Nationales Referenzzentrum
für Surveillance von
nosokomialen Infektionen

KISS
Krankenhaus-Infektions-
Surveillance-System

ONKO
KISS

Protocol

Surveillance of nosocomial infections in patients with allogeneic and autologous stem cell transplantation

at the

Institute of Hygiene and Environmental Medicine
Charité - Universitätsmedizin Berlin

Internet: https://www.nrz-hygiene.de

Protocol version: December 2024
Start of validity: January 2025
Translation: December 2024

Contact address:

Nationales Referenzzentrum für Surveillance von nosokomialen Infektionen
At the Institute of Hygiene and Environmental Medicine
Director: Prof. Dr. med. Christine Geffers
Charité - Universitätsmedizin Berlin
Corporate member of Freie Universität Berlin and
Humboldt-Universität zu Berlin
Hindenburgdamm 27
12203 Berlin
Germany

Phone: +49 (0)30 450 577 612
Fax: +49 (0)30 450 7 577 920
E-Mail: kiss-support@charite.de,
nrz@charite.de
Homepage: www.nrz-hygiene.de

Table of contents

1. Introduction

Patients who receive an allogeneic or autologous bone marrow or blood stem cell transplant have one of the highest infection rates of all patients in internal medicine and especially oncology, particularly during the neutropenia period. Bloodstream infection and pneumonia are the most common and most serious nosocomial (hospital-acquired) infections. It is known from studies that continuous recording of infections, comparison of infection frequencies and analysis of the data (= surveillance*) can make a decisive contribution to reducing nosocomial infections. It therefore makes sense to carry out continuous surveillance of nosocomial bloodstream infection and pneumonia, particularly in this patient group. The aim of surveillance is to prevent nosocomial infections by providing suitable infection data, which is important for decisions on infection prevention.

As the two patient groups with allogeneic and autologous stem cell transplants differ in terms of their infection rates, the data is recorded and analysed separately for both groups.

Due to the crucial importance of vascular catheters for the development of nosocomial infections, these devices are given special consideration in surveillance.

Surveillance of colonization/infection with a multidrug-resistant pathogen (MDRO) for patients with allogeneic and autologous stem cell transplants is available as part of the STATIONS-KISS module.

Patients with acute leukaemia undergoing chemotherapy are also particularly susceptible to infections, especially during the neutropenia period. Surveillance of nosocomial infections and surveillance of colonization/infection with an MDRO is available for this patient group as part of the STATIONS-KISS module.

* Ongoing, systematic collection, analysis and interpretation of health data and the up-to-date communication of data to those who need this information

2. Aims of the surveillance protocol

The primary purpose of the surveillance protocol is to provide the necessary definitions and specifications for the departments involved in ONKO-KISS. The aim is to standardize data collection and data analysis in order to provide reference data for internal quality assurance.

Secondly, other interested haematology-oncology departments can also record nosocomial bloodstream infection and pneumonia according to these definitions. They can evaluate their data analogously and - after analysing department-specific conditions and circumstances - use the results of the departments participating in ONKO-KISS as a reference.

This protocol is based on the (partially modified) definitions of the CDC (Centers for Disease Control and Prevention (USA), the world's largest centre for hospital epidemiology) for recording nosocomial bloodstream infection and pneumonia.

At the end of 2000, the ONKO-KISS module was developed as part of the Hospital Infection Surveillance System (Krankenhaus-Infektions-Surveillance-System, KISS) of the National Reference Centre (Nationales Referenzzentrum, NRZ) for Surveillance of Nosocomial Infections, which has been in existence since 1997. The existing protocol was modified in 2016.

The surveillance protocol is addressed to interested doctors and nursing staff in haematology/oncology as well as hospital hygienists and infection prevention and control (IPC) nurses who wish to participate in surveillance.

3. Requirements for participation of haematology/oncology departments in ONKO-KISS and obligations of the NRZ

Participating departments must fulfil the following requirements:

- Approval of the head of department for participation in ONKO-KISS
- Approval of the application of the ONKO-KISS protocol and the definitions for the diagnosis of nosocomial infections as well as communication of these definitions to the treating physicians
- At least one representative who carries out the surveillance or is responsible for the surveillance must attend the introductory ONKO-KISS course at the NRZ before registering for the module
- A participating department should perform bone marrow or hematopoietic stem cell transplants with a certain regularity in order to generate sufficiently meaningful data
- Acceptance of the web-based data entry system webKess for data entry and provision of the necessary hardware and system requirements
- Regular entry of surveillance data in webKess for the NRZ
- Consent of the head of department to the publication of anonymized reference data
- Participation of a representative of the department in regular NR events (KISS network Exchange Meeting) at least every 2 years
- Willingness to carry out internal quality assurance measures in the event of corresponding surveillance results
- Willingness to participate in validation measures for the quality of the recorded data (e.g. diagnosis of nosocomial infections)

The institutions responsible for KISS assure the departments involved,

- that they will provide advice and technical support in the implementation of surveillance
- that they will handle the data of the individual departments in strict confidence
- that they will provide the hospitals involved with the standardized and stratified reference data
- that they will provide assistance in implementing the surveillance results for quality management purposes

4. Methods

Patients to be included

ONKO-KISS includes all patients who receive a bone marrow transplant (BMT) or a transplant of blood stem cells (peripheral (PBSCT) or from umbilical cord blood (cord blood)), regardless of their underlying disease. Patients with allogeneic and autologous transplantation are included. Patients must be admitted to the participating oncology department as inpatients.

Surveillance period

The surveillance period begins with the patient's admission to the participating oncology department. If the patient is transferred within the hospital to an intensive care unit or another ward within the participating oncology department (e.g. an oncological ward outside the hematopoietic stem cell transplantation (HSCT) unit) during the stay in which he/she received the transplant, the surveillance continues. Surveillance ends when the patient is discharged from the hospital, or transferred to a non-intensive care unit outside the participating oncology department, or after 200 days from the date of transplantation (date of transplantation = day 1), or upon the patient's death, whichever occurs first. If the planned transplantation of bone marrow or blood stem cells is not carried out for any reason, the inclusion criterion (see above) is not fulfilled and the patient is deleted from the record.

If two or more transplants are performed during the inpatient stay, only the first transplant is included. If a patient is re-admitted as an inpatient for a second or further transplantation after the end of surveillance, the surveillance period starts again (see above). Stem cell boosts or donor lymphocyte infusions (DLI) are not recorded as transplants.

Parameters under surveillance

In ONKO-KISS, nosocomial infections are under surveillance. Surveillance of nosocomial infections is limited to two types of infection:

– **primary blood stream infection**
  - laboratory-confirmed primary bloodstream infection (B1)
  - clinically confirmed primary bloodstream infection in patients ≤ 1 year of age (B2)
  - mucosal barrier injury laboratory-confirmed bloodstream infection (B3)

– **pneumonia**
  - clinically defined pneumonia (C1a)
  - pneumonia with common bacterial or filamentous fungal pathogens and specific laboratory findings (as defined in section B or section C of the KISS definitions) (C1b)
  - viral, legionella, and other bacterial pneumonias with definitive laboratory findings (as defined in section B or section C of the KISS definitions) (C1c)
  - pneumonia with special pathogens in immunocompromised patients (C1d)

All infections acquired on a ward within the participating oncology department or in an intensive care unit during the course of the surveillance period are recorded.

The data is always calculated on a departmental basis. Analyses for individual wards of an oncology department by the NRZ are not intended.

4.1 Patient data collection

Patient history form (as paper version under section 9)

A patient history form is created for all patients who are admitted to a participating oncology department for an allogeneic or autologous stem cell transplant, regardless of the length of stay. It remains in the hospital and is intended to facilitate the recording and, if necessary, tracing of patients. For example, microbiological and radiological findings, clinical symptoms, fever, etc. can be noted during the review of the patient chart on the ward/at the computer in order to simplify the diagnosis of nosocomial bloodstream infection or pneumonia.

The patient days, the neutropenia days and the days on which the patient had a central vascular catheter are also documented here. When documenting the vascular catheter days, a distinction is also made between the type of vascular catheter and whether the vascular catheter is present during or outside neutropenia. The corresponding days are recorded on a daily basis, totalled per month and transferred to the patient record sheet or webKess as a total at the end of the surveillance.

Patient registration form/basic Patient data („Patients“ in webKess) (as paper version under section 8)

In addition to the above-mentioned data, further basic patient data is documented in webKess under ‘Patients’. Basic data that must be collected is labelled in webKess as mandatory fields and must be completed in full by the users. The patient registration form remains in the hospital and is intended to facilitate the data collection and, if necessary, the tracing of patients.

For each patient, basic data such as gender, year of birth, date of admission to the ward, date of transplantation, end of surveillance (date) and the reason for this (‘200 days post-TX/transfer/discharge/death’), underlying disease, type of transplantation and information about the infection are entered. If two underlying diseases are present simultaneously, the disease that is relevant for the transplantation is indicated; if it is not possible to decide this, AND (= other) is ticked.

In the event of an infection (primary blood stream infection B1-3/pneumonia C1a-d), an entry is made in webKess as to whether this occurred while the patient was neutropenic. For standardization purposes, the definition of the association of infection with neutropenia specified by the CDC/NHSN for mucosal barrier injury laboratory-confirmed bloodstream infection is used (for definition see section 6.2.2). It is noted in webKess whether there is an association of primary bloodstream infection with a vascular catheter. If two or more central venous accesses are present, only one of them is entered in webKess (for definitions see section 6.3).

After saving the patient data, the system generates a patient list. Each patient is assigned a unique webKessId. This is intended to enable the clinic to identify the anonymized webKess data record by name, but should not allow third parties to draw any conclusions about the patient.
The ONKO-KISS user is responsible for organizing the necessary retrieval of individual patients based on the webKessId (e.g. noting the webKessId on the patient history form and archiving or keeping an anonymization list with webKessId and real name locally in the oncology department). For data protection reasons, patients' real names must not be

entered in webKess.

4.2 Documentation of nosocomial infections

Documentation of nosocomial bloodstream infection and pneumonia in patients admitted to a participating oncology department for allogeneic or autologous stem cell transplantation until the end of surveillance:

- Nosocomial infections (fulfilling the specific definitions under section B or section C of the KISS definitions) are recorded.
- The classification of an infection as nosocomial is based on the length of time from a patient's admission to the department until the first symptoms of the infection appear.
- An infection is considered nosocomial if the day of infection (= day with the first symptom) is on day 3 of the stay in the department at the earliest. The day of admission is considered day 1 and the day with the first (specific or non-specific) signs of infection is considered the day of infection.
- Exception: If the first symptom is a non-specific symptom (e.g. fever) and there are other causes for this symptom at the same time, then the date of infection is the day with the first specific sign/symptom of the infection.
- Infections with initial specific or non-specific signs of infection already present before admission or on day 1 or day 2 of the hospital stay are classified as community acquired infections.
- Every nosocomial infection occurring during the surveillance period (see section 4 for definition) is recorded.

4.3 Calculation of reference data

In webKess, ONKO-KISS users can create an analysis of their own department data at any time by selecting the corresponding menu item. Reference data is calculated once a year and compared with the department data. Data should be entered into webKess continuously. The information of all data sets completed by then (= data collection ended with discharge from hospital / transfer of the patient to a non-intensive care unit outside the participating oncology department /patient deceased /200 days after transplantation) should be entered by the respective cut-off dates (15 February of each year) at the latest so that they can be included in the reference data calculation by the NRZ.

4.3.1 Vascular catheter utilization ratio (presence of a vascular catheter = risk)

It describes the percentage of patient days on which a specific vascular catheter was present and is calculated as the quotient of the vascular catheter days and the total number of patient days in a department. For this purpose, the patient and vascular catheter days collected per patient in the department are summed up.

In detail, the following applies:

$$\text{Central venous catheter (CVC) utilization ratio (total)} = \frac{\text{Number of days with central venous catheter (CVC)}}{\text{Number of patient days}} \times 100$$

$$\text{CVC (conventional) utilization ratio} = \frac{\text{Number of days with CVC (conventional)}}{\text{Number of patient days}} \times 100$$

$$\text{CVC (partially implanted) utilization ratio} = \frac{\text{Number of days with CVC (partially implanted)}}{\text{Number of patient days}} \times 100$$

$$\text{Port utilization ratio} = \frac{\text{Number of days with port}}{\text{Number of patient days}} \times 100$$

4.3.2 Neutropenia rate (presence of neutropenia = risk)

It describes the percentage of patient days on which neutropenia was present and is calculated as the quotient of the neutropenia days and the total number of patient days in a department. For this purpose, the patient and neutropenia days collected per included ONKO-KISS patient in the department are added together.

In detail, the following applies:

$$\text{Neutropenia rate} = \frac{\text{Number of days with neutropenia}}{\text{Number of patient days}} \times 100$$

4.3.3 Nosocomial vascular catheter-associated infection rate

It is the most important rate for quality management and describes the number of vascular catheter-associated infections per 1,000 vascular catheter days. Here, the infections (e.g. bloodstream infection) occurring during the use of a central vascular catheter (e.g. conventional CVC) are related to the risk days of a department (days with conventional CVC) and calculated in detail as follows (= **standardization**). It is particularly interesting to consider microbiologically confirmed bloodstream infection with pathogen detection (B1) separately from mucosal barrier injury laboratory-confirmed bloodstream infection (B3). The vascular catheter-associated bloodstream infection rate can be mapped for the period during or outside neutropenia and can be linked more precisely to the type of central vascular catheter (= **stratification**):

$$\text{Central venous catheter (CVC)-associated blood stream infection rate (for B1)} = \frac{\text{Number of bloodstream infections (only B1) in patients with CVC}}{\text{Number of days with central venous catheter}} \times 1.000$$

$$\text{CVC (conventional)-associated bloodstream infection rate (for B1)} = \frac{\text{Number of bloodstream infections (only B1) in patients with CVC (conv)}}{\text{Number of days with CVC (conv)}} \times 1.000$$

$$\text{CVC (partially implanted)-associated bloodstream infection rate (for B1)} = \frac{\text{Number of bloodstream infections (only B1) in patients with CVC (partially implanted)}}{\text{Number of days with CVC (partially implanted)}} \times 1.000$$

$$\text{Port-associated bloodstream infection rate (for B1)} = \frac{\text{Number of bloodstream infections (only B1) in patients with port}}{\text{Number of days with port}} \times 1.000$$

Central venous catheter (CVC)-associated bloodstream infection rate during neutropenia (for B1) = Number of bloodstream infections (only B1) in patients with CVC during neutropenia / Number of days with CVD during neutropenia x 1.000

CVC (conventional)-associated bloodstream infection rate during neutropenia (for B1) = Number of bloodstream infections (only B1) in patients with CVC (conventional) during neutropenia / Number of days with CVC (conventional) during neutropenia x 1.000

CVC (partially implanted)-associated bloodstream infection rate during neutropenia (for B1) = Number of bloodstream infections (only B1) in patients with CVC (partially implanted) during neutropenia / Number of days with CVC (partially implanted) during neutropenia x 1.000

Port-associated bloodstream infection rate during neutropenia (for B1) = Number of bloodstream infections (only B1) in patients with port during neutropenia / Number of days with port during neutropenia x 1.000

Central venous catheter (CVC)-associated bloodstream infection rate outside neutropenia (for B1) = Number of bloodstream infections (only B1) in patients with CVC outside neutropenia / Number of days with central vascular catheter outside neutropenia x 1.000

CVC (conventional)-associated blood stream infection rate outside neutropenia (for B1) = Number of bloodstream infections (only B1) in patients with CVC (conventional) outside neutropenia / Number of days with CVC (conventional) outside neutropenia x 1.000

CVC (partially implanted)-associated bloodstream infection rate outside neutropenia (for B1) = Number of bloodstream infections (only B1) in patients with CVC (partially implanted) outside neutropenia / Number of days with CVC (partially implanted) outside neutropenia x 1.000

Port-associated bloodstream infection rate outside neutropenia (for B1) = Number of bloodstream infections (only B1) in patients with port outside neutropenia / Number of days with port outside neutropenia x 1.000

4.3.4 Incidence density of nosocomial infections

As the frequency of risk applications (device) or other risk situations (neutropenia) can be very low in some cases and a significant proportion of infections can also occur independently of these risk factors, the incidence densities for bloodstream infections and pneumonia are included in the analysis. This also ensures standardization. The time under risk corresponds to the total number of patient days (until the end of surveillance per patient) in a department.

$$\text{Incidence density of bloodstream infections} = \frac{\text{Number of bloodstream infections (B1 + B3)}}{\text{Number of patient days}} \times 1.000$$

$$\text{Incidence density of pneumonia} = \frac{\text{Number of pneumonia cases}}{\text{Number of patient days}} \times 1.000$$

4.3.5 Nosocomial neutropenia-associated infection rate

It describes the number of neutropenia-associated infections per 1,000 neutropenia days. Here, the infections (e.g. bloodstream infection and pneumonia) that occurred during the presence of a particular risk (= neutropenia) are related to the patient's days at risk (neutropenia days). The time at risk corresponds to the sum of the neutropenia days (until the end of surveillance per patient).

$$\text{Neutropenia-associated bloodstream infection rate (TOTAL)} = \frac{\text{Number of bloodstream infections (B1 + B3) in patients during neutropenia}}{\text{Number of neutropenia days}} \times 1.000$$

$$\text{Neutropenia-associated bloodstream infection rate (for B3)} = \frac{\text{Number of bloodstream infections (only B3) in patients during neutropenia}}{\text{Number of neutropenia days}} \times 1.000$$

$$\text{Neutropenia-associated pneumonia rate} = \frac{\text{Number of pneumonia cases in patients during neutropenia}}{\text{Number of neutropenia days}} \times 1.000$$

4.4 Comparison of surveillance data

The standardized and stratified infection rates are calculated annually by the NRZ for the total number of departments involved and are provided as reference data. These figures are also available on the Internet at https://www.nrz-hygiene.de/en/KISS-Modul/referenzdaten/KISS/ONKO. The infection rates of the individual participating departments are strictly confidential. The data of an individual department is only communicated to the respective department.

In addition to the stratified and standardized pooled data, distribution parameters (1st quartile (Q1), median (Q2), 3rd quartile (Q3)) are also provided. The 3rd quartile, for example, is the value below which 75% of the observed values lie. Differences between a department and the reference data or over time can provide an indication of infection problems, which should then be investigated in more detail.

5. General principles for defining nosocomial infections

A diagnosis of an infection for the purpose of surveillance is based on combinations of clinical symptoms, laboratory data and supporting data (e.g. X-ray examinations, microbiological findings, biopsies) of varying significance and logical composition.

Colonisation (presence of pathogens on the skin, mucous membranes, in open wounds, in excretions or secretions, but without clinical symptoms) is not an infection.

For the definition of a nosocomial infection, see section 4.2 of the protocol.

Starting with the date of infection (in the context of a community acquired or nosocomial infection), no infection of the same type can fulfil the criteria within the next 14 days. In the event of a change of pathogen, all pathogens within this restriction period count as the first infection. After the 14 days have elapsed, a documented cure of the previous infection is also required before a new infection of the same type can be diagnosed. An infection is considered to have ended when all infection parameters are back within the normal range and the patient is clinically stable for three days - regardless of whether the antibiotic therapy has ended or not.

Sections B and C of the KISS definitions (available at https://www.nrz-hygiene.de/files/KISS-Definitionen/KISS_Definitionen_E-Book_Neuauflage_06_2017.pdf) provide the definitions of primary bloodstream infection and pneumonia, which form the basis of infection surveillance in ONKO-KISS. It is important to note once again that these definitions are not intended for clinical use, but only for the surveillance of nosocomial infections. They are intended to enable those not directly involved in treatment to recognize a nosocomial infection on the basis of the patient record. They provide a fixed diagnostic framework in the epidemiological sense in order to achieve comparability between departments.

These definitions cannot be used to decide on the necessity of therapy, which is important for the clinician and the treatment of the individual patient.

It can therefore happen that an infection is diagnosed according to clinical criteria but is not categorized as an infection according to the definitions used in ONKO-KISS (because the criteria are not sufficiently fulfilled) and vice versa.

We recommend collecting the data once or twice a week.

6. Definitions of indicator infections in ONKO-KISS

6.1 Primary bloodstream infection and pneumonia

The definitions of bloodstream infections are based on the definitions of the National Healthcare Safety Network (NHSN) of the Centers for Disease Control and Prevention (CDC). The current KISS definitions are available at https://www.nrz-hygiene.de/files/KISS-Definitionen/KISS_Definitionen_E-Book_Neuauflage_06_2017.pdf. Please familiarise yourself with the 'General principles of the KISS definitions for nosocomial infections' (= Part A of the KISS definitions). Detailed information on the general KISS definitions, which apply to all patients regardless of age or immune status, can be found in Part B of the KISS definitions. For the diagnosis of a primary bloodstream infection or pneumonia, there are additional specifications for the assessment of a symptom complex in special patient groups, which can be found in Part C of the KISS definitions.

ONKO-KISS distinguishes between three different types of primary bloodstream infections:

- laboratory-confirmed primary bloodstream infection (B1)
- clinically confirmed primary bloodstream infection in patients ≤ 1 year of age (B2)
- mucosal barrier injury laboratory-confirmed bloodstream infection (B3)

The secondary dissemination of pathogens in the blood, which originates from an infection elsewhere and is referred to as secondary bloodstream infection, is not included in this category.
Caution: Mucositis (= inflammation) is not an 'infection' per se and does not exclude bloodstream infection.

ONKO-KISS also distinguishes four different types of pneumonia:

- clinically defined pneumonia (C1a)
- pneumonia with common bacterial or filamentous fungal pathogens and specific laboratory findings (as defined in section B or section C of the KISS definitions) (C1b)
- viral, legionella, and other bacterial pneumonias with definitive laboratory findings (as defined in section B or section C of the KISS definitions) (C1c)
- pneumonia with special pathogens in immunocompromised patients (C1d)

To provide a better overview, the definitions used in ONKO-KISS taken from sections B and C of the KISS definitions are summarised in flow charts which can be found at https://www.nrz-hygiene.de/KISS-Modul/anleitungen/KISS/ONKO and https://www.nrz-hygiene.de/files/KISS-Definitionen/KISS_Flowcharts_C1a-C1c_J1_Atemwegsinfektionen_2018.pdf. When using the flow charts, the detailed instructions listed for each definition in the KISS definitions must also be observed.

6.2 Definition of neutropenia

In ONKO-KISS the modified **definition of neutropenia** based on the 1997 guidelines of the Infectious Diseases Society of America is applied:

neutrophil granulocytes < 500/mm³ or white blood cells < 1.000/mm³

6.2.1 Recording of neutropenia days

If a patient shows neutropenia as defined under section 6.2, the day on which the neutropenia is detected is counted as a neutropenia day or noted as such on the patient history form.

6.2.2 Definition of the association of primary bloodstream infection and pneumonia with neutropenia

Association of primary bloodstream infection with neutropenia:

If a patient is neutropenic on at least 2 days (consecutive or separate days) within a 7-day window (3 days before the date of infection, on the date of infection and 3 days after) (see section 6.2 'Definition of neutropenia'), the association of bloodstream infection with neutropenia is affirmed. For the definition of the date of infection in bloodstream infection, see section 4.2 or section A of the KISS definitions.

A neutropenia association can be recognized for each of the three different forms of bloodstream infection (B1-3).

Association of pneumonia with neutropenia:

If a patient is neutropenic on at least 2 separate days within a 7-day window (3 days before the date of infection, on the date of infection and 3 days after) (see section 6.2 'Definition of neutropenia'), the association of pneumonia with neutropenia is affirmed. For the definition of the date of infection in pneumonia, see section 4.2 or section A of the KISS definitions.

6.3 Definition of primary bloodstream infection as "vascular catheter-associated"

Vascular catheter-associated bloodstream infection is diagnosed if a vascular catheter is/was present for at least the 3rd day on the date of infection or the day before the date of infection. The day on which the central vascular access is either inserted or removed counts as a full vascular catheter day. All days between the insertion and removal of the central vascular access count as full vascular catheter days. For the definition of the date of infection in bloodstream infection, see section 4.2 or section A of the KISS definitions.

If different vascular accesses are present at the same time, the primary bloodstream infection is assigned to the vascular access with the highest risk of infection (conventional CVC (= highest risk of infection) > partially implanted CVC (= second highest risk of infection) > port (= lowest risk of infection)), unless there is clear evidence of an association with a central vascular catheter with a potentially lower risk of infection.

An association with a central vascular catheter can (theoretically) be established and recorded for each of the different forms of bloodstream infection (B1-3). The vascular catheter-associated bloodstream infection rate is calculated for B1 (see section 4.3.3).

7. Specifications for surveillance/documentation

All ONKO-KISS data is entered into webKess by the participants themselves. To be able to enter data, participants must first register with webKess and register with the NRZ in Berlin. The identification code for the participating hospital is assigned by the NRZ.

Each module (ONKO-KISS or STATIONS-KISS for haematology/oncology wards) must be registered separately in webKess. This is followed by a written registration (with the consent of the relevant department) at the NRZ in Berlin.

Explanations and definitions of the variables recorded in ONKO-KISS:

Hospital identification code	is assigned by the NRZ in Berlin after registration in webKess for an ONKO-KISS module. If there is already an identification code from other KISS modules, this will also be used in ONKO-KISS.

Patient history form (paper) is used for easier recording and, if necessary, tracing of the patient; it remains in the department or with the person recording the data and can be optionally used or modified. For a better overview, a separate patient history form should be used for each calendar month in which a patient is treated as an inpatient in the department (regardless of the respective ward) or in the intensive care unit (e.g. admission on 21 March, transfer on 4 April: 1 form for March with 11 consecutive days and 1 form for April with 4 consecutive days = a total of 15 patient days).

Patient registration form (paper) is used for easier recording and, if necessary, tracing of the patient; it remains in the department or with the person recording the data. Basic patient data is documented here. Basic data that must be collected is labelled as mandatory fields in webKess and must be completed in full by the participants.
One sepsis and one pneumonia can be recorded per sheet. If the patient has any other infections, a follow-up form must be created.

7.1 Information collected in the patient registration form

Patient ID is assigned by the system after a patient's webKess entry. Important for the consolidation of data and any queries. Should be noted on all of the patient's surveillance documents within the department.

Infection ID If an infection is recorded, the system assigns a consecutive infection number for the respective department/ward in the respective KISS module. This number can be entered here for a better overview of the number of recorded infections.

Gender male or female

Year of birth Enter the patient's year of birth (YYYY) here.

Date of admission to participating ward Date: DD/MM/YY. Enter the date on which the patient was admitted to the haematology/oncology department for the planned stem cell transplant.

Date of HSCT Date: DD/MM/YY. Enter the date on which the stem cell transplant was performed. If several stem cell transplants are carried out during an inpatient stay, only the date of the first transplant is recorded.

Date 200 days post-HSCT Date: DD/MM/YY. Once the HSCT date has been entered in webKess, the system automatically calculates the maximum date up to which data can be recorded if surveillance is not terminated by one of the following events: the patient is discharged from hospital or transferred externally / the patient is transferred in-house to a non-intensive care unit outside the participating oncology department / the patient dies. This date can be noted by the person collecting the data on the patient registration form, which provides the person collecting the data with a better overview. The date is calculated from 200 days from the date of transplantation. The date of the stem cell transplant is the first of the 200 days.

End of surveillance (date) Date: DD/MM/YY. The date up to which the recording was actually carried out is entered here.

Surveillance ended by Tick the appropriate reason for ending the recording here:
- 200 days post-HSCT: 200 days since HSCT are reached
- transfer / discharge: the patient is discharged from the hospital or transferred externally or the patient is transferred in-house to a non-intensive care unit outside the participating oncology department
- Death: Death of the patient

Underlying disease Tick the appropriate box. Abbreviations for underlying diseases:

Acute myeloid leukaemia	AML
Chronic myelogenous leukaemia	CML
Acute lymphoblastic leukaemia	ALL
Non-Hodgkin's lymphoma	NHL
Myelodysplastic syndrome	MDS
Multiple Myeloma	MM
All other diseases	OTH

Transplantation Tick the appropriate type of transplant. Syngeneic transplantation belongs to the category: allogeneic/related. Stem cell boost and donor lymphocyte infusion (DLI) are not recorded as "transplantation".

Bone marrow transplantation	BMT

Transplantation of blood stem cells

- peripheral PBSCT
- from cord blood Cord blood

Patient days	Total the days of attendance on the patients' history forms and enter them into the box. The day of admission and the day of discharge each count as a full day of attendance and therefore as a patient day. The days between the day of admission and the day of discharge are also counted as days of attendance and therefore as patient days.
Neutropenia days	Total the days on which the patient was proven to be neutropenic from the patient's history forms and enter them into the box. For the definition of neutropenia see section 6.2 and of neutropenia days see section 6.2.1.
During neutropenia days with CVC (conv)	Total the days on which the patient had a conventional CVC and was neutropenic at the same time from the patient's history forms and enter them into the box. For the definition of neutropenia days, see section 6.2.1.
During neutropenia days with CVC (part)	Total the days on which the patient had a partially implanted CVC (Hickman/Broviac) and was neutropenic at the same time from the patient's history forms and enter them into the box. For the definition of neutropenia days, see section 6.2.1.
During neutropenia days with port	Total the days on which the patient had a port and was neutropenic at the same time from the patient's history forms and enter them into the box. For the definition of neutropenia days, see section 6.2.1.
Outside neutropenia days with CVC (conv)	Total the days on which the patient had a conventional CVC and was NOT neutropenic at the same time from the patient's history forms and enter them into the box. For the definition of neutropenia days, see section 6.2.1.
Outside neutropenia days with CVC (part)	Total the days on which the patient had a partially implanted CVC (Hickman/Broviac) and was NOT neutropenic at the same time from the patient's history forms and enter them into the box. For the definition of neutropenia days, see section 6.2.1.
Outside neutropenia days with port	Total the days on which the patient had a port and was NOT neutropenic at the same time from the patient's history forms and enter them into the box. For the definition of neutropenia days, see section 6.2.1.
Bloodstream infection	Tick whether bloodstream infection (B1-3) was recorded in the patient. Enter the date of infection (dd/mm/yy) and pathogen name. For the definition of the infection date, see section 4.2 or section A of the KISS definitions.
Pathogen(s)	Specify the suspected etiological infectious pathogen identified by microbiological examination. In webKess, the pathogen is selected from a drop-down list.
Association with neutropenia	Tick whether the primary bloodstream infection can be linked to neutropenia in the patient (= associated). For the definition of the association of primary bloodstream infection with neutropenia, see section 6.2.2.
Association with vascular catheter	Tick whether the patient has vascular catheter-associated bloodstream infection. For the definition of primary bloodstream infection as 'vascular catheter-associated', see section 6.3.
Type of vascular access	If a vascular catheter association with primary bloodstream infection has been identified, tick the type of vascular catheter to which the infection can be linked. To determine the type of access for the vascular catheter association, see section 6.3.
Pneumonia	Tick whether pneumonia (C1a-d) was recorded in the patient. Enter the date of infection (dd/mm/yy), pathogen name and detection site of the pathogen (material).
Association with neutropenia	Tick whether the pneumonia can be linked to neutropenia in the patient (= associated). For the definition of the association of pneumonia with neutropenia, see section 6.2.2.

7.2 Additional information collected in the patient history form

Name of patient	Fill in patient name. Remains with the person who entered it, no entry in webKess.
Internal patient ID	Optional: to facilitate tracking of the patient, the person recording the patient can assign a number or abbreviation to the patient according to an internal system and enter it here.
DOB	Fill in the patient's date of birth. Remains with the person who entered it, no entry in webKess.

Month/year	Date (MM/YY). Enter the current month and year in which the patient is recorded. Remains with the person making the recording, no entry in webKess.
Sheet no.	For a better overview, number the patient history forms of a patient chronologically and fill in the information here. Remains with the person who entered it, no entry in webKess.
Day	The numbers listed here (1-31) represent the calendar days of a month.
Pat. hospitalized	A cross is made on the relevant calendar day of the month for each day on which the patient is present during the surveillance period. The day of admission and the day of discharge each count as a full day of attendance and therefore as a patient day. The days between the day of admission and the day of discharge are also counted as days of attendance and therefore as patient days (e.g. admission on 21 March, transfer on 4 April: 1 sheet for March with 11 consecutive days and 1 sheet for April with 4 consecutive days = a total of 15 patient days).
Neutropenia (N)	For each neutropenia day of the patient, a cross is made on the respective calendar day of the month. For the definition of neutropenia, see section 6.2.
GENERAL INFORMATION on the vascular catheter days to be recorded	A day on which the central vascular access is either inserted or removed counts as a full vascular catheter day. All days between the insertion and removal of the central vascular access are also counted. ONKO-KISS distinguishes between three different types of central vascular access: conventional CVC, partially implanted CVC (Hickman/Broviac) and fully implanted CVC (port system). The days on which each type of vascular catheter is present are counted and recorded separately. If a patient has several central vascular catheters, not just one of these vascular catheters is included in the recording of 'vascular catheter days', but all of them. In addition to the type, a distinction is also made when recording the central vascular accesses as to whether the patient is in neutropenia at the same time as having a vascular access or not. Separate fields are available on the patient history form for recording these situations.
CVC conv, *N yes*	For each day on which the patient had a conventional CVC (also Shaldon) and was simultaneously in neutropenia, a cross is placed on the respective calendar day of the month. For the definition of neutropenia see section 6.2 and of neutropenia day see section 6.2.1.
CVC conv, N no	For each day on which the patient had a conventional CVC (including Shaldon) and was NOT in neutropenia at the same time, a cross is placed on the respective calendar day of the month. For the definition of neutropenia see section 6.2 and neutropenia day see section 6.2.1.
CVC part, *N yes*	For each day on which the patient had a partially implanted CVC (e.g. Hickman/Broviac) and was simultaneously in neutropenia, a cross is placed on the respective calendar day of the month. For the definition of neutropenia see section 6.2 and neutropenia day see section 6.2.1.
CVC part, N no	For each day on which the patient had a partially implanted CVC (e.g. Hickman/Broviac) and was NOT in neutropenia at the same time, a cross is placed on the respective calendar day of the month. For the definition of neutropenia see section 6.2 and neutropenia day see section 6.2.1.
Port, *N yes*	For each day on which the patient had a port and was simultaneously in neutropenia, a cross is placed on the respective calendar day of the month. For the definition of neutropenia see section 6.2 and neutropenia day see section 6.2.1.
Port, N no	For each day on which the patient had a port and was NOT in neutropenia at the same time, a cross is placed on the respective calendar day of the month. For the definition of neutropenia see section 6.2 and neutropenia day see section 6.2.1.
Microbiology	A cross on the relevant calendar day of the month indicates whether the patient has a positive microbiological result. A small arrow at the end of the same column of the relevant calendar day of the month can be used to provide more detailed information in the 'Remarks' field.
Chest X-ray / CT	Here, a cross on the respective calendar day of the month indicates whether there is a positive radiological finding for the patient. With a small arrow at the end of the same column of the relevant calendar day of the month, more detailed information can be entered in the 'remarks' field.
Fever > 38°C	Here, a cross is placed on the respective calendar day of the month to indicate whether the patient has a fever > 38°C.

Other clin. sympt.	Here, a cross on the respective calendar day of the month indicates whether a clinical finding/clinical symptom is present in the patient. A small arrow at the end of the same column of the relevant calendar day of the month can be used to provide more detailed information in the 'Remarks' field.
GI GvHD/Diarrhea	Here, a cross on the respective calendar day of the month indicates whether the patient has a gastrointestinal graft versus host disease or diarrhoea. With a small arrow at the end of the same column of the relevant calendar day of the month, more detailed information can be entered in the 'remarks' field.
Remarks	More detailed handwritten information on the patient's findings can be entered here.
∑ (Sum)	The respective totals of the days for the patient are calculated and entered here per sheet (= month). Please note the above explanations on the different types of days recorded for the patient when calculating the totals.

8. Patient registration form for patients with allogeneic or autologous bone marrow or blood stem cell transplantation (BMT, PBSCT, Cord blood)

Surname: **Date of birth:**

First name: **Hospital identification code:**

Patient ID	**Infection ID**	**Gender f ☐ m ☐**	**Year of birth**

Date of admission to participating ward: _____ **Date of HSCT:** _____

Date 200 days post-HSCT (is generated in webKess): _____

End of surveillance (date): _____

Surveillance ended by: 200 days post-HSCT ☐ transfer / discharge ☐ death ☐

Underlying disease: **AML ☐ CML ☐ ALL ☐ NHL ☐ MDS ☐ MM ☐ OTH ☐**

Transplantation:	**BMT**	**PBSCT**	**Cord blood**
	autologous ☐	**autologous ☐**	
	allogeneic related ☐	**allogeneic related ☐**	**allogeneic related ☐**
	allogeneic unrelated ☐	**allogeneic unrelated ☐**	**allogeneic unrelated ☐**

Patient days:		**Neutropenia days:**	

During neutropenia:	**days with CVC (conv)**	**days with CVC (part)**	**days with port**
Outside neutropenia:	**days with CVC (conv)**	**days with CVC (part)**	**days with port**

Bloodstream infection: yes ☐ no ☐

- □ **Laboratory-confirmed primary bloodstream infection (B1)**
- □ **Clinically confirmed primary bloodstream infection in patients ≤ 1 year of age (B2)**
- □ **Mucosal barrier injury laboratory-confirmed primary bloodstream infection (B3)**

Date: _____ **Pathogen(s): 1**_____ **2**_____ **3**_____

Association with neutropenia	**yes ☐ no ☐**	
Association with vascular catheter	**yes ☐ no ☐**	
	If yes, type of access to which the infection can be linked	**CVC (conv) ☐ CVC (part) ☐ Port ☐**

Pneumonia: yes ☐ no ☐

- □ **Clinically defined pneumonia (C1a)**
- □ **Pneumonia with common bacterial or filamentous fungal pathogens and specific laboratory findings (as defined in section B or section C of the KISS definitions) (C1b)**
- □ **Viral, legionella, and other bacterial pneumonias with definitive laboratory findings (as defined in section B or section C of the KISS definitions) (C1c)**
- □ **Pneumonia with special pathogens in immunocompromised patients (C1d)**

Date: _____ **Pathogen(s): 1**_____ **2**_____ **3**_____

Detection site (material) _____

Association with neutropenia	**yes ☐ no ☐**

9. Patient history form for patients with allogeneic or autologous bone marrow or blood stem cell transplantation (BMT, PBSCT, Cord blood)

Patient history form ONKO-KISS						**Patient ID (webKess):**										**Name of the patient:**															
Date of HSCT:						**Internal patient ID:**										**DOB:**				**Month/Year:**						**Sheet no.:**			
Day	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**∑**
Pat. hospitalized																															
Neutropenia (N)																															
CVC conv, *N yes*																															
CVC conv, N no																															
CVC part, *N yes*																															
CVC part, N no																															
Port, *N yes*																															
Port, N no																															
Microbiology																															
Chest X-ray / CT																															
Fever > 38°C																															
Other clin. sympt.																															
GI GvHD/diarrhoea																															
Remarks:																															

10. List of abbreviations

BMT	Bone marrow transplantation
CDC	Centers for Disease Control and Prevention
CVC	Central venous catheter
DLI	Donor lymphocyte infusion
KISS	German hospital infection surveillance system
MDRO	Multidrug-resistant organism
NHSN	National Healthcare Safety Network
NRZ	National reference centre/ Nationales Referenzzentrum
PBSCT	Peripheral blood stem cell transplant

11. Documentation forms for surveillance

Documentation forms for recording the most important data (patient history form for daily records, patient registration form for the patient's master data and flow charts for the types of infection of primary bloodstream infection and pneumonia) are available in the current version as PDF documents on the NRZ homepage at https://www.nrz-hygiene.de/KISS-Modul/anleitungen/KISS/ONKO. These documentation forms are designed for internal collection of data within the department. They should not be sent to the NRZ. Data is transferred to the NRZ exclusively via webKess.

12. Contact data

E-mail contact address for content-related questions, technical support and webKess support: kiss-support@charite.de
The contact persons are listed on the NRZ homepage (www.nrz-hygiene.de).

Postal address:
Nationales Referenzzentrum (NRZ) für Surveillance von nosokomialen Infektionen
Module ONKO-KISS
Institute of Hygiene and Environmental Medicine, Charité - Universitätsmedizin Berlin
Hindenburgdamm 27
12203 Berlin
Germany

13. Imprint

Nationales Referenzzentrum (NRZ) für Surveillance von nosokomialen Infektionen

at the Institute of Hygiene and Environmental Medicine
(Director Prof. Dr. med. Christine Geffers)
Charité-Universitätsmedizin Berlin
Corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin

Hindenburgdamm 27
12203 Berlin
Germany
Phone: +49 (0)30 / 450 577 612
Fax: +49 (0)30 / 450 7577 920
Email: nrz@charite.de