Protocol

Nosocomial infection surveillance for preterm infants with birthweight <1500g

at the

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24 February 2010

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1. Introduction

Preterm infants have the highest infection rates of all pediatrics patients, and bloodstream infections and pneumonia are the most frequent and most severe nosocomial (hospital-associated) infections. Studies have shown that continual infection monitoring, infection frequency comparison and data analysis (surveillance[1]) can be decisive in reducing nosocomial infections. Continual surveillance of nosocomial bloodstream infections and pneumonia especially makes sense for this patient type. The goal of surveillance is the prevention of nosocomial infections by providing data relevant for making decisions about infection prevention.

Necrotizing enterocolitis (NEC) tends to appear in clusters and is of great importance for patient morbidity and mortality. Even though NEC is not an established infectious disease, it is included as such in the surveillance system.

Because the majority of nosocomial infections among preterm infants appear among those with a birthweight of less than 1500 g, surveillance is limited to this group of patients.

Because of the decisive importance of intravascular catheters and mechanical ventilation in the development of nosocomial infections, these devices are especially taken into account in surveillance.

[1] Continuous, systematic collection, analysis and interpretation of health-related data and its timely transmission to those who need it.

2. Goals of the surveillance protocol

This surveillance protocol has the primary function of providing departments participating in NEO-KISS with necessary definitions and specifications. These definitions standardize data collection and analysis so that reference data for internal quality assurance can be made available.

Secondarily, it allows other, interested but non-participating hospitals to collect data related to nosocomial bloodstream infections, pneumonia and NEC with these definitions and specifications and then evaluate their data analogically. In principle, hospitals can orient themselves on NEO-KISS results in this manner.

Among other sources, the definitions of the National Nosocomial Infections Surveillance (NNIS) Systems of the Centers for Disease Control and Prevention (CDC) in the USA were used as a basis for this protocol.

The CDC nosocomial infectious disease definitions were modified for this patient group with the cooperation of leading neonatologists following a 10-months-long data collection project in the Clinic for Neonatology at the Charité Campus Virchow Clinic and a subsequent pilot phase in 16 neonatology departments in 1999.

This surveillance protocol is directed at interested neonatologists, nursing staff in neonatal intensive care, hospital hygienists and infection control nurses who want to take part in the surveillance project.

3. Requirements for participation in NEO-KISS by neonatology departments

The following conditions must be fulfilled by participating departments:

- Agreement of the department head to participation in NEO-KISS
- Agreement to use the specifications found in the NEO-KISS protocol as well as the definitions for diagnosis of nosocomial infection and the familiarization of treating physicians with these definitions
- Participation by at least one representative who will carry out surveillance or be responsible for surveillance in a introductory course in NEO-KISS from the National Reference Center (*Nationales Referenzzentrum= NRZ*) before registering for the module
- Participating departments must have at least one neonatal ICU with mechanical ventilation available
- Acceptance of the web-based data collection system webKess for data entry and fulfillment of hardware and software system requirements
- Regular data input of surveillance data into webKess for the NRZ
- Agreement of the department head to the publication of anonymous reference data
- Participation by at least one department representative in a meeting regularly held by the NRZ for experience exchange at least every two years
- Preparedness to complete internal quality assurance measures upon receiving relevant surveillance results
- Preparedness to participate in data quality validation procedures (e.g. nosocomial infection diagnosis)

The institutions supporting KISS promise the participating departments to:

- Provide expert advice and support during surveillance
- Handle the data of each department strictly confidentially
- Provide participating hospitals with standardized and stratified reference data regularly (twice per year)
- Provide support in the implementation of surveillance results in quality management

4. Methods

The method used by NEO-KISS has the primary goal of supporting internal quality assurance measures and should make valid statements about the frequency of infection among preterm infants during their stationary treatment in a neonatology department.
Of great importance here is the continuous contact between hygiene and nursing staff and physicians. The usual method of identifying patients with nosocomial infections is the regular examination of current department patient data (ca. twice per week) including laboratory findings. Close contact between surveillance staff (usually infection control professionals) and department staff is an important prerequisite for successful participation in NEO-KISS. Surveillance is limited to three kinds of infection: primary bloodstream infections (BSI), pneumonia and necrotizing enterocolitis. Only those infections acquired on participating neonatology departments are recorded.
Participating departments must have access to at least one neonatal ICU with mechanical ventilation. The number of a department's units included in surveillance depends on the number of units (at least one ICU and any number of non-intensive units or "feeding wards") on which preterm infants with a birthweight of less than 1500 g are cared for during surveillance. Surveillance is carried out on a patient-by-patient basis in NEO-KISS. Children that fulfill entry requirements are observed until the end of surveillance as defined by death, transfer, or reaching a weight of over 1800 g, no matter what unit they are on. Data calculation is completed on a department-by-department basis. Unit-specific data analysis is not completed by the NRZ.

4.1 Patient data collection

Patient progress chart
(hard copy available at on the NRZ web site under NEO-KISS)

A patient progress chart is maintained for all patients on participating neonatology departments with a birthweight of less than 1500 g, no matter how long the patient remains in that department.
The chart is kept in facility and is used to simplify data collection and for tracking patients if necessary. Patient days, device days and antibiotic days are tracked on the chart.
Relevant data are recorded daily, added up each month and entered into webKess under "patients – release data" at the end of surveillance as a sum of monthly records for each child.
If a patient leaves the neonatology department only briefly (up to two days) for surgery, for example, then this is not counted as release.
The data for days not on department is recorded upon re-admission (on the third day at the latest). If there is a longer period of time between transfer and re-admission, the patient is to be released from surveillance (enter release data with "transfer" as the reason for release) and entered as a new patient in NEO-KISS upon re-admission (under "admission" put "transfer within hospital ≥ 24h postnatal").

Patient surveillance master data (“Patients” in webKess)
(A hard copy version of this form is available on the NRZ web site under NEO-KISS)

In addition to the above-mentioned data, basic patient data is recorded in webKess under “Patients.” Basis data that must be recorded are marked as required fields in webKess and should be filled out completely by participants.
Optional data such as CRIB scores can be entered here as well.
After the patient data are saved, a patient list is created by the system. Each patient is assigned a webKessID. This should make it possible for the clinic to use anonymous data to refer back to specific patients, but make it impossible for third parties to do the same.
NEO-KISS participants are responsible for organizing patient data retrieval based on webKessIDs (for example, noting the webKessID on the patient progress chart or keeping and archiving a list of patient names and webKessIDs). No real patient names may be used in webKess to protect patient privacy.

4.2 Infection data collection

Nosocomial bloodstream infections, pneumonia, and NEC in patients with a birthweight of less than 1500g are to be documented until the end of surveillance.

- If a patient under surveillance develops a nosocomial primary bloodstream infection, pneumonia or NEC, the infection should be entered into webKess with other infection-related data under "new infection" in webKess (click the button "new infection" after saving patient data). After selecting the appropriate infection, an infection data collection form will appear and relevant diagnostic criteria should be selected. After saving the infection data, summarized information about the patient will appear in the patient list on webKess. Additional hard copies of the infection data collection form are available on the NRZ web site under NEO-KISS for department internal uses only.
- The infection in question must have been acquired on the neonatology department, i.e. it was not present or incubating at admission. The reference value of 72h after birth or admission to a neonatology department should be applied.

4.3 Reference data calculation

NEO-KISS participants can request evaluation of their department's data at any time in webKess by selecting the appropriate menu. Reference data are calculated twice annually and compared to departmental data. Data entry in webKess should occur continuously. The data of all closed data sets (weight greater than 1800 g achieved, patient transferred or died) should be entered by the respective reference dates (15th February and 15th August of each year) at the very latest so that these data can be included in the NRZ's reference data calculations.
Because of birthweight's considerable importance as a factor for developing nosocomial infections, all rates named (except for the standardized infection rate) are calculated separately for three birthweight classes (newborns with a birthweight (BW) up to 499 g, newborns with a BW of 500g to 999g, and those with a BW of 1000 to 1499g). This procedure is called **stratification**.

4.3.1 Device utilization rate

The device utilization rate describes the procedural percentage of patient days on which a certain device was in use, and is calculated as the quotient of device days and the total number of a department's patient days. The total number of patient and device days for all a department's patients are used for this purpose.

Individual formulae are:

$$\text{CVC}^{1}\text{ utilization rate} = \frac{\text{Total CVC days}}{\text{Total patient days}} \times 100$$

[1] Vascular catheters, flow-directed catheter (even if it does not reach a central blood vessel), and umbilical artery/vein catheters are included in this sum.

$$\text{PVC utilization rate} = \frac{\text{Total PVC days}}{\text{Total patient days}} \times 100$$

$$\text{Intubation utilization rate} = \frac{\text{Total intubation days}}{\text{Total patient days}} \times 100$$

$$\text{CPAP utilization rate} = \frac{\text{Total CPAP days}}{\text{Total patient days}} \times 100$$

4.3.2 Antibiotic utilization rate

The antibiotic utilization rate describes the proportion of patient days in percent on which systematic antibiotics were used. The rate is calculated as the quotient of a department's antibiotic days and total patient days. The total number of patient and device days for all a department's patients are used for this purpose.

$$\text{Antibiotics utilization rate} = \frac{\text{Total antibiotics days}}{\text{Total patient days}} \times 100$$

4.3.3 Device-associated infection rate

This is the most important rate for quality management and describes the number of device-associated infections per 1000 device days. Infections occurring during the presence of a specific risk factor (devices in this case; CVC for example) are put into relation with the total number of risk days (CVC days, for example) and calculated individually as follows. This procedure is referred to as **standardization.**

$$\text{CVC-associated bloodstream infection rate} = \frac{\text{Total bloodstream infection cases in patients with CVC}}{\text{Total CVC days}} \times 100$$

$$\text{PVC-associated bloodstream infection rate} = \frac{\text{Total bloodstream infection cases in patients with PVC}}{\text{Total PVC days}} \times 100$$

$$\text{Intubation-associated pneumonia rate} = \frac{\text{Total pneumonia cases in patients with intubation}}{\text{Total mechanical ventilation days per endotracheal intubation}} \times 100$$

$$\text{CPAP-associated pneumonia rate} = \frac{\text{Total pneumonia cases in patients with CPAP}}{\text{Total CPAP days}} \times 100$$

CVC or PVC-associated primary bloodstream infections and intubation or CPAP-related pneumonia are present when intravascular catheters or mechanical ventilation via intubation or CPAP are present or were present within the 48-hour-period before the start of infection.

If both intubation **and** CPAP were used within the 48-hour-period before the start of infection, the pneumonia should be recorded as intubation-related pneumonia. The same counts for CVC and PVC: if **both** were present within the 48-hour-period before the start of infection, then the bloodstream infection should be recorded as a CVC-associated infection.

4.3.4 Incidence density

Because the frequency of risk factor utilization (device days) is often quite low, and because a considerable proportion of infections appear independently of these risk factors, incidence densities are also calculated for bloodstream infections, pneumonia and NEC. Standardization is also achieved in this manner. The duration of a risk factor is equal to the total number of a department's patient days.

$$\text{Bloodstream infection Incidence density} = \frac{\text{Total primary bloodstream infections}}{\text{Total patient days}} \times 1000$$

$$\text{Pneumonia Incidence density} = \frac{\text{Total pneumonia cases}}{\text{Total patient days}} \times 1000$$

$$\text{NEC Incidence density} = \frac{\text{Total NEC cases}}{\text{Total patient days}} \times 1000$$

4.3.5 Example calculation for the birthweight class 1000 g to 1499 g

Known variables:	BW class 1000 g-1499 g
Patients	4
Patient days	151
CVC utilization days	70
PVC utilization days	40
Intubation utilization days	40
CPAP utilization days	30
Antibiotics utilization days	15
Primary bloodstream infections	1 CVC associated
Pneumonia	1 not associated with device

Unknown: all rates for this BW class

Rate	BW-class 1000 g-1499 g
• device utilization rates (%):	
CVC utilization rate	70/151 x 100 = 46
PVC utilization rate	40/151 x 100 = 26
Intubation utilization rate	40/151 x 100 = 26
CPAP utilization rate	30/151 x 100 = 20
Antibiotics utilization rate	15/151 x 100 = 10
• device-associated infection rate (device-associated infections per 1000 device days) :	
CVC-assoc. bloodstream infection rate	1/70 x 1000 = 14,3
PVC-assoc. bloodstream infection rate	0/40 x 1000 = 0
Intubation-assoc. pneumonia rate	0/40 x .1000 = 0
CPAP-assoc. pneumonia rate	0/30 x 1000 = 0
• Pneumonia infection density	1/151 x 1000 = 6,6
• Bloodstream infection density	1/151 x 1000 = 6,6
• NEC density	0

4.3.6 Standardized infection rates

The seven infection rates (four device-associated infection rates and three incidence densities) described above allow for a very detailed observation of infection frequency in three birthweight classes. The rates, however, do not provide a summary assessment of infection frequency among preterm infants in a specific department. For this reason, NEO-KISS calculates as standardized infection rate that takes a department's patient population composition into account and evaluates that department's infection frequency in comparison to other departments. According to NRZ analyses, birthweight has been identified as a decisive risk factor and is therefore used as an indicator for infection frequency in the calculation of the standardized infection rate.

The standardized infection rate determines the number of infections to be expected in a department based on NEO-KISS reference data in reference to that department's patient population composition. The rate compares the number of expected infections to the number of observed infections on the department in question. All NEO-KISS patients with a birthweight of 499g-1499g are included in the calculation of the standardized infection rate. The probability of a severe hospital-associated infection (bloodstream infection or pneumonia) per patient day is determined with data from the NEO-KISS reference databank. Infection probability (number of infections expected) for an entire department can be determined from the total number of children being treated in accordance with the birthweight of each child and his or her patient days. This number of expected infection is put into relation with the actual number of infections observed (see formula).

$$\text{Standardized Infection rate} = \frac{\text{Total infections observed}}{\text{Total infections expected}}$$

If the standardized infection rate has a value great than 1, then more infections have been observed that were expected.

If the standardized infection rate is equal to 1, then the same number of infections was observed as were expected.

If the standardized infection rate is less than 1, then fewer infections were observed than were expected. This is a sign of a good infection situation in a department.

4.3.7 Example calculation of a standardized department infection rate

In one neonatology department 10 NEO-KISS patients with a birthweight (BW) between 745g and 1495 g were treated. The data of these 10 children and all cases of nosocomial pneumonia and bloodstream infection in these children is presented in the following table:

Patient data		Infections observed		
BW	Patient-days	Pneumonia	Bloodstream Infection	Total Pneumonia + Bloodstream infection
745	71	0	1	1
1240	44	0	0	0
1495	32	0	0	0
1015	72	0	1	1
900	64	0	0	0
780	88	1	0	1
1240	5	0	0	0
785	71	0	0	0
1245	48	0	1	1
920	57	0	0	0
	Total	Infections observed =		**4**

The chance of infection per patient day for each of these children based on his or her birthweight can be determined from the NEO-KISS databank. Multiplying the risk per patient day with the number of stationary treatment days for each child yields the number of infections to be expected for a department.

	Patient data	Infections observed			Infections expected	
BW	Patient days	Pneumo-nia	Blood-stream infections	Total pneumon-ia + blood-stream infection	Per patient day*	for all patient days
745	71	0	1	1	0,012	0,853
1240	44	0	0	0	0,009	0,410
1495	32	0	0	0	0,008	0,254
1015	72	0	1	1	0,011	0,759
900	64	0	0	0	0,011	0,715
780	88	1	0	1	0,012	1,041
1240	5	0	0	0	0,009	0,047
785	71	0	0	0	0,012	0,838
1245	48	0	1	1	0,009	0,446
920	57	0	0	0	0,011	0,631
Total infections		Observed=		**4**	expected=	**5,99**

*determined from reference data

The standardized infection rate is calculated from the numbers of observed and expected infections.

$$\text{Standardized infection rate} = \frac{\text{(Total infections observed)}}{\text{(Total infections expected)}} = \frac{4}{5.99} = 0.67$$

In this example, the department has a standardized infection rate of 0.67. This means that fewer infections appeared that were expected. This department's infection situation is comparatively good.

NEO-KISS participants can calculate their own standardized infection rates by clicking on "Evaluate" in webKess.

4.4. Infection rate comparison

Distribution parameters (first quartile Q1, median Q2, third quartile Q3) are given next to pooled stratified and standardized data. The third quartile, for example, is the value below which 75% of observed data lie. Differences between a department's values and the reference data, or differences within a period of time may be a sign of infection-related problems that would then be a subject for closer investigation.

5. General principles for defining nosocomial infections

1. For the purposes of data collection, infection diagnosis must rely on a combination of clinical symptoms, laboratory data and supportive data (e.g. x-ray examination, biopsy) of various significance and in logical order. There may be no signs that the infection was present or incubating at admission.

2. Neonatal infections acquired from passage through the birth canal are defined as nosocomial, but those acquired transplacentally are not.
*In order to differentiate vertical (transplacentally-acquired) infections manifesting within the first hours of life from nosocomial infections and compensate for the absence of other clinical signs, one has to introduce a time interval after birth **before** which an infection is considered vertically acquired and **after** which it is considered nosocomial. The terms "early onset" and "late onset" are traditionally used here. Times between 24 hours and 5 days are used in the literature to separate vertically acquired infections from nosocomial infections. We have chosen 72 hours because this time is also used by the "Neonatalerhebung" (a Germany-wide neonatal care quality assurance survey). However, if an infection before this time is definitely nosocomial or definitely vertical afterward (e.g., all transplacenally transferred infections that are not apparent at birth such as toxoplasmosis, CMV, HIV, rubella, syphilis) are classified as such.*
A 72 hour postpartum interval should be applied. Infections appearing earlier are generally not considered nosocomial.

Definitions for primary bloodstream infections, pneumonia and NEC for neonates are given in the following section. In the CDC version of these definitions, they are specified only for children under 12 months. Because symptoms of preterm infants cannot be compared with symptoms of older/more mature children, we have further modified the definitions for neonates. Those definitions are given here that form the basis of infection diagnosis for NEO-KISS. It is important to mention that these definitions are not intended for clinical use but exclusively for data collection related to nosocomial infection surveillance. The definitions should make it possible for those who were not directly involved in patient treatment to recognize a nosocomial infection based on patient charts. These definitions form a fixed framework for diagnosis in an epidemiological sense in order to achieve comparability between neonatology departments.

These definitions cannot be used to make therapy decisions relevant to the treatment of individual patients for clinicians.

It is possible that infections are diagnosed from the clinical perspective that are not considered infections by the definitions used for NEO-KISS (because not enough criteria are present) and vice versa.

6. Definitions of indicative infections in NEO-KISS

An interval of 72h after birth or admission in the neonatology department is applied for all illnesses. An infection-free interval is required for the diagnosis of a new infection (e.g., the diagnosis of a second case of pneumonia in one child during its stationary stay). A change in disease agent is not enough to diagnose a new infection of the same type.

6.1 Primary bloodstream infection

NEO-KISS differentiates three different forms of primary bloodstream infection (the secondary spread of agents in the blood from an infection at another body site or a secondary bloodstream infection are not counted!). There are specific definitions for each of the three forms of bloodstream infection respective to proof of one agent or the absence of other agents. The following infections are differentiated:

- Clinical sepsis (infection without a detected pathogen)
- Laboratory-confirmed bloodstream infection with a detected pathogen (but not CNS)
- Laboratory-confirmed bloodstream infection with coagulase negative staphylococci (CNS) as the sole pathogen

Clinical sepsis (infection without proof of pathogen)

ALL of the following criteria must be met:

1.Treating physician institutes appropriate antimicrobial therapy for bloodstream infection for at least 5 days*

2. NO pathogens detected in blood culture or blood cultures not performed**

3. NO apparent infection at another site

AND two of the following criteria must be met (without other recognized cause)

- **Fever (>38 °C) or temperature instability (frequent incubator adjustment) or hypothermia (<36.5 °C)**
- **tachycardia (> 200/min) or new/more frequent bradycardia (<80/min)**
- **recapillarization time >2s**
- **new or more frequent apnea (>20s)**
- **Unexplained metabolic acidosis (BE < -10 mEq/l)**
- **New hyperglycemia (>140mg/dl)**
- **Other signs of bloodstream infection: skin color (only when recapillarization time is not used), laboratory evidence (CRP, interleukin***), increased O2 requirement (intubation), unstable condition, apathy**

Notes to bloodstream infection definitions

*A therapy day is similar to an antibiotics day in that it is a “day on which a patient received systematic antibiotics (oral or parental).” The day on which the first dosage was given is counted as the first therapy day, and the day on which the last dosage was given is counted as the last therapy day. This is independent of the number of dosages, their presumed effectiveness or the duration of their effects.

**One-time evidence of CNS in blood culture cannot exclude the diagnosis of clinical sepsis. Clinical sepsis can also be diagnosed if CNS appears once in blood culture but can be considered contamination of the blood culture and if the remaining criteria for CNS bloodstream infection are not fulfilled but the criteria for clinical bloodstream infection are fulfilled.

***Interleukin must be used as a parameter when laboratory specifications for a pathological value have been fulfilled. Interleukin 6-8 is to be considered.

Laboratory-confirmed bloodstream infection with proof of pathogen (no CNS*)

Non-CNS Pathogen isolated in blood culture or cerebrospinal fluid (pathogen *not* related to infections at other sites)

AND two of the following criteria

- **Fever (>38 °C) or temperature instability (frequent incubator adjustment) or hypothermia (<36.5 °C)**
- **tachycardia (> 200/min) or new/ more frequent bradycardia (<80/min)**
- **Recapillarization time >2s**
- **new or more frequent apnea (>20s)**
- **Unexplained metabolic acidosis (BE < -10 mEq/l)**
- **new hyperglycemia (>140mg/dl)**
- **Other sign of bloodstream infection: skin color (only when recapillarization time is not used); laboratory findings (CRP, interleukin**), increased oxygen requirement (intubation), unstable condition, apathy**

Notes to bloodstream infection definitions

* coagulase negative staphylococci

** Interleukin must be used as a parameter when laboratory specifications for a pathological value have been fulfilled. Interleukin 6-8 is to be considered.

Laboratory-confirmed bloodstream infection with coagulase-negative staphylococci (CNS) as sole pathogen

CNS isolated in blood culture as sole pathogen

AND ONE of the following laboratory parameters (without another recognized cause)

CRP >2,0mg/dl oder 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 another recognized cause)

- **<u>Fever</u> (>38 °C) or <u>temperature instability</u> (frequent incubator adjustment) or <u>hypothermia</u> (<36.5 °C)**
- **<u>tachycardia</u> (> 200/min) or new/ more frequent <u>bradycardia</u> (<80/min)**
- **<u>Recapillarisation time</u> >2s**
- **new or more frequent <u>apnea</u> (>20s)**
- **Unexplained metabolic <u>acidosis</u> (BE < -10 mEq/l)**
- **new hyperglycemia (>140mg/dl)**
- **<u>Other</u> sign of bloodstream infection: skin color (only when recapillarisation time is not used); laboratory findings (CRP, interleukin**), increased oxygen requirement (intubation), unstable condition, apathy**

Notes to bloodstream infection definitions

* One-time evidence of CNS in blood culture cannot exclude the diagnosis of clinical sepsis. Clinical sepsis can also be diagnosed if CNS appears once in blood culture but can be considered contamination of the blood culture and if the remaining criteria for CNS bloodstream infection are not fulfilled but the criteria for clinical bloodstream infection are fulfilled.

** Interleukin must be used as a parameter when laboratory specifications for a pathological value have been fulfilled. Interleukin 6-8 is to be considered.

6.2 Pneumonia

For pneumonia diagnosis, radiological findings in combination with deterioration in oxygenation and at least four other clinical or laboratory findings are required:

ONE of the following radiological findings:

- **new or progressive infiltrate**
- **shadowing**
- **fluid in the intrapleural cavity or interlobar fissure**

AND worsening gas exchange, or sudden decline in blood oxygenation

AND FOUR of the following criteria

- **new or more frequent <u>bradycardia</u> (< 80/min) or new or more frequent <u>tachycardia</u> (>200/min)**
- **new or more frequent <u>tachypnea</u> (>60/min) or new or more frequent apnea (> 20 s)**
- **<u>purulent sputum</u>**
- **<u>bacteria</u> in sputum**
- **new or more frequent <u>dyspnea</u> (retraction, nasal flaring, sighing)**
- **<u>temperature instability/fever/hypothermia</u>**
- **<u>increased</u> respiratory <u>secretion</u> (increased oral suctioning)**
- **<u>CRP > 2.0</u> mg/dl oder interleukin***
- **<u>I/T - ratio > 0.2</u>**

Notes to pneumonia definitions

Deterioration of gas exchange
- Increase in need for FiO_2 > 10% with 24 hours or
- Begin of mechanical ventilation

Purulent sputum
- Secretion from lower respiratory system with <u>≥</u> 25 neutrophile grandulocytes and <u>≤</u> 10 epithelial cells per low power field (x100)

* Interleukin must be used as a parameter when laboratory specifications for a pathological value have been fulfilled. Interleukin 6-8 is to be considered.

6.3 Necrotizing enterocolitis (NEC)

Either a combination of radiological signs and two clinical symptoms or a histological diagnosis based on prepared specimens is required for a diagnosis of NEC. Histology is enough by itself.

ONE of the following radiological signs

- **Pneumoperitoneum**
- **Pneumatosis intestinalis**
- **Unchanging rigid loops of small intestine**

AND TWO of the following criteria (without other cause)

- **Vomiting**
- **Abdominal distention**
- **Persistent microscopic or gross blood in stools**
- **Redness of *regio abdominalis lateralis* (flanks)**
- **Prefeeding residuals**

OR

Histological evidence based on prepared specimens

7. Specifications for surveillance

Explanations and definitions of NEO-KISS variables

7.1 Patient data

webKessID	Granted when a patient's data is entered into the system. Important for collating data and possible questions. Should be noted intradepartment on all of a patient's surveillance documentation.
Patient progress chart	Simplifies data collection and backtracking patients. Remains on-department. Use or modification is optional. To get a better overview, a new patient progress chart should be used for each calendar month during a child's stationary treatment. (For example: a child is admitted on the 21st of March and released on the 4th of April. One chart for March with 11 consecutive days, one chart for April with 4 consecutive days. Total 15 patient days).
Patients (in webKess)	Patient surveillance master data collection on webKess
Device	
CVC =central vascular catheter	Give the number of days on which the patient had a CVC for more than 12 hours. UAC/UVC as well as flow-directed catheters are included.
PVC =peripheral vascular catheter	Give the number of days on which the patient had a PVC for more than 12 hours. Butterfly and cave catheters are counted, but not flow-directed catheters. If a CVC is also present, count the day as a CVC day and do not put anything here.
Intubation =endotracheal intubation	Give the number of days on which the patient was ventilated for more than 12 h with endotracheal intubation.
CPAP	Give the number of days on which the patient was ventilated over CPAP for more than 12 h. If endotracheal intubation is also present,

	count the day as an intubation day.
Antibiotics	Give the number of days on which the patient was given systemic antibiotics (oral or parenteral). Antimycotics, antivirals (virostatics) and locally applied antibiotics are not included.
Σ (Sum) (on hard copy patient progress chart)	Respective sums of days for each patient are recorded here.
Admission	Choose either: —in-hospital birth —transfer to the hospital <24h postnatal —transfer to the hospital ≥ 24h postnatal (This information is used to calculate risk)
Age at admission	This field becomes active when “transfer to the hospital ≥ 24h postnatal” under “Admission” is selected. The age of the child in days should be given. The date of birth is counted as the first day of life, and the next day (starting at 12 a.m.) is counted as the second day. (This information is used to calculate risk)
Birthweight	Child’s weight at birth in grams. Birthweight is the criteria for inclusion (<1500g) and is used for stratification into birthweight classes and for the calculation of the standardized infection rate. Children with a birthweight of ≥1500g are not taken into account in NEO-KISS, even when they might weigh less than 1500g in the future.
Gestational age	Give age in weeks + days, for example 25 weeks and 4 days should be entered as 25 + 4.
Sex	Check where appropriate.
Multiple births	Check where appropriate.
Number of births	Field becomes active when “Multiple Births” is selected. The figure “2” should be given for twins, “3” for triplets and so on.

Type of delivery	Make the appropriate selection from the drop-down list.
CRIB score	If available, please enter.
End of surveillance	Date: DD/MM/YY A child has reached the weight limit when it weighs 1800g. Data collection will not be carried out past this date, even if the child weighs less than 1800g. Otherwise give the date of transfer from the department or the date of death.
Reason	Give the reason for ending surveillance: • Weight of **1800g** • **Transfer** out of the department (transfer between units on a department does not end surveillance!) • **Death**
Patient days	Total days present on department. Add together days from the patient progress chart and give here.
CVC days	Number of days (as totaled on the patient progress chart) on which the patient had a CVC
PVC days	Number of days (as totaled on the patient progress chart) on which the patient had a PVC
Intubation days	Number of days (as totaled on the patient progress chart) on which the patient had endotracheal intubation
CPAP days	Number of days (as totaled on the patient progress chart) on which the patient was mechanically ventilated with CPAP

7.1.1 CRIB Score (Clinical risk index for babies)

Factor	Score
Birthweight (g)	
>1350	0
851-1350	1
701-850	4
≤700	7
Gestational age (weeks)	
>24	0
≤24	1
Congential malformation[1]	
None	0
Not acutely life-threatening	1
Acutely life threatening	3
Maximum bas excess in 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 FiO_2[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 FiO_2[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] Inevitably fatal malformations (e.g. trisomy 13, trisomy 18, bilateral renal agenesis, Potter syndrome) are not included.

[2] FiO_2 with arterial oxygen partial pressure of 50-80 Torr or transcutaneous oxygen saturation of 88-95%. FiO_2 must be used for at least 15 min. to be counted here.

7.2 Infection data

Infection	Fill out the infection form for each new infection
Date of infection	DD/MM/YYYY Date of infection is the day on which the first symptoms appeared.
Bloodstream infection/pneumonia/NEC	Choose the diagnosed nosocomial infection. After choosing an infection, further fields will appear in webKess related to that infection.
Pathogen	See codes for pathogens (8.5). Please enter a pathogen that was etiologically presumed and identified with laboratory tests. When “bloodstream infection” is chosen, additional fields will appear as appropriate for the requirements for diagnosis of clinical sepsis (choice of “no pathogen”), laboratory-confirmed bloodstream infection (choice of any pathogen except CNS) or laboratory-confirmed bloodstream infection with CNS (choice of CNS as primary pathogen).

7.2.1 Terms related to the BSI data collection form

CVC-associated[1]	Select if the patient had a central vascular catheter (CVC or UAC/UVC) within 48 h before the start of infection or has one at the time of infection
PVC-associated[1]	Select if a patient had a peripheral vascular catheter within 48h before the start of infection or has one at the time of infection. If both CVC and PVC are present, only the more invasive device (CVC) should be taken into account.
Clinical sepsis/ laboratory-confirmed bloodstream infection	• If there is no proof of pathogen from blood cultures or cerebrospinal fluid, then give criteria for clinical sepsis plus clinical signs and symptoms • If there is proof of a non-CNS[2] pathogen, then give criteria for laboratory-confirmed bloodstream infection plus clinical signs and symptoms • If there is proof of CNS[2] as the only pathogen, then give criteria for laboratory-confirmed bloodstream infection with CNS plus laboratory evidence as well as clinical signs and symptoms
Other signs of bloodstream infection	The following signs or symptoms can be entered under “other signs of bloodstream infection”: • Skin color (not if “extended time to recapillarization” has already been selected) • Laboratory-confirmed signs (CRP, interleukin, if not already used as a sign for a CNS bloodstream infection) • Increased need for oxygen (intubation) • Unstable condition, apathy

[1] In the event that the time period is greater than 48 hours, compelling reasons must be present in order to consider the infection “device associated.”

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

7.2.2 Terms related to the pneumonia data collection form

Intubation-associated[1]	For patients who had a device to assist or control respiration continuously by endotracheal intubation (not "pharyngeal intubation" within the 48-hour period before the onset of infection.
CPAP-associated[1]	For patients who were assisted with respiration by CPAP (including pharyngeal intubation) within the 48-hour period before the onset of infection. If a patient was ventilated by CPAP and by intubation within the 48-hour period before the onset of infection, the more invasive device (intubation) is taken into account.
Worsening in gas exchange	Increase in FiO_2 requirement >10% within 24 hours or start of mechanical ventilation
Purulent sputum	Secretion of the lungs, bronchia or trachea with $\geq$ 25 neutrophile grandulocytes and $\leq$ 10 epithelial cells per low power field (x100) If your laboratory reports these data qualitatively (e.g. "many neutrophils" or "few squames"), be sure their descriptors match this definition of purulent sputum. This laboratory confirmation is required because written clinical descriptions of purulence are highly variable.

[1] In the event that the time period before infection is greater than 48 hours, compelling reasons must be present in order to consider the infection "device associated."

7.3 Codes for nosocomial pathogens

The following selected pathogens or pathogen croups are coded. The codes are sorted alphabetically. Codes are used for computer-generated statistics and may differ from their usual English abbreviations.

Pathogen	Code
Acinetobacter spp.	ACI
Other Clostridium spp.	ACS
Adenoviruses	ADV
Other Enterobacteriaceae	AEN
Other bacteria	ANB
Other fungi	ANP
Bacteroides	BAC
Burkholderia cepacia	BCE
B-streptococci	BST
Candida albicans	CAN
Clostridium difficile	CDI
Chlamydia	CHL
Citrobacter spp.	CIT
Cytomegalovirus	CMV
Escherichia coli	ECO
Escherichia coli (ESBL-producing)	ESBL_ECO
Enterbacter spp.	ENB
Enterococci	ENT
E. faecium/E.faecalis (vancomycin-resistant)	VRE
Haemophilus spp.	HAE
Klebsiella spp.	KLE
Klebsiella spp. (ESBL-producing)	ESBL_KLE
Coagulase-negative staphylococci	KNS
Legionella spp.	LEG
Listeria monocytogenes	LMO
Neisseria	NEI
Pseudomonas aeruginosa	PAE
Pneomocystis carinii	PCC
Proteus spp.	PRO
Respiratory syncytial virus	RSV
Staphylococcus aureus	SAU
Staphylococcus aureus (Oxacillin resistent)	MRSA
Serratia spp.	SER
Stenotrophomonas maltophilia	STM
Streptococcus pyogenes (A-Streptococci)	STR_A
Streptococcus pneumoniae (Pneumococci)	STR_P
Ureaplasma spp.	URE
Other viruses	VIR

8. Abbreviations used

BE	Base excess
BC	Blood culture
BW	Birthweight
CDC	Centers for Disease Control and Prevention
CNS	Coagulase-negative staphylococci
CPAP	Continuous Positive Airway Pressure
CRP	C-reative protein in mg/dl
CVC	Central vascular catheter
FiO_2	Fraction of inspired oxygen
GA	Gestational age
I/T ratio	Immature to total neutrophils ratio. The ratio of immature neutrophile granulocytes to total granulocytes
PVC	Peripheral vascular catheter
UAC	Umbilical artery catheter
UVC	Umbilical vein catheter

9. Documentation forms for surveillance

Documentation forms for recording the most important data (patient progress charts for daily data collection, patient data forms with basic patient data, infection forms for primary bloodstream infections, pneumonia and NEC) are available in their most current versions as PDF documents on the NRZ homepage (www.nrz-hygiene.de) under NEO-KISS. These documentation forms are intended for department-internal data collection. They are not to be sent to the NRZ. Data exchange with the NRZ occurs entirely via webKess.

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12. Legal Notice

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