Krankenhaus-Infektions-Surveillance-System (KISS)

DRAFT VERSION

AMBU-KISS: Protocol for Surveillance of Surgical Site Infections in Outpatient Surgical Centers
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1. Surgical site infection surveillance

Surveillance refers to collecting infection-related data, analyzing that data, and communicating the results to those who need them (1). In the case of surgical site infection surveillance, surgeons are those who need more data. Various studies have shown that surgical site infection rates can be reduced by surveillance (2).

The significance of an infection rate (incidence) for an operative center or surgical ward can be increased by comparing the data of one center to those of other similar healthcare facilities. By using standardized data collection methods, reference data for benchmarking can be provided for participating facilities.

In 1996, the German National Reference Center for Nosocomial Infection Surveillance (German: Nationales Referenzzentrum = NRZ) developed the Hospital Infection Surveillance System (German: Krankenhaus-Infections-Surveillance-System = KISS). One of the modules of this system, OP-KISS, is for surgical site infection surveillance. The data collected in KISS are made anonymous and evaluated annually by the NRZ. Participants are provided with reference data in the form of average infection rates (available online at www.nrz-hygiene.de). With these data, facilities can evaluate their infection rates in comparison to the others.

The use of standard definitions is especially crucial. The surgical site infection definitions by the Centers for Disease Control and Prevention in Atlanta, USA are widely used internationally and are used by KISS for that reason (3).

According to §23, Para. 1 of the Infektionsschutzgesetz (Protection against Infection Act), directors of outpatient surgical centers are also required to continuously document and evaluate healthcare-associated infections. AMBU-KISS consistently implements this requirement (4). (An unofficial English translation of The Protection against Infection Act is available at www.rki.de under Prevention of Infection>Infectious Disease Surveillance)
2. AMBU-KISS (Surgical site infection surveillance after outpatient procedures)

Until 2003, there were no reference data about surgical site infections (SSI) in outpatient facilities in Germany, and there was relatively little international data available.

In October, 2002, AMBU-KISS was started by the NRZ as a module of KISS. The goal of AMBU-KISS is to create a reference databank for SSI in outpatient facilities.

In OP-KISS, a surveillance module for SSI in hospitals, infection data are stratified by risk factors during evaluation. Because risky patients are underrepresented in outpatient surgical centers, AMBU-KISS does not record patient risk factors.

Reference data consist of pooled AMBU-KISS participant infection rates and the results of risk group 0 in OP-KISS, if the indicator operative procedures tracked in AMBU-KISS are also tracked in OP-KISS.
3. Requirements for participation by outpatient surgical centers in AMBU-KISS and duties of the NRZ

Participating facilities must fulfill the following prerequisites:

- At least one indicator operative procedure must be performed
- This indicator operative procedure must be performed at least 30 times per year
- Facility leadership must agree to participate in the project
- Surveillance data must be transmitted quarterly to the project center in Freiburg
- CDC definitions must be used strictly in SSI diagnosis (see definition for nasal septum surgery and for cataract surgery in the protocol of modified definitions)
- These definitions must be communicated to all doctors performing follow-up care
- The specifications laid out in this protocol must be applied consistently
- Participants must be ready to discuss open questions and take part in validation measures

The NRZ promises participating facilities to:

- Provide advice and expert support during surveillance
- Handle each unit’s data strictly confidentially
- Send standardized infection data as reference data to participating facilities yearly
- Advise them on the implementation of surveillance results for quality management
- Provide certification of participation after one year of infection surveillance and participation in validation measures
4. Methods

In cooperation with diverse professional organizations, various indicator operative procedures were selected for AMBU-KISS that are frequently performed in outpatient surgery centers. It is important that all of the procedures listed in the OPS-301 codes¹ for a certain indicator operative procedures are tracked, and not only a portion.

The following OPS-301 procedures are included in surveillance:

ART
Arthroscopic knee surgery
(Ops-301-Codes: 5-810_h, 5-811_h, 5-812_h, 5-813, 5-819_h)

HALLUX
Correction of hallux valgus
(Ops-301-Codes: 5-788.00, 5-788.01, 5-788.10, 5-788.11, 5-788.20, 5-788.21, 5-788.30, 5-788.31, 5-808.a0, 5-808.b0)

HERN
Closure of inguinal hernia, as well as groin or testicular operation with and without mesh, endoscopically or open surgically (Ops-301-Codes: 5-530, 5-622.5, 5-624.4, 5-625.4)

HODEN
Testicular surgery
(Ops-301-Codes: 5-611, 5-622.0, 5-622.1, 5-624.5, 5-630.0, 5-631.0, 5-631.1, 5-633.1, 5-636.2)

KATARAKT
Cataract surgery
(Ops-Code 5-144)
*Modified definitions for SSIs apply for these procedures. See 6.2*

LASH
Endoscopic supracervical hysterectomy
(Ops-301-Code 5-682.02)

LUMB
Lumbar disc surgery, endoscopic or open
(Ops-301-Codes: 5-831.0, 5-831.1, 5-831.2)
*An example of how to use the CDC definitions is available for this operative procedure at www.nrz-hygiene.de, OP-KISS > Indicator-OP.*

MAMMA_EX
Breast surgery: local excision, including excisional biopsy
(Ops-301-Code 5-870.0)

MAMMA_PLAST
Breast enlargement surgery by implantation of breast prosthesis
(Ops-301-Code 5-883.0)

¹ OPS-301 codes are the German variant of the OPS system and are not available in English.
SEPTEN
Nasal septum surgery
(OPS-301-Codes 5-214.0, 5-214.3, 5-214.4, 5-214.5, 5-214.6)
*Modified definitions for SSIs apply for these procedures. See 6.1*

STRIP
Venous stripping, crossectomy, stripping of varicose veins in lower extremities
(OPS-301-Code: 5-385.7)

- All patients undergoing one of the above procedures are included in surveillance.
- Procedures after which patients remain in the facility for observation for up to 24 hours after the surgery are also considered outpatient.
- Active observation must take place for all patients registered in AMBU-KISS until wound healing. Waiting for physicians in follow-up care to report infections tends to have the effect that not all infections are recorded.
- Patients are kept under surveillance up to the 30th day after surgery. All SSI appearing in this time period are included in surveillance.
- CDC definitions for SSI are the basis for the classifications of SSI, with the exception of nasal septum surgery and cataract surgery (see modified definitions).

AMBU-KISS participants record the number of indicator operative procedures performed as well as the number of SSI that appear afterward. These data should be sent continuously to the project center. Evaluation of individual data, as well as the average SSI rate of all participating facilities are sent to participants regularly by the project center.

The SSI rate describes the number of SSI in the observational period per 100 indicator operations.

\[
\text{SSI rate} = \frac{\text{Total SSI in patients following indicator operative procedure of type Y within observational period A}}{\text{Total indicator operative procedures of type Y performed in observational period A}} \times 100
\]

Benchmarking data consist of the pooled SSI rates for each indicator operative procedure of all AMBU-KISS participants.

When an indicator operative procedure is also under surveillance in hospitals as part of OP-KISS, then an AMBU-KISS SSI rate can also be compared with the rate for OP-KISS risk group 0.
5. Surveillance process

The number of procedures and SSIs per quarter is reported to the project center (Institute for Environmental Medicine and Hospital Hygiene, Freiburg) by data collection form.

The following processes for surveillance are possible:

Variant 1
Patients are requested to come to a follow-up examination in the participating facility. If a patient does not appear at the follow-up examination, inquiries will be made with the patient or attending physician by telephone or in writing.

Variant 2
Patients are requested to come to a follow-up examination. If a patient does not come to the follow-up examination, inquiries are not made, but either:

- All patients are informed before the operation that they should contact the facility if something is wrong with the surgical site
- or
- All referring doctors are informed about AMBU-KISS and requested to refer patients back to the facility for all complications
- or
- All patients routinely receive reply forms about complications as a quality assurance measure
- or
- There is close contact between the outpatient center and physicians attending patients post-op.

Variant 3
Patients are not requested to come to a follow-up examination. Physicians attending patients post-op are sent lists of AMBU-KISS patients with the request to reply in the event of a SSI. These physicians must have been informed of the CDC definitions. All surgeons, all physicians making referrals and all physicians attending patients after surgery must know the CDC definitions in order to diagnose infections in the same way. See also chapter 6 and the CDC definitions, available in English at http://www.cdc.gov/ncidod/dhqppdf/nnis/NosInfDefinitions.pdf.

Basic data like age, sex, type and date of procedure are recorded on a special infection data collection form ONLY for patients with SSI. Furthermore, additional risk factors like an unusually long operation time, high wound contamination class or high ASA are also only recorded for patients with SSI. These factors are also used to stratify risks in OP-KISS data evaluation.

The infection data collection form includes details about the SSI such as symptoms and antibiotic treatment, as well as the date and severity of the infection and the laboratory-confirmed pathogen, when applicable.
Infection data collection forms are also sent to the project center. Patient identification codes given by participating facilities make this information anonymous.

Surveillance data should be transmitted by fax. The AMBU-KISS abbreviation for your facility ensures anonymity in fax transmission. The data can also be sent by mail or by e-mail to the Institute for Environmental Medicine and Hospital Hygiene at the Freiburg University Clinic.
6. CDC Definitions for SSI

A1 superficial incisional SSI must meet one of the following criteria:

Infection occurs within 30 days after the operative procedure and involves only skin and subcutaneous tissue of the incision and patient has at least one of the following:

a. Purulent drainage from the superficial incision.
b. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
c. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, and superficial incision is deliberately opened by surgeon, and is culture-positive or not cultured. A culture-negative finding does not meet this criterion.
d. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

A2 deep incisional SSI

Infection occurs within 30 days after the operative procedure if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operative procedure and involves deep soft tissues (e.g., fascial and muscle layers) of the incision and patient has at least one of the following:

a. Purulent drainage from the deep incision but not from the organ/space component of the surgical site. (Those infections belong to category A3.)
b. A deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured, and the patient has at least one of the following signs or symptoms: fever (>38°C), or localized pain or tenderness. A culture-negative finding does not meet this criterion.
c. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination
d. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

A3 organ/space SSI

Infection occurs within 30 days after the operative procedure if no implant is left in place or within one year if implant is in place and

\[\text{A nonhuman-derived object, material, or tissue that is permanently placed in a patient during an operative procedure and is not routinely manipulated for diagnostic or therapeutic purposes. Examples include: porcine or synthetic heart valves, mechanical heart, metal rods, mesh, sternal wires, screws, cements, and other devices. Human donor organs (transplants) are not implants.}\]
the infection appears to be related to the operative procedure and infection involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure and patient has at least one of the following:

a. Purulent drainage from a drain that is placed through a stab wound into the organ/space

b. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space

c. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination

d. Diagnosis of an organ/space SSI by a surgeon or attending physician.
6.1 Modified definition of SSI for surveillance after nasal septum surgery

**A1 Superficial incisional SSI**

Infection affects only superficial structures without involvement of the perichondrium

Infection occurs within 30 days after the operative procedure and involves only skin and subcutaneous tissue of the incision and patient has at least one of the following:

a. Purulent drainage from the superficial incision.
b. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
c. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, and superficial incision is deliberately opened by ENT surgeon, unless there is a negative culture.
d. Diagnosis of superficial incisional SSI by the ENT surgeon or attending physician.

**A2 Deep incisional SSI**

Infection involves perichondrium and possible involvement of structures below the perichondrium or abscess formation

Infection occurs within 30 days after the operative procedure, and the infection appears to be related to the operative procedure and involves perichondrium and lower lying structures and patient has at least one of the following:

a. Purulent drainage from the deep incision.
b. A deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured, and the patient has at least one of the following signs or symptoms: fever (>38°C), or localized pain or tenderness. A culture-negative finding does not meet this criterion.
c. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
d. Diagnosis of a deep incisional SSI by an ENO surgeon or attending physician.

**A3 Organ/space SSI**

Does not apply.
6.2 Modified definition of SSI for surveillance after cataract surgery

**A1 Superficial incisional SSI**

Does not apply.

**A2 Deep incisional SSI**

Does not apply.

**A3 Acute Organ/Space SSI**

Infection occurs within 1 year after the operative procedure, and the infection appears to be related to the operative procedure, and one of the following criteria is fulfilled:

1. Proof of intraocular pathogen by positive culture or by PCR
2. General signs of infection such as pain or visual disturbance

   and/or

   one of the following criteria:

   - Hypopyon
   - Loss of fundal glow
   - Abscess of iris
   - Infiltration of retina
   - Infiltration of capsular bag
   - Infiltration of vitreous humor

3. Diagnosis by eye surgeon or attending physician
7. Documentation specifications

**AMBU-KISS abbreviation**
Given at registration by the NRZ. Registration takes place only online, see below.

**Patient ID**
Abbreviation for anonymous patient ID

**Length of operation**
Time in minutes between incision and closure.

7.1 Wound contamination class

Classification according to CDC specifications (5).

1 = **Clean**: An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tracts are not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage.

2 = **Clean-Contaminated**: Operative wounds in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination.

3 = **Contaminated**: Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered are included in this category.

4 = **Dirty or Infected**: Includes old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

7.2 ASA Score

Assessment by the anesthesiologist of the patient’s preoperative physical condition using the American Society of Anesthesiologist’ (ASA) Classification of Physical Status (6).

1. Normally healthy patient
2. Patient with mild systemic disease
3. Patient with severe systemic disease that is not incapacitating
4. Patient with an incapacitating systemic disease that is a constant threat to life
5. Moribund patient who is not expected to survive for 24 hours with or without the operation
### 7.3 Pathogen abbreviations

For technical reasons, the abbreviations have not been changed from their German equivalents and may for that reason seem unrelated to the pathogen name.

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acinetobacter spp.</td>
<td>ACI</td>
</tr>
<tr>
<td>Bacteroides spp.</td>
<td>BAC</td>
</tr>
<tr>
<td>Burkholderia cepacia</td>
<td>BCE</td>
</tr>
<tr>
<td>Candida albicans</td>
<td>CAN</td>
</tr>
<tr>
<td>Citrobacter spp.</td>
<td>CIT</td>
</tr>
<tr>
<td>Coagulase negative Staphylococci</td>
<td>KNS</td>
</tr>
<tr>
<td>Corynebacterium spp.</td>
<td>COR</td>
</tr>
<tr>
<td>Enterobacter spp.</td>
<td>ENB</td>
</tr>
<tr>
<td>Enterococci</td>
<td>ENT</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>ECO</td>
</tr>
<tr>
<td>Haemophilus spp.</td>
<td>HAE</td>
</tr>
<tr>
<td>Klebsiella spp.</td>
<td>KLE</td>
</tr>
<tr>
<td>Legionella spp.</td>
<td>LEG</td>
</tr>
<tr>
<td>Methicillin-resistant S.aureus</td>
<td>MRSA</td>
</tr>
<tr>
<td>No growth</td>
<td>KW</td>
</tr>
<tr>
<td>Other anaerobic organisms</td>
<td>ANA</td>
</tr>
<tr>
<td>Other cocci</td>
<td>ANK</td>
</tr>
<tr>
<td>Other enterobacteria</td>
<td>AEN</td>
</tr>
<tr>
<td>Other fungi</td>
<td>ANP</td>
</tr>
<tr>
<td>Other gram positive rod bacteria</td>
<td>APS</td>
</tr>
<tr>
<td>Other nonfermenting organisms</td>
<td>ANO</td>
</tr>
<tr>
<td>Proteus spp.</td>
<td>PRO</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>PAE</td>
</tr>
<tr>
<td>Serratia spp.</td>
<td>SER</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>SAU</td>
</tr>
<tr>
<td>Stenotrophomonas maltophilia</td>
<td>STM</td>
</tr>
<tr>
<td>Streptococci</td>
<td>STR</td>
</tr>
<tr>
<td>Vancomycin-resistant Enterococcus</td>
<td>VRE</td>
</tr>
</tbody>
</table>
8. References

9. Appendix

- Data collection forms for the total number of operations performed and the total number of infections per quarter
- Data collection form for patients with surgical site infections
**AMBU-KISS: Data collection form for total number of operations**

National Reference Center (NRZ) for Surveillance of Nosocomial Infection in Berlin

⇒ send by fax to 0761 270 8253

**AMBU-KISS abbreviation:**

<table>
<thead>
<tr>
<th>Date:</th>
<th>(quarter and year)</th>
<th>Total no. of operations</th>
<th>Total no. of SSI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthroscopic knee surgery</td>
<td>ART</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction of Hallux valgus</td>
<td>HALLUX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inguinal hernia (including combined groin and testicular operations)</td>
<td>HERN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Testicular operations</td>
<td>HODEN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cataract surgery</td>
<td>KATARAKT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endoscopic supracervical hysterectomy</td>
<td>LASH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lumbar disc surgery</td>
<td>LUMB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast surgery / excision</td>
<td>MAMMA_EX</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breast surgery / augmentation mammoplasty</td>
<td>MAMMA_PLAST</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nasal septum surgery</td>
<td>SEPTUM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stripping of varices</td>
<td>STRIP</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

⇒ For every SSI recorded here, an infection data collection form must be completed and sent to the project center in FREIBURG.

**Mailing address:**
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## AMBU-KISS: SSI data collection form

<table>
<thead>
<tr>
<th>AMBU-KISS participant number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient ID</td>
</tr>
<tr>
<td>Type of operation:</td>
</tr>
<tr>
<td>ART ☐ HERN ☐ STRIP ☐</td>
</tr>
<tr>
<td>Age:</td>
</tr>
<tr>
<td>Sex: m ☐ f ☐</td>
</tr>
<tr>
<td>Wound contamination class:</td>
</tr>
<tr>
<td>ASA score:</td>
</tr>
<tr>
<td>Date of infection (dd.mm.yyyy):</td>
</tr>
<tr>
<td>Purulent secretion yes ☐ no ☐</td>
</tr>
<tr>
<td>Pain yes ☐ no ☐</td>
</tr>
<tr>
<td>Swelling yes ☐ no ☐</td>
</tr>
<tr>
<td>Redness yes ☐ no ☐</td>
</tr>
<tr>
<td>Heat yes ☐ no ☐</td>
</tr>
<tr>
<td>Spontaneous dehiscence yes ☐ no ☐</td>
</tr>
<tr>
<td>Opened by surgeon yes ☐ no ☐</td>
</tr>
<tr>
<td>Fever yes ☐ no ☐</td>
</tr>
<tr>
<td>Infection A1 ☐ Infection of skin and subcutaneous tissue</td>
</tr>
<tr>
<td>Infection A2 ☐ Infection of muscle tissue and fascies</td>
</tr>
<tr>
<td>Infection A3 ☐ Infection of organs and spaces opened during the procedure</td>
</tr>
<tr>
<td>Pathogen</td>
</tr>
<tr>
<td>No evidence in microbiological diagnoses ☐</td>
</tr>
</tbody>
</table>

*CDC criteria must be used for diagnosing SSI, see protocol.*
10. Legal Notice

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