“Design and implementation of multinational surveillance systems using routinely collected electronic health records in the EU/EEA.”
(FWC – ECDC/2022/03)

Electronic Health Record (EHR)-based

Bloodstream Infections (BSI)

Country specific protocol

SLOVENIA

Contents

Version History

Version	Date finalised	Created/modified by
1.0	2-February-2024	Irena Klavs[1], Daša Kavka[2], Lucija Tepej Jočić[1], Veronika Učakar[1], Mario Fafangel[1], Uroš Glavan[1], Matija Mozetič[1], Petra Klepac[1], Mojca Serdt[1], Tanja Kustec[1], Marta Grgič-Vitek[1]
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The Slovenian protocol is based on the EHR-based Bloodstream Infections (BSI) Generic protocol v 0.3 (5 September 2004) prepared by Epiconcept (Alexis Sentís, Anthony Nardone, Francisco Orchard), Statens Serum Institut (Tine Dalby, Hanne-Dorthe Emborg) and the European Centre for Disease Prevention and Control (Angelo D'Ambrosio, Carl Suetens, Carlos Carvalho, Diamantis Plachouras, Luis Alves de Sousa, Tommi Karki). The text of the generic protocol is in italic smaller font and respective references are listed under 8. References.

The text of the Slovenian country specific protocol is in normal font. Numbers of references listed in chapter "8. References" are noted in superscript. Numbers of additional references are noted in bold superscript and are listed as notes at the bottom of the page.

Abbreviations

AMR	Antimicrobial resistance
AST	Antimicrobial Susceptibility Testing
BSI	Bloodstream infections
BSI-AMR	Bloodstream Infections and antimicrobial resistance
CA	Community-associated
CDC	Communicable diseases databases
CNB	Communicable Diseases Centre (Slo.: Center za nalezljive bolezni – CNB)
CRPP	Central Register of Patient Data (Slo: Centralni register podatkov o pacientih CRPP)
DL	Deliverable
EARS-Net	ECDC-coordinated European Antimicrobial Resistance Surveillance Network
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EHR	Electronic Health Records
EpoPulse	European surveillance portal for infectious diseases
eTTL	Electronic Temperature Therapy Sheet (Elektronski temperaturni terapijski list - eTTL)
EU	European Union
EUCAST	European Committee on Antimicrobial Susceptibility Testing
GDPR	General Data Protection Regulation
HA	Healthcare-associated
ICU	Intensive care unit
ICD	International Classification of Diseases
ID	Identifier
IT	Information Technology
INSA	Instituto Nacional de Saúde Doutor Ricardo Jorge
LOINC	Logical Observation Identifiers Names and Codes
MIC	Minimal Inhibitory Concentration
Nivel	Netherlands Institute for Health Services Research
NLZOH	National Laboratory for Health, Environment and Food (Slo.: Nacionalni laboratorij za zdravje, okolje in hrano – NLZOH)
OMOP CDM	The Observational Medical Outcomes Partnership Common Data Model)
PDR	Pan-drug resistance
SARI	Severe Acute Respiratory Infection
SIR	Susceptible, Intermediate, and Resistant
SNOMED-CT	Systematized Nomenclature of Medicine Clinical terms
SOP	Standard operating procedures
SSI	Statens Serum Institut
STI	Sexually transmitted infections
SUREHD	SURveillance from Electronic Health Data
TESSy	The European Surveillance System

1. Executive summary

This protocol provides a basis to develop and expand automated or semi-automated system for electronic health records (EHR)-based surveillance of bloodstream infections (BSI), including antimicrobial resistance (AMR) data. The protocol was updated to align, as much as possible, with the ECDC "TESSy Reporting Protocol for Electronic Health Record-based surveillance of Bloodstream Infections (EHR-BSI), version 0.1" and with the relevant definitions developed by the PRAISE network.

The primary aim of the SUREHD (SURveillance from Electronic Health Data; Design and implementation of multinational surveillance systems using routinely collected electronic health records in EU/EEA) is to support countries establishing data collection through an EHR-based surveillance system. This generic protocol provides a template for countries to prepare their own country-specific protocols for EHR-based BSI surveillance according to their national context, data sources and infrastructure, as well as available financial and technical resources. It offers different options to monitor BSI (e.g., case definitions, episode periods) so that countries start at an appropriate point (e.g. initiating with only a few sites) with the aim to improve and evolve their surveillance systems over the course of the SUREHD project and beyond.

The primary objective is to monitor the incidence of healthcare-associated (HA) BSI employing automated/semi-automated EHR surveillance systems. Secondary objectives are to identify possible pan-drug resistance (PDR) in BSIs, enable alerts for emerging pathogens in BSIs, and submit AMR data according to the European Antimicrobial Resistance Surveillance Network (EARS-Net) protocol.

The protocol provides the definitions for laboratory-confirmed BSI cases (coherent with the European case definition for BSI), episode type and duration as well as HA, hospital-onset HA, and community-associated BSI. The protocol provides options for using simpler operational definitions at the national level that can be used in the initial stages of implementing the surveillance system.

Data can be reported to surveillance sites in aggregated or case-based format. Case-based data should be reported by hospital and with specialty-specific denominator data to allow stratified epidemiological analysis. If case-based data is not available, aggregated data should be reported to monitor the incidence of HA-BSI at the national, regional, hospital or laboratory level. The present protocol proposes the data extraction periods needed to achieve each objective. Near real-time reporting is recommended to achieve the objectives of monitoring PDR and emerging pathogens in BSI, but a less frequent periodicity is recommended for the objectives of measuring the incidence of HA-BSI and establishing electronic reporting of AMR according to the EARS-Net protocol.

To reflect the TESSy Reporting Protocol EHR-BSI version 0.1, the variables have been divided into five related datasets, in hierarchical levels, which can be divided into aggregated and case-based reporting sets: i) Surveillance type and hospital-related dataset (aggregated and case-based data) which is mandatory to be used for all reporting of EHR-BSI data, ii) Denominator dataset (aggregated and case-based data), iii) Information on patients dataset (case-based data), iii) Isolate-based dataset (isolate-based data), and iv) AMR profiles of isolates dataset (isolate-based data).
Countries will need to provide information on existing surveillance systems, data sources, and their list of collected variables as well as a description of methods and variables used for linking of data sources. Different data processing options are presented, identifying where data can be stored and processed using either a decentralised or centralised approach at different levels (local/national/international). Data processing requires the use of patient identifiers to link laboratory, hospital and patient pathway data.

Data processing details need to be communicated by countries, including the level of centralisation, pseudonymisation, data exchange format (after data extraction and linkage), data transfers, standard coding systems and vocabularies. Data will be submitted to ECDC through TESSy as described in the Reporting protocol for EHR-BSI v0.1. Codification systems at source level (i.e. laboratory or hospital) will be considered compatible if a mapping towards the target vocabulary exists or if it is expected to be developed in the near future. A description of the data protection and communication procedures will also be provided by the countries.

This Slovenian country specific protocol provides a basis to develop electronic health records (EHR)-based surveillance of bloodstream infections (BSI), including antimicrobial resistance (AMR) in Slovenia. The protocol is aligned with the ECDC "TESSy Reporting Protocol for Electronic Health Record-based surveillance of Bloodstream Infections (EHR-BSI), version 0.1".

The main objectives of planned EHR-based BSI and AMR surveillance are in the general population of Slovenia and among patients of all Slovenian acute care hospitals: (a) to assess the incidence of healthcare-associated (HA) and community-associated (CA) BSI and monitor changes over time, (b) to assess mortality and case fatality for HA and CA BSI and monitor changes over time, (c) to assess the proportion of resistant isolates in HA as well as CA BSI and monitor changes over time, and (d) to detect and monitor the emergence of pan-drug resistance (PDR) microorganisms as well as new pathogens causing HA and CA BSI.

The protocol provides the definitions for laboratory-confirmed BSI cases, coherent with the European case definition for BSI, episode type and duration as well as hospital-associated and community-associated BSI.

The data models (variables lists) together with coding for EHR-based BSI and AMR surveillance to be submitted near real time from microbiology laboratories, hospitals and all health care providers and medical examiners, who submit data about deaths, to the Central Registry of Patients' Data (Slo.: Centralni register podatkov o pacientih – CRPP) are defined.

Respective information technology (IT) solutions for submitting such data to the CRPP, harvesting data to the Communicable Diseases Database (CDD) and generating national EHR-based BSI and AMR surveillance reports are expected to be developed with resources from the GRANT AGREEMENT Project 101182971 — NSS-SI between the European Health and Digital Executive Agency (HADEA) and National Institute of Public Health (Slo.: Nacionalni inštitut za javno zdravje - NIJZ) and the project Electronic Temperature Therapy Sheet (Elektronski temperaturni terapijski list - eTTL) which is coordinated by the Ministry of Health within the Slovenian Recovery and Resilience Plan.

Once all IT solutions mentioned above have been developed, an IT solution will be created to submit the anonymised structured BSI and AMR surveillance data from the CDD to the European Surveillance System (Tessy) / European surveillance portal for infectious diseases (EpiPulse) or to store such data at the decentralised Slovenian communicable diseases data storage on the NIJZ server, accessible to ECDC personnel for EU/EEA level analyses.

The major limitation to implement EHR-based BSI and AMR surveillance according to this protocol may prove to be insufficient resources to develop all proposed IT solutions for appropriate data flow and generation of EHR-based BSI and AMR surveillance reports by planned deadlines, as there will be many competing priorities for digitalization of healthcare in Slovenia in the next few years.

The protocol will be updated according to further developments with respect to EHR-based surveillance of communicable diseases and changes of the Slovenian and European legal framework.

2. Background

2.1. Bloodstream infections (BSI) surveillance based on electronic health records (EHR) data

Electronic health records (EHR) - based surveillance systems allow the automatic extraction and secondary use of EHR, and have the advantage of reducing the burden on hospital staff and being a data source less affected in times of high workload at the hospital. To date, these systems have only been adopted by some countries across Europe, although there is growing evidence of the positive impact, they could have on public health surveillance[1-3] such as potential improvements in flexibility, timeliness, data completeness, sustainability and coverage compared to traditional approaches.

Bloodstream infections (BSI) are a growing concern of major public health importance mostly due to an ageing population[4]. A study in 2013 of the overall burden of BSI in North America and Europe estimated a total of 2 million cases of BSI and 250 000 deaths attributed to BSI, which represented the leading cause of infectious disease mortality in these regions[5]. Studies have estimated that the one-month case-fatality rates varied from 17% to 28% for nosocomial BSIs and from 10% to 19% for community-acquired BSIs[6-9]. In the last decade, the BSI incidence has shown an increase in Western countries, ranging from 122 to 220 cases/100 000 population per year[10]. However, a high degree of discrepancy has been described between countries, regions or hospitals in the estimation of BSI incidence rates attributed to case detection (number or rates of blood cultures performed) and reporting factors (reporting of contaminated samples and duplicates)[10-11].

The European Centre for disease Prevention and Control (ECDC)-coordinated European Antimicrobial Resistance Surveillance Network (EARS-Net)[12] provides data from European Union/European Economic Area (EU/EEA) countries on antimicrobial resistance (AMR) for eight pathogens isolated from bloodstream and central-nervous system infections. Higher percentages of AMR were described in the southern and eastern parts of Europe and some bacterial species–antimicrobial group combinations under surveillance showed a significant increase during the period 2016–2020, such as carbapenem resistance in Escherichia coli and Klebsiella pneumoniae and vancomycin resistance in Enterococcus faecium[13].

For current BSI surveillance, most of the evidence and reports focus on selected hospitals or hospital units, a specific causative agent, or either healthcare-associated or community-associated BSIs, and thus those surveillance systems represent specific patient populations. BSI surveillance can be strengthened by routine and automated data collection from EHR, which, in contrast to isolate-based surveillance initiatives, such as EARS-Net, should be based on the individual patient episode. Linkage capabilities between different data sources within EHR can enhance and facilitate the uni- and multivariable analysis of different factors that may be associated with BSI incidence.

In Slovenia, we do not have estimates of bloodstream infections (BSI) incidence and mortality as we have not yet implemented BSI surveillance. The Slovenian Communicable Diseases Act[1] does not list BSI as communicable diseases under surveillance. However, we do have information about antimicrobial resistance (AMR) for eight EARS-Net pathogens isolated from bloodstream and central-nervous system infections, as we participate in the European Centre for disease Prevention and Control (ECDC)-coordinated European Antimicrobial Resistance Surveillance Network (EARS-Net) and collect data according to respective ECDC protocol[2,3].

[1] Državni zbor RS. Zakon o nalezljivih boleznih – ZNB (uradno prečiščeno besedilo) (ZNB-UPB1), Uradni list RS št. 33/2006. Available from: http://www.uradni-list.si/1/objava.jsp?urlid=200633&stevilka=1348

[2] Ribič H, Glavan U, Klavs I, EARS-Net Slovenija. Odpornost proti antibiotikom pri povzročiteljih invazivnih okužb v Sloveniji v letu 2022 (Rezultati EARS-Net Slovenija). Odpornost proti antibiotikom pri povzročiteljih invazivnih okužb v Sloveniji. 2024:1-27. Available from: https://nijz.si/nalezljive-bolezni/spremljanje-nalezljivih-bolezni/odpornost-proti-antibiotikom-pri-povzrociteljih-invazivnih-okuzb-v-sloveniji/

[3] European Centre for Disease Prevention and Control. TESSy – The European Surveillance system. Antimicrobial resistance (AMR) reporting protocol 2024. European Antimicrobial Resistance Surveillance data for 2023. ECDC, March 2024. Available from: https://www.ecdc.europa.eu/en/publications-data/antimicrobial-resistance-amr-reporting-protocol-2024

2.2. Scope and purpose of the protocol

The SUREHD (SURveillance from Electronic Health Data; Design and implementation of multinational surveillance systems using routinely collected electronic health records in EU/EEA) project aims to support European Union/European Economic Area (EU/EEA) countries to pilot, implement and evaluate surveillance systems for specific infectious diseases or health conditions, groups of diseases or syndromes, based on automatic extraction, cleaning, validation, analysis, reporting and sharing of health data stored electronically in EU/EEA countries' health information systems and other similar sources. To date, specific contracts have been signed to design and implement multinational surveillance using routinely collected electronic health records in EU/EEA for Severe Acute Respiratory Infection (SARI), for Bloodstream Infection (BSI), and Sexual transmitted infections (STI).

As described in section 3.1, the aim of this protocol is to support countries to develop and expand automated/semiautomated EHR-based surveillance systems for BSI within a harmonised EU/EEA surveillance framework/system. The generic protocol is aligned with the "TESSy Reporting Protocol for Electronic Health Record-based surveillance of Bloodstream Infections (EHR-BSI), version 0.1" and will provide a template for countries to prepare their own country-specific protocols.

Countries will adapt the generic protocol to their own national context and identify appropriate data sources and infrastructure as well as the necessary financial and technical resources. It is recognised that countries will have different starting points in their ability to establish an EHR-based surveillance system for BSI, with some already well-established systems while others may not have such systems in place. As outlined below in the grey box, the generic protocol endeavours to address this divergence in three ways. Firstly, we include some key questions that countries may wish to address as they adapt the generic protocol to their own specific circumstances. Secondly, we offer different graded options for monitoring BSI (e.g., case definitions, episode periods) so that countries start at an appropriate point with the aim to improve and evolve their surveillance systems over the course of the project and beyond. Thirdly, as mentioned in the reporting protocol for EHR-BSI v0.1, data collection can be seen as an observable output of the primary focus of developing an EHR-based BSI surveillance system. Certain characteristics within the data, especially the coding systems used, availability of selected variables, and countries' methods of reporting aggregated or case-based data, will be considered as the primary target in the analysis instead of epidemiological comparisons of the countries and their exact BSI incidence.

Throughout the document, to facilitate study sites/countries to build their country-specific protocols, we will use these boxes to highlight information that needs to be provided by each country, including the recommended specific categories or values of the suggested surveillance variables.
When appropriate, different options will be identified and listed to allow countries to adapt the generic protocol according to their national context, specific reality and requirements.

The Slovenian country specific electronic health record (EHR)-based BSI surveillance protocol was developed based on the E-SURE consortium and ECDC EHR-based BSI generic protocol v 0.3 (5 September 2024) while taking in to account our national context, potential data sources and infrastructure as well as the necessary financial and technical resources. The protocol will be updated according to further developments with respect to EHR-based surveillance of communicable diseases and expected changes of the Slovenian and European legal framework.

2.3. General country overview

Each study site/country must provide a general overview on the:
- *Epidemiology of BSI and BSI-AMR.*
- *Each country will describe their surveillance approach at the current status of the project (EHR-based, isolated based vs individual based, etc.) and their plans to transition into EHR and individual based surveillance if that is not their current approach.*
- *Rationale to implement or strengthen an integrated BSI/AMR surveillance including a brief description of plans to do so.*
- *Details on their existing BSI surveillance systems as described in "Section 9.1. Annex 1. Existing BSI-related surveillance systems and data sources".*

As the Slovenian Communicable Diseases Act does not list BSI as communicable diseases under surveillance and we do not have BSI surveillance system, we do not have reliable information about the epidemiology of BSI.

We participate in the ECDC-coordinated EARS-Net[12]. At the National Institute of Public Health (Slo.: Nacionalni inštitut za javno zdravje – NIJZ) we collect national data on AMR for eight EARS-Net pathogens (*Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Acinetobacter spp., Staphylococcus aureus, Enterococcus faecalis, Enterococcus faecium and Streptococcus pneumoniae*) isolated from patients with BSI and central-nervous system infections according to ECDC EARS-Net protocol[4]. The data is submitted once per year in disaggregated format in Excel sheets from all laboratories that serve Slovenian acute care hospitals to Communicable Diseases Centre (Slo.: Center za nalezljive bolezni – CNB) at the NIJZ. During the period from 2019 to 2022 all participating laboratories used the guidelines of the European Committee on Antimicrobial Susceptibility Testing (EUCAST) for antibiotic susceptibility testing and interpretation of results[5,6,7,8].

Annual Slovenian EARS-Net surveillance reports are published[9]. Data is also submitted to ECDC for European union (EU) and European Economic Area (EEA) level analysis and publication of EARS-Net surveillance reports[10].

This protocol defines our plan to develop national EHR-based BSI surveillance system including AMR surveillance within the EHR-based surveillance of all communicable diseases. Figure 1 shows the planned data flow from different data sources to the Central Registry of Patients Data (Slo.: Centralni register podatkov o pacientih – CRPP) at the NIJZ and from CRPP to the Communicable Diseases Databases (CDD) in the CNB at NIJZ as well as data management within CNB and surveillance data use for different purposes and data transmission to different stakeholders and Table 1 provides information on the available data sources and systems planned to be used for collecting BSI-related data as described in Section 9.1. in Annex 1 of the generic protocol.

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[4] European Centre for Disease Prevention and Control. TESSy – The European Surveillance system. Antimicrobial resistance (AMR) reporting protocol 2024. European Antimicrobial Resistance Surveillance data for 2023. ECDC, March 2024. Available from: https://www.ecdc.europa.eu/en/publications-data/antimicrobial-resistance-amr-reporting-protocol-2024

[5] The European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters. Version 9.0, EUCAST; 2019. Available from: http://www.eucast.org

[6] The European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters. Version 10.0, EUCAST; 2020. Available from: http://www.eucast.org

[7] The European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters. Version 11.0, EUCAST; 2021. Available from: http://www.eucast.org

[8] The European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters. Version 12.0, EUCAST; 2022. Available from: http://www.eucast.org

[9] Ribič H, Glavan U, Klavs I, EARS-Net Slovenija. Odpornost proti antibiotikom pri povzročiteljih invazivnih okužb v Sloveniji v letu 2022 (Rezultati EARS-Net Slovenija). Odpornost proti antibiotikom pri povzročiteljih invazivnih okužb v Sloveniji. 2024:1-27. Available from: https://nijz.si/nalezljive-bolezni/spremljanje-nalezljivih-bolezni/odpornost-proti-antibiotikom-pri-povzrociteljih-invazivnih-okuzb-v-sloveniji/

[10] European Centre for Disease Prevention and Control. Antimicrobial resistance in the EU/EEA (EARS-Net) - Annual Epidemiological Report 2022. Stockholm: ECDC; 2023. Available from: https://www.ecdc.europa.eu/en/publications-data/surveillance-antimicrobial-resistance-europe-2022

Figure 1. Description of communicable diseases data flow from different data sources to the CRPP and to Communicable diseases dataset at the NIJZ data management within CNB (in blue), surveillance data use for different purposes and data transmission to different stakeholders

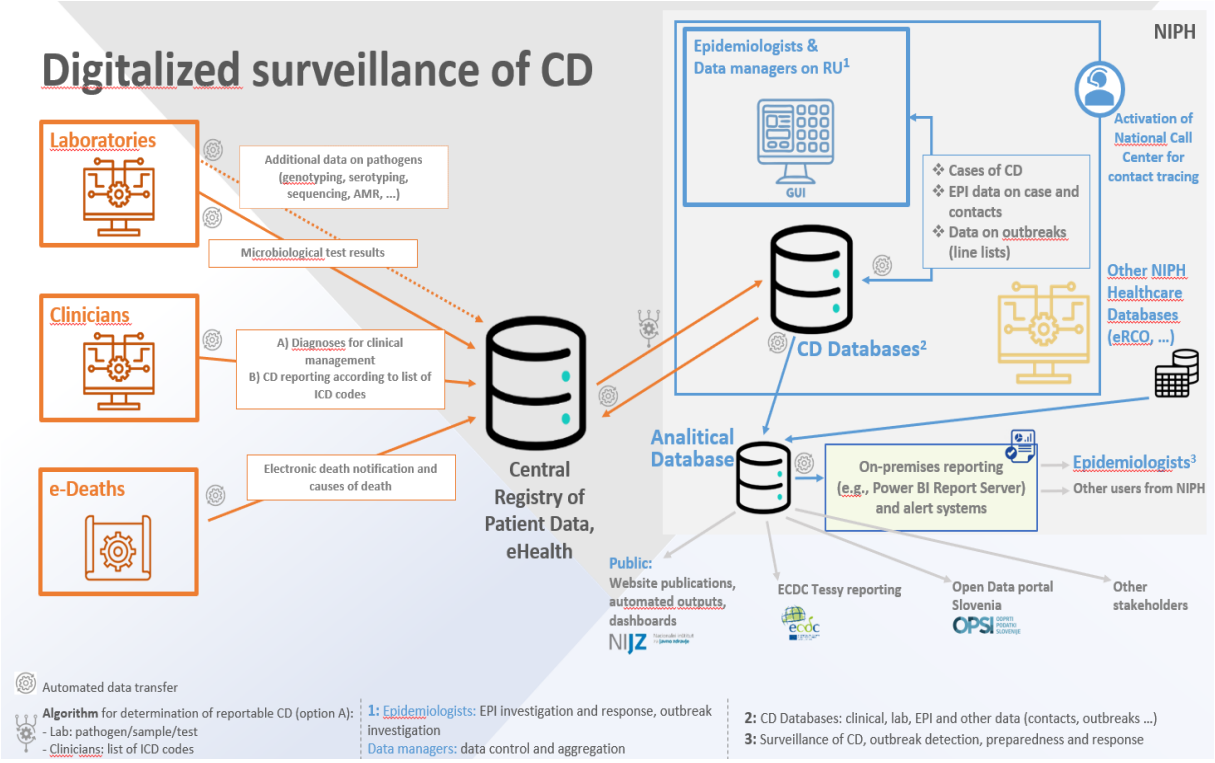

Table 1. Information on the available data sources and systems for planned collection of EHR-based BSI surveillance information in Slovenia by all surveillance objectives

Study objectives	Data source official Name/ information expected to be collected	Availability of data source	Electronic / EHR-based	Automated (specify)/ Semiautoma-ted/data manually collected	Reporting legal status	Data linkage variable available
Healthcare-associated BSI (HA-BSI incidence) AND **Pan-drug resistance (PDR) in BSIs (surveillance and alert) AND** **Emerging pathogens in BSIs (surveillance and alert) AND** **AMR according to EARS-Net protocol**	*Central Registry of Patients Data (Slo.: Centralni register podatkov o pacientih (CRPP)) at the NIJZ to collect data on all BSI cases)*	*Some data is already available in CRPP (e.g. pdf documents with results of laboratory tests).* *All respective information from laboratories, hospitals and other healthcare providers is planned to be available in CRPP in appropriately structured format.*	*Electronic*	*Planned to be automated for all variables listed in the chapter 3.5. of this protocol.*	*Planned to be mandatory.*	*Data linkage is planned to be possible in the CRPP before harvesting data for BSI surveillance purposes into the Communicable Diseases Database in the CNB at the NIJZ.*

EHR-based BSI and AMR surveillance system will allow the automatic extraction and secondary use of EHR data collected in the CRPP, and will have the advantage of reducing the burden on hospital and laboratory staff as well as being a data source less affected in times of high workload. The surveillance system will provide information about the incidence of BSI with respective AMR profiles Slovenia, BSI mortality and case-fatality rates. In addition, it will result in improvements in flexibility, timeliness, data completeness, sustainability and coverage compared to more traditional surveillance approach based on reporting new diagnoses of communicable diseases by clinicians on paper reporting forms.

3.1. Aim and objectives

3.1.1. Overall aim – Justification of implementation

This project aims to support participating countries to develop and expand EHR based surveillance systems for BSI within a harmonised EU/EEA surveillance system to inform public health action for disease prevention and control at local, national and European levels by:

- *Creating a European network which will facilitate building national and European BSI surveillance systems based on EHR.*
- *Building a system to enable reporting of an individual's episodes of care (e.g., admissions to different hospitals, readmission with BSI, etc).*
- *Creating a database linking patient and pathogen information.*
- *Digitalising and automatisation of BSI surveillance to reduce workloads and improve timeliness, which may result in an improved system that can provide information about a possible increase in cases or a certain resistance pattern. Collecting data on emerging or re-emerging pathogens causing BSI (e.g., outbreaks of C. auris).*
- *Automatically collecting standardised data on AMR profiles, including pan-drug resistance, of BSI isolates.*

The aim of the Slovenian EHR-based BSI surveillance protocol is consistent with the aim of the SUREHD (SURveillance from Electronic Health Data; Design and implementation of multinational surveillance systems using routinely collected electronic health records in EU/EEA) project that aims to support EU/EEA countries to pilot, implement and evaluate surveillance systems for specific infectious diseases or health conditions, groups of diseases or syndromes, based on automatic extraction, cleaning, validation, analysis, reporting and sharing of health data stored electronically in EU/EEA countries, health information systems and other similar sources. The EHR-based BSI Generic protocol v 0.3 was prepared under the framework contract between the ECDC and the E-SURE consortium[11]. The project supports participating countries to develop and expand automated or semi-automated systems for EHR based surveillance of BSI, including AMR data.

The Slovenian EHR-based BSI surveillance protocol was prepared under the framework contract between E-SURE consortium and NIJZ, SPECIFIC CONTRACT No 6 ECD. 16697 ID240241/27429 implementing activities to the Framework Contract n° ECDC/2022/003. The protocol is consistent with the E-SURE consortium EHR-based BSI generic protocol v 0.3, the methods used by the EARS-Net, coordinated by ECDC [12] and ECDC Reporting protocol for EHR-based BSI,

[11] Epiconcept and European Centre for Disease Prevention and Control. Electronic Health Record (EHR)-based Bloodstream Infections (BSI) Generic protocol v 0.3 (5 September 2024).

[12] European Centre for Disease Prevention and Control. TESSy – The European Surveillance system. Antimicrobial resistance (AMR) reporting protocol 2024. European Antimicrobial Resistance Surveillance data for 2023. ECDC, March 2024. Available from: https://www.ecdc.europa.eu/en/publications-data/antimicrobial-resistance-amr-reporting-protocol-2024

version 0.1[13]. The protocol is also consistent with the previously prepared Slovenian protocol BSI generic surveillance protocol based on EHR v 1.0 that was prepared under the framework contract between E-SURE consortium and NIJZ, SPECIFIC CONTRACT No 2 – ECD.14485 ID25621 implementing activities to the Framework Contract n° ECDC/2022/003. This previous Slovenian protocol aim was only to digitalize the Slovenian national EARS-Net surveillance system[14]. The essential parts of a preliminary draft of that protocol were presented and discussed at a workshop in Ljubljana with participants from ECDC, E-SURE consortium, NIJZ, National Laboratory for Health, Environment and Food (Slo.: Nacionalni laboratorij za zdravje, okolje in hrano – NLZOH), Institute of Microbiology and Immunology, Medical Faculty, University of Ljubljana (IMI), General hospital Slovenj Gradec and the Ministry of Health in November 2023[15].

On the country level this protocol aims to contribute to the development of EHR-based surveillance systems for BSI and AMR within a harmonised EU/EEA surveillance system to inform public health action for disease prevention and control at local and national levels by:

- Building a system to enable reporting of an individual's episodes of care (e.g., admissions to different hospitals, readmission with BSI, etc).
- Creating a database linking patient and pathogen information.
- Digitalising and automatization of BSI surveillance to reduce workloads and improve timeliness, which may result in an improved system that can provide information about a possible increase in cases or a certain resistance pattern. Collecting data on emerging or re-emerging pathogens causing BSI.
- Automatically collecting standardised data on AMR profiles, including pan-drug resistance, of BSI isolates.

3.1.2. Surveillance objectives

Through routinely collected data from EHR, and by automatising/semi-automatising as much as possible specific processes within the surveillance systems, the project surveillance objectives include:

1) Incidence of healthcare-associated (HA) BSI
2) Possible pan-drug resistance (PDR) in BSIs
3) Emerging pathogens in BSIs (e.g., C. auris)
4) AMR data according to EARS-Net protocol

Primary and secondary surveillance objectives

We consider as the primary surveillance objective the establishment of automated EHR based surveillance of BSI for the estimation of HA-BSI incidence by collecting data from EHR (objective 1). A better and more timely understanding of the most frequent microorganisms causing BSI, including AMR profiles, by country or region, sites (hospitals and wards), subpopulations (e.g., age groups) and risk groups (e.g. procedures) will enable more timely prevention and control actions.

We consider the secondary objectives to be:

- *Establishing the surveillance and alert of*
  - *possible pan-drug resistant microorganisms*
  - *emerging pathogens*

  In these cases, it is crucial to have the information as close to real time as possible in order to control outbreaks or the spread of a specific resistant microorganism.

[13] European Centre for Disease Prevention and Control. TESSy – The European Surveillance system. Reporting Protocol for Electronic Health Record-based surveillance of Bloodstream Infections (EHR-BSI), version 0.1. ECDC, July 2024.

[14] Klavs I, Kavka D, Tepej Jočić L, Učakar V, Fafangel M, Glavan U, Mozetič M, Klepac P, Serdt M, Kustec T, Grgič-Vitek M. Bloodstream infections generic surveillance protocol based on electronic health records – Slovenia v 1.0 (2-February-2024).

[15] Klavs I, Kavka D, Tepej Jočić L, Učakar V, Fafangel M, Glavan U, Mozetič M, Klepac P, Serdt M, Kustec T, Grgič-Vitek M. Report for the E-SURE HER-BSI/AMR Specific Contract No. 2 – ECD.14485 ID25621 implementing activities to the Framework Contract n^0 ECDC/2022/003; Slovenia, 2024.

- *Achieving full digitalisation and reducing manual steps in the EARS-Net reporting process. This last objective will reduce workload for countries to report to ECDC and so facilitate increased frequency from the current yearly reporting.*

Countries can prioritise which of the surveillance objectives to address according to national context and needs. Implementing all the different surveillance objectives in each country is a longer-term process and each one of the objectives can be achieved gradually over time. For this reason, we envisage that some countries will prefer to address one or more of the secondary surveillance objectives first and not the primary surveillance objective of estimating BSI incidence. For example, countries could start using an isolate-based system with limited data linkage between laboratory data and patient and clinical specific variables. This may be the case of the surveillance and alert of possible pan-drug resistant and emerging pathogens as well as the automatisation of the EARS-Net protocol (objectives 2 to 4), which, as an initial step, can be more easily achieved by starting with an isolate-based system.

→ Study sites/countries to prioritise surveillance objectives according to national contexts and to specify the expected timeframe to start working with each one of the objectives (e.g., during the first, second or third year), a brief description of their plans, and which objectives are feasible to accomplish during the three years of the project.

Our surveillance objectives defined in the Slovenian protocol "Bloodstream infections generic surveillance protocol based on electronic health records" (v 1.0, 2-February 2024) were in the general population of Slovenia (in patients of all Slovenian acute care hospitals):

- to assess the incidence of BSI caused by EARS-Net species or genera of bacteria (*E. coli, K. pneumoniae, P. aeruginosa, Acinetobacter spp., S. aureus, E. faecalis, E. faecium and S. pneumoniae*) and monitor changes in time,
- to assess the proportion of resistant isolates in BSI caused by "EARS-Net" species or genera of bacteria to antibiotics and monitoring changes over time and
- to compare our results with respective results of other EU/EEA countries[16].

In this protocol "Bloodstream infections generic surveillance protocol based on electronic health records" (v 2.0, 23-January 2024), we have expanded our objectives in accordance with the EHR-based BSI surveillance Generic protocol v 0.3 (5-September 2024). These objectives are in the general population of Slovenia and among patients of all Slovenian acute care hospitals:

- to assess the incidence of healthcare-associated (HA) and community-associated (CA) BSI and monitor changes over time,
- to assess mortality and case fatality for HA and CA BSI and monitor changes over time,
- to assess the proportion of resistant isolates in HA as well as CA BSI and monitor changes over time,
- to detect and monitor the emergence of pan-drug resistance (PDR) microorganisms causing HA and CA BSI,
- to detect and monitor the emergence of new pathogens causing HA and CA BSI,
- to digitalise the Slovenian EARS-Net surveillance system,
- to compare our results with respective results of other EU/EEA countries and
- to submit EHR-based BSI surveillance data, including AMR data to ECDC.

Whether all above national level objectives will be achieved by the end of 2026 will depend on negotiations with different stakeholders and competing priorities for digitalizing communicable diseases surveillance in Slovenia.

[16] European Centre for Disease Prevention and Control. Antimicrobial resistance in the EU/EEA (EARS-Net) - Annual Epidemiological Report 2023. Stockholm: ECDC; 2024 Available from: https://www.ecdc.europa.eu/sites/default/files/documents/antimicrobial-resistance-annual-epidemiological-report-EARS-Net-2023.pdf

The data model and information technology (IT) solution for receiving data on admissions and discharges from hospitals near real time in the CRPP has been developed in 2024. The development of IT solutions for submitting such data from all hospitals that use different IT systems could be achieved by the end of 2025. Ideally, this objective would be included into the development of IT solutions within the project Electronic Temperature Therapy Sheet (Elektronski temperaturni terapijski list - eTTL). eTTL will be a clinical information system for monitoring the patient's vital signs in hospitals and for monitoring, implementing and controlling the prescription and administration of drugs with one of the objectives being storing medical data in real time in the CRPP. The eTTL project is coordinated by the Ministry of Health within the Slovenian Recovery and Resilience Plan and is fully financed from the European Mechanism for Recovery and Resilience, except for VAT, which is financed from the budget of the Republic of Slovenia.

The data model for BSI and respective AMR microbiological data to be submitted from microbiology laboratories near real time to the CRPP is presented in this protocol. Respective IT solution for receiving data near real time by the CRPP is planned to be developed in 2025 by the resources from GRANT AGREEMENT, Project 101182971 — NSS-SI between the European Health and Digital Executive Agency (HADEA) and NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ).

The data model and respective IT solution for data about all deaths including deaths from BSI (e-Deaths - Slo.: e-Smrti) to be submitted from healthcare providers and medical examiners near real time to the CRPP with instructions for all data providers have already been developed[17].

An IT solution to harvest BSI surveillance data from the CRPP to the national CDD could be developed in 2025 by the resources from GRANT AGREEMENT, Project 101182971 — NSS-SI between the European Health and Digital Executive Agency (HADEA) and NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ).

IT solutions to generate national:
- BSI surveillance reports including AMR isolates profiles data quarterly,
- emergence of PDR microorganisms causing HA and CA BSI alerts near real time,
- emergence of new pathogens causing HA and CA BSI alerts near real time, and
- EARS-Net surveillance reports quarterly

could be developed in 2026 by the resources from GRANT AGREEMENT, Project 101182971 — NSS-SI between the European Health and Digital Executive Agency (HADEA) and NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ).

Finally, once all IT solutions mentioned above, in accordance with the Slovenian national BSI and AMR surveillance objectives have been developed, an IT solution will be created to submit the anonymised structured HA BSI and AMR surveillance data from the CDD to the European Surveillance System (Tessy) / European surveillance portal for infectious diseases (EpiPulse) or

[17] Nacionalni inštitut za javno zdravje. Navodila za uporabo aplikacije eSmrti - Informacijska rešitev za izvajanje digitalizacije procesa poročanja o vzrokih smrti. NIJZ, 2024. Available from: https://nijz.si › wp-content › uploads › 2024/06

to store such data at the decentralised Slovenian communicable diseases data storage at the NIJZ, accessible to ECDC personnel for EU/EEA level analyses for surveillance purposes. This could be achieved in 2027.

3.2. Study population

The primary objective of the protocol is to measure HA-BSI incidence, so the study population will be all hospitalised patients within the study site, whether that be a single hospital, a group of hospitals or within a geographic area (district, region or national).
A hospitalised patient is defined as someone admitted for a defined period of time, whether this is calculated as the number of hours (e.g., >24 hours) or days (e.g., an admission of >1 day).
When possible, data from all cases of BSI, HA-BSI or hospital-onset HA-BSI and community-associated BSI (CA-BSI) from the whole country will be included.

→ Study sites/countries to specify and describe the coverage and study population as described in "Section 9.2. Annex 2. Coverage and Population under Surveillance"

The population under surveillance will be the whole Slovenian general population as well as all the patients hospitalised in Slovenian acute care hospitals, which will enable us to ascertain all HA BSI and almost all CA BSI occurring in the population of Slovenia, to detect the emergence of PDR microorganisms causing BSI and the emergence of new pathogens causing BSI as well as obtain national EARS-Net surveillance data.

A hospitalised patient is defined as someone admitted for a defined period of time, whether this is calculated as the number of hours (e.g., >24 hours) or days (e.g., an admission of >1 day).

For the purpose of EARS-Net surveillance objectives the estimated coverage of the population of Slovenia regarding the occurrence of BSI with EARS-Net pathogens in the current Slovenian EARS-Net surveillance system was 99%[18].

3.3. Data collection period

The project aims to collect and report data timely enough to allow actions for disease prevention and control. This is understood as producing a real-time single data set from which all the objectives of the project can be achieved (see table 1).
But taking into account the challenge of digitalisation and automatisation for many countries, initially countries can aim to collect and report data differently for each project objective.
For objectives 1 (HA-BSI incidence) and 4 (EARS-Net reporting), countries should aim to collect and report all data sources quarterly or more frequently (see table 1). Although less frequent reporting can be accepted (e.g., biannual or annual) at the start of the project. For objectives 2 (BSI PDR) and 3 (Emerging BSI pathogens), countries should aim to provide data as close to real-time as possible (see Table 1).

Table 1. *Suggested data collection periods by objectives.*

[18] Ribič H, Glavan U, Klavs I, EARS-Net Slovenija. Odpornost proti antibiotikom pri povzročiteljih invazivnih okužb v Sloveniji v letu 2022 (Rezultati EARS-Net Slovenija). Odpornost proti antibiotikom pri povzročiteljih invazivnih okužb v Sloveniji. 2024:1-27. Available from://nijz.si/nalezljive-bolezni/spremljanje-nalezljivih-bolezni/odpornost-proti-antibiotikom-pri-povzrociteljih-invazivnih-okuzb-v-sloveniji/

Objective 1. Healthcare-associated BSI (HA-BSI incidence)	*Quarterly*
Objective 2. Possible pan-drug resistance in BSIs (PDR) (surveillance and alert)	*Near real-time*
Objective 3. Emerging pathogens in BSIs (surveillance and alert)	*Near real-time*
Objective 4. AMR according to EARS-Net protocol	*Quarterly*

→ Study sites/countries to specify expected and feasible frequency of reporting.
Study sites should prepare a timeframe that describes how frequency of reporting will be enhanced for each of the surveillance objectives over the course of the project (e.g. from year one to year three).

It is planned that by the end of 2025, data about hospital admissions and discharges for all patients admitted to acute care hospitals and about microbiological examinations of blood cultures together with respective antimicrobial susceptibility testing (AST) results will be submitted near real time to the CRPP at the NIJZ by all acute care hospitals managing patients with BSI and all microbiological laboratories performing blood culture examinations. An IT solution to harvest BSI surveillance data from the CRPP to the national CDD is planned to be developed in 2025.

When respective IT solutions to generate surveillance and alert reports would be developed, Slovenian BSI surveillance reports that would include AMR isolates profiles would be generated quarterly, alerts about the emergence of PDR microorganisms and new pathogens causing BSI would be generated near real time and EARS-Net surveillance reports would be generated quarterly.

Finally, IT solutions are planned to be developed to submit the anonymised structured BSI surveillance data from the CDD to Tessy/EpiPulse or to store at the decentralised communicable diseases data storage at the NIJZ, accessible to ECDC personnel for EU/EEA level analyses. BSI surveillance data with AMR isolates profiles would be submitted quarterly, alerts about the emergence of PDR microorganisms and new pathogens causing BSI would be submitted near real time and EARS-Net surveillance data would be submitted quarterly.

3.4. Key definitions

In this updated protocol, we have endeavoured to ensure as much as possible that the definitions employed are aligned with those used by both the PRAISE network and the TESSy Reporting Protocol for EHR v0.1.

3.4.1. Laboratory-confirmed Bloodstream infection (BSI) case definition

The ECDC case definition used is coherent with the one published in the Official Journal of the European Union (Commission Implementing Decision (EU) 2018/945)[14]:

- Patient has at least one positive blood culture for a recognised pathogen

OR

- two positive blood cultures for the same species/subtype of common skin contaminant (from two separate blood cultures, within three calendar days) (the first date of specimen = day one)

*Common skin contaminants/Common commensals: The European definition lists five possible common skin contaminants (coagulase-negative staphylococci, *Micrococcus* spp., *Propionibacterium acnes*, *Bacillus* spp., *Corynebacterium* spp.). However, a more complete list is provided by the CDC's National Healthcare Safety Network (NHSN) Common Commensals microorganism list, version February 2024[15]

In the ECDC official EU case definition, for a common skin contaminant identified in blood, it is also required that the patient has at least one of the following signs or symptoms: fever (> 38 °C), chills, or hypotension. However, several countries have pointed out that clinical symptoms are usually either not recorded or recorded as free text in EHR complicating collection of these data in an automated way, and therefore the definition above omits the symptoms. When symptoms cannot be collected, the case definition for common skin contaminants may be two separate positive blood cultures with the same pathogen as outlined above. Furthermore, some countries may be able to timestamp their samples, in which case "within three calendar days" can be replaced by "within 48 hours'' as published in the EU case definition.

→ Study sites/countries to specify within their protocol:
1. The case definition employed and whether it complies with the European definition
2. If they can identify two positive blood cultures in a patient by the same common commensal with no more than three calendar days between both blood cultures (and if they will use hours or calendar days as time period between both blood cultures).
    2a. When using a semi-automated system: if a common skin contaminant in a blood culture is detected, if at least one of the following signs or symptoms are recorded (indicate the level of completeness of the variable(s)); fever (> 38 °C), chills, or hypotension.

The BSI case definition will be consistent with the ECDC BSI surveillance case definition published in the Official Journal of the European Union (Commission Implementing Decision (EU) 2018/945) will be used[19]:

- Patient has at least one positive blood culture for a recognised pathogen

OR

- two positive blood cultures for the same species/subtype of common skin contaminant* (from two separate blood cultures, within three calendar days) (the first date of specimen = day one)

*Common skin contaminants/Common commensals: The European definition lists five possible common skin contaminants (coagulase-negative staphylococci, *Micrococcus* spp., *Propionibacterium acnes*, *Bacillus* spp., *Corynebacterium* spp.).

3.4.2. Contextual BSI data

To identify BSI cases, a dataset with results from all positive blood cultures performed during each study period for the defined area under surveillance will be required. Data about the causative pathogen will be collected. If possible, the total number of blood cultures performed will also be reported in aggregated format (see variable "Number of blood culture sets per year" from the TESSy Reporting Protocol for EHR-BSI v0.1).

→ Study sites/countries to specify within their protocol:
1. The availability of data source(s) for positive blood cultures and the coverage of the data collected (hospital (s)/region/national)
2. The number of blood culture sets (set of aerobic and anaerobic blood cultures) obtained per year (see Reporting Protocol for EHR-BSI v0.1) and, if possible, per 1 000 patient days. To provide the patient-days denominator, administrative data is needed; specify which data will be used and, if not available, provide the number of blood cultures by the catchment population during the study period.
3. Describe the indications for blood cultures and the frequency of taking these in general wards and Intensive Care Units (ICU).
4. Proportion of positive blood cultures: Proportion of positive among all performed blood cultures, if possible, per patient/ward/hospital/region/country during the study period.

[19] European Centre for Disease Prevention and Control. EU case definition, webpage last updated 3 Jul 2018. https://www.ecdc.europa.eu/en/all-topics/eu-case-definitions

It is planned that near real time data about hospital admissions and discharges for all patients admitted to acute care hospitals in Slovenia as well as data about all blood culture testing results (positive and negative results) will be submitted to the CRPP in appropriately structured format from all Slovenian acute care hospitals and all Slovenian microbiology laboratories. Thus, our future EHR-based BSI and AMR surveillance system will have national coverage and we will also be able to estimate the number of blood culture sets (aerobic and anaerobic) obtained per year as well as per 1000 patient days. We will also be able to estimate the proportion of positive blood culture results among all performed blood cultures per country and hospital.

3.4.3. Microorganisms under surveillance

We recommend monitoring all microorganisms detected in blood cultures. However, depending on data availability and national priorities, countries may prefer to start implementing the protocol focusing on:

- ***Microorganisms under surveillance in EARS-Net***

  In this category we include the eight microorganisms currently under surveillance in EARS-Net: Streptococcus pneumoniae, Staphylococcus aureus, Enterococcus faecalis, Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Acinetobacter spp[13]

In addition, countries may select any of the microorganism groups listed below:

- ***Common commensals/skin contaminants*** *(see section 3.4.1 Laboratory-confirmed BSI case definition)*
- ***Emerging microorganisms***

  Any pathogen considered emerging or re-emerging in the country. The list will be provided by each country in the adapted protocol.

- ***Fungi***
- ***Other microorganisms***

  Any other microorganisms not covered in the above categories; countries need to provide the list of microorganisms under surveillance.

We envisage that at the start of the project, countries may prefer to work with their own list/categories of common commensals/skin contaminants. For example, countries may wish to include only coagulase-negative staphylococci and exclude other skin contaminants. If this is the case, they will need to provide their own list of microorganisms under surveillance. Furthermore, it is required that countries share classification system in use for microbiological data in EHRs (see variable "MicrobiologicalTerminology" in the TESSy Reporting Protocol for EHR-BSI v0.1)

Besides providing data on the pathogens to be monitored, when possible, hospital admission codes (e.g., International Statistical Classification of Diseases and Related Health Problems 10th Revision -ICD-10- or 11 Revision -ICD-11) related to BSI (infection) should be collected.

→ Study sites/countries to specify in their protocols:

1. Microorganism categories (All microorganisms/Priority /Skin contaminants/Emergent/Fungal/Others/Unknown) they will include when implementing the project OR provide their own list of microorganisms

2. Classification system most used for microbiological data in EHRs, standardisation efforts (see variable "MicrobiologicalTerminology" in the TESSy Reporting Protocol for EHR-BSI v0.1) and microorganism codes used - species & subtype (e.g., Systematized Nomenclature of Medicine Clinical terms - SNOMED-CT) (see variable MicroorganismCodeSystem in the TESSy Reporting Protocol for EHR-BSI v0.1)

3. The list of skin contaminants to be reported (e.g., national list, ECDC pathogens according BSI case definition[14]*, or Centers for Disease Control and Prevention list*[15]*)*

4. The countries that use hospital admission codes (e.g., ICD10 or ICD11) should provide the codes used (see variable HospitalisationAdmissionCodeSystem in the TESSy Reporting Protocol for EHR-BSI v0.1) and the full list of codes used related to BSI (infection)

We plan to monitor all microorganisms detected in blood cultures, however the implementation of respective IT solutions for:

- receiving all blood culture results in the CRPP,
- submitting all blood culture results from microbiology laboratories to CRPP,
- harvesting BSI surveillance data from the CRPP to the national CDD,
- generating national BSI surveillance and EARS-Net reports and alerts about emerging PDR microorganisms and new pathogens causing BSI,

- submitting anonymised structured BSI, EARS-Net, emerging PDR microorganisms and new pathogens causing BSI data from CDD to Tessy/EpiPulse or to store data at the decentralised communicable diseases data storage at the NIJZ, accessible to ECDC personnel for EU/EEA level analyses for surveillance purposes,

will be developed in stages depending on negotiations with different stakeholders and competing priorities for digitalizing communicable diseases surveillance in Slovenia.

Microorganisms under surveillance in EARS-Net (*Streptococcus pneumoniae, Staphylococcus aureus, Enterococcus faecalis, Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Acinetobacter* spp.) will be included first, followed by other pathogens, any common commensals/skin contaminants (ECDC, European list[14]). The list of microorganisms we aim to include into national BSI surveillance system until the end of 2026 is given in the chapter "3.5.1. Data (variables) to be transferred to CRPP from microbiology laboratories" – variable name 16 - Pathogen. NCBI codes will be used to classify microorganisms under surveillance to be reported to CRPP and harvested from CRPP to the national CDD in the CNB at the NIJZ.

Finally, for the purpose of submitting anonymised structured BSI surveillance data from the CDD to Tessy/EpiPulse or to store such data at the decentralised communicable diseases data storage at the NIJZ, accessible to ECDC personnel for EU/EEA level analyses the codes suggested by ECDC reporting protocols will be used[20,21].

3.4.4. Personal identifiers and data linkage

Personal identifiers

To identify individuals and episodes of care, a personal identifier (ID) is needed to link records from different data sources (patient transfers) or to deduplicate records from the same episode of care (e.g., multiple blood cultures, see section 3.4.5). If available in the country, a unique personal identifier will be used, such as a pseudonymised national insurance number.

Other countries may use unique hospitalisation codes (patient's Hospital IDs) which may change for the same individual in different hospitals. The patient's hospital ID can be theoretically linked to a national ID but, even if this is not possible, it can be used to discriminate between episodes that have occurred in the same hospital. On some occasions, a patient's laboratory level ID (patient's Lab IDs) is necessary to link a patient's hospital ID to the associated diagnosis of the patient.

All data submitted will be processed conforming to national and European data protection regulations (see Section 5). The data submitted to ECDC will include a pseudo-anonymised identifier that allows the reporting countries/sites to go back and possibly ask for clarifications regarding a particular case.

Data linkage

If a unique personal identifier is not available, countries will describe which variables can be used for linkage and the methods they can use to link different datasets and registries in their country to collect information for each individual case.

These are the main methods of data linkage and their characteristics[16] are:

- *Deterministic linkage: pairs of records are classified as matches if their linking variables predominantly agree.*
- *Probabilistic linkage: record pairs are given scores representing the likelihoods of belonging to the same individual given the strength of agreement of variables (i.e. the strength of the match between record pairs). This method may be applied where there are no unique identifiers or linking keys, where linking variables are not reliable [17].*

→ Study sites/countries to specify in their protocol if there is a unique personal identifier available.

[20] European Centre for Disease Prevention and Control. TESSy – The European Surveillance system. Reporting Protocol for Electronic Health Record-based surveillance of Bloodstream Infections (EHR-BSI), version 0.1. ECDC, July 2024.

[21] European Centre for Disease Prevention and Control. TESSy – The European Surveillance system. Antimicrobial resistance (AMR) reporting protocol 2024. European Antimicrobial Resistance Surveillance data for 2023. ECDC, March 2024. Available from: https://www.ecdc.europa.eu/en/publications-data/antimicrobial-resistance-amr-reporting-protocol-2024

- If available, countries to specify:
1. How they will build their patient identifier.
2. If they will use a patient's hospital and laboratory IDs and if both can be linked between them and with other available patient identifiers.
3. How they will build their pseudonymised data to be reported.
4. Details on the options, barriers and challenges related with data linkage
- If not available:
1. Countries will specify how they identify BSI belonging to the same person and episode and how they make sure not to count it as a separate BSI.
2. Countries to specify how they will build their pseudonymised data to be reported.
3. If countries need to use different data sources, to specify which variables and methods will be used to identify and link individuals from different datasets within the project.

In Slovenia, a unique personal identifier of a citizen (Slo.: enotna matična številka občana – EMŠO) will be used to identify individual patients in hospitals, laboratories, CRPP and CDD at the NIJZ. EMŠO will be used to link the data from different data sources. For foreigners (persons without EMŠO or ZZZS number) CRPP foreigner identifier can be obtained by entering respective request into the CRPP/RDSP system for allocating a unique identifier.

The future Digitalization of Health Care Act that is being prepared at the Ministry of Health and is expected to be passed by the Slovenian parliament in 2025 will address all potential challenges with data linkage relevant to the national CDD.

BSI episodes will be defined according to the definition given bellow in chapter "3.4.5. Episode definitions".

A solution consistent with the communicable diseases surveillance national and European legal framework at that time for an appropriate pseudonymised identifier for data submission to Tessy/EpiPulse will be developed after all respective national BSI and AMR surveillance objectives IT solutions will have been developed.

3.4.5. Episode definitions

Episodes and potential related variables need to be computed but are not requested in the TESSy Reporting Protocol for EHR-BSI v0.1.
The date of onset of the episode will be the date of specimen collection in specimen with pathogen or first date of specimen with common skin contaminant that is a part of a set of at least two cultures (see variable "DateOfSpecCollection" in the ECDC Reporting Protocol for EHR-BSI v0.1). If not available, the following dates can be used as date of onset in the order presented here: i) date of onset of signs or symptoms coherent with a BSI, ii) date of diagnosis, or iii) date of notification (understood as reporting date).
BSI episode
An episode of BSI is defined for each BSI matching the case definition as a 14-day period defined starting from the date of onset (date of onset = day one). In case the same species/subtype is reported multiple times within the 14-day episode, these recurring isolates are considered to be part of the same episode.

We have used a period of 14 days[18] to define an episode to be consistent with both the PRAISE network and the TESSy Reporting Protocol for EHR-BSI v0.1. However, the period defining episodes may vary by country if different period duration (e.g. 30-days) have been used, and this may be reported in the TESSy Reporting Protocol v0.1[4,9-11].
Episode type (Monomicrobial/Polymicrobial episodes)
The BSI can be:

- *Monomicrobial episode: episode in which only one species/subtype is isolated within three calendar days from the date of onset (from the first positive blood culture).*
- *Polymicrobial episode: episode in which more than one species/subtype are isolated within three calendar days from the date of onset (from the first positive blood culture). In case of reporting of different species/subtype after three or more calendar days after the date of onset, a new 14-day BSI episode is recorded.*

→ Study sites/countries to specify in their protocol:

• The feasibility of using the definitions indicated in the generic protocol for the episode and episode type. When not possible to follow the definitions as written in the generic protocol, to indicate the operational definitions that will be employed.
• The different timeframes used to define an episode (e.g., 14 or 30 days) (see variable "EpisodeDuration" from the TESSy Reporting Protocol for EHR-BSI v0.1). It is recommended that countries explain the rationale behind the length of an episode.*
• The process employed to deduplicate episodes.
**We have used a period of 14 days to define an episode. However, we note that this period can vary by country and/or site.*

The date of onset of the episode will be the date of specimen collection in specimen with pathogen or first date of specimen with common skin contaminant that is a part of a set of at least two cultures. If not available, the date of notification date will be used as the date of onset (understood as reporting date).

An episode of BSI will be defined for each BSI matching the case definition as a 14-day period defined starting from the date of onset (date of onset = day one). In case the same species/subtype will be reported multiple times within the 14-day episode, these recurring isolates will be considered to be part of the same episode. We will use a period of 14 days to define an episode to be consistent with both the PRAISE network and the TESSy Reporting Protocol for EHR-BSI v0.1.

The BSI can be:

- Monomicrobial episode: episode in which only one species/subtype is isolated within three calendar days from the date of onset (from the first positive blood culture).
- Polymicrobial episode: episode in which more than one species/subtype are isolated within three calendar days from the date of onset (from the first positive blood culture). In case of reporting of different species/subtype after three or more calendar days after the date of onset, a new 14-day BSI episode is recorded.

Episodes will be deduplicated with the IT solution to generate national BSI and EARS-Net surveillance reports.

3.4.6. Healthcare-associated, hospital-onset Healthcare-associated, and community-associated BSIs

We envisage that in most countries, the blood cultures will be almost exclusively taken at hospitals providing secondary and tertiary healthcare, at emergency departments, inpatient wards or (rarely) in hospital-based outpatient care[4]. We recommend that dates and times of admission, discharge and specimen collection should be collected when available, allowing for healthcare-associated or community-associated episodes to be reported.
Episode definitions for healthcare-associated (HA)-BSI, hospital-onset HA-BSI and imported HA-BSI

A BSI episode is defined as HA BSI episode if the date of onset is after three calendar days of the hospital admission (date of admission = day one) or within three calendar days after a discharge from a healthcare facility (date of discharge = day one).
A BSI episode (see above) is defined as Hospital-onset HA-BSI episode if the date of onset is after three calendar days of the hospital admission (date of admission = day one).
A BSI episode (see above) is defined as an imported HA-BSI episode, i.e. episodes with readmission for BSI, if the date of onset is within three calendar days after a discharge from a healthcare facility (date of discharge = day one).
Community-associated (CA) episode
Those BSI episodes in non-hospitalised patients or patients hospitalised (but not transferred from another healthcare facility) within three calendar days after the date of onset.

Each study site/country must specify in their protocol if they can implement the definitions of HA, Hospital-onset HA, imported HA and CA episodes or if they decide to use other definitions (please specify).

In Slovenia, blood cultures are almost exclusively taken at hospitals, at emergency departments, inpatient wards or (rarely) in hospital-based outpatient care. Dates and times of admission, discharge and specimen collection will be collected, allowing for healthcare-associated or community-associated episodes to be monitored.

A BSI episode will be defined as HA BSI episode, if the date of onset will be after three calendar days of the hospital admission (date of admission = day one) or within three calendar days after a discharge from a healthcare facility (date of discharge = day one). A BSI episode will be defined as hospital-onset HA-BSI episode, if the date of onset will be after three calendar days of the hospital admission (date of admission = day one) and a BSI episode will be defined as an imported HA-BSI episode, i.e. episodes with readmission for BSI, if the date of onset is within three calendar days after a discharge from a healthcare facility (date of discharge = day one).

Community-associated (CA) episode will be defined as a BSI episode in non-hospitalised patients or patients hospitalised (but not transferred from another healthcare facility) within three calendar days after the date of onset.

3.5. Variables to be collected

The number and types of variables to be collected, as outlined in this protocol, has been reduced compared to previous versions and has been aligned more closely to the structure proposed in the "TESSy Reporting Protocol for Electronic Health Record-based surveillance of Bloodstream Infections (EHR-BSI), version 0.1". Nonetheless, this protocol does list a larger number of variables than that proposed in the TESSy Reporting Protocol as the intention is to anticipate future needs and developments of the EHR surveillance system.
The TESSy Reporting Protocol for EHR-BSI (version 0.1) is accompanied by a metadata set "to support the timely and complete reporting of key information for surveillance of bloodstream infections at local, regional/national and European level by providing flexible options for uploading aggregated or case-based EHR-BSI data to ECDC". In the reporting protocol, the variables have been divided into five datasets in hierarchical levels, which can be divided into aggregated and case-based reporting sets (case-based reporting includes aggregated denominators and other items). The $-sign below indicates the hierarchical relations between the levels, and the relation between levels is indicated with RecordId-ParentId-pairs. These are the five datasets and their variables:

1. *Surveillance type and hospital-related dataset (named as ´EHRBSI´ level of reporting in the metadata): ´EHRBSI´ level is mandatory to be used for all reporting of EHRBSI data, case-based as well as aggregated. This level includes variables from three different groups:*
    a. *Common TESSy variables (referring to the structure of the relational CSV/XML files)*
        i. *Record Identifier (mandatory)*
        ii. *Record type (mandatory)*
        iii. *Record type version*
        iv. *Subject (mandatory)*
        v. *Status (mandatory)*
        vi. *Data source (mandatory)*
        vii. *Reporting country (mandatory)*
        viii. *Date used for statistics (mandatory)*
    b. *Variables on hospital and surveillance system characteristics*
        i. *Hospital identifier*
        ii. *Laboratory code*
        iii. *Geographical location*
        iv. *Hospital size*
        v. *Hospital type*
        vi. *Current degree of automation of surveillance of HA-BSI*
        vii. *Level of data aggregation*

viii. *Definition of duration of BSI episode*
ix. *Terminology / classification system in use for clinical data in EHRs*
x. *Specification of the terminology / classification system in use for clinical data in EHRs*
xi. *Terminology / classification system in use for microbiological data in EHRs*
xii. *Specification of the terminology / classification system in use for microbiological data in EHRs*

c. *Variables on high-level aggregated indicators and denominators*
i. *Number of blood culture sets*
ii. *Number of discharges (or admissions) per surveillance period*
iii. *Number of patient-days per surveillance period*
iv. *Estimated proportion of the national or regional population covered by the surveillance*
v. *Number of hospital-onset HA-BSIs*
vi. *Number of imported HA-BSIs*
vii. *Number of total BSIs*

2. *Denominator dataset (aggregated and case-based data) (named as "EHRBSI$Denom" level of reporting in the metadata): ´EHRBSI$Denom´ is optional and may be used together with ´EHRBSI' if reporting data at hospital unit level. This level includes variables from two different groups:*
   a. *Common TESSy variables (referring to the ´EHRBSI´ tables)*
      i. *Record Identifier (mandatory)*
      ii. *Parent Identifier (mandatory, linking to EHRBSI RecordID)*
   b. *Variables for stratified aggregated indicators and denominators*
      i. *End date of this surveillance period (mandatory)*
      ii. *Start date of this surveillance period (mandatory)*
      iii. *Unit Identifier*
      iv. *Specialty of the Unit (Ward)*
      v. *Number of discharges (or admissions) per surveillance period per selected stratification*
      vi. *Number of patient-days per surveillance period per selected stratification*
      vii. *Number of hospital-onset HA-BSIs per selected stratification*
      viii. *Number of imported HA-BSIs per selected stratification*
      ix. *Number of total BSIs per selected stratification*
3. *Information on patient's dataset (case-based data) (named as "EHRBSI$Patient" level of reporting in the metadata): ´EHRBSI$Patient´ is optional and may be used together with ´EHRBSI' if reporting case-based data on BSIs and is used to report information related to the patient. This level includes variables from two different groups:*
   a. *Common TESSy variables (referring to the ´EHRBSI´ table)*
      i. *Record Identifier (mandatory)*
      ii. *Parent Identifier (mandatory, linking to EHRBSI RecordID)*
   b. *Variables for patient information*
      i. *Unit Identifier*
      ii. *Specialty of the Unit (Ward)*
      iii. *Consultant/Patient specialty*
      iv. *Patient counter*
      v. *Age*
      vi. *Gender*
      vii. *Origin of patient*
      viii. *Date of hospital admission*
      ix. *Date of hospital discharge*
      x. *Outcome*
      xi. *Primary code for hospital discharge or admission*
      xii. *Primary code label of admission event of the patient*
      xiii. *Code system of the primary code of the admission event of the patient*
      xiv. *Specification of the code system of the primary code of the admission event of the patient*
      xv. *Code system version of the primary code of the admission event of the patient*
      xvi. *Previous admission to a healthcare facility*

4. *Isolate-based dataset (isolate-based data) (named as "EHRBSI$Patient$Isolate" level of reporting in the metadata): ´EHRBSI$Patient$Isolate' is optional and may be used together with ´EHRBSI' and ´EHRBSI$Patient´ if reporting case-based data on BSIs and is used to report information related to the microbiological sample/isolate. This level includes variables from two different groups:*
    a. *Common TESSy variables (referring to the EHRBSI$Patient)*
        i. *Record Identifier (mandatory)*
        ii. *Parent Identifier (mandatory, linking to EHRBSI$Patient RecordID)*
    b. *Variables for the information on the isolate*
        i. *Date of specimen collection (mandatory)*
        ii. *Laboratory code*
        iii. *Isolate Identifier*
        iv. *Code of the microorganism responsible for the BSI episode*
        v. *Code label of the microorganism responsible for the BSI episode*
        vi. *Code system that includes the code of the microorganism responsible for the BSI episode*
        vii. *Specification of the code system that includes the code of the microorganism responsible for the BSI episode*
        viii. *Code system version that includes the code of the microorganism responsible for the BSI episode*
5. *AMR profiles of isolates dataset (isolate-based data) (named as "EHRBSI$Patient$Isolate$Res" level of reporting in the metadata): ´EHRBSI$Patient$Isolate$Res' is optional and may be used together with ´EHRBSI', ´EHRBSI$Patient´ and ´EHRBSI$Patient$Isolate´ if reporting case-based data on BSIs including antimicrobial resistance results. This level is used to report information related to the antimicrobial susceptibility testing of the microbiological sample/isolate. The level and all variables are optional, also for case-based reporting. This level includes variables from two different groups:*
    a. *Common TESSy variables (referring to the ´EHRBSI$Patient$Isolate table*
        i. *Record Identifier (mandatory)*
        ii. *Parent Identifier (mandatory, linking to EHRBSI$Patient$Isolate RecordID)*
    b. *Variables for the results on the antimicrobial susceptibility testing*
        i. *Antibiotic code*
        ii. *SIR*
        iii. *PCR mec-gene*
        iv. *PBP2a-agglutination*
        v. *ESBL present*
        vi. *Carbapenemases*
        vii. *Zone value*
        viii. *Interpretation of zone test*
        ix. *MIC sign*
        x. *MIC value*
        xi. *Interpretation of MIC test*
        xii. *Gradient strip sign*
        xiii. *Gradient strip value*
        xiv. *Interpretation of the gradient strip test*
        xv. *Disk load*
        xvi. *Reference Guidelines SIR*

Under the mandatory variable to be reported ´data source´, within the "Surveillance type and hospital-related dataset", the investigators should identify which data source the variable (or group of variables) will be collected from. In cases where a variable is available in two or more data sources, hierarchical rules should be included to decide which data source the variable will be collected from in cases of divergent or missing information.

→ study sites/countries to specify:
1. The current degree of availability of each one of the different variables to be collected (feasibility to collect the variables included in the generic protocol or adapt their variables to project definitions/categories/values). What variables can be realistically collected in the short, mid and long term. What leverages could be used to boost the process?
2. The data source of origin for each variable (group of variables)
3. The feasibility of creating and collecting those missing variables during the timeframe of the study

3.5.1. Data (variables) to be transferred to CRPP from microbiology laboratories

The following set of variables with respective coding will be used for the submission of structured BSI and AMR data to the CRPP from all microbiology laboratories serving Slovenian acute care hospitals. When relevant for submission of data to Tessy/EpiPulse, variables' numbers and names listed above in theder chapter "3.5. Variables to be collected" are given also. Some coding lists are provided in Slovenian language.

Variable name	**1 - EMŠO**
Variable type	Numeric
Comment	A unique personal identifier of a Slovenian citizen.
Variable name	**2 - KZZ**
Variable type	Numeric
Comment	The number of a health insurance card, which is a document for exercising rights from mandatory and voluntary health insurance in Slovenia.
	3 – NonEMŠOId
Variable type	Numeric
Comment	A unique personal identifier of an individual who does not have EMŠO can be obtained by entering respective request into the CRPP/RDSP system.
Variable name	**4 - PatientIndex**
Variable type	Coded value
Comment	Patient ID at the hospital that ordered a test. It stays the same at the same hospital. In a different hospital patient gets different ID.
Variable name	**5 - Gender**
E-SURE & ECDC EHR-based BSI generic protocol	**3.b.vi. Gender**
Variable type	Coded value
Codes	M = male Ž = female
Variable name	**6 - DateOfBirth**
Variable type	Date
Codes	DD.MM.LLLL
Comment	Needed to calculate the age of the patient when the sample was taken.
Variable name	**7 - Age**
E-SURE & ECDC EHR-based BSI generic protocol	**3.b.v. Age**
Description	Age of the patient when sample was taken.

Variable type	Numeric
Comment	Calculated as: DateOfSpecimenCollectin - DateOfBirth
Variable name	**8 - IsolateID**
E-SURE & ECDC EHR-based BSI generic protocol	**4.b.iii. Isolate identifier**
Description	A code for each blood culture/patient isolate, that is unique within the laboratory within a calendar year (lab protocol number).
Variable type	Coded value
Codes	XX/YYYYYYYY
Comment	Within a calendar year, XX represents short identifying code for microbiology laboratory and yyyyyyyy represent consecutive number of tested isolate in particular microbiology laboratory.
Variable name	**9 - DateOfSpecimenReceiptInLab**
Codes	DD.MM.LLLL
Variable name	**10 - LaboratoryId**
E-SURE & ECDC EHR-based BSI generic protocol	**4.b.ii. Laboratory code**
Codes	1080100 = IMI 5050604 = NLZOH KR 5050600 = NLZOH MB 5050601 = NLZOH CE 0001600 = Laboratorij SBNG 5050603 = NLZOH KP 5050608 = NLZOH NM 5050607 = NLZOH MS 1230700 = Laboratorij Klinike Golnik 1445000 = Laboratorij SBSG 5050602 = NLZOH NG
Comment	The codes are composed of RIZDDZ codes (5 figures) and location code (2 figures).
Variable name	**11 - Specimen**
Codes	**Number Sample name** **2000 Hemokultura*** 2120 Kri iz katetra - aerobna steklenička 2220 Kri iz katetra - anaerobna steklenička 2100 Kri v gojišču - aerobna steklenička 2200 Kri v gojišču - anaerobna steklenička 2300 Kri v gojišču - otroška steklenička 2800 Kri za hemokulturo (TBC)

	2110 Periferna kri - aerobna steklenička 2210 Periferna kri - anaerobna steklenička
Comment	If missing use code 2000. We can update the list of samples later.
Variable name	**12 - DateOfSpecimenColection**
E-SURE & ECDC EHR-based BSI generic protocol	**4.b.i. Date of specimen collection**
Codes	DD.MM.LLLL If unavailable code 99.99.9999
Variable name	**13 - HospitalId**
E-SURE & ECDC EHR-based BSI generic protocol	**1.b.i. Hospital identifier**
Variable type	Numeric
Codes	06001 = University Medical Centre (UMC) Ljubljana 10481 = Institute of Oncology 10001 = General hospital (GH) Trbovlje 04071 = GH Jesenice 04031 = Hospital for Gynecology and Obstetrics Kranj 08051 = UMC Maribor 07644 = GH Ptuj 02727 = GH Celje 00128 = GH Brežice 09601 = Hospital Topolšica 00016 = GH Nova Gorica 03821 = GH Izola 00374 = GH Novo mesto 08664 = GH Murska Sobota 12307 = Hospital Golnik 14450 = GH Slovenj Gradec
Comment	Codes present the RIZDDZ number.
Variable name	**14 - HospitalUnitID**
E-SURE & ECDC EHR-based BSI generic protocol	**3.b.ii. Specialty of the Unit (ward)**
Codes	INTMED = Internal Medicine PEDS = Pediatrics/neonatal PEDSICU = Pediatrics/neonatal ICU SURG = Surgery ONCOL = Haematology/Oncology OBGYN = Obstet./Gynaec ICU = Intensive Care Unit ED = Emergency Department URO = Urology Ward INFECT = Infectious Disease Ward O = other UNK = Unknown

Comment	Codes will be upgraded in LIS. Variable type and codes may be different than currently proposed.
Variable name	**15 - PatientType**
E-SURE & ECDC EHR-based BSI generic protocol	**3.b.vii. Origin of patient**
Code (ECDC)	INPAT = admitted to hospital OUTPAT = outpatient O = other (e.g. emergency room, dialisis, day hospital care) UNK = unknown
Comment	Codes will be upgraded in LIS. Variable type and codes may be different than currently proposed.
Variable name	**16 - DateOfHospitalisation**
E-SURE & ECDC EHR-based BSI generic protocol	**3.b.viii. Date of ospital admission**
Codes	DD.MM.LLLL If unavailable code 99.99.9999
Variable name	**17 - Pathogen**
E-SURE & ECDC EHR-based BSI generic protocol	**4.b.iv. Code of the microorganism responsible for the BSI episode**

Codes

NCBI coded value	*Pathogen*
354276	*Enterobacter cloacae complex*
562	*Escherichia coli*
286	*Pseudomonas aeruginosa*
1280	*Staphylococcus aureus*
1313	*Streptococcus pneumoniae*
134375	*Achromobacter spp.*
85698	*Achromobacter xylosoxidans*
187327	*Acidaminococcus intestini*
106648	*Acinetobacter bereziniae*
29430	*Acinetobacter haemolyticus*
28090	*Acinetobacter lwoffii*
108980	*Acinetobacter ursingii*
544580	*Actinomyces oris*
59505	*Actinotignum (Actinobaculum) schaalii*
1872146	*Actinotignum spp.*
1377	*Aerococcus viridans*
648	*Aeromonas caviae*
644	*Aeromonas hydrophila*
214856	*Alistipes finegoldii*
28264	*Arcanobacterium haemolyticum*

1383	*Atopobium rimae*
1397	*Bacillus licheniformis*
1408	*Bacillus pumilus*
1428	*Bacillus thuringiensis*
674529	*Bacteroides faecis*
817	*Bacteroides fragilis*
204516	*Bacteroides massiliensis*
29523	*Bacteroides spp.*
818	*Bacteroides thetaiotaomicron*
820	*Bacteroides uniformis*
216816	*Bifidobacterium longum*
35833	*Bilophila wadsworthia*
33889	*Brevibacterium casei*
1701	*Brevibacterium spp.*
197	*Campylobacter jejuni*
57706	*Citrobacter braakii*
545	*Citrobacter diversus (koseri)*
67824	*Citrobacter farmeri*
1896336	*Citrobacter spp.*
1496	*Clostridioides difficile*
1492	*Clostridium butyricum*
1529	*Clostridium cadaveris*
1531	*Clostridium clostridiiforme*
154046	*Clostridium hathewayi*
1547	*Clostridium ramosum*
1506	*Clostridium spp.*
1559	*Clostridium tertium*
144183	*Corynebacterium afermentans afermentans*
169292	*Corynebacterium aurimucosum*
39791	*Corynebacterium glucuronolyticum*
156978	*Corynebacterium imitans*
38301	*Corynebacterium minutissimum*
57171	*Corynebacterium mucifaciens*
1720	*Corynebacterium species*
1747	*Cutibacterium (Propionibacterium) acnes*
39950	*Dialister pneumosintes*
84112	*Eggerthella (Eubacterium) lentum*
61645	*Enterobacter asburiae*
881260	*Enterobacter bugandensis*
37734	*Enterococcus casseliflavus*
1351	*Enterococcus faecalis*
1352	*Enterococcus faecium*

938288	*Fenollaria massiliensis*
292800	*Flavonifractor plautii (Clostridium orbiscindens)*
859	*Fusobacterium necrophorum*
851	*Fusobacterium nucleatum*
860	*Fusobacterium periodonticum*
1379	*Gemella haemolysans*
29391	*Gemella morbillorum*
46124	*Granulicatella adiacens*
727	*Haemophilus influenzae*
571	*Klebsiella oxytoca*
244366	*Klebsiella variicola*
1597	*Lacticaseibacillus (Lactobacillus) paracasei*
1613	*Lactobacillus fermentum*
1596	*Lactobacillus gasseri*
1360	*Lactococcus lactis subsp. lactis*
83655	*Leclercia adecarboxylata*
1639	*Listeria monocytogenes*
34059	*Moraxella atlantae*
480	*Moraxella (Branhamella) catarrhalis*
34062	*Moraxella osloensis*
582	*Morganella morganii*
487	*Neisseria meningitidis*
90245	*Oligella urethralis*
58172	*Paenibacillus spp.*
521520	*Paenibacillus urinaris*
1505	*Paeniclostridium (Clostridium) sordellii*
823	*Parabacteroides distasonis*
823	*Parabacteroides distasonis*
33033	*Parvimonas (Micromonas) micra*
54005	*Peptoniphilus harei*
33030	*Peptoniphilus indolicus*
1478	*Peribacillus (Bacillus) simplex*
821	*Phocaeicola (Bacteroides) vulgatus*
322095	*Porphyromonas somerae*
28131	*Prevotella intermedia*
28132	*Prevotella melaninogenica*
210425	*Proteus hauseri*
183417	*Proteus mirabilis*
158850	*Providencia spp.*
589	*Providencia stuartii*
78327	*Pseudomonas mosselii*
306	*Pseudomonas spp.*

	316	*Pseudomonas stutzeri*
	190721	*Ralstonia insidiosa*
	575	*Raoultella planticola*
	1873496	*Raoultella spp.*
	599	*Salmonella spp.*
	614	*Serratia liquefaciens*
	615	*Serratia marcescens*
	84109	*Slackia (Eubacterium) exigua*
	29379	*Staphylococcus auricularis*
	29382	*Staphylococcus cohnii*
	1282	*Staphylococcus epidermidis*
	246432	*Staphylococcus equorum*
	1283	*Staphylococcus haemolyticus*
	1290	*Staphylococcus hominis*
	45972	*Staphylococcus pasteuri*
	170573	*Staphylococcus pettenkoferi*
	33028	*Staphylococcus saccharolyticus*
	29385	*Staphylococcus saprophyticus*
	1295	*Staphylococcus schleiferi*
	29387	*Staphylococcus spp.*
	1292	*Staphylococcus warneri*
	40324	*Stenotrophomonas maltophilia*
	1328	*Streptococcus anginosus*
	1329	*Streptococcus canis*
	76860	*Streptococcus constellatus*
	1302	*Streptococcus gordonii*
	313439	*Streptococcus massiliensis*
	28037	*Streptococcus mitis*
	1303	*Streptococcus oralis*
	1318	*Streptococcus (parasanguis) parasanguinis*
	1314	*Streptococcus pyogenes (skupina A)*
	1304	*Streptococcus salivarius*
	1305	*Streptococcus sanguinis*
	1349	*Streptococcus uberis*
	1343	*Streptococcus vestibularis*
	1661	*Trueperella (Arcanobacterium) pyogenes*
	29466	*Veillonella parvula*
	343874	*Wautersiella falsenii*
Comment	For pathogen we use NCBI codes.	
Variable name	**18 - PathogenCriticalInfo**	

E-SURE & ECDC EHR-based BSI generic protocol	**5.b.iv. PBP2a-agglutination,** **5.b.v. ESBL present,** **5.b.vi. Carbapenemases**
Codes	**Coded value** **Pathogen critical info** 000 - MRSA CAM - CA-MRSA 001 - ESBL+ 017 - CRAb 018 - CRAb-CP 007 - CRE 008 - CRE-CPE 013 - CPE 015 - CRPs 016 - CRPs-CP VRE - VRE
Variable name	**19 - AntibioticDD**
E-SURE & ECDC EHR-based BSI generic protocol	**5.b.i Antibiotic code**

Codes

Coded value	Antibiotic - disk difusion
AN-30	amikacin
AN-30ur	amikacin - okužba izvira iz sečil
AN-30so	amikacin - sistemska okužba
AMXp	amoksicilin paranteralni
AMC-30u	amoksicilin+klavulanska kislina
AMC-3	amoksicilin+klavulanska kislina
AMC-30	amoksicilin+klavulanska kislina
AMC-30p	amoksicilin+klavulanska kislina paranteralni
AMX	amoksicillin
AM-2	ampicilin
AM-2o	ampicilin
AM-10	ampicilin
SAM-20	ampicilin+sulbaktam
AZM-15	azitromicin
ATM-30	aztreonam
P1-BL	betalaktamski presejalni disk
CFR-30	cefadroksil
CEC-30	cefaklor
CZ-30	cefazolin
CZ-30ur	cefazolin - okužba izvira iz sečil
FEP-30	cefepim
FDC-30	cefiderokol
CFM-5	cefiksim

FOX-30	cefoksitin	
FOC 230	cefoksitin+kloksacilin (LCH)	
CTX-5	cefotaksim	
CTH	cefotaksim	
CTX-30	cefotaksim	
CTX-30m	cefotaksim - meningealni kriterij	
CTX-5m	cefotaksim - meningealni kriterij	
CTX30	cefotaksim (ROSCO)	
CPD-10	cefpodoksim proksetil	
C/T	ceftalozan+tazobactam	
CPT-30	ceftarolin	
CPT-5	ceftarolin	
CPT-5pn	ceftarolin (pljučnica)	
CAZ-30	ceftazidim	
CAZ-10	ceftazidim	
CZA-14	ceftazidim+avibaktam	
CAZ/CLA	ceftazidim+klavulanska kislina	
CTB-30	ceftibuten	
CTB-30ur	ceftibuten - okužba izvira iz sečil	
C/T-40	ceftolozan+tazobaktam	
CRO-30	ceftriakson	
CRO-30m	ceftriakson - meningealni kriterij	
CXM-30	cefuroksim-oralni	
CXM-30p	cefuroksim-parenteralni	
NOR-10c	ciprofloksacin	
CIP-5	ciprofloksacin	
PEF-5c	ciprofloksacin	
D-30	doksiciklin	
Te-30d	doksiciklin	
DOR-10	doripenem	
E-15	eritromicin	
ETP-10	ertapenem	
FOS-200	fosfomicin	
FFL-50	fosfomicin	
FOS-200p	fosfomicin - parenteralni	
FA-10	fucidinska kislina	
GM-10	gentamicin	
GM-15	gentamicin	
GM-10ur	gentamicin - okužba izvira iz sečil	

GM-10so	gentamicin - sistemska okužba	
GM-30	gentamicin HL	
GM-120	gentamicin HL	
IPM-10	imipenem	
I/R	imipenem+relebaktam	
CLR-15	klaritromicin	
CC-2	klindamicin	
C-30	kloramfenikol	
CL-10	kolistin	
SYN-15	kvinupristin-dalfopristin	
LVX-5	levofloksacin	
LZD-10	linezolid	
MEC-10	mecilinam	
MEM-10	meropenem	
MEM-10m	meropenem - meningealni kriterij	
M/V	meropenem+vaborbaktam	
MTZ-5	metronidazol	
MI-30	minociklin	
MXF-5	moksifloksacin	
MUP-200	mupirocin	
NA-30	nalidiksna kislina	
NET-10	netilmicin	
FM-100	nitrofurantoin	
NI-30	nitroksolin	
NOR-10	norfloksacin	
OFX-5	ofloksacin	
OX-1	oksacilin	
FOX-30ox	oksacilin	
P-opt	optohin	
PEF-5	pefloksacin	
PGL	penicilin	
OX-1P	penicilin	
P-10	penicilin	
PIP-100	piperacilin	
PIP-30	piperacilin	
TZP-36	piperacilin+tazobaktam	
P-1	presejalni disk za beta-laktame	
P-1m	presejalni disk za beta-laktame - meningealni kriterij	
RA-5	rifampicin	

ROX-30	roksitromicin	
S-10	streptomicin	
S-300	streptomicin HL	
G-25	sulfonamidi	
TEC-30	teikoplanin	
TEL-15	telitromicin	
TEM-30	temocilin	
TEM-30ur	temocilin - okužba izvira iz sečil	
Te-30	tetraciklin	
TGC-15	tigeciklin	
TIC-75	tikarcilin	
TIM-85	tikarcilin+klavulanska kislina	
NN-10	tobramicin	
NN-10ur	tobramicin - okužba izvira iz sečil	
NN-10so	tobramicin - sistemska okužba	
TMP-5	trimetoprim	
SXT-25	trimetoprim+sulfametoksazol	
VA-30	vankomicin	
VA-5	vankomicin	

Variable name	**20 - AntibioticMIC**
E-SURE & ECDC EHR-based BSI generic protocol	**5.b.ix. MIC sign**

Codes

Coded value	Antibiotic - MIC
AK	amikacin
AKur	amikacin - okužba izvira iz sečil
AKso	amikacin - sistemska okužba
AC	amoksicilin
ACm	amoksicilin - meningealni kriterij
ACp	amoksicilin - parenteralni nemening.kriterij
XLu	amoksicilin+klavulanska kislina
XL	amoksicilin+klavulanska kislina
XLp	amoksicilin+klavulanska kislina paranteralni
AM	ampicilin
AMm	ampicilin - meningealni kriterij
AB	ampicilin+sulbaktam
AZ	azitromicin
AT	aztreonam
CF	cefaklor

CX	cefaleksin
CFZ	cefazolin
CFZur	cefazolin - okužba izvira iz sečil
PML	cefepim
PMH	cefepim
FDC	cefiderokol
IX	cefiksim
FX	cefoksitin
CTH	cefotaksim
CTL	cefotaksim
CTLm	cefotaksim - meningealni kriterij
CTLp	cefotaksim - paranteralni nemening. kriterij
PX	cefpodoksim
CPT	ceftarolin
CPT-pn	ceftarolin (pljučnica)
TZ	ceftazidim
CB	ceftibuten
CBur	ceftibuten - okužba izvira iz sečil
C/T	ceftolozan+tazobaktam
TXL	ceftriakson
TXH	ceftriakson
TXLm	ceftriakson - meningealni kriterij
XM	cefuroksim
XMp	cefuroksim parenteralni
CI	ciprofloksacin
CIm	ciprofloksacin - meningealni kriterij
DAL	dalbavancin
DPC	daptomicin
DC	doksiciklin
EM	eritromicin
ETP	ertapenem
CT/CTL	ESBL - cefotaksim
TZ/TZL	ESBL - ceftazidim
FM	fosfomicin
FMp	fosfomicin - parenteralni
FU	fusidna kislina
GML	gentamicin
GMLur	gentamicin - okužba izvira iz sečil
GMLso	gentamicin - sistemska okužba

GMH	gentamicin HL
IP	imipenem
I/R	imipenem+relebaktam
CH	klaritromicin
CM	klindamicin
CL	kloramfenikol
CO	kolistin
QDA	kvinupristin-dalfopristin
RP	kvinupristin/dalfopristin
LE	levofloksacin
LZ	linezolid
MP	meropenem
MEm	meropenem - meningealni kriterij
MZ	metronidazol
MC	minociklin
MX	moksifloksacin
MU	mupirocin
NA	nalidiksna kislina
NC	netilmicin
NI	nitrofurantoin
NX	norfloksacin
OF	ofloksacin
OX	oksacilin
PE	pefloksacin
PGH	penicilin
PGL	penicilin
PP	piperacilin
PTc	piperacilin+tazobaktam
RIL	rifampicin
RIH	rifampicin
SC	spektinomicin
SML	streptomicin
SMH	streptomicin HL
SU	sulfadiazin
TP	teikoplanin
TMO	temocilin
TMOur	temocilin - okužba izvira iz sečil
TC	tetraciklin
TGC	tigeciklin

	TI	tikarcilin
	TLc	tikarcilin+klavulanska kislina
	TM	tobramicin
	TMur	tobramicin - okužba izvira iz sečil
	TMso	tobramicin - sistemska okužba
	TR	trimetoprim
	TS	trimetoprim+sulfametoksazol
	VA	vankomicin
Variable name	**21 – SIR & Interpretation of zone and MIC value**	
E-SURE & ECDC EHR-based BSI generic protocol	**5.b.ii. SIR** **5.b.viii. Interpretation of zone test** **5.b.xi. Interpretation of MIC test**	
Codes	**Coded value**	**Interpretation**
	WT	DIVJI TIP
	IR	INTRINZIČNO ODPOREN
	NWT	NI DIVJI TIP
	NI	NI INTERPRETACIJE
	LLR	NIZKA STOPNJA ODPORNOSTI
	S-DD	OBČUTLJIV ODVISNO OD DOZE
	I	OBČUTLJIV, POVEČANA IZPOSTAVLJENOST
	S	OBČUTLJIV, STANDARDNI REŽIM ODMERJANJA
	R	ODPOREN
	(S)	POGOJNO OBČUTLJIV
	(R)	PRISOTNI MEHANIZMI ODPORNOSTI
	VI	VARIABILNA INTERPRETACIJA
	HLR	VISOKA STOPNJA ODPORNOSTI
	HR	VISOKO ODPOREN
Variable name	**22 - ResultZoneValue**	
E-SURE & ECDC EHR-based BSI generic protocol	**5.b.vii. Zone value**	
Codes	0-70	
Comment	Value in mm. Result has to be connected with Antibiotic – disk difusion.	
Variable name	**23 - ResultMICValue**	
E-SURE & ECDC EHR-based BSI generic protocol	**5.b.x. MIC value**	
Codes	<,> and numeric value 0,001-2048	
Comment	Value in mg/L. Result has to be connected with Antibiotic – MIC.	

3.5.2. Data (variables) to be transferred to CRPP from hospitals

The following set of variables with coding will be used for the submission of structured data to the CRPP from all Slovenian acute care hospitals. When relevant for submission of data to Tessy/EpiPulse, variables' numbers and names listed above under chapter "3.5. Variables to be

collected" are given also. Some coding lists are provided in Slovenian language and for some Slovenian coding lists references are given. For the purpose of EHR-based BSI and AMR surveillance only the following variables for individuals with microbiologically confirmed BSI will be used:

Variable name	**1 - EMŠO**
Variable type	Numeric
Comment	A unique personal identifier of a Slovenian citizen.
Variable name	**2 - KZZ**
Variable type	Numeric
Comment	The number of a health insurance card, which is a document for exercising rights from mandatory and voluntary health insurance in Slovenia.
	3 – NonEMŠOId
Variable type	Numeric
Comment	A unique personal identifier of an individual who does not have EMŠO can be obtained by entering respective request into the CRPP/RDSP system.
Variable name	**4 - HospitalId**
E-SURE & ECDC EHR-based BSI generic protocol	**1.b.i. Hospital identifier** also basis for information on: 1.b.iii. Geographical location 1.b.iv. Hospital size 1.b.v. Hospital type
Variable type	Coded value
Codes	06001 = University Medical Centre (UMC) Ljubljana 10481 = Institute of Oncology 10001 = General hospital (GH) Trbovlje 04071 = GH Jesenice 04031 = Hospital for Gynecology and Obstetrics Kranj 08051 = UMC Maribor 07644 = GH Ptuj 02727 = GH Celje 00128 = GH Brežice 09601 = Hospital Topolšica 00016 = GH Nova Gorica 03821 = GH Izola 00374 = GH Novo mesto 08664 = GH Murska Sobota 12307 = Hospital Golnik 14450 = GH Slovenj Gradec
Comment	Codes present numbers from the National Registry of Healthcare Providers and Healthcare workers (Slo.: Register izvajalcev zdravstvene dejavnosti in delavcev v zdravstvu – RIZDDZ[22]).

[22] Nacionalni inštitut za javno zdravje (NIJZ). Register izvajalcev zdravstvene dejavnosti in delavcev v zdravstvu. NIJZ, 2025. Available at: https://nijz.si/podatki/podatkovne-zbirke-in-raziskave/izvajalci-zdravstvene-dejavnosti/

	Hospital identification provides basis for additional information about geographical location of hospital, hospital size and type.
Variable name	**5 - WardId**
E-SURE & ECDC EHR-based BSI generic protocol	**3.b.i. Unit identifier**
Variable type	Coded value
Comment	Codes present numbers from the National Registry of Healthcare Providers and Healthcare workers (Slo.: Register izvajalcev zdravstvene dejavnosti in delavcev v zdravstvu – RIZDDZ[22]). Hospital identification provides basis for additional information about geographical location of hospital, hospital size and type.
Variable name	**6 – TypeofHealthcareService**
E-SURE & ECDC EHR-based BSI generic protocol	**3.b.ii. Specialty of the Unit (Ward)**
Variable type	Coded value
Comment	Codes present numbers from the National Registry of Type of Healthcare Service (Slo.: Šifrant vrst zdravstvene dejavnosti – VZD[23]).
Variable name	**7 - DateOfAdmissionToHospital**
Variable type	Date
E-SURE & ECDC EHR-based BSI generic protocol	**3.b.viii. Date of hospital admission**
Codes	DD.MM.LLLL
Variable name	**8 – HospitalAdmissionTime**
Variable type	Time
Codes	HH.MM
Comment	Time is recorded in hours (HH) and minutes (MM).
Variable name	**9 - DateOfAdmissionToWard**
Variable type	Date
Codes	DD.MM.LLLL
Variable name	**10 – WardAdmissionTime**
Variable type	Time
Codes	HH.MM
Comment	Time is recorded in hours (HH) and minutes (MM).
Variable name	**11 - DateOfDischargeFromWard**
Variable type	Date
Codes	DD.MM.LLLL
Variable name	**12 – DischargeTimeFromWard**
Variable type	Time

[23] Nacionalni inštitut za javno zdravje (NIJZ). Šifrant vrst zdravstvene dejavnosti. NIJZ, 2025. Available at: https://nijz.si/podatki/klasifikacije-in-sifranti/sifrant-vrst-zdravstvene-dejavnosti-vzd/

Codes	HH.MM
Comment	Time is recorded in hours (HH) and minutes (MM).
Variable name	**13 - DateOfDischargeFromHospital**
Variable type	Date
E-SURE & ECDC EHR-based BSI generic protocol	**3.b.ix. Date of hospital discharge**
Codes	DD.MM.LLLL
Variable name	**14 – DischargeTimeFromHospital**
Variable type	Time
Codes	HH.MM
Comment	Time is recorded in hours (HH) and minutes (MM).

In the case of transfer of patients within hospital, dates and times of admission and discharge from different wards as well as type of healthcare service of particular wards will be recorded.

3.5.3. Data (variables) about deaths to be submitted to CRPP by healthcare providers

The list of variables with coding that will be used for the submission of structured data about all deaths from all healthcare providers in Slovenia to the CRPP together with instructions for data submission is available in the document "Instructions for using the eDeaths application - Information solution for implementing the digitization of the process of reporting the causes of death" on the website of the NIJZ[24].

For the purpose of EHR-based BSI and AMR surveillance only the following variables for individuals with microbiologically confirmed BSI will be used:

- EMŠO
- KZZ
- NonEMŠOId
- HospitalId
- DateofDeath
- TimeofDeath
- DeathCauses (MKB-10 codes)

3.5.4. Data (variables) to be harvested from CRPP to Communicable Diseases Database

Data harvested from CRPP to the CDD for EHR-based BSI and AMR surveillance purposes will include all variables with respective coding listed under chapters 3.5.1, 3.5.2 and 3.5.3.

[24] Nacionalni inštitut za javno zdravje. Navodila za uporabo aplikacije eSmrti - Informacijska rešitev za izvajanje digitalizacije procesa poročanja o vzrokih smrti. NIJZ, 2024. Available from: https://nijz.si › wp-content › uploads › 2024/06

3.5.1. Data (variables) to be submitted to Tessy/EpiPulse

The following data (variables) from the list proposed in the generic protocol will be submitted to Tessy/EpiPulse. The following fonts are used to indicate the planned data source:

- the variables where the data source for CRPP and/or CDD will be microbiology laboratories are listed in bold text,
- the variables where the data source for CRPP and/or CDD will be hospitals are underlined,
- the variables to be added to the BSI and AMR surveillance data set within CDD in the Communicable Diseases Centre at the NIJZ for BSI and AMR surveillance data to be submitted to Tessy/EpiPulse according to respective ECDC reporting protocol are given in italic and
- variables that will not be available according to this version of the protocol are crossed over.

In cases where a variable will be available in two or more data sources, hierarchical rules are added to decide which data source the variable will be collected from in cases of divergent or missing information

1. Surveillance type and hospital-related dataset:
    a. Common TESSy variables
        i. Record Identifier (mandatory)
        ii. Record type (mandatory)
        iii. Record type version
        iv. Subject (mandatory)
        v. Status (mandatory)
        vi. Data source (mandatory)
        vii. Reporting country (mandatory)
        viii. Date used for statistics (mandatory)
    b. Variables on hospital and surveillance system characteristics
        i. **Hospital identifier** (hospital data to be used as a primary source)
        ii. Laboratory code
        iii. Geographical location
        iv. Hospital size
        v. Hospital type
        vi. Current degree of automation of surveillance of HA-BSI
        vii. Level of data aggregation
        viii. Definition of duration of BSI episode
        ix. Terminology / classification system in use for clinical data in EHRs
        x. Specification of the terminology / classification system in use for clinical data in EHRs
        xi. Terminology / classification system in use for microbiological data in EHRs
        xii. Specification of the terminology / classification system in use for microbiological data in EHRs
    c. Variables on high-level aggregated indicators and denominators
        i. Number of blood culture sets
        ii. Number of discharges (or admissions) per surveillance period

iii. *Number of patient-days per surveillance period*
iv. *Estimated proportion of the national or regional population covered by the surveillance*
v. *Number of hospital-onset HA-BSIs*
vi. *Number of imported HA-BSIs*
vii. Number of total BSIs

2. Denominator:
    a. Common TESSy variables (referring to the ´EHRBSI´ tables)
        i. *Record Identifier (mandatory)*
        ii. *Parent Identifier (mandatory, linking to EHRBSI RecordID)*
    b. Variables for stratified aggregated indicators and denominators
        i. *End date of this surveillance period (mandatory)*
        ii. *Start date of this surveillance period (mandatory)*
        iii. Unit Identifier
        iv. Specialty of the Unit (Ward)
        v. *Number of discharges (or admissions) per surveillance period per selected stratification*
        vi. *Number of patient-days per surveillance period per selected stratification*
        vii. *Number of hospital-onset HA-BSIs per selected stratification*
        viii. *Number of imported HA-BSIs per selected stratification*
        ix. Number of total BSIs per selected stratification
3. Information on patient's dataset:
    a. Common TESSy variables (referring to the ´EHRBSI´ table)
        i. *Record Identifier (mandatory)*
        ii. *Parent Identifier (mandatory, linking to EHRBSI RecordID)*
    b. Variables for patient information
        i. Unit Identifier
        ii. Specialty of the Unit (Ward)
        ~~iii. Consultant/Patient specialty~~
        iv. *Patient counter*
        v. Age (hospital data to be used as a primary source)
        vi. Gender (hospital data to be used as a primary source)
        vii. Origin of patient
        viii. Date of hospital admission (hospital data to be used as a primary source)
        ix. Date of hospital discharge
        x. Outcome
        ~~xi. Primary code for hospital discharge or admission~~
        ~~xii. Primary code label of admission event of the patient~~
        ~~xiii. Code system of the primary code of the admission event of the patient~~
        ~~xiv. Specification of the code system of the primary code of the admission event of the patient~~
        ~~xv. Code system version of the primary code of the admission event of the patient~~
        xvi. Previous admission to a healthcare facility
4. Isolate-based dataset:

a. Common TESSy variables (referring to the EHRBSI$Patient)
   i. *Record Identifier (mandatory)*
   ii. *Parent Identifier (mandatory, linking to EHRBSI$Patient RecordID*)
b. Variables for the information on the isolate
   i. **Date of specimen collection (mandatory)**
   ii. **Laboratory code**
   iii. **Isolate Identifier**
   iv. **Code of the microorganism responsible for the BSI episode**
   ~~v. Code label of the microorganism responsible for the BSI episode~~
   vi. ***Code system that includes the code of the microorganism responsible for the BSI episode***
   vii. ***Specification of the code system that includes the code of the microorganism responsible for the BSI episode***
   viii. ***Code system version that includes the code of the microorganism responsible for the BSI episode***

5. AMR profiles of isolates dataset:
   a. Common TESSy variables (referring to the ´EHRBSI$Patient$Isolate table
      i. Record Identifier (mandatory)
      ii. Parent Identifier (mandatory, linking to EHRBSI$Patient$Isolate RecordID)
   b. Variables for the results on the antimicrobial susceptibility testing
      i. **Antibiotic code**
      ii. **SIR**
      ~~iii. PCR mec-gene~~
      iv. P**BP2a-agglutination**
      v. **ESBL present**
      vi. **Carbapenemases**
      vii. **Zone value**
      viii. **Interpretation of zone test**
      ix. **MIC sign**
      x. **MIC value**
      xi. **Interpretation of MIC test**
      ~~xii. Gradient strip sign~~
      ~~xiii. Gradient strip value~~
      ~~xiv. Interpretation of the gradient strip test~~
      ~~xv. Disk load~~
      xvi. ***Reference Guidelines SIR***

The EHR-based BSI and AMR surveillance data, including EARS-Net data are planned to be submitted to Tessy/EpiPulse according to the TESSy Reporting Protocol for Electronic Health Record-based surveillance of Bloodstream Infections (EHR-BSI) and Antimicrobial resistance (AMR) reporting protocols provided by ECDC at the time of submission.

3.6. Granularity of data collected

It is recommended to report case-based data by hospital and with specialty-specific aggregation of denominator data to allow for stratified epidemiological analysis.

BSI data can be reported in both formats, aggregated or case-based, to achieve the primary surveillance objective of estimating the incidence of HA-BSI. This allows those countries that cannot report case-based data to report aggregated data on BSIs at the national, regional, hospital or laboratory level.

Case-based data described in under chapters 3.5.1, 3.5.2 and 3.5.3. will be submitted to the CRPP and harvested from CRPP for BSI and AMR surveillance purposes to the CDD and transferred to Tessy/EpiPulse or stored at the decentralised Slovenian communicable diseases data storage at the NIJZ, accessible to ECDC personnel for EU/EEA level analyses for surveillance purposes.

3.7. Data processing, interoperability and structure

The protocol proposes a BSI EHR-based surveillance system which defines data processing from laboratories and hospitals (and other data sources) into a centralised database to compute indicators for country and EU-wide BSI surveillance. Different countries may choose different data processing depending on the particularities of their data sources and existing surveillance systems (annex 3, section 9.3)
Different possible models are described for the organisation of this data flow that could suit different scenarios. Still, a model where data storage is at the national level and data processes such as standardisation, validation, and indicators calculation can be done at any level (local, regional, National or EU) according to national needs, is the recommended option (annex 3, section 9.3)
Pseudonymisation approaches produced by non-reversible hashing techniques are recommended to ensure that, at least at the hospital/lab level, each individual is associated with a unique and stable identifier. Data will be submitted to ECDC through TESSy/EpiPulse as described in the ECDC Reporting Protocol for EHR-BSI v0.1. The coordination team, with the support of ECDC, will engage with individual countries to define the most suitable approach for data submission taking in consideration possible GDPR constraints (annexe 4, section 9.4).
Some variables (i.e. treatments, pathogens, diagnoses and procedures) will need to be coded using standardised vocabularies. A country specific codification system will be considered compatible if a mapping towards the target vocabulary exists or if it is expected to be developed in the near future. The mapping implementation can be done in iterations, including on the first steps only a subset of codes and defining a roadmap for the mapping of the pending codes. The coordination team will advise and support countries and pilots to choose the best strategy to select and map standards to use (annexe 4, section 9.4).
It is recommended to use the proposed data structure for case-based and aggregated, at local, regional or national level even in cases when only aggregated data is submitted to TESSy. We propose the tabular structure presented in Annexe 5 (section 9.5). This diagram only includes 'raw variables' from which BSI/AMR indicators can be computed. Having this homogenous data collection format at the source of the surveillance network will ensure that the same methodology is applied to all countries.

→ study sites/countries to provide details on data processing, data interoperability, and data structure for BSI (current situation and plans):
1. Data processing option choose by the country to implement the project:
- Existence or not of nationally or regionally centralised databases containing the data required for the protocol.
- Are there particular regulatory limitations for sharing the pseudonymised individual data indicated in the protocol with ECDC?
2. Data interoperability: coding system used, data format and how data will be exchange:
- What are the most widely deployed vocabularies for registering procedures, devices, drugs, diagnosis, microbiology results, signs, symptoms and comorbidities in hospitals and labs?
- Provide information on classification system in use for clinical and microbiological data in EHRs (see variables ClinicalTerminology and MicrobiologicalTerminology in the ECDC Reporting Protocol for EHR-BSI v0.1)
- Are there any mappings to transform local data to international vocabularies (e.g. SNOMED-CT, LOINC, RxNorm, ICD-10 etc)?
3. Data structure used to collect and share data with the coordination team:
- Are some hospitals/labs in the country already using EHR data modelling standards such as the OMOP CDM[19] (The Observational Medical Outcomes Partnership Common Data Model)?

All data sources, variables and coding systems that are planned to be used for EHR-based BSI and AMR surveillance system are described in chapters 3.5.1, 3.5.2 and 3.5.3.

The data flow is described in Figure 1. "Description of communicable diseases data flow from different data sources to the CRPP and to Communicable diseases dataset at the NIJZ, data management within CNB, surveillance data use for different purposes and data transmission to different stakeholders" in chapter 2.3. General country overview.

The current legal framework for communicable diseases surveillance, the Communicable Diseases Act[25] and the Act on Databases in the Field of Health Care[26] address collecting personal or pseudonymised data within Slovenia. By the time we would be able to submit EHR-based BSI and AMR data to Tessy/EPiPulse or provide data for ECDC personnel at the decentralised Slovenian communicable diseases data storage at the NIJZ, this would be done according to legal framework at that time.

4. Data management and analysis

4.1. Type of analysis

In order to accomplish the four surveillance objectives (see section 3.1, aim and objectives), we consider different types of analysis:

- *A retrospective cohort in which patients are followed-up and outcomes recorded over the study period to calculate an incidence rate based on a time-dependent denominator (person-time);*
  OR
- *A retrospective cohort study in which outcomes in patients are recorded and a cumulative incidence is calculated over the study period based on the population denominator at the start of the study period. This study design does not take person-time into account;*
  OR
- *A retrospective cohort where only the number of alerts of single pathogens defined as Emerging microorganisms (see section 3.4.3) or as pan-drug-resistant microorganisms are taken into account (eventually, incidence can be provided if the number of BSI episodes allows).*

→ Study sites/countries to specify the type of analysis they envisage implementing to achieve each of the project objectives (different types of analysis may be required according to feasibility for each objective).

A retrospective cohort in which patients are followed-up and outcomes recorded over the study period to calculate an incidence rate based on a time-dependent denominator (person-time) and a cumulative incidence is calculated over the study period based on the population denominator at the start of the study period will be used for the following objectives:

- to assess the incidence of healthcare-associated (HA) and community-associated (CA) BSI and monitor changes over time,

[25] Državni zbor RS. Zakon o nalezljivih boleznih – ZNB (uradno prečiščeno besedilo) (ZNB-UPB1), Uradni list RS št. 33/2006. Available from: http://www.uradni-list.si/1/objava.jsp?urlid=200633&stevilka=1348

[26] **Državni zbor RS.** Zakon o zbirkah podatkov s področja zdravstvenega varstva (ZZPPZ), Uradni list RS št. 65/2000. Available from: https://www.uradni-list.si/glasilo-uradni-list-rs/vsebina/26736

- to assess mortality for HA and CA BSI and monitor changes over time,

A retrospective cohort where only the number of alerts of single pathogens defined as Emerging microorganisms or as pan-drug-resistant microorganisms are taken into account, will be used for the following objectives:

- to detect and monitor the emergence of pan-drug resistance (PDR) microorganisms causing HA and CA BSI,
- to detect and monitor the emergence of new pathogens causing HA and CA BSI.

4.2. Data extraction

As described in section 3.3 (data collection period), although the aim for the future is to have a real-time single dataset, initially the countries can start working with different datasets and study periods per objective. As mentioned in section 3.3, the protocol envisages that to achieve the objectives of surveillance and alert of possible pan-drug resistance and emerging pathogens (objectives 2 and 3) these are best implemented as real-time, or nearly real-time as possible, mostly using laboratory datasets.

In contrast, achieving the objectives of measuring the incidence of HA-BSI and establishing electronic reporting of AMR according to the EARS-Net protocol (objectives 1 and 4) will benefit by the use of defined study periods and data extractions. Countries will run script(s) to compute the different indicators and this may require using different data sources (e.g. clinical, laboratory, hospitalisation etc) and more complex computations to define episodes and other variables. The data extraction for these objectives will require a download of data from X previous days to define the episodes (see section 3.4, key definitions, episodes definitions), which means that data will need to be extracted for a longer time period than the reporting period. For example, to report results for January to March 2023, data will need to be extracted for both periods before January (e.g., December 2022) and after (e.g. April 2023) the quarter in order to deduplicate episodes and allow data consolidation for key outcomes (e.g. death).

We recommend that sites perform an analysis of the time needed for data consolidation, for example, by comparing the number of BSI episodes in the same fixed period in different data extractions.

→ Study sites/countries to specify how they are planning to perform data extraction by each study objective (periodicity, datasets, data consolidation period, etc…)

As stated in chapter 3.3. Data collection period, data extraction periods for Slovenian EHR-based BSI surveillance reports that would include AMR isolates profiles and for EARS-Net surveillance reports are planned to be quarterly and data extraction periods for alerts about the emergence of PDR microorganisms and new pathogens causing BSI are planned to be near real time.

4.3. Denominator

Two types of denominators can be collected and reported to ECDC, although the provision of hospital rather than population denominators is recommended:

- *Population denominators: related to the population of a region or the catchment population of a hospital, to calculate incidence in general population.*
- *Hospital denominators: to calculate incidence among all the patient admissions. It is collected at the level of ward/hospital/region/country or by patient characteristics (e.g. age groups or sex) and consists of the number of discharges/admissions or of patient-days. Patient-days are the number of days admitted at hospital, counting as a different day from 12 am. Transfer to another hospital is not considered a discharge.*

Study sites/countries can choose to collect denominators for other relevant subgroups, such as age-groups, sex, geographical regions, clinical characteristics etc. for their own use.

→ Study sites/countries to specify if they could have:

- *Population denominators and for which subgroups*
-
- *groups or sex)*

It is planned to obtain and report to ECDC overall Slovenian population denominators including age groups and hospital denominators, numbers of admissions and patient days per surveillance period, overall and by age groups.

4.4. Censoring events (only in case-based analysis)

All individuals (all admitted patients or the entire population) with an episode of BSI will be followed from the start of the observation period (see data collection period, section 3.3) to:

- *Death of any cause (on the date of death).*
- *Discontinuation in the administrative database (i.e., emigration).*
- *End of observation period (see data collection period, section 3.3, depending on the country specific observation period, e.g., monthly or quarterly or others).*

All individuals admitted to hospitals with an episode of BSI will be followed from the start of the observation period to:

- death of any cause (on the date of death),
- discontinuation in the administrative database (i.e., emigration) and
- end of observation period.

4.5. Data checking and validation

The following data checking and data validation should be undertaken before analysis:

- *Identification of inconsistencies.*
- *Checking unusual values and outliers, including alert microorganisms and resistance patterns.*
- *Inclusion/exclusion criteria adherence.*
- *Missing data for essential variables that can lead to exclusion of the records from the analyses.*
- *Missing values, missing clinical details, missing laboratory results.*
- *Duplicate cases and multiple admissions.*
- *Consistency among dates (specimen collection, admission, discharge, death).*

→ Study sites/countries to list data checking and validation items to be performed

We plan the following data checking and data validation before analysis:

- identification of inconsistencies,
- checking unusual values and outliers, including alert microorganisms and resistance patterns,
- missing data for essential variables that can lead to exclusion of the records from the analyses,
- missing values, missing clinical details, missing laboratory results,
- duplicate cases and multiple admissions and
- Consistency among dates (specimen collection, admission, discharge, death).

4.6. Data analysis

4.6.1. Descriptive analysis

A descriptive analysis should be performed each study period including (according availability in each country) age, gender, region (if relevant), previous episodes (before the study period), type of episode (mono/polymicrobial), number of episodes (during the study period), pathogens, outcomes, antibiotic prescription and comorbidities.
Countries should provide a flowchart to describe the total population for which data have been extracted and the subsequent exclusions (including number and reasons) in order to obtain the final data set used for the analysis.

A descriptive analysis is planned to be performed for the whole population of Slovenia and for the whole population of hospitalized patients during surveillance periods. In addition to overall analyses, analyses by hospital, age, type of episode (mono/polymicrobial), number of episodes (during the study period), pathogens and outcomes (deaths) will be performed.

4.6.2. Analysis plan

We recommend starting from individuals instead of isolates; for this, the use of personal identifiers will be required. Even when personal identifiers are not available, results for each one of the project objectives should be provided if at all possible.

Where possible, incidence rates will be computed as the number of new (incident) cases during study follow-up divided by the person-time-at-risk throughout the observation period. Incidence rates will be computed to cover all the objectives which means that HA-BSI incidence, PDR BSI incidence, emergent BSI incidence and EARS-Net pathogens incidence will be computed.

Duplicates from the same patients and same pathogens should be eliminated taking only the first positive blood culture by date of specimen collection for each episode (see section 3.4.4 personal identifiers and data linkage).

Countries could calculate incidence rates for the general population and/or admitted patients (and provide stratified incidences by subgroups) according to the availability of denominators. For each study period, crude incidence rates will be determined by dividing the number of BSI episodes with the general population or admitted patients (sites/countries can additionally choose to calculate incidence by other available subgroups for their own use, e.g., specialities).

When possible, to identify the individuals (case-based analysis), if the denominators are available, it will facilitate countries to estimate incidence rates adjusted by specialties, age-groups or sex. Under these circumstances, incidence rates could also be stratified by patient characteristics or specialities.

→ Study sites/countries to specify which objectives can be tackled and which results can be provided/computed in each case.

It is planned to calculate incidence rates, the number of new (incident) cases during surveillance period divided by the person-time-at-risk (patient days) during surveillance period, for the whole population of Slovenia and overall and by age groups, as well as for individual hospitals, overall and by age groups. Incidence rates will be computed to cover all the objectives: HA-BSI incidence, PDR BSI incidence, emergent BSI incidence and EARS-Net pathogens incidence.

It is also planned to calculate incidence rates for the general population and/or admitted patients during surveillance period and provide stratified incidences by subgroups according to age. For each surveillance period, crude incidence rates for BSI, PDR BSI, emergent BSI and EARS-Net pathogens will be determined by dividing the number of BSI episodes, PDR BSI episodes, emergent BSI episodes and EARS-Net pathogens episodes with the number of individuals in the general population or number of admitted patients.

5. Ethical and data protection considerations

Each surveillance site/country establishing the surveillance system must ensure that they have complied with national ethics committee requirements.

Countries should abide by national data protection legislation and frameworks, specifically those applied to surveillance of communicable disease surveillance and public health.

Each country should comply with national data protection committee requirements to collect, maintain, extract, link, analyse and share surveillance data at the national level. Special considerations may be needed for case-based data, such as pseudo-anonymisation.

Likewise, countries must comply with the GDPR and cross-border data-sharing requirements within Europe. Note that although Article 9 of the GDPR prohibits the processing of data concerning health or personal details (e.g. demography), unless processing is necessary for public health reasons including protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care[20]. This exception applies to surveillance of communicable diseases under EU surveillance such as BSIs.
The data collected as part of the surveillance systems and submitted to ECDC via EpiPulse/TESSy is under:

- *The policy on data submission, access and the use of data in EpiPulse/TESSy[21]*
- *The privacy statement/data protection notice, which describes how ECDC processes and protects personal data particularly in managing and handling external requests[22]*
- *The regulation (EU) 2022/2371 on serious cross-border threats to health (SCBTH) and repealing decision no 1082/2013/EU, Art. 13 and 14[23]*
- *The ECDC mandate as described in the Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control[24]*

⇒ Each study site/ country to describe:

- *The procedures to comply with the national data protection committee (e.g., data sharing approvals, data protection impact assessment)*
- *The database anonymisation processes prior to data transfer to ECDC and the procedures to comply with the GDPR requirements*
- *If data protection approvals are required and if these have been obtained*
- *Send a copy of the data protection committee approval (if relevant)*

The EHR-based BSI and AMR surveillance data will be collected and processed according to Slovenian Communicable Diseases Act[27], Act on Databases in the Field of Health Care[28], Personal Data Protection Act[29] and future Digitalization of Health Care Act that is being prepared at the Ministry of Health and is expected to be passed by the Slovenian parliament in 2025.

We will comply with the General Data Protection Regulation (GDPR) Article 9 and all EHR-based BSI and AMR surveillance data will be processed for public health purposes only, including protecting against serious cross-border threats to health and ensuring high standards of quality and safety of health care within Europe[20].

The data collected for EHR-based BSI and AMR surveillance purposes is planned to be submitted to ECDC via EpiPulse/TESSy or made available at the decentralised Slovenian communicable diseases data storage at the NIJZ, accessible to ECDC personnel for EU/EEA level analyses under:

- the policy on data submission, access and the use of data in EpiPulse/TESSy[21],
- the privacy statement/data protection notice, which describes how ECDC processes and protects personal data particularly in managing and handling external requests[22],
- the regulation (EU) 2022/2371 on serious cross-border threats to health (SCBTH) and repealing decision no 1082/2013/EU, Art. 13 and 14[23] and the ECDC mandate as described in the Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control[24].

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By the time we will be able to submit EHR-based BSI and AMR surveillance data to Tessy/EpiPulse or provide data for ECDC personnel at the decentralised Slovenian communicable diseases data storage at the NIJZ, this will be done according to legal framework at that time.

6. Dissemination and communication of data

Countries are encouraged to disseminate their results according to national schedules and to present these according to national frameworks (e.g. internal geographical units) and priorities (e.g. risk groups). Study site coordinators are responsible for the publication and communication of their results. The list of authors should respect the recommendations of authorship stated by the International Committee of Medical Journal Editors.
Initial results will be discussed with project participant countries and published when relevant after the establishment of the surveillance systems and data has been shared with ECDC.
Publications using data collected through the EHR-BSI project involving multiple countries may be published only after written approval from ECDC after consultation with the national teams, unless the data has entered the public domain or has otherwise been made publicly available. Publications of national or sub-national data that include data reviewed journals with open access[25]. The manuscripts should take into account the ECDC authorship policy[26].

Example of wording on funding

- *The data on xx was originally collected as part of the "Design and implementation of multinational surveillance systems using routinely collected electronic health records in EU/EEA", funded by the European Centre for Disease Prevention and Control through service contracts with the E-Sure Consortium (ECD.14485 and ECD.16697[, and …] implementing framework contract ECDC/2022/003).*

⇒ Each study site/country to describe:

- *Describe how surveillance outputs will be disseminated at national-level*
- *Seek ECDC approval before publication of data funded by ECDC projects*
- *Add appropriate wording on funding to manuscripts*

The Slovenian EHR-based BSI and AMR results are planned to be published on the NIJZ website according to internal procedures for NIJZ surveillance reports.

7. Limitations

Representativeness of the study population (or population under surveillance)
In many countries the BSI surveillance will only be performed in a few hospitals or regions which means that the results obtained will not represent the entire population of the country in terms of socio-demographics, socio-economics or medical characteristics.

Denominators
The availability of the denominators will determine which indicators can be provided at country and EU levels. Some countries can provide hospital denominators and others only population denominators so results at the hospital level will not be possible in all countries. Furthermore, the ability to calculate the incidence by geography (e.g., region), within healthcare facilities (e.g., general or ICU wards) or demography (e.g., by sex or by age group) may differ by sites and countries.
Medical and laboratory practices
We are aware that medical and laboratory practices in performing and processing blood culture (first one and follow-ups) differ across different countries. These facts will likely make the comparability of estimates in different countries or the calculation of pooled indicators (EU-level) complex, hard to explain, with a wide range of variability across countries, and not always possible to be done.
Definitions and codes
Although this generic protocol provides definitions and, in some cases, suggest codes to be used (e.g., pathogens), as it is described above, operational definitions and national codes can be used when starting the project implementation. As for the section "Medical and laboratory practices", this heterogeneity across sites can make both comparisons between sites and pooled analyses difficult.

Existing data sources and surveillance systems and Level of automatisation and data linkage

Existing data sources and surveillance systems as well as the level of automatisation and the variables and methods for data linkage will differ across the participating countries which will impact on the availability and completeness of the variables to be collected and the heterogeneity of the results.

Technical and staff limitations

Technical and staff capacities in the country will determine the capacity of each country on implementing this protocol and obtaining surveillance results.

Data interoperability, data processing, and data storage

This protocol presents suggestions and different possibilities on data interoperability, data processing, and data storage. Depending on the capacity and priorities in each country the implementation of these processes may differ which may contribute to having a non-unified surveillance system (multiple surveillance systems in different countries) and increasing the heterogeneity of the results. This includes the efforts and capacity needed to extract laboratory results or clinical data in compliance with correct inclusion criteria and formats.

Other limitations

To be specified by each country

⇒ Each study site/country to describe the potential limitations in terms:

- *Representativeness of the study population (or population under surveillance)*
- *Denominators*
- *Medical and Lab practices*
- *Definitions and codes*
- *Existing data sources and surveillance systems and Level of automatisation and data linkage*
- *Technical and staff limitations*
- *Data interoperability, data processing, and data storage*
- *Other limitations*

The major limitation to implement EHR-based BSI and AMR surveillance according to this protocol may prove to be insufficient resources to develop of all proposed IT solutions for appropriate data flow and generation of EHR-based BSI and AMR surveillance reports by the planned deadlines as there will be many competing priorities for digitalization of healthcare in Slovenia in the next few years.

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9. Annexes

9.1. Annex 1. Existing BSI surveillance systems and data sources

Participating countries will need to identify both available sources and data needed according to feasibility and their priorities regarding the project surveillance objectives. In case no specific data sources or surveillance systems are available at the national level, countries can specify if the data collected for other initiatives, such as EARS-Net, may be used for this study.

Existing surveillance systems and relevant data sources

BSI-related information can be captured from different available surveillance systems, health registries or databases, which can be paper based or electronic and data entry can be either automated or manually entered.

It is important to identify the legal status of the surveillance system data reporting:

- *Mandatory: there is a legal or regulatory basis, at the national or subnational administrative level, under which reporting of cases is compulsory;*
- *Voluntary: reporting of cases is voluntary;*
- *Other: part of a research project, special agreement, etc.*

Potential data sources

These are the main potential systems or data sources where we expect countries will be collecting BSI/AMR related data:

1. *Bloodstream infections or surveillance of invasive infections surveillance systems*
2. *Antimicrobial resistance surveillance systems*
3. *Notifiable disease surveillance systems (only for those infectious diseases mandatory to be reported)*
4. *Laboratory surveillance systems and/or Laboratory Information Management Systems (LIMS)*
5. *Hospital databases*
6. *Primary care databases*
7. *Pharmacy databases (prescription/sales)*
8. *Insurance databases*
9. *Administrative databases*

→ Study sites/countries will describe the data sources they plan to use to meet the project objectives. The list of "Potential data sources" above can be used, and/or adding other sources if needed, including only those sources needed.

→ Taking into account their data sources' availability and feasibility to achieve the different project objectives, study sites/countries will fill the table below (table S1) to provide details about their data sources and systems to collect BSI-related information.

Table S1. *Descriptive information on the available data sources and systems collecting BSI-related information (dummy information in italics) by surveillance objective*

Study objectives	***Data source official Name/ information expected to be collected***	***Availability of data source***	***Electronic / EHR-based***	***Automated (specify)/ semiautomated/ data manually collected***	***Reporting legal status***	***Data linkage variable available***
Healthcare-associated BSI (HA-BSI incidence)	*e.g., National BSI surveillance system (to collect all the BSI cases)*	*Yes, available*	*Electronic*	*Automated (only collection of the following variables….)*	*Mandatory*	*e.g., data linkage only possible at hospital level and only for some data sets (Lab-clinical data)*
Possible pan-drug resistance (PDR) in BSIs (surveillance and alert)	*Hospital data*	*Yes available but only data from some hospitals.*	*EHR-based*	*Automated (only collection of the following variables….)*	*Voluntary*	*No*
Emerging pathogens in BSIs (surveillance and alert)						
AMR according to EARS-Net protocol						

9.2. Annex 2. Coverage and population under surveillance

Participating countries will need to describe the coverage and population under surveillance of existing systems and data sources.

Furthermore, we envisage that participating countries will start implementing the protocol at different levels (national, regional, or even in a few hospitals), according to their possibilities and feasibility. During the project development, it is expected that participating countries can expand the coverage and the population under surveillance.

There are four main aspects countries should describe:

A. *Coverage*

The coverage of the system can be national (i.e., the entire national territory is covered by the surveillance system) or subnational (i.e., one or more regions/districts participate in the surveillance system).

B. *Sentinel or comprehensive surveillance system*

A sentinel surveillance system is a system where only a subset of hospitals provides EHR to report their cases (within one or more administrative units), whereas in a comprehensive surveillance system, all hospitals report their cases (within one or more administrative units). Comprehensive systems may or may not cover the entire national territory.

C. *Population under surveillance*

The population under surveillance will be those individuals within the area of coverage that are covered by the BSI-related surveillance systems in each country. If the surveillance includes a few hospitals, the population under surveillance will be the hospital catchment population.

D. *Representativeness*

Representativeness is the degree to which data from the cases detected in the surveillance system reflect all cases in the population under surveillance and should be evaluated by:

a. *Demographic representativeness.*
b. *Geographic representativeness.*
c. *Type of healthcare facility (e.g., secondary vs tertiary hospitals).*
d. *Severity representativeness.*

Expected coverage and population under surveillance by objective

⇒ By filling the table below (table S2), each study site/country will specify for each one of the project objectives the available data sources, described in section 9.1 (Annex 1), and their expectation regarding the coverage, the population under surveillance, the representativeness, the limitations and feasibility.

Table S2. *Data sources, coverage and population under surveillance expected by each project objective (dummy information in italics).*

Objective	***Coverage***	***Data sources***	***Population under surveillance***	***Representative-ness***
Healthcare-associated BSI (HA-BSI incidence)	*e.g., subnational or regional*	*e.g., Lab, Hospitals, and administrative databases*	*e.g., 5 tertiary hospitals*	*e.g., Only urban areas, different SE status*
Possible pan-drug resistance (PDR) in BSIs (surveillance and alert)				
Emerging pathogens in BSIs (surveillance and alert)				
AMR according to EARS-Net protocol				

Table S2. Data sources, coverage and population under surveillance by each project objective

Objective	**Coverage**	**Data sources**	**Population under surveillance**	**Representative-ness**
Healthcare-associated BSI (HA-BSI incidence)	*national*	*Microbiology laboratories, Hospitals, and Central Registry of Patients Data*	*national*	*national*
Possible pan-drug resistance (PDR) in BSIs (surveillance and alert)	*national*	*Microbiology laboratories, Hospitals, and Central Registry of Patients Data*	*national*	*national*
Emerging pathogens in BSIs (surveillance and alert)	*national*	*Microbiology laboratories, Hospitals, and Central Registry of Patients Data*	*national*	*national*
AMR according to EARS-Net protocol	*national*	*Microbiology laboratories, Hospitals, and Central Registry of Patients Data*	*national*	*national*

9.3. Annex 3. Data processing overview

By definition, a BSI EHR-based surveillance system defines a data flow from laboratories and hospitals (and other data sources) into a centralised database to compute surveillance indicators . Building such systems requires implementing or reusing a series of processes at hospital level including data linkage with detailed patient information and aggregation to produce final indicators. In this section, we present three possible options for the data processing flow and the key differences between them. Different countries may choose different data flows depending on the particularities of their data sources and existing surveillance systems. Each country will choose and adapt the most suitable data flow for their own surveillance protocols.

Before entering into the structure of the data process, it is useful to define its compounding elements.

- ***Primary data**: Source of the EHR surveillance systems, it refers to software and databases in hospitals and laboratories used for patient care and for facility management. These systems collect the individual patient data that will be used as a source for the EHR surveillance system to determine the patient pathway.*
- ***Standardised Fact extraction:** Data extracted from the primary sources is expected to describe/indicate timestamps of key stage of the patient pathway (e.g. date of admission, initial diagnostic, associated diagnostics, symptoms, blood cultures performed, pathogen identified in the blood culture, dates with a catheter, etc.). This extraction is expected to take place at the local/laboratory/hospital level and can exist already for a different purpose or may need to be created for BSI surveillance. When data are extracted, they may come from a large number of institutions having heterogeneous data sources. Thus, a first level of standardisation needs to be applied to ensure data can be consolidated. The standardisation at this level defines a country wide data structure and a set of acceptable vocabularies for interpreting the data.*
- ***Pseudonymisation**: Individual data about the patient pathway when direct identifiers are replaced by new unrelated identifiers. The resulting data still contains detailed information about individuals, so it is not considered anonymous as it could be possible to identify individuals when combined with other datasets. Fields removed include personal identification numbers, patient id, name, date of birth and location of birth. Pseudonymisation techniques will be chosen by countries and can include identifier hashing, encryption (with a trusted party) or random replacement (with mapping retention)*
- ***Data linkage**: Data obtained from the same individual is linked together using the patient's unique (or pseudonymised) ID or probabilistic methods. Countries may choose to use non-pseudonymised IDs for data linkage prior to sending data to the coordination team.*
- ***Hospital/laboratory data submission**: Extracted primary data may need to be sent to a national/regional repository where surveillance indicators will be calculated. A process of data validation and protection needs to be defined so hospitals and laboratories can ensure the correctness and security of data being sent.*
- ***Standardisation**: This process includes two actions: renaming variables and transcoding referential codes to the target coding defined on the main protocol, e.g. diagnostic or micro-organism codes.*
- ***Individual BSI records (protocol model):** Database containing standardised individual patient pathway data for potentially multiple sources/hospitals/laboratories. Variable names and coding must respect the protocol definition.*
- ***Indicator calculation (protocol-defined scripts)**: Calculating surveillance AMR-BSI indicators from individual records and aggregating data at the required regional level. The output of this process is expected to be anonymous data, including defined statistics and indicators.*
- ***European data submission**: Submission of either aggregated or individual pseudonymised data to the European level.*
- ***Aggregated BSI Indicators**: Surveillance indicators that can be aggregated to produce the BSI surveillance report.*

Before the implementation of these processes, many questions need to be addressed:

- *Hospital/laboratory level*
    - *Does the country prefer that hospitals/laboratories host and run the scripts to implement the protocol? Do hospitals/laboratories have this capacity?*
    - *Does the country prefer that hospitals/laboratories develop and maintain the pseudonymisation and data submission processes? Do hospitals/laboratories have this capacity?*
    - *Which authentication / security / integrity methods to implement?*

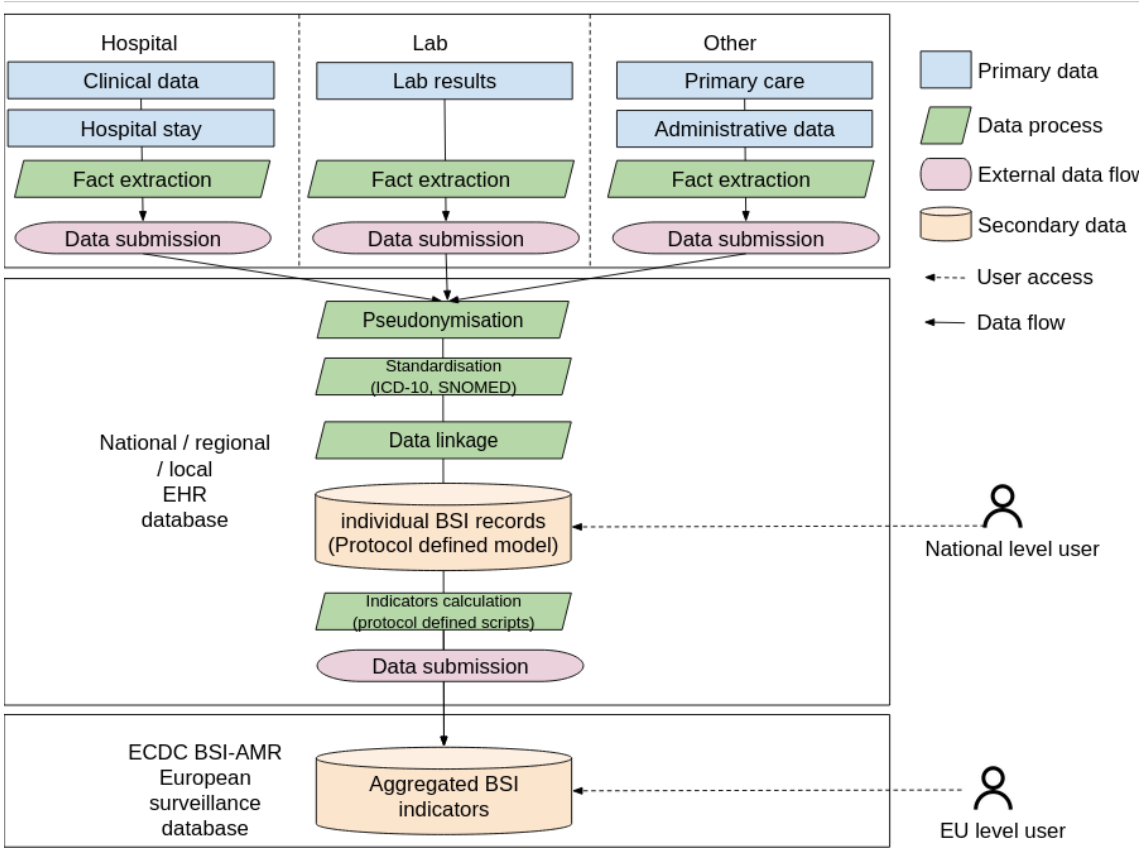
    - *If data linkage can include data coming from different sites, the same pseudonymisation method should be used.*
    - *Are there existing dataflows in hospitals and laboratories that can be reused to build this EHR surveillance process?*
- *National/regional level*
    - *Does the country have the resources to link different data sources and host EHR databases from different hospitals?*
    - *Does the country prefer that the national level hosts and runs the scripts to implement the protocol? Does the national level have this capacity?*
    - *Does the country prefer that the national level develops and maintains the pseudonymisation and data submission processes? Does the national level have this capacity?*
    - *Which authentication / security / integrity methods to implement?*
- *Coordination team/ECDC (European level)*
    - *What is the target platform to host this surveillance database?*
    - *Can the coordination team /ECDC host and maintain national EHR databases?*
    - *Are ECDC and participating countries aligned on what will be the target standard to use for coding pathogens, diagnostics and medical acts?*
    - *Which authentication / security / integrity methods to implement?*

We describe three possible models for organisation of this data flow that could suit different scenarios. It is important to note that in all cases IT staff, data managers, or staff with expertise in developing/adapting scripts will need to be available to work at the specific data sources in the country to implement the protocol.

9.3.1. Option A: National/local storage and processing

The option of "National/local storage and processing" answers mainly to the constraint of keeping individual data at national or regional or local (hospital) level. In order to fulfil objectives of the BSI surveillance, countries following this approach will need to build a national/regional/local database following this protocol including the defined data model, supported standards and coding, and run defined scripts in order to produce the expected aggregated surveillance indicators. This option can suit an existing national centralised database or the development of a small pilot hosting all individual data at local level, with the perspective of adding some level of centralisation as the network grows (see Figure S1). As described by the PRAISE network[23,24], this option can reflect a locally implemented surveillance if scripts are run on site level or centrally if this is done at national/regional level.

Figure S1. *Data processing flowchart in national/local storage and processes option.*



Key points:

- *Simpler General Data Protection Regulation (GDPR) compliance effort.*
- *Countries will need to maintain a centralised surveillance database.*
- *Countries will need to transform their data to the expected coding system.*
- *The coordination team defines scripts that will be run by national / regional / local level on their databases to ensure comparability among countries*
- *Low reactiveness for updating the surveillance indicators.*
- *Pseudonymisation may occur at national rather than local/site level prior to countries submitting data to international authorities*

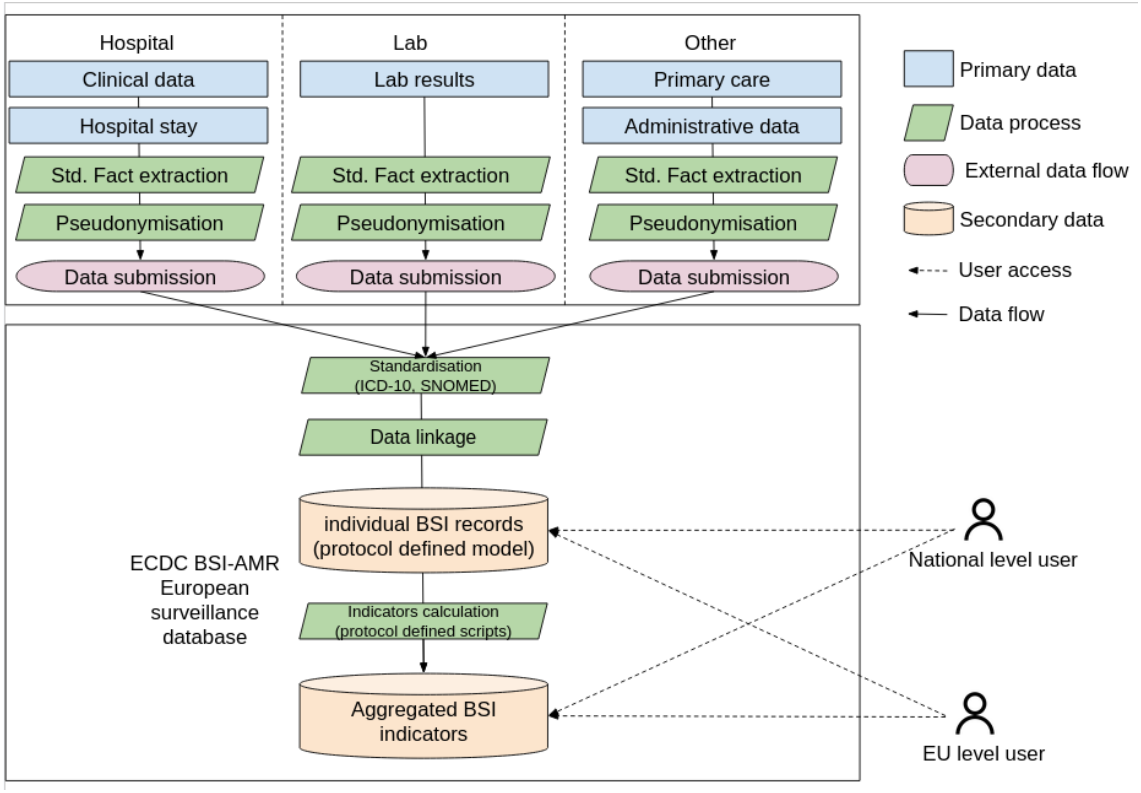
9.3.2. Option B: EU shared storage and processes

The option of "EU/national shared storage and process data" may be the easiest to implement for countries not having the capacity to build and maintain a centralised surveillance database and wanting to minimise data processing at hospital/national level. The fact extraction and pseudonymisation is implemented at the hospital/laboratory level in one of the supported codification systems and pseudonymised[30] and directly sent to the coordination team (or ECDC when implemented). There is no centralised database at country level. The maintenance of coherent individual BSI records, transcodification and surveillance indicator calculation is centralised at the European level. This option may be useful when starting with a small pilot but requires the coordination team to build a GDPR-compliant database to

[30] If pseudonymisation is done by stable non-reversible methods patients can still be tracked among sites; This means that the personal ID is always transformed to the same identifier but it is nearly impossible to guess the original identifier using the pseudonym.

hold individual pseudonymised records (see Figure S2). This option reflects centrally implemented surveillance in terms of the PRAISE network[27,28].

Figure S2. *Data processing flowchart in EU shared storage and processes option.*



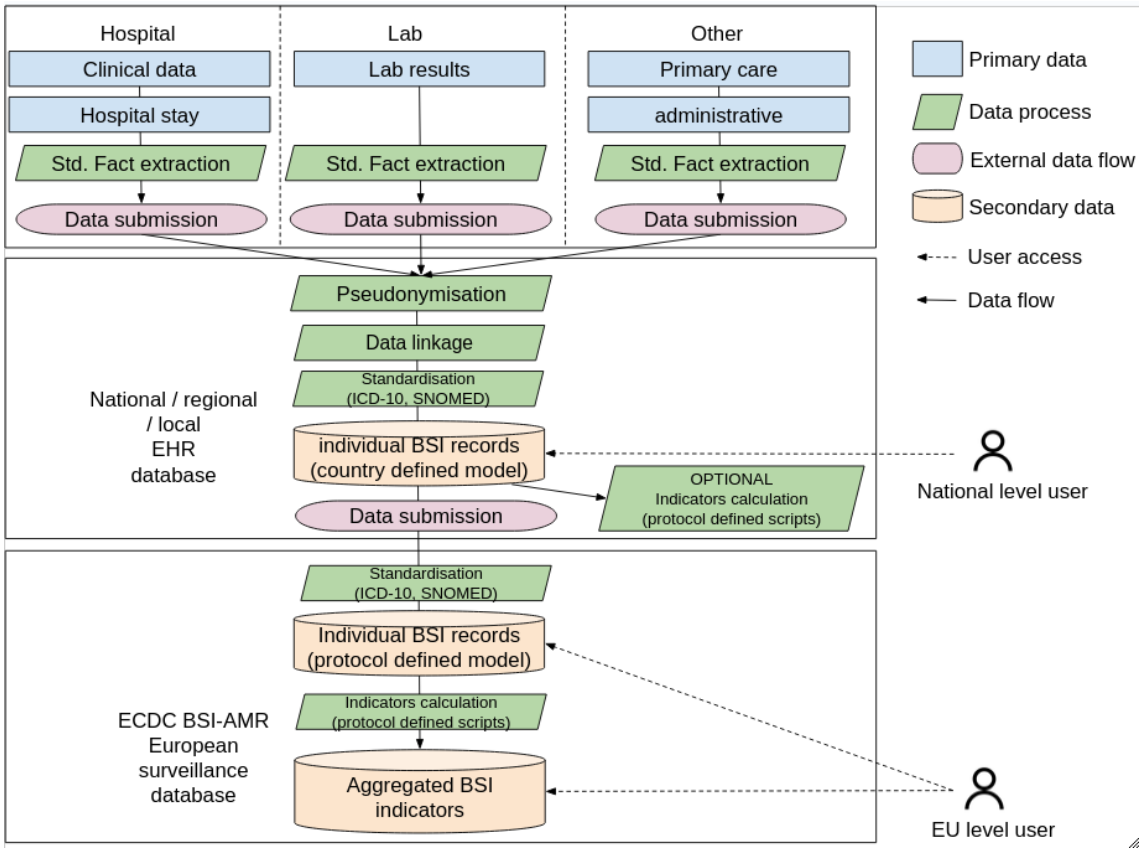
Key points:

- *GDPR compliance needs to be addressed.*
- *Less investment needed by countries since only data extraction by care institutions needs to be implemented (hospital lab investment still necessary).*
- *Better timeliness of indicators.*
- *Easier to ensure coherence of indicators.*
- *Need the implementation of a GDPR compliant database at EU level with individual patient data.*

9.3.3. Option C: National storage and National/EU processes option

The option of "National storage and EU processes option" is most suitable for countries already having or planning to have a centralised BSI surveillance system and for which sharing pseudonymised individual data with the coordination team (or ECDC) is feasible. No additional databases may be needed at national/regional/local level as long as the existing codification systems are supported as an input of the European database. The standardisation and indicator calculation can be performed at any level (local, regional, national or EU level) (see Figure S3). This option reflects a centrally implemented surveillance in terms of the PRAISE network[27,28].

Figure S3. *Data processing flowchart in National storage and EU processes option.*



Key points:

- *GDPR compliance needs to be addressed.*
- *Capitalisation over existing national surveillance investment.*
- *Easier to ensure coherence of indicators.*
- *Need the implementation of a GDPR compliant database at EU level with individual patient data.*

9.4. Annex 4. Data Interoperability

The implementation of automated EHR-based surveillance of BSI and AMR imposes the need to address the interoperability between different hospitals, laboratories and centralised surveillance systems across Europe. A high degree of heterogeneity is expected in terms of maturity, coding systems, organisation and resources available. In this section, we analyse different issues and the suggested approaches to take in terms of variable names and link homogenisation, coding system compatibility and data format and exchange.

Decentralisation

We expect that different countries will take different approaches in terms of the level of centralisation in the implementation of the surveillance system. While some countries may choose to use already existing centralised databases, others may choose to create regional or local implementations. The systems will be designed to support such a mix of configurations by using a distributed database approach. The data processing pipeline will always be split into two components: ad hoc and common.

1. *Ad hoc component: the process of extracting data from source systems and transforming it to a predefined set of individual BSI records, a tabular-like schema of linked files with individual pseudonymised data about the patient pathway, tests results and administrative information. This component is not necessarily executed on a single site and may contain data transfers between entities. The Ad hoc components should ensure that the codification system of the resulting data is in one of the supported vocabularies of the common components.*
2. *Common component: the common component includes standardisation and indicator calculation. It will be a set of scripts provided by the coordination team that will ensure the coherence of the methodology among countries. Common components will ensure the same code is executed on country databases with the same structure around the surveillance system, ensuring coherent aggregation of indicators and homogeneous methodology. Indicators of the common component will be designed so it can be aggregated between countries to produce European-level results. A deployment system needs to be defined to ensure correct versioning and updates on the surveillance network. A possibility could be to develop an R package with all common components.*

Different levels of data availability

Data systematically collected will largely differ between countries, e.g., linking clinical data with lab results may not be possible at the current stage of development of the project. To tackle this, we will take an iterative approach, letting countries include data as it becomes available and adhere to the protocol objectives progressively. Some countries may choose to develop small pilots for objectives that are too ambitious at the national level. The common component scripts will take this heterogeneity in consideration when calculating BSI indicators.

Pseudonymisation

Not all countries have a unique identifier in their EHR, and data may not be able to be linked between regions. We will propose pseudonymisation approaches to ensure that, at least at the hospital/lab level, each individual is associated with a unique and stable identifier produced by non-reversible hashing techniques.

Data exchange format (after data extraction and linkage)

Data will be submitted to ECDC through TESSy/EpiPulse as described in the TESSy Reporting Protocol for EHR-BSI v0.1. Output files produced by the common component containing indicators will be stored as CSV files following a simple data model to facilitate analysis.

Data transfers

Data transfers will need to be properly secured using encryption, authentication and secure protocols such as gpg, sFTP or HTTPS REST APIs and certificates. These precautions are mandatory when transferring individual data (pseudonymised or not). The coordination team, with the support of ECDC, will engage with individual countries to define the most suitable approach taking in consideration GDPR constraints.

Standard coding systems and vocabularies

One of the main challenges for building large scale EHR-based surveillance systems is the lack of a single standard for coding EHR terms. As described by the PRAISE network[27,28] different countries in Europe have defined their own vocabularies, e.g., Danish adaptation of the ICD-10 classification, Nordic Classification of Surgical Procedures, or the

French CCAM (from common classification of medical acts in French) codes. At this stage of the project, each country will choose the vocabularies to report data and will specify it on the input files. Based on this, the coordination team will provide support to find a strategy to migrate/translate to a single vocabulary (e.g., SNOMED-CT).

A codification system will be considered as compatible if a mapping towards the target vocabulary exists or if it is expected to be developed in the near future. The mapping implementation can be done in iterations including on first steps only a subset of codes and defining a roadmap for the mapping of the pending codes. This approach will avoid paralysing the development of the surveillance network because of the heterogeneity of the coding systems while keeping a clear pathway towards standardisation. In some cases, such as SNOMED-CT and LOINC, mappings already exist for subsets of the codes and a collaboration agreement was signed in 2022 to incrementing interoperability[29].

9.5. Annex 5. Data collection structure

As much as possible, with all case-based variables, it is recommended to use a specific data structure, which will be implemented at the local, regional or national level depending on the needs of each participating country. We propose the tabular structure presented in the diagram below (Figure S4) which is an extension of the Reporting Protocol for EHR-BSI v0.1. This diagram only includes 'raw variables' and BSI/AMR computed indicators. Additional variables are not necessary to be reported at this stage of the project but we encourage countries to acquire them to anticipate evolutions in the reporting protocol. Having this homogenous data collection format at the source of the surveillance network will ensure that the same methodology is applied to all countries.

We have grouped the tables in two categories:

- *Aggregated data (dark blue in diagram) These tables contain aggregated data. These can be used by countries not being able to share individual records. Additional variables are not necessary to be reported at this stage of the project but we encourage countries to acquire them to anticipate evolutions on the reporting protocol.*

- *Individual records (green in diagram) These tables contain individual records of patient history related to BSI episodes including admissions, isolates and susceptibility tests.*

Figure S4. Data collection structure