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Antimicrobial Resistance and Healthcare-Associated Infections

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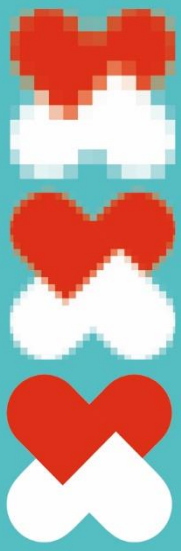
# Infection case definitions of HAI in European Surveillance Systems



BUILDING A ONE HEALTH WORLD
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WP7 | Infection case definitions of HAI in European Surveillance Systems
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# I SUMMARY

This report presents the findings of a study conducted under the EU-JAMRAI 2 project to identify and analyse the case definitions used in Healthcare-Associated Infection (HAI) surveillance systems across Europe.

The countries that were requested their HAI surveillance systems were the following: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia (Czech Republic), Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and Ukraine.

A two-phase approach was employed: first, identifying existing HAI surveillance systems in European countries; second, conducting a targeted survey to gather detailed information on the case definitions of four HAI types selected by the ECDC for their high relevance at the European level: bloodstream infections (BSI), surgical site infections (SSI), *Clostridioides difficile* infections (CDI), and ventilator-associated pneumonia (VAP).

The study analysed 28 HAI surveillance systems across 23 European countries/regions. It revealed a strong foundational alignment with ECDC protocols, in line with the European Commission's Implementing Decision (EU) 2018/945. However, significant national and local adaptations were widespread. These range from limiting surveillance to specific microorganisms or procedures to using adapted or own case definitions.

These variations, combined with differing levels of system maturity, from electronic national registries to paper-based reporting, and voluntary participation models, create substantial barriers to data comparability at the European level.

The report concludes that while ECDC frameworks provide a crucial common reference, a fully harmonised EU-wide HAI surveillance system does not yet exist. To address this, recommendations are provided for enabling inter-country and local benchmarking, promoting harmonization, reinforcing the adoption of common reference frameworks, developing a European repository of protocols, strengthening Information Technology (IT) interoperability, and fostering multi-country collaboration to address definitional inconsistencies.

# 2 BACKGROUND

HAIs remain a major public health challenge in Europe, contributing to increased morbidity, mortality, and healthcare costs. Effective surveillance is essential for monitoring HAI trends, evaluating prevention strategies, and guiding policy decisions for patient safety.

Under the EU-JAMRAI 2 framework, this task aimed to map and analyse the case definitions used in HAI surveillance systems across European Member States (MS). Harmonized case definitions are crucial for enabling valid benchmarking, supporting collaborative research, and strengthening infection prevention and control programmes at the EU level. The development of the ECDC's HAI-Net protocols, evolving from earlier European projects like HELICS/IPSE, has included formal comparisons with other international systems, such as those of the U.S. CDC, to identify and address points of divergence [1], [2].

# 3 OBJECTIVE

The primary objectives of this study were:

1. To identify and catalogue HAI surveillance systems operating in European countries.
2. To survey relevant institutions on the specific case definitions used for key HAI types.
3. To analyse the level of harmonization and identify gaps or inconsistencies in case definitions.

# 4 METHODOLOGY

The study was conducted in two sequential phases:

- **Identification phase:** Desk research and consultations with Liaison Officer's (LO), national focal points, project's partners and ECDC networks to compile a list of HAI surveillance systems in Europe.
- **Survey phase:** Development and dissemination of an online questionnaire to representatives of identified systems, focusing on case definitions and adherence to European Commission's Implementing Decision (EU) 2018/945.

# 5 RESULTS

## 5.1 Overview of HAI Surveillance Systems in Europe

- **Survey scope:** 43 responses from 29 countries (EEA + Ukraine).
- **Exclusion:** Systems that were purely ECDC-coordinated initiatives without national adaptation (e.g., PPS, HALT, HAI-Net).
- **Final analysis set:** 28 independent, country-led surveillance systems across 23 countries/regions, operating at national, regional, or facility levels.

The majority of these systems operate at the national level and cover multiple types of HAIs, though scope and maturity vary significantly.

**Table 1.** Overview of Country-Specific HAI Surveillance Systems in Europe.

| Country | Surveillance System name (Acronym) | Scope | HAI Types Covered (based on survey) | Definition Alignment |
|---|---|---|---|---|
| **Austria** | Austrian HAI (A-HAI) | National | BSI, SSI, CDI, VAP | ECDC PPS v6.1 |
| **Belgium** | National Surveillance of Hospital-acquired Infections (NSIH) | National | BSI, SSI, CDI, VAP | ECDC PPS v6.1, with minor national adaptations |
| **Bulgaria** | National HAI Surveillance System | National | BSI, SSI, CDI, VAP | ECDC PPS v6.1 |
| **Denmark** | Hospital Associated Infections Database (HAIBA) | Regional | BSI (microbiological), SSI (hip/knee), CDI | ECDC-based, but symptom criteria often omitted |
| **Estonia** | Tervishoiutekkeste infektsioonide seire | National/Local | SSI, CDI, VAP (voluntary reporting) | Use of ECDC protocols:<br>○ BSI: automated system is under development within the ECDC EHR-BSI project<br>○ SSI: ECDC HAI-Net SSI protocol v2.3<br>○ CDI: ECDC CDI protocol v2.4<br>○ ICU: ECDC HAI-Net ICU protocol v2.3 |
| **Finland** | National Surveillance of HAIs | National | BSI, SSI, CDI (no VAP incidence) | Use of ECDC protocols;<br>○ CDI:Follow ECDC CDI protocol v2.4<br>○ SSI: Follow ECDC HAI-Net SSI protocol v2.3. Superficial SSI excluded from 2024. |
| **France** | Surveillance et Prévention des Infections associées à un dispositif invasif (SPIADI) | National | BSI, VAP | ECDC PPS v6.1 |
| | Surveillance et Prévention du risque Infectieux en Chirurgie et Médecine Interventionnelle (SPICMI) | National | SSI | ECDC PPS v6.1 |
| **Germany** | Krankenhaus-Infektions-Surveillance-System (KISS) | National | BSI (primary only), SSI, CDI, VAP | ECDC alignment (SSI, CDI and VAP), BSI definition differs (primary only) |
| **Hungary** | Nemzeti Nosocomialis Surveillance Rendszer (NNSR) | National | BSI, SSI, CDI, VAP | ECDC PPS v6.1, except CDI from LTCF excluded |

**Table 1 continuation.** Overview of Country-Specific HAI Surveillance Systems in Europe.

| Country | Surveillance System name (Acronym) | Scope | HAI Types Covered (based on survey) | Definition Alignment |
|---|---|---|---|---|
| **Iceland** | Landspitali University Hospital Nosocomial surveillance system | Facility | BSI, SSI, CDI, VAP | ECDC PPS v6.1 |
| | Akureyri Hospital surveillance system | Facility | BSI, SSI, CDI | ECDC PPS v6.1 |
| **Ireland** | HSE Antimicrobial Resistance Infection Control (AMRIC) HAI Key performance indicators (KPIs) | National | BSI (*S. Aureus* only), SSI (hip), CDI (no VAP) | ECDC PPS v6.1 with modifications |
| | *C. difficile* enhanced surveillance system | National | CDI (in-depth epidemiological information) | ECDC PPS v6.1 |
| **Italy** | Sorveglianza attiva Prospettica delle Infezioni Nosocomiali nelle Unità di Terapia Intensiva (SPIN-UTI) | National coordination/Regional data collection | BSI, SSI, CDI, VAP (ICU focus) | ECDC PPS v6.1 |
| | Gruppo Italiano per la Valutazione degli Interventi in Terapia Intensiva (GiVITI) | National coordination/Regional data collection | BSI, SSI, CDI, VAP (ICU focus) | ECDC PPS v6.1 |
| **Lithuania** | HAIs Surveillance (PPS, CDI, SSI, ICU) | National | BSI, SSI (specific surgeries), CDI, VAP | ECDC PPS v6.1 |
| **Malta** | Multiple hospital-based systems (SSI, BSI-ICU, CDI, MRSA) | Hospital | BSI (ICU), SSI (specific surgeries) CDI | ECDC PPS v6.1 |
| **Netherlands** | Preventie van Ziekenhuisinfecties door Surveillance (PREZIES) | National | BSI, SSI, CDI, VAP (device-related, not associated) | ECDC-based, with modifications (e.g., VAP criteria) |
| **Norway** | The Norwegian Surveillance System for Antibiotic Use and Healthcare-associated Infections (NOIS) | National | BSI, SSI, VAP (grouped with LRTI) | ECDC PPS v5.5 with updates |
| **Poland** | Sanitary Inspection (alert pathogens) | National | BSI, SSI, CDI, VAP (via ECDC protocols) | ECDC PPS v6.1, Neo-KISS for newborns |
| **Portugal** | HAI-NET (HELIX) | National | BSI, SSI, CDI, VAP | ECDC PPS v6.1 |

**Table 1 continuation.** Overview of Country-Specific HAI Surveillance Systems in Europe.

| Country | Surveillance System name (Acronym) | Scope | HAI Types Covered (based on survey) | Definition Alignment |
|---|---|---|---|---|
| **Romania** | HAIs National Surveillance | National | BSI, SSI, CDI, VAP | ECDC PPS v6.1 |
| **Slovakia** | Epidemiological Information System (EPIS) | National | BSI, SSI, CDI, VAP | ECDC PPS v6.1 |
| **Slovenia** | Mreža za epidemiološko spremljanje bolnišničnih okužb | National | BSI, SSI, CDI, VAP | ECDC PPS v6.1 |
| **Spain** | Red Nacional de Vigilancia Eidemiológica (RENAVE) | National | BSI, SSI, CDI, VAP | ○ BSI: Uses both ECDC HAI-Net ICU protocol v2.3 and ECDC PPS v6.1.<br>○ SSI: Follows ECDC HAI-Net SSI protocol v2.3.<br>○ CDI: ECDC definitions with adaptations.<br>○ VAP: Uses ECDC HAI-Net ICU protocol v2.3. |
| | Vigilància de les Infeccions Relacionades amb l'Atenció Sanitària a Catalunya (VINCat) | Regional | BSI (CLABSI specific, hospital ward and ICU), SSI, CDI, VAP | ○ Central venous catheter-related bacteremia (hospital ward): VINCat's own criteria, more restrictive than ECDC (combines microbiological and clinical criteria).<br>○ Central venous catheter-related bacteremia in critically ill patients: Uses ECDC HAI-Net ICU protocol v2.3.<br>○ SSI: ECDC-based for major procedures; other surgeries use VINCat-defined criteria.<br>○ CDI: VINCat's own criteria.<br>○ VAP: Uses ECDC HAI-Net ICU protocol v2.3. |
| **Sweden** | Infektionsverktyget | National | BSI, SSI, CDI, VAP | BSI follows ECDC PPS v6.1. Remaining definitions local/clinical judgment, intention-to-treat based. |

## 5.2 Analysis of Case Definitions in use

Based on survey responses from 28 surveillance systems across 23 countries/regions, the analysis reveals both a strong foundation of ECDC protocol adoption and notable national and regional adaptations that affect definitional harmonisation.

### 5.2.1 Alignment with International Guidelines

The vast majority of systems explicitly report using ECDC PPS v6.1 or other specified ECDC protocols (such as HAI-Net ICU or SSI protocols) as their primary reference framework. This

includes systems in Austria, Belgium, Bulgaria, Estonia, Finland, France (SPIADI, SPICMI), Hungary, Iceland (Landspitali, Akureyri) Ireland (HSE, HPSC), Italy (SPIN-UTI, GiVITI), Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, and Spain (RENAVE, VINCat).

A few systems employ definitions that are either independent or represent significant adaptations:

- Denmark's HAIBA uses ECDC-based definitions but omits clinical symptom criteria for BSI, relying instead on microbiological and temporal data only.
- Germany's KISS uses its own definitions, which are closely aligned with ECDC for SSI, CDI, and VAP but have a meaningful difference for BSI (including only primary infections).
- Ireland's AMRIC HAI KPIs base it's definitions on ECDC's protocols, but focus in specific priorities. In BSI, surveillance is limited to *Staphylococcus aureus* and SSI only follows hip fracture surgeries. For VAP, ECDC definitions are recommended for hospital-level surveillance, but are not surveyed in national surveillance.
- Spain's VINCat uses a hybrid model: it employs ECDC HAI-Net ICU criteria for Central line-associated bloodstream infections (CLABSI) in Intensive Care Units (ICU) and for VAP, follows ECDC-based definitions for trauma, colorectal, and cardiac SSIs, and for other relevant surgeries, CLABSI in hospital wards and CDI uses its own criteria.
- Sweden's Infektionsverktyget primarily relies on local/clinical judgment and intention-to-treat principles, with BSI being the only type explicitly noted to follow ECDC PPS v6.1.

Other systems, while ECDC-aligned, have implemented specific modifications relevant to their national or regional context, such as the Netherlands' device-related (vs. device-associated) criteria for VAP in PREZIES.

### 5.2.2 Definitional Variations by HAI Type

The survey focused on four key HAI types, revealing the following patterns of variation:

*Bloodstream Infection (BSI):*

Most national and regional systems follow ECDC PPS v6.1 definitions. Key variations include:

- **Denmark (HAIBA):** Uses a simplified definition based on microbiological findings and time-periods, omitting clinical symptom criteria.
- **Germany (KISS):** Includes only primary BSI, excluding secondary infections.

- **Spain (VINCat):** Focuses only on CLABSI. Uses its own, more restrictive criteria for CLABSI in hospital wards, combining microbiological and clinical elements. For ICU-acquired CLABSI, it follows the ECDC HAI-Net ICU criteria.
- **Ireland (AMRIC):** Surveillance is limited to hospital-acquired *S. aureus* BSI, defined as isolation of *S. aureus* from a blood culture >48 hours after admission.

### *Surgical Site Infection (SSI)*

ECDC definitions are widely adopted. Notable national and regional adaptations are:

- **Denmark (HAIBA):** Hip/knee implants infection only, based upon re-operation within 90 days.
- **Finland (National Surveillance of HAIs):** Excludes superficial SSI from its national incidence surveillance reporting (from 2024 onwards).
- **Ireland (AMRIC):** While ECDC definitions are recommended nationally, current surveillance is limited to SSI following hip fracture surgeries. Hospitals may use other definitions for local surveillance.
- **Spain (VINCat):** Follows ECDC-based definitions for trauma, colorectal and cardiac SSIs. For other relevant surgeries, it applies VINCat-defined criteria.
- **Sweden (Infektionsverktyget):** Uses definitions based on intention-to-treat, length of stay, medical procedure, and clinical judgment.

### *Clostridioides difficile Infection (CDI)*

Nearly all systems follow ECDC PPS v6.1. One significant adaptation was reported:

- **Hungary (NNSR):** Does not classify CDI cases imported from long-term care facilities (LTCF) into hospitals as healthcare-associated infections, managing them as a separate category.
- **Spain (VINCat):** Uses its own criteria. Data is only collected on the first infection; recurrences are not monitored.
- **Sweden (Infektionsverktyget):** Uses definitions based on intention-to-treat, length of stay, medical procedure, and clinical judgment.

*Ventilator-Associated Pneumonia (VAP)*

While many use ECDC PPS v6.1 or other ECDC protocols, several countries have adapted their approach:

- **Netherlands (PREZIES):** Use a "device-related" criterion instead of the ECDC's "device-associated" definition. Criteria ‘P4-5 fever, leucocytosis, leukopenia’ not used.
- **Norway (NOIS):** VAP is reported together with pneumonia, LRTI-BRON and LRTI-LUNG, not separately.
- **Spain (VINCat):** Follows ECDC HAI-Net ICU criteria.
- **Sweden (Infektionsverktyget):** Relies on clinical judgment and intention-to-treat principles.

## 5.3 Variability and Harmonisation Gaps

The analysis of the 28 systems confirms that while ECDC protocols serve as a common reference point, full harmonisation has not been achieved. Persistent variability due to country-context adaptations and resources exists in several critical areas, which can be categorised as follows:

*1. Scope of Surveillance and Inclusion Criteria:*

Systems vary in which infections are included under the HAI umbrella. For example, Germany's KISS excludes secondary BSI, Hungary's NNSR excludes CDI originating in LTCFs, Ireland's AMRIC surveillance is limited to *S. aureus* BSI and specific SSI procedures and Spain’s VINCat focuses in CLABSI, omitting other BSI.

*2. Clinical vs. Laboratory-Based Criteria:*

The level of detail and requirement for clinical symptoms differ. Denmark's HAIBA, for instance, relies solely on laboratory and timing data for BSI, omitting clinical criteria.

*3. Categorisation and Reporting of Specific Infections:*

Variations in how infections are classified and reported affect comparability. Norway’s NOIS groups VAP with other respiratory infections, and the Netherlands uses distinct "device-related" criteria for VAP.

*4. Application and Interpretation of Definitions:*

Some systems, like Sweden's Infektionsverktyget, grant significant discretion to local clinical judgment, leading to potential variability even within the national system.

*5. Implementation Level and Mandatory Status:*

Systems operate at different levels (national, regional, facility), and some countries do not have any national surveillance system (e.g., Iceland and Malta). Also the systems have differing mandates (mandatory vs. voluntary), as seen in the contrast between Spain's national RENAVE system and Sweden's voluntary Infektionsverktyget, where the decision to participate it's local/regional.

## 5.4 Impact on Comparability

The inconsistencies detailed above have a direct impact on the comparability of HAI data at the European level.

- **Data Harmonisation:** The national and regional adaptations, while contextually justified, create barriers to aggregating and harmonizing data across borders for EU-wide benchmarking and trend analysis.
- **Benchmarking:** Meaningful comparison of infection rates between countries is complicated by differing case definitions, potentially leading to misinterpretation of performance.
- **Evaluation of Interventions:** Assessing the effectiveness of infection prevention and control (IPC) measures across Europe is challenged by the lack of a uniform measurement standard.
- **Countries with hybrid or independent systems** (e.g., Germany, Sweden) create additional layers of complexity for cross-national aggregation.

## 5.5 Country-Specific Comments and Context

The survey responses provided additional context on the operational landscape of HAI surveillance:

- Bulgaria reported having no electronic surveillance system; national surveillance is conducted via a mandatory paper-based reporting system to regional health inspections. The data is collected by the hospital departments and every 3 months sent to Regional Health Inspection (RHI). The RHIs perform an annual report with analyses and send them to the Ministry of Health. There are plans to later expand the surveillance of *C. difficile* and *Clostridium Difficile*-Associated Diarrhoea (CDAD).

- Croatia, Cyprus, Latvia, Luxemburg and Ukraine indicated they do not yet have a continuous, routine national surveillance system in place, relying instead on periodic participation in ECDC-coordinated surveys like PPS.
- Estonia reported that HAI surveillance is primarily conducted at the facility level. Some hospitals also report ICU, SSI, and CDI data at the national level. The Health Board is responsible for submitting these data to the ECDC. However participation rate at the national level is low, as the reporting is mainly manual. In addition, some hospitals conduct annual facility-level PPS surveys using their own surveillance protocols, which are generally modified versions of the ECDC PPS methodology. Moreover, since 2023, Estonia has participated in the ECDC EHR-BSI project to develop a nationwide automated BSI surveillance system. The system is based on blood culture results supplemented with available clinical data.
- Greece was not reachable during the period of time were this survey was conducted (July 2025 - December 2025).
- Iceland's surveillance is conducted at the facility level of the two main hospitals in the country (Landspitali University Hospital and Akureyri Hospital). However, the Chief Epidemiologist is currently working on a national BSI surveillance system, as a part of the EHR-BSI project (ECDC). They plan to later expand this EHR-BSI surveillance system to other types of HAIs such as *C. difficile* and SSI.
- Ireland's national HAI surveillance operates through two complementary systems. The HSE AMRIC HAI KPIs focus on key performance indicators for hospital-level monitoring. Surveillance is currently limited to *S. aureus* BSI and SSI after hip fracture surgery, while recommending ECDC definitions for broader use and local surveillance; it does not cover VAP. For *C. difficile*, the AMRIC system captures only new hospital-associated CDI cases for high-level monitoring. In parallel, the enhanced CDI surveillance system collects more detailed epidemiological data on CDI, including recurrence, onset, severity, and ribotype, and covers both community-acquired and healthcare-associated cases. While both systems capture CDI data, the AMRIC KPIs provide high-level performance metrics, and the enhanced system offers in-depth epidemiological insight. For all other HAI types, only the AMRIC KPI system applies.
- Italy's systems SPIN UTI and GiVITI focus in Intensive Care Units (ICU).
- Lithuania's national surveillance of HAIs is mandated by a ministerial order and applies to all inpatient healthcare facilities. Long-term care facilities (LTCF) are also included in the surveillance of CDI and PPS. Epidemiological surveillance of SSI is mandatory for coronary artery bypass grafting and orthopaedic surgeries. For other surgical procedures, healthcare institutions may conduct surveillance at their own discretion. In all cases, ECDC protocol definitions are used. CDI surveillance is performed year-round (January 1 – December 31) in inpatient facilities, with a minimum requirement of four months per year, though continuous surveillance is recommended. For the HAIs surveillance in Intensive Care Units (ICU), it's mandatory to register pneumonia, bloodstream and urinary tract infections.

- Malta's surveillance is conducted at the facility level of the main national hospital (Mater Dei Hospital). Respondents noted that SSI surveillance, which is only applied to specific surgeries, was paused in 2024-2025 due to staff shortages.
- In Norway's NOIS, VAP is only reported together with pneumonia, LRTI-BRON and LRTI-LUNG, not separately. SSI after coronary artery bypass graft, caesarean section and hip replacement are also under continuous surveillance. There is at present no surveillance of healthcare-associated CDI in Norway, but they are currently working to establish a fully automated surveillance of CDI, BSI and SSI using simplified definitions based on microbiological findings and time-periods, omitting clinical symptom criteria. At present CDI without specification of the healthcare-associated infection, are under surveillance by the Norwegian Surveillance System for Communicable Diseases (MSIS).
- Spain is a decentralised country where autonomous communities hold primary responsibility for implementing their own HAI and antimicrobial resistance (AMR) surveillance systems at the regional level. These regional systems report to the National Epidemiological Surveillance Network (RENAVE) in accordance with standardized national protocols and case definitions. The VINCat programme, featured in this report, exemplifies one such regional system, that surveys data from the region of Spain, Catalonia, with 8 milions of citizens. It uses ECDC HAI-Net ICU criteria for CLABSI in ICU and for VAP, aligns with ECDC definitions for trauma, colorectal, and cardiac SSIs, and uses its own criteria for other relevant surgical site infections, CLABSI and CDI. Nevertheless, VINCat has reported ongoing efforts to implement the most recent ECDC definitions. Concurrently, Spain is actively revising its national RENAVE protocols, with updated versions slated for publication and implementation in 2026, reflecting an ongoing commitment to harmonising and strengthening national surveillance.
- Sweden's Infektionsverktyget is not mandatory, the decision to participate is local/regional.

# 6 SUMMARY OF FINDINGS

This study, based on data from 28 HAI surveillance systems across 23 European countries/regions, yields key findings that could inform the future European surveillance harmonization efforts. A strong foundation of ECDC alignment was identified, which is consistent with the European Commission's Implementing Decision (EU) 2018/945. The ECDC's PPS and HAI-Net protocols serve as the dominant reference frameworks, providing a crucial common basis for HAI surveillance in Europe [3], [4].

However, national and regional adaptations to local context are widespread. These modifications, range from limiting surveillance to specific pathogens or procedures (e.g., Ireland's *S. aureus* BSI) to the use of simplified laboratory-based definitions (e.g., BSI in Denmark), which significantly reduce true data comparability. Notably, regional systems

within decentralized countries, such as Spain's VINCat programme, exemplify how local case definition criteria (e.g., for CLABSI in wards and CDI) and the adoption of alternative international standards (e.g., ECDC HAI-Net ICU for VAP) create a hybrid model that, while effective locally, adds complexity to national and EU-wide harmonization. In addition, some systems, as Germany's KISS, diverge significantly from ECDC's definitions, while others like Sweden's Infektionsverktyget, depend on voluntary participation from Healthcare. These represent notable exceptions to the ECDC-aligned model and add a layer of complexity to European harmonisation efforts. Diverse levels of maturity and implementation also contribute to the divergence in the systems found. Countries exhibit a wide spectrum of system development, from well-established electronic national systems to paper-based reporting (Bulgaria), surveillance limited to specific indicators (Ireland), or surveillance confined to single hospitals (Iceland and Malta). Several countries, including Norway (currently trying to establish fully automated surveillance of BSI, SSI and CDI) and Spain (updating national protocols), are in a transitional phase.

The study confirms that a fully harmonised EU-wide HAI surveillance system does not yet exist. The variability in case definitions, driven by local adaptations, independent systems, and differing implementation contexts and scopes, presents a substantial barrier to achieving comparable data for EU-level public health action.

# 7 DISCUSSION

The findings of this mapping reveal a fundamental tension in European public health surveillance: the need for local adaptability versus the imperative for standardised comparability. While the widespread adoption of ECDC protocols signifies major progress toward a common European framework, the extensive national and regional adaptations documented in this report demonstrate that harmonisation remains a procedural aspiration rather than an operational reality.

This variability is not merely technical; it has direct public health implications. Divergent case definitions can lead to significant under- or over-reporting of HAIs, distorting national and EU-level burden estimates. Consequently, benchmarking becomes an exercise of comparing divergent metrics, undermining its value for driving quality improvement and assessing the effectiveness of IPC policies across borders.

The challenge of achieving comparable data is not new. Historical efforts to align European (HELICS/IPSE) and U.S. (CDC/NHSN) definitions have shown that while high concordance is possible for certain infections, significant differences persist in areas such as the classification of BSI cases secondary to another infection site [1]. Furthermore, subsequent updates have introduced new divergences between ECDC and the CDC, which show poor concordance and reflect differing priorities between clinical prevention and surveillance objectivity [2].

The path to robust, harmonised surveillance is not uncharted. Successful models exist that demonstrate the feasibility and value of sustained collaborative standardisation. For instance, the UK's NHS Compendium of HCAI Guidance [5] provides a single, dynamically updated source for all relevant IPC policies and definitions, ensuring clarity and consistency across the healthcare system. Similarly, the decades-long evolution of the U.S. CDC's National Notifiable Diseases Surveillance System (NNDSS), built in close collaboration with the Council of State and Territorial Epidemiologists (CSTE), illustrates a successful journey from fragmented state reporting to a modernised, interoperable system with nationally standardised case definitions [6]. These examples underscore that achieving harmonisation is a continuous, collaborative process that requires dedicated governance, technological investment, and a commitment to a common framework.

The persistence of paper-based systems, voluntary participation models, and a wide spectrum of IT maturity further exacerbates these definitional inconsistencies in Europe. These infrastructural disparities create a two-tier surveillance landscape where countries with advanced, automated systems can generate timely, objective data, while others remain reliant on manual, resource-intensive processes that are more prone to bias and delay.

Therefore, achieving the goal of a truly comparable EU-wide HAI surveillance system, as envisioned in the European Commission's Implementing Decision (EU) 2018/945, requires moving beyond the mere adoption of common protocols. The challenge is to translate common framework into a common practice, addressing not just the definitions themselves, but the capacity, resources, and technological foundations that determine their consistent application on the ground.

The path forward must reconcile the legitimate need for contextual adaptation with the non-negotiable requirement for core data benchmarking. The strategic recommendations outlined in the following section propose a multi-pronged approach to navigate this tension and build a surveillance network that is both locally relevant and collectively powerful.

# 8 STRENGTHS AND LIMITATIONS

*Strengths*

This study presents several notable strengths:

- **Comprehensive European Scope:** This is one of the most recent and extensive mappings of HAI surveillance systems across the EEA and Ukraine, capturing data from 28 systems in 23 countries/regions. It provides a unique, contemporaneous snapshot of the surveillance landscape post-Implementation of Decision (EU) 2018/945.

- **Direct Engagement with Practitioners:** Data was collected directly from national focal points, public health institutes, and infection control units responsible for operating these systems. This primary-source engagement ensures the findings reflect real-world implementation.
- **Analysis of Harmonisation:** By focusing specifically on case definitions for four key HAI types (BSI, SSI, CDI, VAP), the study moves beyond a superficial catalogue of systems to analyse the core element affecting data comparability. The identification of specific adaptations provides concrete evidence of harmonisation gaps.
- **Clarification of "National System" Status:** The methodology distinguished between country-owned, continuous surveillance systems and participation in ECDC-coordinated surveys (e.g., PPS, HALT). This clarification is crucial for accurately assessing the capacity for routine, comparable data generation at the EU level.

*Limitations*

The study's findings must be interpreted considering the following limitations:

- **Self-Reported Data:** The survey relied on the knowledge and interpretation of a single respondent or team per country/system. Inconsistencies in understanding the questions may have occurred, particularly regarding distinctions between "national surveillance system" and "ECDC survey participation", or between continuous incidence surveillance and periodic prevalence surveys. Internal variations within federalised health systems may not have been fully captured.
- **Non-Response and Partial Coverage:** Not all European countries participated (Greece was missing) and not all the region/facility-level scope surveillance systems were reached (Spain).
- **Static Snapshot vs. Dynamic Systems:** The report captures the state of systems at a single point in time (2025). Several countries (e.g., Finland, Spain) reported being in active transition: updating protocols, developing new modules, or pausing certain activities due to resource constraints. Norway, on the other hand, is working in developing a new fully automated surveillance system. This dynamism means the landscape is continually evolving.
- **Focus on Definitions:** While case definitions are fundamental, true comparability also depends on other protocol elements not deeply explored in this study. This analysis does not address the construction of HAI occurrence indicators, specifically the definitions of denominators for underlying patient populations. For the main HAI targets, differences in denominator definitions constitute a source of inter-country variability at least as significant as differences in case definitions, which limits the direct comparability of incidence data.
- **Lack of Validation:** The reported alignment with ECDC definitions was not externally validated through audits or parallel data testing. A system may report using

"ECDC PPS v6.1" but apply it with local interpretations or exemptions not disclosed in the survey.

Despite these limitations, the study successfully achieves its primary objective: to document and analyse the current state of case definition harmonisation for HAI surveillance in Europe. The findings provide a robust evidence base highlighting both the widespread adoption of ECDC frameworks and the persistent, context-driven adaptations that hinder full data comparability. This analysis is a vital first step for guiding targeted investments in capacity building, IT infrastructure, and collaborative standardisation efforts at the EU level.

# 9 RECOMMENDATIONS

Evidence from previous comparative studies highlights both the feasibility and the pitfalls of definitional alignment. Research demonstrates that excellent concordance between different definitional frameworks (e.g., pneumonia) is achievable [1]. However, it also cautions that changes in surveillance paradigms (e.g., current CDC/NHSN definition of Vetilator Associated Event (VAE) and probable VAP in contrast of ECDC's definition for VAP) can rapidly degrade comparability [2]. Therefore, a sustainable European harmonization strategy must prioritize stability in core definitions while establishing agile, collaborative mechanisms for updates.

To address the identified gaps and move towards a more harmonised, efficient, and actionable European HAI surveillance system, the following recommendations are proposed.

**Foundational Steps for Harmonisation:**

- Develop and maintain a centralised ECDC manual and repository of case definitions and surveillance protocols. Following the model of the UK NHS HCAI Compendium, this should be a single, clear, and regularly updated source of truth applicable across all EU MS, fundamental to ensuring uniform interpretation and application, and forming the cornerstone of data benchmarking.
- Establish a sustained, collaborative governance mechanism with MS, inspired by the long-standing partnership between the U.S. CDC and the Council of State and Territorial Epidemiologists (CSTE). This should include formal multi-country technical working groups to address definitional grey areas, review complex cases, and jointly update guidelines, ensuring ownership and feasibility at the national level.
- Conduct an EU-wide assessment of HAI incidence indicators and their denominators. Standardising the measurement of underlying patient populations is a critical next step to enable direct comparison of incidence rates.

**B. Strategic Integration and Innovation**

- Promote the integration of HAI surveillance with national AMR and antimicrobial use monitoring programs under a One Health approach, leveraging shared IT infrastructure and data streams.
- Invest in capacity building and standardized training across all MS to ensure consistent understanding and application of ECDC definitions and surveillance methodologies.
- Support the development and adoption of automated, laboratory-based surveillance modules, particularly for BSI, following models like Denmark's HAIBA. This enhances objectivity, timeliness, and reduces reporting burden.
- Foster the implementation of automated data submission pipelines to the ECDC surveillance portal to facilitate real-time benchmarking and European-level analysis, a key lesson from modernisation initiatives like the CDC's NNDSS Modernization Initiative (NMI).
- Explore the application of Artificial Intelligence (AI) and machine learning to support case ascertainment, data validation, and signal detection within the framework of standardised ECDC definitions.
- Encourage the expansion of surveillance to include new priority indicators and ensure surveillance data is actively used to design, implement, and evaluate targeted IPC interventions.

# 10 CONCLUSIONS

This study provides a comprehensive, contemporary overview of the case definitions used in HAI surveillance across the EEA and Ukraine. The findings confirm both significant progress and persistent challenges in the journey towards a harmonised European surveillance system.

A clear strong foundation for harmonisation exists, driven by the widespread adoption of ECDC PPS and HAI-Net protocols as mandated by the European Commission's Implementing Decision (EU) 2018/945. This provides a crucial common language for HAI surveillance across most countries. However, the study also demonstrates that full harmonisation remains an unmet goal. The evidence reveals a landscape marked by extensive national and regional adaptations, where ECDC definitions are routinely tailored to local contexts, resources, and historical practices. These modifications, such as excluding specific infection types, fundamentally limit the comparability of aggregated data.

The existence of national and regional systems with distinct definitional frameworks, alongside systems dependent on voluntary participation, adds further layers of complexity to a unified European approach. Furthermore, the wide disparity in system maturity and

digital infrastructure exacerbates these definitional inconsistencies, creating practical barriers to standardised data collection and exchange.

Consequently, while the strategic framework for a coordinated EU-wide HAI surveillance network is established, it's operational realisation is hindered by a fragmented implementation landscape. Achieving true data comparability for effective benchmarking, trend analysis, and evaluation of prevention policies at the EU level will require targeted, sustained action. This must address not only definitional alignment but also the underlying capacity gaps, technological disparities, governance structures, and critically, the need for dedicated, sustainable funding that currently perpetuate variability. The long-term sustainability of surveillance systems and their capacity to inform and evaluate effective prevention interventions depend on this secure financial commitment.

The recommendations outlined in this report propose concrete steps to address these barriers, emphasizing the need for coordinated investment in capacity, technology, and collaborative governance to translate the common framework into a truly comparable and actionable European surveillance reality.

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