Protocol

Surveillance of nosocomial infections, multi-resistant pathogens and Antibiotic applications for Premature babies with a Birth weight under 1,500g

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on

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1. Introduction

Premature babies have the highest infection rates of all paediatric patients, with sepsis and pneumonia being 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 sepsis and pneumonia in this patient group in particular. The aim of surveillance is to prevent nosocomial infections by providing suitable infection data, which is important for decisions on infection prevention.

Necrotising enterocolitis (NEC) often occurs in clusters and has a major impact on patient morbidity and mortality. Even if it is not a confirmed infectious disease, NEC is also included in the surveillance system as an additional disease.

As the majority of all nosocomial infections occur in premature babies with a birth weight of less than 1,500 g, surveillance is limited to this patient group.

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

Surveillance is also carried out for the colonisation/infection of a premature infant with a multi-resistant pathogen (MRE) and for antibiotic use.
applications.

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

2. Objectives of the surveillance protocol

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

Secondly, other interested hospitals can also record nosocomial sepsis, pneumonia and NEC according to these definitions and specifications and analyse their data analogously. In principle, these hospitals also have the opportunity to orientate themselves on the results of NEO-KISS.

The CDC definitions for nosocomial infections were modified for the patient clientele with the collaboration of leading neonatologists after evaluation of a 10-month survey phase in the neonatology clinic of the Charité Campus Virchow Klinikum and a subsequent pilot phase in which 16 neonatology departments throughout Germany took part in 1999. In consultation with the participants in NEO-KISS, the surveillance was repeatedly adapted and expanded in the years that followed.

The surveillance protocol is aimed at interested neonatologists, nursing staff in neonatal intensive care medicine as well as hospital hygienists and hygiene nurses who wish to participate in surveillance.

3. Requirements for neonatology departments to participate in NEO-KISS

Participating departments must fulfil the following requirements:

- Approval of the head of department for participation in NEO-KISS
- Approval of the application of the NEO-KISS protocol specifications and the definitions for the diagnosis of nosocomial infections and publicising these definitions to the treating physicians
- At least one representative who carries out surveillance or is responsible for surveillance must attend the NRC's NEO-KISS introductory course before registering for the module.
- A participating department must have at least one neonatal intensive care unit with ventilation facilities
- 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 anonymised reference data
- Participation of a representative of the department in regular NRZ events (exchange of experience) 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 reported data (e.g. diagnosis of nosocomial infections).

The institutions supporting KISS assure the departments involved,

- to advise and support them professionally in the implementation of surveillance
- handle the data of the individual departments with strict confidentiality
- to provide the participating hospitals with the standardised and stratified reference data
- Provide assistance in the implementation of surveillance results for quality management

4. Methods

The method used by NEO-KISS primarily aims to support internal quality assurance measures and is intended to provide information on the frequency of infections, the occurrence of MRE and the use of antibiotics in premature babies during inpatient care in a department.
Continuous intensive contact between hygiene staff and doctors, nurses and carers in the departments involved is therefore of great importance. The usual way to identify nosocomially infected patients is to regularly study the current patient data on the wards (approx. twice a week), including the microbiological findings. Close contact between the surveillance staff (usually hygiene specialists) and the ward staff is an essential prerequisite for successful participation in NEO-KISS.

Patients to be included

NEO-KISS includes premature babies with a birth weight <1,500g from a department participating in NEO-KISS.

Surveillance duration

The survival period begins with the patient's admission to the ward and ends with the transfer, death or when the daily weight reaches or exceeds the limit of 1,800g.

Surveillance parameters

NEO-KISS contains three parameters under Surveillance:

- **Nosocomial infections**
- **Multi-resistant pathogens**
- **Antibiotic applications**

Nosocomial infections

Surveillance of nosocomial infections is limited to three types of infection

- primary sepsis,
- Pneumonia,
- necrotising enterocolitis.
-

Only infections acquired in the neonatology departments involved are recorded. Infections already brought to the department are not recorded as nosocomial infections.

Multi-resistant pathogens

The following multi-resistant pathogens are recorded in NEO-KISS:

- MRSA
- MRGN (2MRGNNeoPaed, 3MRGN, 4MRGN)
- AER

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Antibiotic applications

In addition, systemic antibiotics (incl. substance) are recorded per day for premature babies.

In NEO-KISS, surveillance is carried out on a patient-by-patient basis. Children who fulfil the inclusion criteria are observed until the end of surveillance (transfer/death/weight>1,800g), regardless of the ward on which they are currently lying. The data is always calculated on a ward-specific basis. Evaluations for individual wards of a neonatology department by the NRZ are not planned.

4.1 Patient data collection

Patient history sheet

(as paper version under http://www.nrz-hygiene.de/fileadmin/nrz/module/neo/NEO-KISS_Patientenverlaufsbogen.pdf)

A *patient history sheet* is created for all patients with a birth weight of less than 1,500g who are admitted to a participating neonatology department, regardless of the length of stay.

It remains in the clinic and is used for easier recording and, if necessary, tracing of patients. Patient days, device days and antibiotic days are recorded on it.

The corresponding data is recorded on a daily basis, added up per month and transferred to webKess at the end of the surveillance as the sum of a child's monthly records under "Patients - Discharge data"

If a patient leaves the neonatology department only briefly (up to 2 days), e.g. for a surgical procedure, this is not counted as a discharge. On re-admission (on the 3rd day at the latest), the missing data for the absent days are added. If there is a longer period of time between transfer and readmission, the patient is first discharged from surveillance (enter discharge data, reason "Transfer") and later readmitted to the department as a new patient in NEO-KISS (under "Admission" now enter "Transfer to own hospital≥ 24h postnal").

Patient master data ("Patients" in webKess)

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 as mandatory fields in webKess and must be completed in full by the participants.

In addition, optional data can also be entered here, e.g. CRIB score.

After saving the patient data, the system generates a patient list. Each patient is assigned a unique webKessId here. This is intended to enable the anonymised webKess data record to be assigned by name in the clinic, but not to allow third parties to draw any conclusions about the patient.

The NEO-KISS participant is responsible for organising the necessary retrieval of individual patients using the webKessId (e.g. noting the webKessId on the patient history sheet and archiving or keeping an anonymisation list with webKessId and clear name location in the neonatology department). For data protection reasons, patients' real names must not be entered in webKess.

4.2 Recording nosocomial infections

Documentation of nosocomial sepsis, pneumonia and NEC in patients with a birth weight of <1,500 g until the end of surveillance:

- If a patient under surveillance develops nosocomial primary sepsis, pneumonia or NEC, the infection is entered in webKess with other infection-relevant data under "New infection" (click on the "New infection" button after saving the patient data). After selecting the relevant infection, the corresponding diagnostic criteria must be marked on the infection form that appears. After saving the infection, the summarised information on the patient appears in the patient list in webKess. Paper versions of the infection recording forms are also available at for internal departmental documentation
- Only nosocomial infections are recorded. An infection is nosocomial if it was acquired in the neonatology department, i.e. it was not present on admission and not in the incubation phase. The reference value is 72 hours after birth or after admission to a neonatal ward.

4.3 MRE detection

Documentation of the detection of multi-resistant pathogens (MRE) at the VLBWs.
If an MRE is detected in a child with a birth weight <1,500g during the surveillance period (from admission/birth to transfer/death/day weight >1,800g), this is entered in webKess.
The following MREs are recorded:

- Methicillin-resistant *Staphylococcus aureus* (**MRSA**)
- Vancomycin-resistant *Enterococcus faecium* and *Enterococcus faecalis* (**VRE**)
- Multi-resistant Gram-negative bacteria with resistance to 2, 3 or 4 classes of antibiotics (**MRGN**)

If an MRE is detected, the information brought in/nosocomial and infection/colonisation must also be provided.

4.4 Antibiotic consumption surveillance

In paediatric patients and especially in premature infants, the usual use of DDDs (Defined Daily Dose) as a measure for antibiotic consumption surveillance is not suitable.
The NEO-KISS therefore documents the days on which systemic antibiotics are administered, including the name of the substance administered, on each day during the surveillance period.

4.5 Calculation of comparative data

In webKess, NEO-KISS participants can create an analysis of their own department data at any time by selecting the corresponding menu item. Reference data is calculated annually and compared with the department data. Data should be entered in webKess on an ongoing basis; by the deadline for reference data creation (15 February each year) at the latest, the data of all data records completed by then (weight >1,800g reached, patient transferred or deceased) should have been entered so that they can be included in the reference data calculation by the NRZ.
Due to the significant importance of the birth weight factor for the development of nosocomial infections and the use of antibiotics, all rates mentioned (except standardised infection rate and MRE rates) are calculated separately for three birth weight classes (group of newborns with a birth weight (BW) up to 499 g, group with a BW of 500-999 g, and BW 1,000 - 1,499 g) (**= Stratification**).

4.5.1 Device application rate

It describes the percentage of patient days on which a specific device/procedure (vascular catheter, ventilation/respiratory support) was used and is calculated as the quotient of the device days and the total number of patient days in a department. For this purpose, the patient and device days collected per patient in the department are added together.

The following applies in detail:

$$\text{ZVK *Application rate} = \frac{\text{Number of days}}{\text{Number of patient days}} \times 100$$

$$\text{PVK application rate} = \frac{\text{Number of PVK days}}{\text{Number of patient days}} \times 100$$

$$\text{INV application rate} = \frac{\text{Number of INV days (intubation)}}{\text{Number of patient days}} \times 100$$

$$\text{NIV application rate} = \frac{\text{Number of NIV days (CPAP, high-flow)}}{\text{Number of patient days}} \times 100$$

* This includes central vascular catheters, indwelling catheters (even if they do not reach a central vessel), umbilical vein and umbilical artery catheters

4.5.2 Nosocomial device-associated infection rate

It is the most important rate for quality management and describes the number of device-associated infections per 1,000 device days. Here, the infections (e.g. sepsis) occurring during the use of a particular risk (=device, e.g. CVC) are related to the risk days of a department (CVC days) and calculated in detail as follows (= **standardisation**):

CVC-associated Sepsis rate = Number of sepsis in patients with CVC / Number of CVC days x 1.000

PVK-associated Sepsis rate = Number of sepsis in patients with PVK / Number of PVK days x 1.000

INV-associated Pneumonia rate = Number of pneumonias in INV patients (invasive ventilation: endotracheal tube, subglottic) / Number of INV days x 1.000

NIV-associated Pneumonia rate = Number of pneumonias in NIV patients (non-invasive respiratory support: CPAP, High-Flow) / Number of NIV days x 1.000

A CVC- or PAC-associated primary sepsis and an INV- or NIV-associated pneumonia are present if the vascular catheter or ventilation/breathing support via tube/CPAP/high-flow goggles was present within 48 hours before the start of the infection or is still present.

In the presence of invasive ventilation (INV) **and** non-invasive respiratory support (NIV) in the last 48 hours before the onset of infection, the pneumonia is categorised as INV-associated, as invasive ventilation via endotracheal tube is considered the more invasive and therefore presumably more relevant procedure for the infection. The same applies to CVC and PAC, if **both were** in place in the 48 hours prior to the onset of infection, the sepsis is categorised as CVC-associated.

4.5.3 Incidence density nosocomial infections

As the frequency of risk applications (device days) is sometimes very low and a significant proportion of infections also occur independently of these risk factors, the sepsis, pneumonia and NEC density are also calculated, thereby also achieving standardisation. The time under risk corresponds to the total number of patient days (until the end of surveillance per patient) in a department.

$$\text{Sepsis density} = \frac{\text{Number of primary sepsis}}{\text{Number of patient days}} \times 1.000$$

$$\text{Pneumonia density} = \frac{\text{Number of pneumonias}}{\text{Number of patient days}} \times 1.000$$

$$\text{NEC density} = \frac{\text{Quantity NEC}}{\text{Number of patient days}} \times 1.000$$

4.5.4 MRE rates

Various parameters are calculated to describe the MRE situation in premature babies in a department.

Proportion of inpatients with MRE Indicates the proportion of MRE patients among premature babies the department			
Overall MRE prevalence	=	$\frac{\text{Number of patients with MRE}}{\text{Number of recorded Patients}}$	x 100

Proportion of admitted patients with MRE Allows statements on MRE entry to the ward			
MRE admission prevalence	=	$\frac{\text{Number of patients with MRE brought in}}{\text{Number of recorded Patients}}$	x 100

Proportion of patients with newly acquired MRE Allows statements on MRE acquisition on the ward			
MRE incidence	=	$\frac{\text{Number of patients with nosocomial MRE}}{\text{Number of recorded Patients}}$	x 100

New acquisition density of MRE on the ward Allows statements on the transmission/selection frequency of MRE on the ward			
Incidence density of MRE acquired on the ward	=	$\frac{\text{Number of patients with MRE acquired on the ward}}{\text{Number of patient days}}$	x 1.000

Infection rate with MRE Indicates the proportion of patients for whom the MRE is a therapeutic option. Relevance has			
Prevalence of MRE infections	=	Number of patients with MRE infection / Number of recorded Patients	x 100

Infection rate with nosocomial MRE infections Indicates the proportion of patients who have developed a nosocomial infection with an MRE pathogen			
Incidence of nosocomial MRE infections	=	Number of patients with nosocomial infection with MRE as a pathogen / Number of recorded Patients	x 100

New disease density during the inpatient stay with the MRE Allows an assessment of the efficiency of infection control measures on the ward			
Incidence density of nosocomial MRE infections	=	Number of patients with nosocomial infection with MRE as a pathogen / Number of patient days	x 1.000

New acquisition density of MRE with subsequent MRE infection Allows an assessment of potential MRE infections to be avoided			
Incidence density of nosocomial MRE infections with nosocomial MRE	=	Number of patients with nosocomial MRE infections nosocomial MRE / Number of patient days	x 1.000

4.5.5 Antibiotic use density

It describes the proportion of patient days on which systemically effective antibiotics were administered and is calculated as the quotient of the antibiotic days (total and per substance) and the total number of patient days in a department. For this purpose, the patient and antibiotic days collected per patient in the department are added together.

$$\text{Antibiotic use density} = \frac{\text{Number of antibiotic days}}{\text{Number of patient days}} \times 100$$

4.5.6 Calculation of an example for the birth weight class 1,000g-1,499g of a neonatology department:

Given:	GG class 1,000 g-1,499 g
Patients	4
Patient days	151
ZVK application days	70
PVK application days	40
INV days	40
NIV application days	30
Antibiotic application days	15
Ampicillin	10
Gentamicin	10
Cefotaxime	5
Primary sepsis	1 CVC-associated
Pneumonia	1 not device-associated
NEC	0
MRE	0

Wanted: all described instalments for this GG class

Rate	GG class 1,000 g-1,499 g
• device application rates (%):	
ZVK application rate	70/151 x 100 = 46
PVK application rate	40/151 x 100 = 26
INV application rate	40/151 x 100 = 26
NIV application rate	30/151 x 100 = 20
• Antibiotic use density	
Total AB application density	15/151 x 100 = 10
Ampicillin application density	10/151 x 100 = 6,6
Gentamicin application density	10/151 x 100 = 6,6
Cefotaxime application density	5/151 x 100 = 3,3
• Device-associated infection rate (device-associated infections per 1,000 device days) :	
CVC-associated sepsis rate	1/70 x 1.000 = 14,3
PVK-associated sepsis rate	0/40 x 1.000 = 0
INV-associated pneumonia rate	0/40 x 1.000 = 0
NIV-associated pneumonia rate	0/30 x 1.000 = 0
• Pneumonia density	1/151 x 1.000 = 6,6
• Sepsis density	1/151 x 1.000 = 6,6
• NEC density	0
• MRE rates	all 0

4.5.7 Standardised infection rate n

The 7 infection rates described above (4 device-associated infection rates and 3 incidence densities) allow a very detailed consideration of the frequency of the individual nosocomial infections in the three birth weight classes, but do not easily allow a summarised assessment of the infection frequency of premature babies in a department. For this reason, NEO-KISS also calculates a standardised infection rate that takes into account the patient composition of a department and at the same time assesses the frequency of infections in one department compared to others. Based on the NRZ's own analyses, birth weight and age (day of life after birth) were identified as decisive risk factors and are therefore used as indicators for infection frequencies when calculating the standardised infection rate.

The standardised infection rate determines the number of expected infections in a department on the basis of the NEO-KISS reference database, taking into account the patient composition of the respective department, and compares this with the number of observed infections in this department. All NEO-KISS patients are included in the calculation of the standardised infection rate. The probability of a severe infection (sepsis and pneumonia) on the respective day of life (smoothed +-1 day) is determined for each birth weight (in 5g increments) from the data in the NEO-KISS reference database. An infection probability (number of expected infections) for the entire department can be calculated from the number of children treated in a department according to the individual birth weight of each child and the number of days of life spent in the department . This expected number of infections is related to the observed infections in a department (see formula).

$$\text{standardised Infection rate} = \frac{\text{Number of infections observed}}{\text{Number of expected infections}}$$

If the standardised infection rate is greater than 1, this means that more infections were observed than would have been expected given the patient composition of the department.

If the standardised infection rate is 1, exactly as many infections were observed as were expected.

If the value is below 1, this indicates a favourable infection situation in a department, as fewer infections occurred than expected due to the patients treated there.

4.5.8 Calculation of an example of the standardised infection rate of a department

In one department, 10 NEO-KISS patients with a birth weight (BW) of 745g to 1,495g were treated. The data of the 10 children and the nosocomial pneumonia and sepsis cases observed in these children are shown in the table:

Patient data		Observed infections		
GG	Days of life	Pneumonia	Sepsis	Total pneumonia + sepsis
745	56-71	0	1	1
1240	1-44	0	0	0
1495	1-32	0	0	0
1015	48-72	0	0	0
900	41-64	0	0	0
780	67-88	1	0	1
1240	1-5	0	0	0
785	52-71	0	0	0
1245	1-48	0	1	1
920	38-57	0	0	0
	Total		Observed inf.=	**3**

The NEO-KISS database can now be used to determine the probability of infection for each day of life of each of these children based on their birth weight. By adding this risk per day of life for all days of life that the children have spent in the ward, the number of expected infections in a ward is calculated:

Patient (GG 745 g):

Day of life	Expected infections on day of life[1]
56	0,0128
57	0,0122
...	...
70	0,0049
71	0,0043
Sum:	**0,1374**

Patient (GG 1240 g):

Day of life	Expected infections on day of life[1]
1	0,0018
2	0,002
...	...
43	0,0047
44	0,0042
Sum:	**0,410**

[1] Determined from the reference data for the respective birth weight

Patient data		Observed infections			Expected infections
GG	Days of life	Pneumo-nia	Sepsis	Total pneu-monia + sepsis	Sum of expected infec-tions on day of
745	56-71	0	1	1	0,137
1240	1-44	0	0	0	0,410
1495	1-32	0	0	0	0,254
1015	48-72	0	0	0	0,207
900	41-64	0	0	0	0,216
780	67-88	1	0	1	0,168
1240	1-5	0	0	0	0,047
785	52-71	0	0	0	0,203
1245	1-48	0	1	1	0,446
920	38-57	0	0	0	0,213
Total infections			observed=	**3**	**2,301**

The standardised infection rate is calculated from the number of observed and expected infections

$$\text{standardised Infection rate} = \frac{\text{(number of infections observed)}}{\text{(number of expected infections)}} = \frac{\mathbf{3}}{\mathbf{2,301}} = \mathbf{1,30}$$

In this example, the department has a standardised infection rate of 1.30. This means that more infections have occurred than expected. The infection situation for this department is comparatively unfavourable.

The standardised infection rate is calculated automatically in NEO-KISS in webKess and can be requested by NEO-KISS participants at any time in webKess under *"Evaluation".*

4.6 Comparison of surveillance data

In addition to the stratified and standardised pooled data, distribution parameters (1st quartile (Q1), median (Q2), 3rd quartile (Q3)) are also shown. 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 within the time course can provide an indication of infection problems, which should then be investigated in more detail.

5. General definition principles nosocomial infections

1. **a diagnosis of infection for the purpose of recording is based on combinations of clinical symptoms, laboratory data and supporting data (e.g. X-ray examinations, biopsies), in varying degrees of significance and logical composition.**
There must be no evidence that the infection was already present on admission or in the incubation phase.

2. a neonatal infection that has occurred as a result of passage through the birth canal is defined as nosocomial, whereas transplacentally acquired infections are not categorised as nosocomial.
If a vertical (transplacentally acquired) infection manifesting later than the first few hours of life is to be distinguished from a nosocomial infection, for which there are often no clinical distinguishing features, a time interval after birth must be introduced ***before*** *which an infection is considered vertically acquired and* ***after*** *which it is considered nosocomial. This has traditionally been attempted with the terms "early onset" versus "late onset". In the literature, between 24 hours and 5 days can be found as an interface for vertical versus nosocomial infections. We have opted for 72 hours, as this time is also used by the neonatal survey in Germany. However, if an infection is clearly nosocomial* ***before*** *this time or clearly vertical* ***afterwards*** *(e.g. all transplacentally transmitted infections that may not be apparent at birth, such as toxoplasmosis, CMV, HIV, rubella, Lues), it is categorised accordingly.*
The 72 h interval after birth applies; an infection occurring earlier is generally not considered nosocomial.

3. a change of pathogen alone is not sufficient to record a new infection after an already recorded infection. For the recording of a new infection of the same organ system, there is a blocking period of 14 days from the onset of the previous and a clinically free interval is also required before the new infection.

The definitions of primary sepsis, pneumonia and NEC for neonates, which form the basis of infection diagnostics for NEO-KISS, are listed below. It is important to note once again that these definitions are not intended for clinical use, but only for recording nosocomial infections. They are intended to enable those not directly involved in treatment to recognise a nosocomial infection on the basis of the patient file. They provide a fixed grid for diagnostics in the epidemiological sense in order to achieve comparability between departments.

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

It is therefore possible that an infection is diagnosed according to clinical criteria but is not categorised as an infection according to the definitions used in NEO-KISS (because the criteria are not sufficiently present) and vice versa.

6. Definitions of indicator infections in NEO-KISS

The following applies to all diseases: onset of symptoms >72h after birth or after admission to the neonatology department. A clinically clear interval is required for the diagnosis of a new infection (e.g. second pneumonia in a child during hospitalisation). A change of pathogen alone is not sufficient to diagnose a new infection of the same type.

6.1 Primary sepsis

NEO-KISS distinguishes between three different primary forms of sepsis (the secondary spread of pathogens in the blood, which originates from an infection elsewhere and is referred to as secondary sepsis, is not included in this category). There are specific definitions for each of the three forms of primary sepsis depending on the pathogen detected or the lack of pathogen detection. A distinction is made between

- Clinical sepsis (without pathogen detection),
- Microbiologically confirmed sepsis with pathogen detection (but no CNS) and
- Microbiologically confirmed sepsis with coagulase-negative staphylococci (CNS) as the sole pathogen

6.1.1 Clinical sepsis (without pathogen detection)

ALL of the following criteria:

1. **attending physician starts appropriate antimicrobial therapy for sepsis for at least 5** days*
2. **NO pathogen detection** in the blood culture or not tested**
3. **NO obvious infection elsewhere**

AND two of the following criteria (without any other recognisable cause)

- **Fever (>38° C) or temperature instability (frequent readjustment of the incubator) or hypothermia (<36.5° C)**
- **Tachycardia (> 200/min) or new/increased bradycardia (<80/min)**
- **Recapillarisation time (RKZ) >2s**
- **New or increased apnoea(s) (>20s)**
- **Unexplained metabolic acidosis (BE < -10 mval/l)**
- **New onset of hyperglycaemia (>140mg/dl)**
- **Other signs of sepsis (skin colour (only if RCC is not used), laboratory signs (CRP, interleukin***), increased oxygen demand (intubation), unstable AZ, apathy)**

Notes for sepsis definitions

*A therapy day is, analogous to the definition of antibiotic days, a "day on which the patient received systemically effective antibiotics (orally or parenterally)". The day on which the first dose was administered is counted as the first day of therapy, the day on which the last dose was administered is counted as the last day of therapy.
This applies regardless of the number of doses or their presumed efficacy/duration of effect.

**A single detection of CNS in the blood culture does not necessarily rule out the diagnosis of clinical sepsis. Clinical sepsis can also be diagnosed if CNS have grown once in the blood culture, this is assessed as contamination of the blood culture, but the other criteria of CNS sepsis are not fulfilled and those of clinical sepsis are fulfilled.

***Interleukin can be evaluated as a parameter if the laboratory's own specifications of a pathological value are fulfilled; interleukin 6-8 are evaluated.

6.1.2 Microbiologically confirmed sepsis with pathogen detection (but no CNS)*

Pathogen isolated from blood or cerebrospinal fluid that is not a CNS*
(Pathogen must not be related to infection elsewhere)

AND two of the following criteria

- **Fever (>38° C) or temperature instability (frequent readjustment of the incubator) or hypothermia (<36.5° C)**
- **Tachycardia (> 200/min) or new/increased bradycardia (<80/min)**
- **Recapillarisation time (RKZ) >2s**
- **New or increased apnoea(s) (>20s)**
- **Unexplained metabolic acidosis (BE < -10 mval/l)**
- **New onset of hyperglycaemia (>140mg/dl)**
- **Other signs of sepsis (skin colour (only if RCC is not used), laboratory signs (CRP, interleukin**), increased oxygen demand (intubation), unstable AZ, apathy)**

Notes for sepsis definitions

* Coagulase negative staphylococci

**Interleukin can be evaluated as a parameter if the laboratory's own specifications of a pathological value are fulfilled, interleukin 6-8 are evaluated.

6.1.3 Microbiologically confirmed sepsis with coagulase-negative staphylococci (CNS) as the sole pathogen

KNS is the only pathogen isolated from blood

AND ONE of the following laboratory parameters (without any other recognisable cause)

CRP >2.0mg/dl or interleukin**	**I/T ratio >0.2 (immature granulocytes / total granulocytes)**
Thrombocytes < 100/nl	**Leukocytes < 5/nl (without erythroblasts)**

AND two of the following criteria (without any other recognisable cause)

- **Fever (>38° C) or temperature instability (frequent readjustment of the incubator) or hypothermia (<36.5° C)**
- **Tachycardia (> 200/min) or new/increased bradycardia (<80/min)**
- **Recapillarisation time >2s**
- **New or increased apnoea(s) (>20s)**
- **Unexplained metabolic acidosis (BE < -10 mval/l)**
- **New onset of hyperglycaemia (>140mg/dl)**
- **Other signs of sepsis (skin colour (only if RCC is not used), increased oxygen requirement (intubation), unstable AZ, apathy)**

Notes for sepsis definitions

*A single detection of CNS in the blood culture does not necessarily rule out the diagnosis of clinical sepsis. Clinical sepsis can also be diagnosed if CNS have grown once in the blood culture, this is evaluated as contamination of the blood culture, but the other criteria of CNS sepsis are not fulfilled and those of clinical sepsis are fulfilled.

**Interleukin can be evaluated as a parameter if the laboratory's own specifications of a pathological value are fulfilled, interleukin 6-8 are evaluated.

6.2 Pneumonia

The diagnosis of pneumonia requires radiological findings in combination with a deterioration in oxygenation and four additional clinical/laboratory signs:

ONE radiological finding

- **New or progressive infiltrate**
- **Shading**
- **Fluid in the interlobar or pleural space**

AND deterioration in gas exchange, drop in saturation

AND FOUR of the following criteria

- **Newly occurring or increased bradycardia (< 80/min) or new/increased tachycardia (>200/min)**
- **New/increased tachypnoea (>60/min) or new/increased apnoea (> 20 s)**
- **purulent tracheal secretion**
- **Germ from tracheal secretion**
- **New/increased dyspnoea (retractions, nasal flaring, moaning)**
- **Temperature instability/fever/hypothermia**
- **Increased respiratory secretion (increased aspiration)**
- **CRP > 2.0 mg/dl or interleukin***
- **I/T ratio > 0.**

Notes for pneumonia Definition

Deterioration of the gas exchange

-increase in FiO_2 requirement >10% within 24h or

-Start of mechanical ventilation

Purulent tracheal secretion

Secretion from deep airways with≥ 25 neutrophil granulocytes and≤ 10 epithelial cells per field of view (x100)

*Interleukin can be evaluated as a parameter if the laboratory's own specifications of a pathological value are fulfilled, interleukin 6-8 are evaluated.

6.3 Necrotising enterocolitis (NEC)

For the diagnosis of NEC, either the combination of a radiological sign and two clinical symptoms or the histological diagnosis from material from the surgical specimen is required (histology alone is sufficient):

ONE of the following radiological* signs

- **Pneumoperitoneum**
- **Pneumatosis intestinalis (gas bubbles in the intestinal wall)**
- **Unchanged standing loops of small intestine**

AND TWO of the following criteria (without any other cause)

- **Vomiting**
- **Food ("stomach") residues**
- **distended abdomen**
- **Flank erythema**
- **Repeated microscopic (haemoccult) or macroscopic blood in the stool**

OR

Diagnosis by histological examination of the surgical specimen

* The radiological signs mentioned can be provided by conventional X-rays, but also by meaningful findings from other imaging procedures (ultrasound, CT, MRI).

7. Specifications for surveillance

Explanations and definitions of the variables collected in NEO-KISS

7.1 Patient data:

webKessId	Assigned by the system after a patient has been entered. Important for collating data and any queries. Should be noted on all of the patient's surveillance documents within the department.
Patient history sheet (paper)	Used for easier recording and, if necessary, tracking of the patient, it remains in the department and can optionally be used or modified. For a better overview, a separate patient history sheet should be used for each calendar month in which a child is treated as an inpatient in the department (regardless of the respective ward) (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).
Patients (in webKess)	Recording basic patient data in webKess
Device	
ZVK = central Vascular catheter	Indicate days on which the patient had a CVC for more than 12 hours. Central vascular catheters (umbilical vein and umbilical artery catheters), indwelling catheters are counted.
PVK = peripheral Vascular catheter	Indicate days on which the patient had a PVC for more than 12 hours. Flex needles, brown needles, butterfly count Cave: no indwelling catheters
INV = Endotrachel-tubus	Indicate days on which the patient was ventilated via an endotracheal tube for more than 12 hours.
="revenge tube", CPAP, high-flow	Indicate days on which the patient received non-invasive respiratory support (CPAP, high-flow) for more than 12 hours. If ventilation is performed via endotracheal tube at the same time, do not enter anything here; the day then counts as an INV day.

Antibiotics	Indicate the days on which the patient received systemically effective antibiotics (oral or parenteral). Antimycotics or antivirals as well as local applications are not counted. If a patient receives more than one antibiotic per day, the day is still only counted as 1 antibiotic day.
Substances	Select the antibiotic substance from the drop-down list (in webKess) and enter the number of days on which the patient received the substance.
∑ (total) (on paper flow sheet)	The respective totals of the days for the patient are calculated.
Recording	-Transfer from the delivery room of your own hospital/perinatal centre immediately after the birth, -Transfer to own hospital/perinatal centre < 24 h postnatal Transfer/readmission to own hospital/perinatal centre≥ 24 h postnatal (information is used for risk assessment)
Recording on Day of life	Field active if "Transfer/readmission to own hospital/perinatal centre≥ 24 h postnatal" was specified under Admission. The day of life on which the child was admitted is entered, whereby the day of birth is counted as the first day of life and the following day (from 00:00) as the second day of life. (information is used for risk assessment)
Birth weight	Weight of the child at birth in grams. Applies as an inclusion criterion (< 1,500g), for stratification into the GG classes and for calculating the Standardised Infection Rate SIR. Children with GG≥ 1,500g are **NOT** included in NEO-KISS, even if they later weigh less than 1,500g.
Gestational age	Enter in weeks + days, e.g. 25 weeks and 4 days is entered as the value "25+ 4".
Gender	male or female.
Multiple birth	Tick the appropriate box.
Quantity	Field active if multiple birth is confirmed. The value 2 is entered for twins, 3 for triplets and so on.

Type of delivery	Tick the appropriate box.
CRIB score	If available, enter the point value.
End of the Surveillance	Date: DD/MM/YYY. When the weight limit is reached, the date of the day on which the child weighs 1,800 g applies. After this day, the recording is not continued, even if the child weighs less than 1,800 g again. Otherwise date of transfer from the department or date of death.
Reason	State the reason for ending the surveillance •**1,800g** achieved •**Transfer** from the department (Transfers between wards in the same department do NOT end the surveillance!) •**Died**
Patient days	Total the days of attendance on the patient history forms for the patient and enter them here.
ZVK days	Number of days (sum of follow-up questionnaires) on which the patient had a central vascular access (CVC, NPC, NAC, PICC).
PVK Days	Number of days (sum of follow-up questionnaires) on which the patient had an indwelling peripheral venous cannula.
INV days	Number of days (sum of follow-up questionnaires) on which the patient was ventilated via endotracheal tube.
NIV days	Number of days (sum of follow-up questionnaires) on which the patient had respiratory support via CPAP or high-flow goggles.

7.1.1 The CRIB score (Clinical risk index for babies)

Factor	Score
Birth weight (g)	
>1350	0
851-1350	1
701-850	4
≤700	7
Gestational age (weeks)	
>24	0
≤24	1
Congenital malformations	
None	0
Not acutely life-threatening	1
Acute life-threatening	3
Maximum base excess in the first 12 hours of life (mmol/L)	
> -7,0	0
-7 to -9.9	1
-10 to -14.9	2
≤ -15,0	3
Minimum required FiO2 [2] in the first 12 hours of life	
≤0,4	0
0,41-0,60	2
0,61-0,90	3
0,91-1,00	4
Maximum required ^{FiO2} [2] in the first 12 hours of life	
≤0,4	0
0,41-0,80	1
0,81-0,90	3
0,91-1,00	5

[1] Unavoidable lethal malformations (e.g. trisomy 13, trisomy 18, bilateral renal agenesis, Potter syndrome) are excluded.

[2] FiO2 with arterial oxygen partial pressure of 50-80 Torr or arterially or transcutaneously measured oxygen saturation of 88-95%. FiO2s that are used for at least 15 minutes are required

7.2 Infection data

Infection

In each case, complete the relevant infection form with the criteria for the infection.

Infection date

DD/MM/YY

The date of infection is the day on which the first symptoms appeared.

Sepsis/ pneumonia/ NEC

Select the type of nosocomial infection diagnosed. After selecting the infection, the dialogue fields to be completed for the selected infection type appear in webKess.

Pathogen

See codes for nosocomial infectious agents (8.5). Please indicate the suspected aetiological infectious agent identified by microbiological examination.

For infection type "Sepsis", depending on the pathogen/no pathogen selected in webKess, the dialogue fields adapt according to the requirements for the diagnosis of clinical sepsis (no pathogen), microbiologically confirmed sepsis (selection of a pathogen that is not a CNS) or microbiologically confirmed sepsis with CNS (selection of a CNS as pathogen) for further processing.

7.2.1 Infection sheet concerning sepsis

CVC-associated[1]	Primary sepsis is associated with CVC if a central vascular access (CVC, NPC, NAC, PICC) was in place for at least the 3rd day on the day with the first symptoms of infection (=day of infection) or the day before.
PVK-associated[1]	Primary sepsis is associated with PBC if a peripheral intravenous cannula was in place for at least the 3rd day on the day with the first symptoms of infection (= day of infection) or on the day before If both the definition for ZVK-associated and PVK-associated are fulfilled, both devices are counted (since 01/2017).
Clinical sepsis/ laboratory confirmed sepsis	•No pathogen detection from blood culture or cerebrospinal fluid, then state criteria for clinical sepsis plus clinical signs and symptoms. •Detection of a pathogen that is not a CNS[2] 2, then specify criteria for microbiologically confirmed sepsis plus clinical signs and symptoms. •Detection of [KNS2] as the only pathogen, then criteria for microbiologically confirmed sepsis with KNS plus laboratory signs plus clinical signs and symptoms.
Other signs with clinical signs of sepsis	The following symptoms or signs are assessed here: •Septic skin colour (not if recapillarisation time has already been assessed as a symptom). •Laboratory signs (CRP, interleukin, if not already assessed as a sign of sepsis with CNS). •Increased oxygen demand (intubation). •unstable AZ, apathy.

[2] Coagulase negative staphylococci e.g. S. epidermidis, S. haemolyticus, other CNS

7.2.2 Infection sheet concerning pneumonia

INV-associated[1]	Pneumonia is associated with invasive ventilation (INV-associated) if invasive ventilation via an endotracheal tube (not "revenge tube") has taken place for at least the 3rd day on the day with the first symptoms of the infection (=day of infection) or on the day before.
NIV-associated[1]	Pneumonia is associated with non-invasive respiratory support (NIV-associated) if respiratory support via high-flow or CPAP (including via a rescue tube) was provided for at least the 3rd day on the day with the first symptoms of the infection (= day of infection) or the day before If a patient fulfils both the definition of ventilator-associated and NIV-associated, only the more invasive procedure (INV) is considered and the pneumonia is assessed as INV-associated.
Deterioration of the gas exchange	Increase in FiO_2 requirement >10% within 24h or start of mechanical ventilation.
purulent tracheal secretion	Secretion of the lungs, bronchi or trachea with≥ 25 neutrophil granulocytes and≤ 10 epithelial cells per field of view (x100). If the laboratory provides quantitative information (high neutrophil granulocytes or low epithelial cells), it must be ensured that this information corresponds to the above definition. Laboratory assessment is necessary because the clinical description of tracheal secretions is too variable.

7.3 List of nosocomial infectious agents

The complete list of pathogens stored in NEO-KISS can be found at http://www.nrz-hygiene.de/fileadmin/nrz/module/import/ImportPathogens.csv

7.4 MRE surveillance

The following information is required when documenting an MRE case:

MRE case

If a patient has more than one MRE (e.g. MRSA and MRGN) or two different MRGN (e.g. 2MRGMN *E.coli* and 4MRGN *Klebsiella pneumoniae*), a separate MRE case must be created for each MRE.

Definition of MRE

MRSA Methicillin-resistant *Staphylococcus aureus*

AER Vancomycin-resistant *Enterococcus faecium* and *Enterococcus faecalis*

MRGN Multi-resistant **Gram-negative** bacteria (*Enterobacteriaceae*, *Acinetobacter baumannii* and *Pseudomonas aeruginosa*) that are sensitive/susceptible (S) to only two (**2MRGNNeoPäd**), one (**3MRGN**) or none (**4MRGN**) of the following bactericidal antibiotic substance classes:

- Penicillins (also with beta-lactamase inhibitor)
- Cephalosporins
- Carbapenems
- Fluoroquinolones

Sensitivity to aminoglycosides, fosfomycin, colistin, tigecycline is not taken into account.

Type of MRE Indicate the type of MRE known/detected in the patient

- MRSA
- AER
- MRGN

MRSA No further specification required

AER

Bacterial species In the case of AER, the bacterial species must also be specified

- *Enterococcus*
- *Enterococcus faecalis*.

MRGN

MRGN class In the case of MRGN, the MRGN class must also be specified:

- **2MRGN NeoPäd** (only sensitive/sensitive (S) to two bactericidal antibiotic substance classes (penicillins (also with beta-lactamase inhibitor), cephalosporins, carbapenems, fluoroquinolones),
- **3MRGN** (only sensitive/sensitive (S) to one antibiotic substance class with a bactericidal effect (penicillins (also with beta-lactamase inhibitor), cephalosporins, carbapenems, fluoroquinolones),
- **4MRGN** (not sensitive/sensitive (S) to any antibiotic substance class with a bactericidal effect (penicillins (also with beta-lactamase inhibitor), cephalosporins, carbapenems, fluoroquinolones)
- **3MRGN or 4MRGN not differentiated** (e.g. ESBL detected

	on selective media without available antibiogram)
	For bacteria that fulfil the definition of a 4MRGN, the simultaneously applicable classification as a 3MRGN must be ignored (also for 3MRGN and 2MRGNNeo-Paed).
	For patients who have two different MRGN (e.g. a 3MRGN ESBL-E. coli and a 4MRGN *Klebisiella pneumoniae*), a separate MRE case sheet must be created for each MRGN.
Bacterial species	The bacterial species must be specified for MRGN. The species of the MRGN detected must be stated in accordance with the table under 8.1. If only the genus of the pathogen is known (e.g. *Klebsiella spp*.), without further differentiation, this must be stated accordingly. If a species is detected that is not listed in the table, it must be indicated under the corresponding genus under "Other" or, if the genus is not listed in the table, as "Other MRGN".
Carbapenemase tested	When entering a 4MRGN, indicate whether a carbapenemase test was performed: • Carbapenemase tested • No carbapenemase test performed • No information on carbapenemase testing
Carbapenemase detected	If a carbapenemase was tested for, state whether a carbapenemase was detected: • Yes • No
Specify the type of	If carbapenemase is detected, indicate

carbapenemase	the type of carbapenemase (multiple entries possible): • KPC-like • Oxa-48-like • VIM-like • NDM-like • IMP-like • Oxa-23-like • Oxa-24/40-like • Oxa-58-like • Other (with mention of carbapenemase)
MRE was brought along	MRE colonisation was already known on admission (even if only communicated verbally) or evidence from a material taken on day 1 (day of admission), 2 or 3 of stay in the department.
MRE was acquired on the ward	MRE is isolated for the first time from an examination material taken in this department on day 4 of the stay or later. This also applies if it cannot be ruled out that colonisation with MRE may already have been present on admission, but no test material was taken in the first three days and no evidence is available from pre-treatment hospitals/wards/doctors.
First-time verification **(optional field)**	Date (date of material acceptance) on which the MRE was first detected (if known). In the case of brought-in MRE, the date of the first proof is therefore before the date of admission up to a maximum of day 3 of the stay. In the case of MRE acquired on the ward, the date of first detection≥ is day 4 of the stay.
Clinical relevance of MRE colonisation	This question is intended to allow statements on the therapeutic consequences of MRE colonisation during the stay on the ward. Only one selection is permitted. An MRE infection that has arisen from a previous MRE colonisation is indicated as

an MRE infection.

During the ward stay...	
...patient was only colonised with the MRE	Patient is only colonised with the MRE during the stay on the ward and has no infection with the MRE.
...there was an MRE Infection before	The decision on the presence of an MRE infection is made on the basis of clinical findings and the results of laboratory medicine/microbiology in combination with treatment for infection. Patient has an MRE infection according to the following definition: Local or systemic signs of infection are present in response to the presence of microorganisms or their toxins AND MRE involvement is clinically probable and/or microbiologically confirmed AND treatment (antimicrobial therapy or surgical intervention) is carried out due to infection. Pure sanitising measures (e.g. Mupirocin nasal ointment) are not considered therapy.

Additional information for MRE infections

Type of MRE infection	Indicate the type of infection in which MRE involvement is clinically probable and/or microbiologically confirmed. Multiple selection is possible.
Allocation of the infection to brought in/acquired on the ward	For each MRE infection, it must be stated whether the infection was brought in or acquired on the ward.
Infection brought to the ward	The infection is considered to be an acquired infection if there are already indications that the infection is present on admission to the ward (first symptoms, signs of infection before or on admission). MRE involvement may already be present in the infections brought in on admission or may only be added during the stay on the ward.
Infection acquired on ward	The infection is considered to have been acquired on the ward if there is no evidence that the infection was already present on admission to the ward.
MRE detection in relatives	If MRE is detected in a premature infant, information is required on the performance of MRE tests on the child's relatives (mother, father, others)
Examination of relatives	Indicate whether relatives of the MRE case (premature infant with MRE) were tested for MRE.
Proof of MRE in relatives	Specify the result of the test (MRE detected yes/no)

Relatives already colonised with MRE before the premature baby	In the case of relatives colonised with MRE, it must be stated whether the colonisation was already known before the MRE was detected in the child or whether the colonisation only occurred after the MRE was detected in the child
Affected by MRE Specify relatives	Mother/father/other (multiple entries possible)

8.1 Pathogen list

The complete list of pathogens stored in NEO-KISS can be found at

9. List of abbreviations

BE	Base Excess
BK	Blood culture
CDC	*Centres for Disease Control and Prevention*
CRP	C-reactive protein in mg/dl
FiO_2	Inspiratory O_2 content
GA	Gestational age
GG	Birth weight
I/T Ratio	*Immature to total neutrophils*. Gives the Ratio of immature neutrophil granulocytes to the sum of all granulocytes on
KNS	Coagulase negative staphylococci
NAK	Umbilical artery catheter
NIV	Non-invasive respiratory support (CPAP, high-flow; **no** pure O_2 therapy without CPAP effect);
NPC	Umbilical venous catheter
PVK	Peripheral vascular catheter
ZVK	Central vascular catheter

10. Documentation forms for surveillance

Documentation forms for recording the most important data (patient history forms for daily records, patient form with the patient's master data and infection forms for the three types of infection primary sepsis, pneumonia and NEC) are available in the current version on the NRZ homepage at
as a PDF document. These documentation forms are designed for internal departmental data collection. They are not sent to the NRZ. Data is exchanged with the NRZ exclusively via webKess.

11. NEO-KISS Contact

Email contact address:
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Contact persons can be found on the NRZ homepage (www.nrz-hygiene.de).

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12. Imprint

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