

	Attr.	Variable Label	Variable Name	Format	Length
L1,2	M	⁵ ICU code	icu_id	text	3
L1,2	M	⁶ Patient ID	pat_id	text	20
L1,2	M	⁷ Date ICU admission	addt_icu	date	10
L1,2	M	⁸ Infection date	inf_dt	date	10
L1,2	M	⁹ Infection site (categories)	inf_site	text	5
L1,2	R	¹⁰ Micro-organism 1	mo1	text	6
L1,2	R/O	¹¹ Resistance micro-organism 1	res1	number	2
L1,2	R	¹² Micro-organism 2	mo2	text	6
L1,2	R/O	¹³ Resistance micro-organism 2	res2	number	2
L1,2	O	¹⁴ Micro-organism 3	mo3	text	6
L1,2	O	¹⁵ Resistance micro-organism 3	res3	number	2
L1,2	R/O	¹⁶ Invasive device in 48 hours preceding infection	inv_dev	number	2

unique key = country code + network code + surveillance component code + hospital code + ICU code + patient ID + date ICU admission + infection date + infection site

5. **ICU code** : A code which identifies a particular unit
6. **Patient ID** unique patient code. This code should be anonymous and prevent the network coordination from tracing back the patient. However, a patient that is infected or admitted several times to the ICU 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.
7. **Date ICU admission** (dd/mm/yyyy): date of admission in the ICU.
8. **Infection date** (dd/mm/yyyy): date onset infection (date all necessary case definition criteria are met, date of sample if appropriate); include all infections occurring after day 2 in the ICU for which the infection date falls within the surveillance period; infections occurring on day 1 and day 2 may be reported but will not be included in the indicators.
9. **Infection site (also see case definitions): PN1-5, BSI-A/B, UTIA-C, CRI1-3, CCO, OTH**
Pneumonia :
PN1: protected sample + quantitative culture (10⁴ CFU/ml BAL/10³ PB,DPA)
 - PN2: non-protected sample (ETA) + quantitative culture (10⁶ CFU/ml)
 - PN3: alternative microbiological criteria
 - PN4: sputum bacteriology or non-quantitative ETA
 - PN5: no microbiological criterion (only clinical criteria, see case definition)
 BSI: Bloodstream infection
 - BSI-A: positive hemoculture recognized pathogen/ 2 HC+ skin contaminant
 - BSI-B: CDC extension (see case definition) - optional
 CRI: CVC-related infection (optional)
 - CRI1: local catheter infection
 - CRI2: generalized catheter infection
 - CRI3: CVC-related bloodstream infection
 -
10. **Micro-organism1**: Required. 6 character code list (WHOCARE-based) – see HELICS Protocol; if no micro-organism is available, specify either _NONID (Micro-organism not identified or not found), _NOEXA(examination not done) or _STERI (Sterile examination).
11. **Antimicrobial resistance1**: 1 digit (see code list HELICS protocol)
 - required: oxacillin resistance in *S. aureus* (0=MSSA 1=MRSA -1= unknown)
 - other micro-organisms: optional
12. **Micro-organism2**: Required
13. **Antimicrobial resistance2**: Required for *S.aureus* , optional for other micro-organisms
14. **Micro-organism3**: Optional
15. **Antimicrobial resistance3**: Required for *S.aureus* , optional for other micro-organisms
16. **Invasive device in 48 hours preceding the infection**: Mandatory for pneumonia (to distinguish device-associated pneumonia from other pneumonia), optional (but recommended) for bloodstream infection (presence of central venous catheter) and UTI (presence of urinary catheter). 0=no 1=yes - -1= unknown (unknown not allowed if infection site=PN)

(ii) Patient data: table icu_p

In level 2, patient data and exposure data are collected for each patient staying longer than 2 days in the ICU.

Data table icu_p:

L	Attr.	Variable Label	Variable Name	Format	Length
L2	M	³ ICU code	icu_id	text	3
L2	M	⁴ Patient ID	pat_id	text	20
L2	M	⁵ Date ICU admission	addt_icu	date	10
L2	M	⁶ Discharge date from the ICU	disdt_icu	date	10
L2	R	⁷ Discharge status	dis_st	number	2
L2	R	⁸ Gender	sex	text	1
L2	R	⁹ Age in years	age	number	3
L2	O	¹⁰ Patient origin	pt_ori	number	2
L2	O	¹³ APACHE II score	apache	number	3
L2	R	¹⁴ Type of admission	adm_typ	number	2
L2	R	¹⁵ Trauma	trauma	number	2
L2	O	¹⁶ Impaired immunity	immune	number	2
L2	R	¹⁷ Antimicrobial treatment within 48 h around admission (<>48h)	amt_adm	number	2
Oa	R	¹⁸ Acute coronary care	coro	number	2
Oa	R	¹⁹ Surgery in 30 days before admission (2 variables for 2 possible sites)	surg_sit1 surg_sit2	number number	2 2
Oa	O	²⁰ Glasgow coma score, estimated	glas_est	number	2

unique key = country code + network code + surveillance component code + hospital code + ICU code + patient ID + date ICU admission

3. **ICU code**: : A code which identifies a particular unit
4. **Patient ID**: unique patient code. This code should be anonymous and prevent the network coordination from tracing back the patient. However, a patient that is infected or admitted several times to the ICU 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.
5. **Date ICU admission** (dd/mm/yyyy): date of admission in the ICU
6. **Date ICU discharge** (dd/mm/yyyy): date of discharge from the ICU - it is recommended to include patients based on this date, e.g. when participating to the surveillance from 1/4/2002 to 30/4/2002, include all patients that are discharged in this period and where (date of discharge - date of admission + 1) > 2 (=patients staying more than 2 calendar days in the ICU); patients may also be included prospectively based on admission date (see higher)
7. **Discharge status** (numeric 1): status at discharge from ICU (1 = discharged alive from ICU, 2 = death in ICU, -1 = unknown); record date of death as date of discharge from ICU; (Note:DNR/withdrawal may be added as supplementary category- discharged alive with therapeutic withdrawal - DNR=do not resuscitate)
8. **Gender** (string 1): gender of the patient (M/F/U)
9. **Age** (numeric 3): age in years, -1= unknown
10. **Patient origin**: 1=ward in this/other hospital; 2=other ICU; 3=community (patient came from his home, via emergency or not); 4=long term care/nursing home; -1= unknown
13. **APACHE II score** on admission (numeric 3): Acute Physiology, Age, Chronic Health Evaluation score (13) - see appendix 1; -1= unknown; prefer SAPS II score because of use in NI risk score. Also see appendices for details on risk scores.
14. **Type of admission** (numeric 1): as defined in SAPS II score (1=medical: no surgery within 1 week of admission to ICU; 2=scheduled surgical: surgery was scheduled at least 24 hours in advance +/- 7 days ICU admission; 3=unscheduled surgical: patients added to the operating room schedule within 24 hours of the operation); -1 = unknown
15. **Trauma**: ICU admission resulted from blunt or penetrating traumatic injury to the patient, with or without surgical intervention; 1=yes; 0=no; -1= unknown
16. **Impaired immunity**: 1=yes; 0=no; -1= unknown; yes: <500 PMN/mm³, due to treatment (chemotherapy, radiotherapy, immune suppression, corticosteroids long duration or high doses recently), due to disease (leucemia, lymphoma, AIDS) - Apache II definition
17. **Antimicrobial therapy around admission**: 1=yes; 0=no; -1= unknown; specify "yes" if any antibiotic therapy in the 48 hours *preceding* ICU admission and/or during the first 2 days of ICU stay (=antibiotic therapy for an infectious event around ICU admission, excl. antifungal and antiviral treatment) has been given; not: antimicrobial prophylaxis, SDD, local treatment

18. **Acute coronary care** : All acute non-surgical cardiac disease. Larger than coronary suffering; 1=yes; 0=no; -1 = unknown
19. **Surgery before admission + site**: specify whether patient had surgery in the last 30 days before ICU admission including the day of admission, and if so, specify the surgery site; codes: 0=no surgery; 1=coronary surgery; 2=other cardiac; 3=other thoracic; 4=other vascular; 5= neurosurgery; 6=other surgery; -1= unknown
20. **Glasgow Coma score, estimated** (numeric 2): Use the lowest value in first 24 hours; -1= unknown; record both a. the "original"=estimated GCS, i.e. if the patient is sedated, record the estimated Glasgow Coma Score before sedation (see appendix 1) (=component of both SAPS II and APACHE II score)..

(iii) Day by day exposure data: table icu_e

Level 2 day-by-day exposure data (one record per day and per patient-device-exposure during that day)

L	Attr.	Variable Label	Variable Name	Format	Length
L2	M	³ ICU code	icu_id	text	3
L2	M	⁴ Patient ID	pat_id	text	20
L2	M	⁵ Date ICU admission	addt_icu	date	10
L2	M	⁶ Date in ICU	e_date	date	10
L2/Oa	R/O	⁷ ICU Exposure	icu_exp	text	5

unique key = country code + network code + surveillance component code + hospital code + ICU code + patient ID + date ICD admission + date in ICU

3. **ICU code**: see 6.3.2
4. **Patient ID**: unique patient code. This code should be anonymous and prevent the network coordination from tracing back the patient. However, a patient that is infected or admitted several times to the ICU 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.
5. **Date ICU admission** (dd/mm/yyyy): date of admission in the ICU
6. **Date in the ICU**: day in the ICU for which daily exposure data are recorded
7. **ICU Exposure**: Required for Level 2: CVC and INT; Optional for Level 2: UC; Required for option a: NIT, FNIT, PN; Optional for option a: NIV, VEN, REINT. **CVC=Central venous catheters**: specify whether >=1 CVC was present in this patient on that day; CVC = vascular access device that terminates at or close to the heart or one of the great vessels; excluded: arterial catheters, external pacemaker, implanted chambers; included: v. subclavia, v. jugularis, v. basilica, v. cephalica, v. femoralis, v.umbilicalis, other veins, dialysis catheters, Swann-Ganz; optionally fill out one record by catheter (option b); **INT=Intubation**: patient has oro-tracheal or naso-tracheal intubation or tracheotomy , even if intermittent during the day (1 hour is counted as 1 day); **UC=Urinary catheter**: urinary catheter use; suprapubic catheters are included; intermittent urinary catheterization excluded (e.g. for urinary sampling or in case of urine retention); optional, if UTI are registered; **NIT=Naso-oro intestinal tube without feeding in ICU**: specify whether patient had a naso-oro intestinal tube without feeding in the ICU; **FNIT=Naso-oro intestinal tube with feeding in ICU**: specify whether patient had a naso-oro intestinal tube with feeding in the ICU; **PN=Parenteral nutrition in ICU**: specify whether patient had parenteral nutrition in the ICU =patient receives minimum 2 nutritional elements via perfusion (2 out of 3: proteins, fats and sugars); **NIV=Non-invasive mechanical ventilation**: patient is ventilated (any form of mechanical respiratory assistance of inspiration and/or expiration) without intubation (BIPAP/CIPAP); **VEN=Invasive mechanical ventilation**: patient is ventilated (any form of mechanical respiratory assistance of inspiration and/or expiration) with intubation; **REINT=Re-intubation**: patient was extubated and re-intubated on that day (at least once)

APPENDIX II CASE DEFINITIONS

(a) CASE DEFINITION OF BLOODSTREAM INFECTION

CODE: BSI

BSI-A:

- 1 positive blood culture for a recognised pathogen*
- OR**
- Patient has **at least one** of the following signs or symptoms: fever (>38°C.), chills, or hypotension

AND

- 2 positive blood cultures for a common skin contaminant (from 2 separate blood samples drawn within 48 hours).

Skin contaminants:

Coagulase-negative staphylococci
Micrococcus sp.
Propionibacterium acnes
Bacillus sp.
Corynebacterium sp.

BSI-B:

- Patient has **at least one** of the following signs or symptoms: fever (>38°C), chills, or hypotension

AND EITHER

- 1 positive blood culture with a skin contaminant in patient with an intravascular line in place and in whom the physician instituted appropriate antimicrobial therapy.

OR

- Positive blood antigen test :

Haemophilus influenzae
Streptococcus pneumoniae
Neisseria meningitidis
Group B *Streptococcus*

*These exclude specified skin contaminants

(b) CASE DEFINITION OF PNEUMONIA

CODE: PN

X-Ray

Two or more serial chest X-rays or CT-scans with a suggestive image of pneumonia for patients with underlying cardiac or pulmonary disease. In patients without underlying cardiac or pulmonary disease one definitive chest X-ray or CT-scan is sufficient.

AND at least one of the following

- Fever > 38 °C with no other cause
- Leukopenia (<4000 WBC/mm³) or leucocytosis (≥ 12 000 WBC/mm³)

AND at least one of the following

OR at least two of the following if clinical pneumonia only [PN 4 and PN 5]

- New onset of purulent sputum, or change in character of sputum (color, odor, quantity, consistency)
- Cough or dyspnea or tachypnea
- Suggestive auscultation (rales or bronchial breath sounds), ronchi, wheezing
- Worsening gas exchange (e.g. O₂ desaturation or increased oxygen requirements or increased ventilation demand)

AND according to the used diagnostic method

a – Bacteriologic diagnostic performed by :

Positive quantitative culture from minimally contaminated LRT¹ specimen (PN 1)

- Broncho-alveolar lavage (BAL) with a threshold of ≥ 10⁴ CFU²/ml or ≥ 5 % of BAL obtained cells contain intracellular bacteria on direct microscopic exam (classified on the diagnostic category BAL).
- Protected brush (PB Wimberley) with a threshold of ≥ 10³ CFU/ml
- Distal protected aspirate (DPA) with a threshold of ≥ 10³ CFU/ml

Positive quantitative culture from possibly contaminated LRT specimen (PN 2)

- Quantitative culture of LRT specimen (e.g. endotracheal aspirate) with a threshold of 10⁶ CFU/ml
-

b – Alternative microbiology methods (PN 3)

- Positive blood culture not related to another source of infection
- Positive growth in culture of pleural fluid
- Pleural or pulmonary abscess with positive needle aspiration
- Histologic pulmonary exam shows evidence of pneumonia
- Positive exams for pneumonia with virus or particular germs (*Legionella*, *Aspergillus*, mycobacteria, mycoplasma, *Pneumocystis carinii*)
 - Positive detection of viral antigen or antibody from respiratory secretions (e.g., EIA, FAMA, shell vial assay, PCR)
 - Positive direct exam or positive culture from bronchial secretions or tissue
 - Seroconversion (ex : influenza viruses, *Legionella*, *Chlamydia*)
 - Detection of antigens in urine (*Legionella*)

c – Others

- Positive sputum culture or non-quantitative LRT specimen culture (PN 4)
- No positive microbiology (PN 5)

Note: PN 1 and PN 2 criteria were validated without previous antimicrobial therapy

Comment: The subdivision of the pneumonia definition in five categories allows for the comparison of similar entities of pneumonia. *It is essential that PN4 and PN5 (clinical pneumonia without microbiological evidence) are reported in order to achieve overall comparability, even if a microbiological exam was performed and yielded negative results.* It is also advised, both for clinical and surveillance purposes, that microbiological confirmation (PN1-3) is promoted as a routine practice in the ICU.

Intubation-associated pneumonia (IAP): a pneumonia is defined as intubation-associated (IAP) if an invasive respiratory device (endo-tracheal tube or tracheostomy tube) was present (even intermittently) in the 48 hours preceding the onset of infection.

¹ LRT = Lower Respiratory Tract

² CFU = Colony Forming Units

(c) Case DEFINITION OF CVC-RELATED INFECTION

CODE: CRI

A central venous catheter-related infection relies on:

CRI1: Local CVC-related infection (no positive blood culture)

- Quantitative CVC culture $\geq 10^3$ CFU/ml (3) or semi-quantitative CVC culture > 15 CFU (4)

AND

- Pus inflammation at the insertion site or tunnel

CRI2: General CVC-related infection (no positive blood culture)

- Quantitative CVC culture $\geq 10^3$ CFU/ml or semi-quantitative CVC culture > 15 CFU

AND

- clinical signs* improve within 48 hours after catheter removal

CRI3: CVC-related BSI

- BSI (according to the definition for BSI A or BSI B) occurring 48 hours before or after catheter removal

AND positive culture with the same micro-organism of **EITHER**:

- Quantitative CVC culture $\geq 10^3$ CFU/ml or semi-quantitative CVC culture > 15 CFU
- Quantitative blood culture ratio CVC blood sample/peripheral blood sample $> 5^1$
-
- Differential delay of positivity of blood cultures²: CVC blood sample culture positive 2 hours or less before peripheral blood culture (blood samples drawn at the same time)
- Positive culture with the same micro-organism from pus from insertion site

ICU-acquired:

An infection is considered as ICU-acquired if it occurs later than 48 hours following admission to the ICU. However, details of all infections occurring in the ICU should be reported irrespective of when they occur. HPS will report only those infections occurring 48 hours after admission to the ICU to be acquired in the ICU.

Second infection episode:

The combination of 1) new signs and symptoms **AND** 2) radiographic evidence (for pneumonia) **OR** other diagnostic testing is required.

*Fever ($>38^\circ\text{C}$), chills, or hypotension