



# **Protocol**

## **CDI-KISS**

### **Surveillance of *Clostridioides difficile*- associated diarrhoea in hospitals**

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Surveillance of Nosocomial Infections  
on  
Institute of Hygiene and Environmental Medicine  
Charité - University Medicine Berlin

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## 1. Aim of CDI recording for the hospital

CDI-KISS is a module within the Hospital Infection Surveillance System (KISS). Since the beginning of 1997, the KISS of the National Reference Centre (NRZ) for Surveillance of Nosocomial Infections has been collecting data on nosocomial infections and special pathogens from an increasing number of hospitals throughout Germany that are voluntarily participating in KISS and generating reference data.

*Clostridioides difficile* are the most common anaerobic pathogens of nosocomial infections. In addition to *C. difficile*-associated diarrhoea (CDI), they cause the most serious diseases such as pseudomembranous enterocolitis and the often fatal toxic megacolon. In the countries surrounding Germany and in North America, the incidence and mortality of diseases caused by the pathogen have increased rapidly in recent years. Surveillance in CDI-KISS makes it possible to obtain data on the frequency of CDI cases and severe CDI cases in hospitals and to detect CDI outbreaks earlier. Recording according to KISS is used for quality assurance in the hospital itself. Both nosocomial CDI cases and CDI cases brought into the hospital are recorded in CDI-KISS.

The purpose of the surveillance protocol is to provide the necessary definitions and specifications for the hospitals participating in CDI-KISS. The aim is to standardise data collection and data analysis.

Other interested hospitals can also record data according to these definitions and specifications and analyse their data in the same way. This gives all hospitals the opportunity to orientate themselves on the CDI-KISS reference data.

This surveillance protocol is aimed at interested hospital hygienists, hygiene specialists and clinically active physicians and nursing staff who wish to participate in the surveillance of CDI.

Any suggestions for possible improvements are welcome.

## **2. Requirements for the participation of hospitals in CDI-KISS and obligations of the institutions supporting KISS**

The participating hospitals must fulfil the following requirements:

- Employment of full-time hygiene specialists in the hospital.
- Strict application of the mandatory provisions of the surveillance protocol (in addition to the recommended data, hospitals can of course record other data if they are relevant to the hospital's quality management).
- Annual data collection and transmission of tables
- Willingness to communicate descriptive parameters (structural and process parameters of the ward and the hospital, e.g. size of the hospital).
- Willingness to participate in validation measures.

The institutions supporting the KISS assure the hospitals:

- To advise and support you professionally in the implementation of surveillance.
- To handle the data of the individual hospitals with strict confidentiality.
- To provide the participating hospitals with an analysis of the data.

## **3rd method**

### **Participants**

Hospitals interested in CDI-KISS can in other KISS modules independently of . CDI data must recorded for the entire hospital.

Only data that is already available in most hospitals is recorded.

The data is compiled once a year for the previous calendar year and sent to the NRZ (the cut-off date 31 March).

The survey only refers to inpatients. Outpatients in outpatient clinics etc. are not included in the surveillance.

### **B calculation of CDI rates**

The following dimensions are calculated:

<b>Designation</b>	<b>Calculation</b>
Overall prevalence	Total number of CDI cases per 100 patients
CDI prevalence on admission	Number of CDI cases brought to the hospital per 100 patients in the hospital
Incidence density of nosocomial CDI	Number of nosocomial CDI cases per 1000 patient days
Incidence density of severe CDI cases	Number of severe CDI cases per 1000 patient days

### **Stratification**

Depending on the number of participants, there may be a stratification according to diagnostic procedure or hospital size.

### **Comparison of CDI rates**

The above-mentioned CDI rates are calculated annually for the participating hospitals by the institutions supporting KISS n and published as orientation data on the NRZ website.

### **Recommendation for recording**

It has been shown that purely laboratory-based surveillance can only incompletely record CDI cases throughout the hospital, e.g. if the diagnosis is made endoscopically, intraoperatively or post mortem by the pathologist. It is therefore advisable to involve the departments of surgery, endoscopy and pathology in surveillance.

### 3. Specifications for the documentation

#### Overview of the parameters requiring documentation

A detailed explanation of the individual parameters follows in this chapter.

- Year of acquisition
- Total number of patients at the hospital
- Diagnostic criterion 1 (suspected)
- Diagnostic criterion 2 (for diarrhoea)
- Diagnostic criterion 3 (Other)→ Other Text
- Number of patient days
- Number of patients with CDI
- Number of CDI cases according to case definition criterion 1 (symptoms and toxin detection)
- Number of CDI cases according to case definition criterion 2 (pseudomembranous colitis)
- Number of CDI cases according to case definition criterion 3 (histopathological evidence)
- Number of CDI cases brought in (first manifestation)
- Number of CDI cases brought in (recurrence)
- Number of nosocomial CDI cases (first manifestation)
- Number of nosocomial CDI cases (recurrence)
- Number of severe CDI cases according to criterion 2 (transfer to ICU)
- Number of severe CDI cases according to criterion 3 (surgical intervention)
- Number of severe CDI cases according to criterion 4 (death due to CDI/CDI categorised as contributing to death))
- Number of stool tests for *C. difficile*
- Number of stool samples tested positive for *C. difficile*

**Diagnostic criteria**

Specification of the criteria for the diagnosis of *Clostridioides difficile*: For

1. Clinical suspicion of CDI
2. all patients with diarrhoea, after a stay of more than three days in hospital
3. other criteria

**CDI**

*C. difficile* associated diarrhoea. A case of CDI is diagnosed if one or more of the following criteria are present.

**CDI case definition**

A CDI case must include one or more of the following fulfil the criteria:

1. Diarrhoea or toxic megacolon and laboratory diagnostic detection of CDI in the stool: detection of *C. difficile* toxins (e.g. ELISA) and/or nucleic acid detection (e.g. PCR) of the *C. difficile* toxin A or B gene and/or cultural detection of toxin-producing *C. difficile*;
2. Pseudomembranous colitis detected by endoscopy;
3. Histopathological evidence of a *C. difficile* infection (with or without diarrhoea) in an endoscopy, colectomy or autopsy. (ECDC case definition)  
ECDC = European Centre for Disease Prevention and Control

**Asymptomatic patients with positive culture or toxin detection do not fulfil the case definition.**

The criterion that is found when CDI is first diagnosed should be specified. Patients do not have to be tracked with regard to the fulfilment of other criteria (only one criterion is recorded per patient). If several criteria are fulfilled at the time of diagnosis, the criterion with the highest numerical value is specified.

Example: Patient undergoes surgery for a megacolon.

Histopathological evidence of CDI is obtained. Toxin detection is taken before the operation and diarrhoea is also described in the file. Both criterion 1 (diarrhoea + toxin detection) and criterion 3 (histopathological evidence in a colectomy) apply here. However, only criterion 3 (3>2>1) is recorded in this example.

The CDI case is assigned to the department/hospital in which the CDI was first diagnosed or known, i.e. the case is not counted again if it is transferred to another department in the same hospital. If the CDI case is hospitalised over the turn of the year, this case is only counted for the year in which it was first diagnosed.

**CDI patient**

Both cases and patients with CDI are counted, i.e. if a CDI patient is readmitted within a year, it is considered a new case (see above), but remains a patient for the calendar year.

Example: If a patient comes with a CDI three times in the recording year, a new CDI case is counted each time and the patient with CDI is only counted once (CDI cases: 3; patients: 1)

**Year**

Calendar year of the recording period

**CDI diagnostics in hospital**

Indication of when the CDI diagnosis is performed in the hospital:

In case of clinical suspicion

In all patients with diarrhoea after a stay of > 3 days in hospital

Other criteria (specify criteria)

**CDI case brought along  
(see illustration p.10)**

CDI was already known on admission to hospital or the first symptoms of CDI appear on the day of admission to hospital or on the following day.

**Nosocomial CDI case  
(see illustration p.10)**

Case definition for CDI is fulfilled and the first symptoms occur later than day 2 after admission

**or**

Case definition for CDI is fulfilled and the first symptoms



occur within the first 2 days of admission if the patient has been treated as an inpatient in the same hospital within the last 4 weeks (discharge date no longer than 4 weeks before admission date)

**or**

Symptoms occur up to 4 weeks after discharge from hospital and the case definition is fulfilled.

**Residence day rule:** Definitions: Admission day = day 1, nosocomial from day 3

Figure: Classification of CDI into "brought in" and "nosocomially acquired"

Admission to the hospital						Discharge/transfer from the hospital
Day 1	2	3	4	5	6	7
First symptoms before admission or on days		First symptoms from day 3				
<b>CDI brought along</b>		<b>Nosocomial CDI</b>				

Admission to the hospital			Discharge from hospital	Readmission to the hospital after discharge	
Day 1	2	3	5	Day 1 - 28 after discharge	Day ≥ 29 after discharge
No symptoms				First symptoms or first symptoms before admission	
				<b>CDI nosocomial</b>	<b>CDI brought along</b>

## Recurrence

A new episode and thus a new case requiring documentation is considered to have occurred if at least one week has elapsed between the end and recurrence of symptoms. Two episodes of CDI in one patient are regarded as different events if more than eight weeks have elapsed between the cessation of symptoms and their recurrence. In this case, both episodes are regarded as first manifestations.

An episode that occurs within eight weeks of a previous episode (return of symptoms less than eight weeks after improvement of the clinical picture) is considered a relapse of the initial illness.

Relapse can refer to either a relapse with the same strain or a reinfection with a different strain. In practice, it is not possible to distinguish between these two

**Serious CDI case**

possibilities and the term "relapse" is used to describe both events.

It is a severe case if at least one of the four criteria for a severe course is fulfilled:

2. Admission or transfer to an intensive care unit due to CDI or its complications.
3. Surgical intervention (e.g. colectomy) due to megacolon, intestinal perforation or therapy-refractory colitis.
4. Death  $\leq 30$  days after diagnosis and CDI as cause or disease contributing to death.

The criterion that is found when CDI is first diagnosed should be specified. Patients do not have to be tracked with regard to the fulfilment of other criteria (only one criterion is recorded per patient). If several criteria are fulfilled at the time of diagnosis, the criterion with the highest numerical value is specified.

**Number of Patient days**

In general, the hospital count patient days as follows: the day of admission is the first patient day, the day of discharge is no longer counted (example: patient A was admitted from 1 to 10 January, resulting in 9 patient days).

**Number of Patients**

Number of patients. Total number of all inpatients (= number of cases) at the hospital from 1 January to 31 December of the recording year, excluding internal transfers.

**Number of faecal examinations**

Number of stool tests for *C.*

**Number of positive tests**

Number of stool examinations for *C. difficile* with a positive test result

## **4. imprint**

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