

TECHNICAL REPORT

**Survey protocol for the ECDC
genomic-based survey of
carbapenem-resistant
Acinetobacter baumannii in Europe
Version 1.3**

ECDC TECHNICAL REPORT

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This protocol of the European Centre for Disease Prevention and Control (ECDC) was coordinated by the Antimicrobial Resistance and Healthcare-Associated Infections (ARHAI) Section and the Microbiology and Molecular Surveillance Group, Surveillance Section.

This survey protocol is accompanied by the 'Laboratory manual for the ECDC genomic-based survey *Acinetobacter baumannii* in Europe' [1], which was developed in consultation with the 'ECDC Expert Group for microbiological support to the ECDC CRAB survey'. The members of the Expert Group, and the recruitment process for group membership, are in Annex 1.

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Acknowledgements

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Errata: On 2 October 2024, the following corrections were made to this report:

- In Table 2, the number of 'Level 2' regions for the selected EU candidate and potential candidate countries was updated, from 26 to 38. This also increased the total number of 'Level 2' regions. Box 1 is also updated, to reflect the updated number of 'Level 2' regions in eligible countries (N=291).
- Annex 3 contains minor updates. As stated in the section 'metadata structure', these metadata will be included in the annual ECDC metadata update process, so remain subject to additional changes. In Table 7, the changes include removing a duplicated row ("HospitalId"); updating a variable name ("PrescribedAntimicrobial"); and updating variable descriptions to align with the main text of this survey protocol.
- In the section 'How to complete Form C (hospital staff +/- national staff)', the definition of a survey period is now stated explicitly.
- In 'planned data analyses', a reference to an annex has been corrected, to Annex 8 rather than Annex 7.
- Annex 10 was edited so that the third green box from top contains "AND 'n' isolates from CSAb colonisation, so that the 'N' of submitted isolates is 10" rather than "AND 'n' isolates from CSAb infection, so that the 'N' of submitted isolates is 10".

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Abbreviations

AST	Antimicrobial susceptibility testing
CCRE	Carbapenem- and/or colistin-resistant Enterobacteriaceae
CLSI	Clinical and Laboratory Standards Institute
CRAb	Carbapenem-resistant <i>Acinetobacter baumannii</i>
CSAb	Carbapenem-susceptible <i>Acinetobacter baumannii</i>
DALY	Disability-adjusted life year
EUCAST	European Committee on Antimicrobial Susceptibility Testing
EuSCAPE	European survey on carbapenemase-producing Enterobacteriaceae
IS	Insertion sequence elements (ISAb)
MIC	Minimum inhibitory concentration
NUTS	Nomenclature of territorial units for statistics
MBL	Metallo- β -lactamase
PCR	Polymerase chain reaction
WGS	Whole-genome sequencing

Intended audience for this document

The intended audience includes those who may implement, or participate in, an ECDC survey to collect carbapenem-resistant *Acinetobacter baumannii* (CRAb) specimens and patient metadata from acute care hospitals, such as national-/sub-national-level public health institutes, and hospital and clinical laboratory staff.

Short overview of the survey

ECDC considers CRAB a key priority pathogen, amenable to 'strategy-orientated surveillance' as 'sentinel surveillance or surveys' of the ECDC European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net) [2,3]. This ECDC survey protocol describes the technical requirements for implementing a genomic surveillance-based survey of CRAB isolates from patients seeking hospital care. It is intended for first use in 2024–2025.

The primary public health objective of this survey is to describe the occurrence and geographic distribution of CRAB strains and transmissible resistance/genetic elements of critical public health importance within CRAB strains, among hospital patients, at the regional (NUTS 2 level), national, and European levels. The secondary objectives seek to enable national activities to target infection control interventions for *Acinetobacter* spp., by supporting countries in their development of technical capabilities and proficiency for genomic-based surveillance of CRAB, and by identifying epidemiological factors for CRAB infection at bacterial clonal and sub-genomic level.

The ECDC CRAB survey 2024–2025 is designed to collect specimens from most or all imported CRAB in countries with a low incidence of CRAB infections, and a systematic sample of circulating CRAB in countries with a higher incidence. In Europe, countries with higher incidence of *A. baumannii* infections also generally identify a high proportion with resistance [4,5]. Conversely, countries that notify low numbers of isolates from invasive *A. baumannii* infections also tend to report that a low proportion of those isolates were resistant to carbapenems. According to ECDC estimates (see Annex 2), a large regional hospital in a country with low incidence might identify one patient with a CRAB infection each year. Reports from such countries identified cross-border patient transfer as a common risk factor among their few notified CRAB isolates [6].

According to the survey design, each participating country should seek to recruit one acute care hospital from each NUTS 2 region (generally 0.8–3 million population) to act as a sentinel site for that region. Note that this is a guide and is not strict, and there may be situations where it is not possible to recruit one acute care hospital in each NUTS 2 region. Ideally, the recruited hospitals should cover as much of the national population as possible.

During a 6-month survey period between October 2024 and June 2025, participating hospitals, with clinical laboratories, should collect 10 consecutive, non-duplicate *A. baumannii* isolates, and associated metadata, from 10 patients. Initially, laboratories should collect the first 10 *A. baumannii* isolates during the survey period, no matter whether they are from colonisation or infection. Subsequently, if fewer than 10 of these are from patients with CRAB infection, they should include isolates from newly detected cases of CRAB infection, by replacing other isolates from the group of 10 isolates. The first isolates eligible for replacement are isolates from carbapenem-sensitive *A. baumannii* (CSAb) colonisations, followed by isolates from CSAb infection, followed by CRAB colonisation. This should continue until there are 10 stored isolates from CRAB infections, or the end of the survey period, whichever is first.

National reference/expert laboratories are requested to confirm the resistance phenotype of the collected isolates if the sending laboratory did not use European Committee on Antimicrobial Susceptibility Testing (EUCAST)-recommended methods, and to prepare bacterial samples for shipment to an ECDC contractor for verification of sample quality, to enable eventual whole-genome sequencing (WGS). The contractor will generate raw files (FASTQ) for the sending laboratories and ECDC, to enable achievement of the primary and secondary survey objectives.

Nationally designated 'National Survey Coordinators' (ECDC Operational Contact Points for Antimicrobial-resistant isolates (AMRISO)) are requested to coordinate the survey nationally, including the collation of isolate- and patient-level metadata to accompany each submitted isolate, and hospital-level metadata for each participating hospital, subsequently submitting it ECDC (to 'EpiPulse Cases').

This survey design is based on the European survey on carbapenemase-producing Enterobacteriaceae (EuSCAPE) project (2013–2015) [7]. The EuSCAPE project demonstrated the feasibility of conducting integrated epidemiological and microbiological sentinel multi-centre surveys that provide comparable, quality-assessed data for EU-level analysis. This design was also used in the ECDC survey of carbapenem- and/or colistin-resistant Enterobacteriaceae (CCRE) in 2019, which focussed on *Escherichia coli* and *Klebsiella pneumoniae* [8]. Indeed, the metadata specified in this protocol for a ECDC CRAB survey ('AMRISO'; Annex 3) are a minor update of the patient metadata from the 2019 ECDC CCRE survey ('AMRISO') [9]. They remain mutually compatible. However, in the ECDC CRAB survey in 2024–2025, unlike the EuSCAPE project and the CCRE survey, national reporting of metadata from CRAB patients to ECDC is envisaged to follow standard processes for the reporting of national surveillance data to the ECDC database 'EpiPulse cases' (formerly 'TESSy') [10]. In this process, contact points designated by ECDC coordinating competent bodies¹ for Antimicrobial-resistant isolates (AMRISO), upload and approve national data.

¹ Operational Contact Points (OCPs) for Epidemiology, Microbiology, Bioinformatics, IT/data manager. For more information, see <https://www.ecdc.europa.eu/en/about-ecdc/who-we-are/governance/competent-bodies>

Background

Genomic-level investigations for antimicrobial-resistant pathogens, when combined with epidemiological data, can support the generation of targeted control measures. Together, they provide sufficient analytical resolution to describe transmission chains and the distribution of resistance genes by 'person, place and time' [4].

Relevant activities and legislation

CRAB is one of the three 'antimicrobial-resistant priority pathogens' that are deemed 'critical priorities' in the [2017 WHO global priority pathogens list](#) [11]. ECDC considers CRAB a key priority pathogen, amenable to 'strategy-orientated surveillance' as 'sentinel surveillance or surveys' of the ECDC European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net; Table 1; [2,3]). It is also a key pathogen of the European Commission project 'EURGen-RefLabCap', which aims to strengthen the capacities of National Reference Laboratories in European countries for genotypic and phenotypic characterisation, for surveillance and outbreak investigation of selected pathogens [12].

The (European) Commission Implementing Decision (EU) 2018/945 contains case definitions to report data from carbapenem-resistant and -sensitive *Acinetobacter* spp. strains, for epidemiological surveillance [13]. The 'network activities' for epidemiological surveillance, between ECDC and EU Member States in close cooperation with third countries, are specified within Regulation (EU) 2022/2371 of the European Parliament and of the Council on 'serious cross-border threats to health'. Its Article 13 specifies the aims of such a network. These include the monitoring of trends and cross-border transmission, identification of risk factors for transmission, and contribution to assessments of the capacity of health systems to prevent and treat specific communicable diseases [14].

Table 1. ECDC public health objectives for EU molecular or genomic-based operations for carbapenem-resistant *Acinetobacter baumannii*, as applicable for mid-term (2019–2021) implementation

Objectives for outbreak investigation	Objectives for strategy-oriented surveillance
1. Early confirmation of multi-country dimension of outbreaks. 2. Identification of genetic vector/modes/sources of transmission. 3. Targeting of control measures 4. Assessment of effect of the control measures.	1. Detection and genotypic identification of high-risk clones*. 2. Identification of high prevalence geographical areas associated with the spread of specific high-risk clones. 3. Detection/delineation of cross-region or cross-border dissemination of high-risk clones. 4. Monitoring time trends in the frequency of occurrence of particular genotypes in the population and identification of high prevalence population groups. 5. Impact assessment of prevention and control programmes. 6. Targeting high-risk populations, geographical areas and dissemination pathways.

Source: [3]; * High-risk clones/plasmids: ecologically successful clonal types carrying chromosomal resistance determinants or plasmid-borne resistance genes associated with high or increasing population prevalence across surveys and/or displaying extensive or expanding geographical distribution (interregional spread or international spread) and/or association with multiple hospital outbreaks reported in literature [15].

Epidemiology of carbapenem-resistant *Acinetobacter baumannii* in the EU/EEA, 2019–2022

Acinetobacter spp. are associated with nosocomial outbreaks, particularly among very ill patients, and survives well on dry surfaces. In Europe, most infections with *Acinetobacter* spp. are from *A. baumannii*, following an incubation period of 7–12 days, with 4–40 days reported [16–20]. The risk of CRAB isolation is increased by factors including prior antimicrobial use [21].

ECDC estimates that, in 2019, there were 56 960 (50 148–64 187) infections with CRAB in EU/EEA hospitals, and 2 749 (2 294–3 211) deaths attributable to CRAB. Its health burden is relatively high, contributing an estimated 92 991 (79 640 – 106 652) disability-adjusted life years (DALYs) of the 1 101 288 (988 703 – 1 222 498) DALYs for all HAIs [19].

In 2020–2021, EU/EEA countries reported a large increase in notifications of CRAB from invasive isolates, compared to the years pre-2020 [4]. Then, in 2022, the notification rates in these countries returned towards a level similar to 2019 [5]. This 2020–2021 'peak' coincided with the changes to hospital healthcare provision imposed by the global COVID-19 pandemic. Importantly, the increases in notifications were especially prominent among countries that had reported high percentages of carbapenem-resistance among invasive *A. baumannii* isolates in 2018–2019 [4]. In the non-EU/EEA countries of the WHO EURO region, the percentages of invasive *A. baumannii* isolates that are carbapenem-resistant are generally high [22].

In 2019, 37 European countries responded to an ECDC survey regarding their epidemiological situation, laboratory capacity, and preparedness for CRAB. Eleven countries reported having a national policy or guideline for 'selective screening' for CRAB; the remainder reported that they did not [17]. Since 2019, some countries have established screening policies/guidelines, as a response to the 2020–2021 'peak' in CRAB incidence, or in response to the increase in patient transfers from countries with high CRAB prevalence, such as Ukraine [6,23].

Key genetic mechanisms for carbapenem resistance among *Acinetobacter baumannii*

A. baumannii exhibit a range of AMR mechanisms relevant to carbapenem resistance, including enzyme-based antibiotic inactivation, target site modifications, increased expression of efflux pumps, and the depletion of porins [24,25]. The primary mechanism for phenotypic carbapenem resistance in *A. baumannii* are the carbapenemases, especially carbapenem-hydrolyzing oxacillinases [26]. In Europe, class D β -lactamases (e.g. *bla*_{OXA-23}, *bla*_{OXA-24/40}, *bla*_{OXA-58}, and *bla*_{OXA-51-like} enzymes) are particularly common, although its intrinsically expressed carbapenemases (e.g. '*bla*_{OXA-51-like}') only mediate clinically relevant resistance to carbapenems in the presence of strong promoter, such as insertion sequence (IS) elements (*ISAb*) [24,26]. Furthermore, genes encoding class B metallo- β -lactamases (MBLs) that contribute to enzymatic inactivation of carbapenem antibiotics, such as *bla*_{IMP}, *bla*_{VIM}, and *bla*_{NDM}, have also been reported in *A. baumannii* strains [24-26].

The acquisition and spread of these carbapenem resistance genes among *Acinetobacter* spp. involve horizontal gene transfer through mobile genetic elements including conjugate plasmids, transposons, and integrons.

Although systematic surveys of the genetic mechanisms conferring carbapenem resistance to *A. baumannii* are relatively rare, recent peer-reviewed articles summarise studies from several continents [24,27].

Survey aim

The aim is to conduct a survey of CRAB identified in clinical laboratories in European countries, to acquire a snapshot of circulating strains for the purposes of genomic surveillance; and to support national activities to collect a representative sample of CRAB isolates, to support national CRAB infection prevention and control efforts.

Survey EU-level public health objectives

Primary objective

The primary objective is to describe the occurrence and geographic distribution of CRAB strains, and/or transmissible resistance/genetic elements of critical public health importance within CRAB strains, among patients in acute care hospitals in Europe, to inform prevention and control activities.

Secondary objectives

The secondary objectives are:

- To support EU/EEA countries, Western Balkan countries, and Türkiye in developing technical capabilities and proficiency in genomic-based surveillance and risk assessments of CRAB, to facilitate their identification of transmission chains, to enable targeted infection control interventions.
- To estimate the cumulative incidence of CRAB infections in participating hospitals during the survey period, to provide additional contextual information for the genomic results.
- To identify epidemiological factors for infection (or colonisation) with CRAB at clonal and sub-genomic level, to inform CRAB preparedness, prevention and control activities.

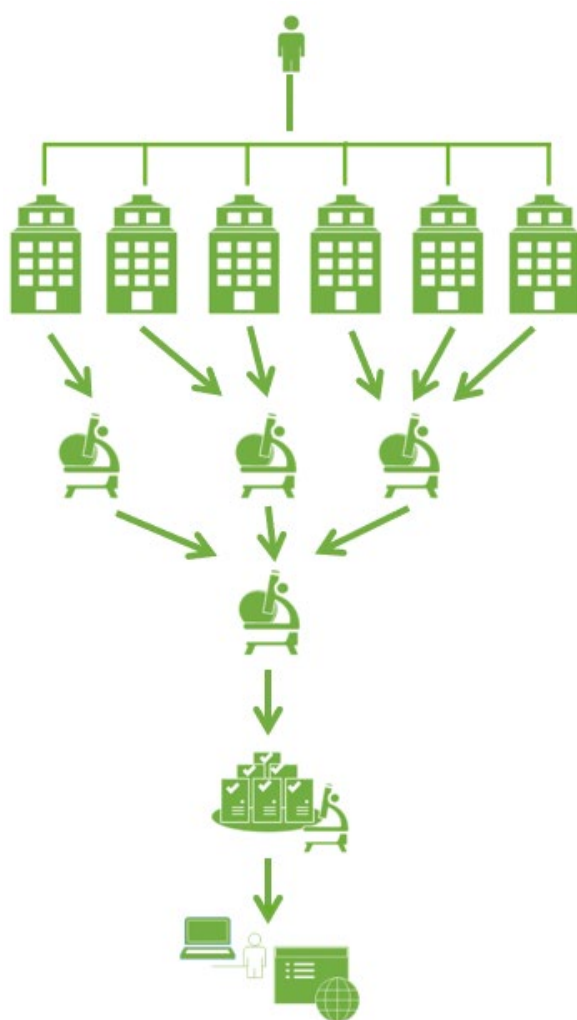
Survey design

The survey design is a structured, multi-centre, periodic, molecular epidemiological survey of CRAB, by genotype, among patients seeking hospital care in Europe. These surveys are expected to take place at a frequency indicated by the epidemiological situation, and subject to resource availability at ECDC and national and regional levels.

Figure 1 presents the steps in the survey design. It follows the design of the EuSCAPE project (2013-2015) survey [7] and ECDC CCRE survey (2019) [2,8].

Unlike the CCRE survey, submission of data to ECDC is completed by the standard route for surveillance data (Annex 7 – Reporting to TESSy under EpiPulse), and there is no genotypic (PCR) screening step for carbapenemase/colistin resistance genes, and no collection of nationally generated WGS data.

Figure 1. National workflow for participation in ECDC genomic-based survey of carbapenem-resistant *Acinetobacter baumannii*



National Survey Coordinator

- Recruits hospitals and laboratories.
- Collates and reports all metadata.
- Technical contact point for technical/logistic questions regarding the national survey and its metadata.

Hospitals

- Collects samples during normal clinical practice and sends them to regional/local laboratories for this survey.
- Collects hospital level metadata (Form C)
- On request from regional/local laboratories, collects patient level metadata (Form B) for eligible patients.

Regional/local laboratories

- Isolates *Acinetobacter baumannii** from sample.
- Performs phenotypic carbapenem susceptibility testing.
- Collects metadata at isolate (specimen) level (Form A).
- Asks hospital to collect patient-level metadata (Form B) from each patient that supplied the eligible sample.
- Stores all eligible isolates (N=10/hospital).
- Sends sample to national reference/expert laboratory.

National reference/expert laboratory

- Confirmatory AST for carbapenem susceptibility.
- (Optional) AST for NRL-selected antimicrobial agents.
- Prepares and stores isolates; and sends bacterial sample to 'central strain collection laboratory'.

Central strain collection laboratory (ECDC contractor)

- Confirms quality of submitted samples (bacterial sample).
- Liaises with National Survey Coordinator(s), if applicable, to identify samples that should be resubmitted, due to insufficient quality of the bacterial sample.
- Sends bacterial sample to central sequencing laboratory.

Central sequencing laboratory (2x ECDC contractors)

- Performs DNA extraction (Dante Labs SRL) and WGS (Eurofins Genomics GmbH), generating raw reads.
- Sends raw read data to each national reference/expert laboratory (national data) and to ECDC (all data).

AST: antimicrobial susceptibility testing; NRL: national reference laboratory; *: see 'Criteria for bacterial species'

Phase 1. Before the start of a national survey: actions for National Survey Coordinators

National participation and coordination

National designation of a national reference/expert laboratory

The **National Focal Point for Antimicrobial Resistance**² in each participating country should designate, for their country, a national reference/expert laboratory. It should perform reference services related to carbapenem resistance of *A. baumannii*, including antimicrobial susceptibility testing (AST) and genotyping.

National designation of a 'National Survey Coordinator'

The **National Focal Point for Antimicrobial Resistance**² in each participating country should designate a 'National Survey Coordinator' with expertise in molecular characterisation of CRAB. Ideally, they should be associated with the national reference/expert laboratory, such as a member of its laboratory staff. The 'National Survey Coordinator' should be designated as an 'Operational Contact Point for AMRISO', so that they can receive information emails from ECDC, and have relevant access to the ECDC surveillance system (EpiPulse Cases).

Roles of the 'National Survey Coordinator'

The role of the **National Survey Coordinator** is to coordinate the national activities for the survey (Figure 1). Specifically, their coordination activities should include:

1. Before the study

- A. Recruit hospitals (see 'Criteria to select hospitals') and laboratories (see 'Criteria to select clinical laboratories') to participate, in particular identifying a contact person in each institution. Note: ECDC does not request this contact list. The contact persons should support the National Survey Coordinator, for example, through collection, collation and reporting of compatible survey metadata.
- B. Liaise with participating hospitals and laboratories in their country:
 - To reply to technical questions regarding survey preparations, liaising with ECDC as necessary.
 - To present the 'Isolate selection strategy for the survey'.
 - To present Forms A, B, and C (Annexes 4–6), including their permitted values, and optional variables.
 - To communicate the preferred formats for unique identifiers for the survey metadata (see 'Preferred data formats for unique identifiers')

Note (1): these unique identifiers can be existing national unique identifiers.

Note (2): the final national dataset should not contain unique identifiers that contain 'true patient identifiers' such as the date of birth.
 - To agree about the survey start date(s) for the six-month survey period (i.e. at earliest from 1 October 2024 and at latest from 1 January 2025).

2. During the study

- A. Act as focal point for participating hospitals and laboratories in their country, replying, for example, to technical questions regarding survey execution, such as questions regarding completion of Forms A–C using the permitted values.
- B. Act as focal point for ECDC, for example, to support to resolution of technical issues with biological specimens submitted for this survey by participating laboratories, as identified by ECDC or its contractors.

3. After the study

- A. The same as during the study, i.e. 2A and 2B above.
- B. Collate data from participating hospitals and laboratories into a dataset (Annex 3) to report to ECDC (Annex 7), ensuring that it meets the specifications described in Annex 3. Optionally, National Survey Coordinators may choose to replace antimicrobial susceptibility results reported by a clinical laboratory with those provided by a national reference/expert laboratory.

Survey start and end dates

The start of the six-month surveillance period should be at earliest on 1 October 2024, and end before 30 June 2025.

*Note: hospitals in countries with relatively low incidence of infections with *Acinetobacter* spp. may need the entire six months to collect 10 eligible isolates, and so the latest start date would be 1 January. By contrast, in countries with relatively high incidence, hospitals may collect 10 eligible isolates relatively quickly (Annex 2), implying that they can start the survey later than that.*

² 'Observer National Focal Points for Antimicrobial Resistance' in the Western Balkan countries and Türkiye.

Eligibility and selection criteria

Criteria for countries

The eligible countries for the ECDC CRAB survey in 2024–2025 are the **30 EU/EEA countries, Western Balkan countries** (Albania, Bosnia and Herzegovina, Kosovo³, Montenegro, North Macedonia, and Serbia) **and Türkiye**.

Criteria to select hospitals

Eligible hospitals

Hospitals are eligible to participate if they provide acute care services as part of the national healthcare system, and they are able to:

- to send patient samples to participating laboratories for this study, and
- to collect metadata for this study, both for their hospital (Form C); and also, if indicated by their clinical laboratory, for each patient that provided an eligible isolate (Form B).

Participating hospitals will not be excluded from the survey dataset if they detect fewer than 10 eligible isolates (*Acinetobacter* spp. colonisations or infections) during the survey period, due to low national incidence.

Selection of hospitals

In the EU/EEA, there are over 2 500 acute care hospitals, in 244 NUTS 2 regions (Table 2).

National Survey Coordinators should aim to recruit **one hospital from each NUTS 2 region**, to be used as 'sentinel' hospitals for this survey. **Note that this is a guide and is not strict, and there may be situations where it is not possible to recruit one acute care hospital in each NUTS 2 region. Ideally, the recruited hospitals should cover as much of the national population as possible.** The NUTS classification for 2024 is available from <https://ec.europa.eu/eurostat/web/nuts/overview>.

If the National Survey Coordinator identifies ≥1 eligible hospital within a NUTS 2 region, they should prioritise:

- the hospital with a patient catchment area that is mostly within its NUTS 2 region; and
- hospitals that have demonstrated a capacity to conduct similar surveys, especially if they were conducted with the National Survey Coordinator and/or national reference/expert laboratory.

If the National Survey Coordinator does not recruit an eligible hospital from a NUTS 2 region, they should:

- EITHER recruit another hospital that commonly receives patients from that NUTS 2 region, such as a hospital close to the NUTS 2 border, or a large tertiary acute care hospital in a nearby large city;
- OR reduce the national sample size, by recruiting one hospital from each NUTS 1 region.

If a hospital has more than one geographical site, the National Survey Coordinator may include each site as a separate hospital if each site has a catchment area (mostly) in different NUTS 2 regions. Otherwise, a hospital with more than one geographical site but within the same NUTS2 region may be considered as one hospital.

Hospital survey period

Each participating hospital should agree a survey start date for their hospital with their National Survey Coordinator.

Criteria to select clinical laboratories

Laboratories are eligible to participate if they provide clinical laboratory services for the participating hospital(s) including having the capability to isolate *A. baumannii* from a clinical sample, and routinely test isolates of *A. baumannii* for susceptibility against any of the commonly available carbapenems (doripenem, imipenem, or meropenem).

For practical purposes, this may be local/regional clinical laboratories or the national reference/expert laboratory, and one laboratory may provide the above services to more than one participating hospital.

Criteria to select patients

Both inpatients and outpatients in acute care hospitals are eligible for inclusion in the survey.

De-duplication of patients from inter-hospital transfers

If feasible, de-duplicate patients identified in >1 participating hospital during this survey, such as inter-hospital transfers. This is unlikely to be feasible in all countries, for all inter-hospital transfers.

³ This designation is without prejudice to positions on status and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

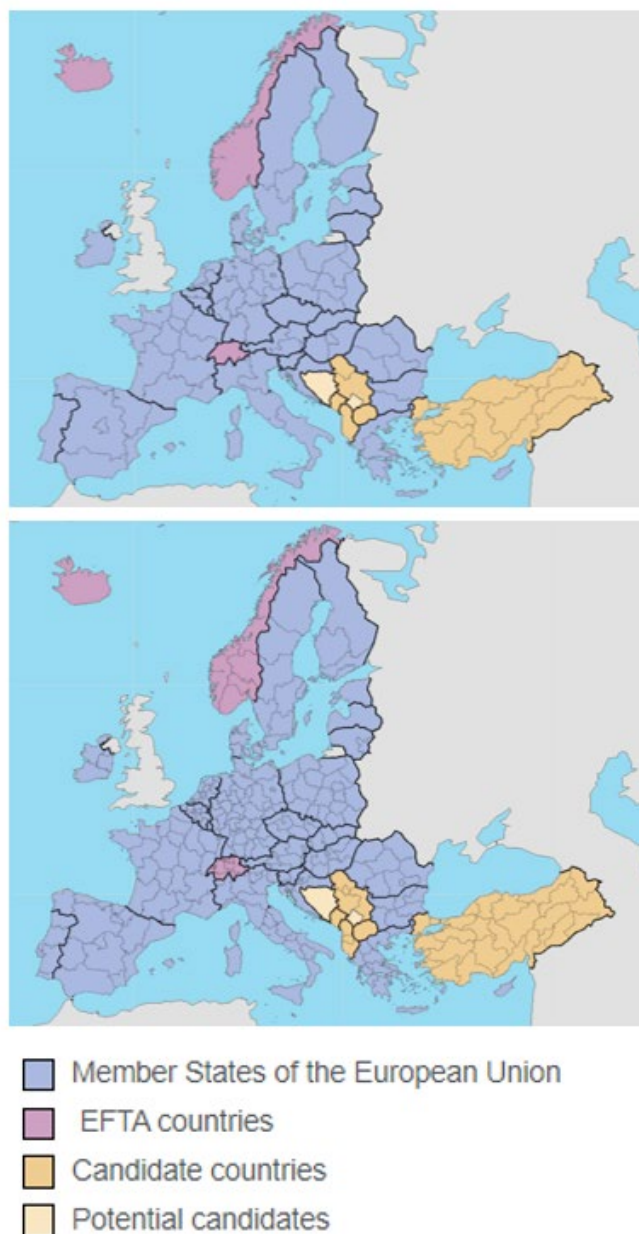
Table 2. Number of regions in countries eligible to participate in the ECDC carbapenem-resistant *Acinetobacter baumannii* survey, 2024–2025

	Country	N of regions ^{a,b}	
		Level 1	Level 2
EU	Austria	3	9
	Belgium	3	11
	Bulgaria	2	6
	Croatia	1	4
	Cyprus	1	1
	Czechia	1	8
	Denmark	1	5
	Estonia	1	1
	Finland	2	5
	France	14	27
	Germany	16	38
	Greece	4	13
	Hungary	3	8
	Ireland	1	3
	Italy	5	21
	Latvia	1	1
	Lithuania	1	2
	Luxembourg	1	1
	Malta	1	1
	The Netherlands	4	12
	Poland	7	17
	Portugal	3	9
	Romania	4	8
	Slovakia	1	4
	Slovenia	1	2
	Spain	7	19
	Sweden	3	8
	Total EU	92	244
EEA	Iceland	1	1
	Liechtenstein	1	1
	Norway	1	7
	Total EEA	3	9
Selected EU candidate and potential candidate countries^c	Albania	1	3
	Bosnia and Herzegovina	NA ^b	NA ^b
	Kosovo [*]	1	1
	Montenegro	1	1
	North Macedonia	1	1
	Serbia	2	4
	Türkiye	12	26
	Total EU candidate and potential candidate countries	18 ^b	38 ^b
All EU/EEA and non-EU/EEA		114 ^b	291 ^b

Source: Eurostat 'NUTS 2024 classification' (Available from: <https://ec.europa.eu/eurostat/web/nuts/overview>).

^a: N of NUTS regions (EU/EEA countries) or Statistical Regions (EU candidate and potential candidate countries), excluding all 'Extra-Region' regions; ^b: for the purposes of the ECDC CRAB survey 2024–2025, Bosnia and Herzegovina can be considered to have one Level 1 Region and two Level 2 Regions; ^c: priority countries for ECDC accession support under the EU enlargement policy; NA: not applicable (country does not have Statistical Regions); *: This designation is without prejudice to positions on status, and is in line with UNSCR 1244 and the ICJ Opinion on the Kosovo declaration of independence.

Figure 2. NUTS 1 and NUTS 2 regions in EU/EEA countries, EU candidate and potential candidate countries (2021)



Regions in the Member States of the European Union according to NUTS 2021. Statistical regions in EFTA countries, candidate countries and potential candidates according to latest available bilateral agreement.

Source: Eurostat 2021, <https://ec.europa.eu/eurostat/web/nuts/visualisations>

Box 1. NUTS regions

NUTS regions are subnational geographical areas designated by EU/EEA countries, to support harmonised statistical analyses [28]. In EU candidate and potential candidate countries, 'Statistical Regions' are analogous to NUTS regions. In the countries eligible to participate in this CRAB survey, there are 114 'Level 1' regions (generally 3 – to 7 million population), which are subdivided into 291 'Level 2' regions (generally 0.8–3 million population) (Table 2 [28]).

Criteria for bacterial species and isolates

Eligible species

The laboratory manual that accompanies this protocol contains instructions on how participating laboratories should include or exclude a strain, based on the output from their laboratory system [1]. During analysis, ECDC will describe the phylogenetic distribution of the submitted strains. In subsequent surveys, other species from the genus *Acinetobacter* may be included, depending on changes in the epidemiological situation.

Inclusion criteria: participating clinical laboratories may submit isolates that they consider to be '*A. baumannii*' according to their standard laboratory practices.

Exclusion criteria: clinical laboratories should not include isolates with a speciation result obtained with their standard practice(s), if that result excludes that the species is *A. baumannii*. For the purposes of this survey, the 'gold standard species definition' of *A. baumannii* is [NCBI:txid470](#) (Bouvet and Grimont, 1986 [29]). For example, if the output from a standard laboratory practice identifies that an isolate is *A. pittii*, that isolate is not eligible for inclusion.

Eligible isolates

Only include non-duplicate bacterial isolates of eligible species from non-duplicate patients, collected during the survey period in a participating hospital, that meet the case definition. Preferably, include isolates from clinical specimens collected for diagnostic purposes (e.g. blood, urine, sputum and wound secretions).

Infection and colonisation

The designation of a case of colonisation or infection should follow national criteria. In general, the designation of colonisation may be indicated from a screening sample that is positive for an eligible species. Designation of infection may be indicated by a clinical specimen, collected for diagnostic purposes, that is positive for an eligible species, and may also consider factors such as identification at a normally sterile site (e.g. blood, cerebrospinal fluid, pleura) and the presence of signs or symptoms of infection (e.g. fever, elevated inflammatory markers, elevated white cell count, abnormal imaging) [18].

Case definitions

Case of CRAb infection: an individual patient with an infection (positive clinical specimen, collected for diagnostic purposes) with *A. baumannii* identified by AST as phenotypically resistant to carbapenem(s).

Case of CRAb colonisation: an individual patient with colonisation (positive screening sample) with *A. baumannii* identified by AST as phenotypically resistant to carbapenem(s).

Case of CSAb infection: an individual patient with an infection (positive clinical specimen, collected for diagnostic purposes) with *A. baumannii* identified by AST as phenotypically susceptible to carbapenem(s).

Case of CSAb colonisation: an individual patient with colonisation (positive screening sample) with *A. baumannii* identified by AST as phenotypically susceptible to carbapenem(s).

Isolate selection strategy for the survey

Brief overview

In brief, participating laboratories should collect the first 10 eligible *Acinetobacter* spp. isolates during the survey period. Subsequently, laboratories should include isolates from newly detected cases of CRAb infection, by replacing other isolates from the group of 10 isolates. The first isolates eligible for replacement by CRAb infection isolates are isolates from CSAb colonisation, followed by isolates from CSAb infection, followed finally by isolates from CRAb colonisation. This should continue until the laboratory has isolates from 10 cases of CRAb infection, or the end of the survey period, whichever is first.

National incidence, and anticipated survey activity

In Europe, the national incidence of CRAb infection is quite skewed, with most countries having either high or relatively low incidence (see 'Annex 2 – Sample size calculation').

In countries with higher CRAb incidences, the participating hospitals are likely to detect 10 cases from CRAb infections within some weeks. In these hospitals, the survey start date might coincide with a suspected outbreak. The strategy for these is presented in the next section.

In countries with relatively low CRAb incidence, the participating hospitals are unlikely to detect 10 cases from CRAb infections during the survey period. For many hospitals, the sampling strategy means that they are likely to report every CRAb isolate identified during the survey period, including all imported cases.

How to process suspected outbreaks or clusters of cases

No change to the sampling frame is required for isolates from known or suspected outbreaks or clusters of cases. In other words, if outbreaks or clusters are known or suspected, there is no need to exclude isolates, or select only representative isolates.

This 'clean' approach to the sampling frame will simplify the subsequent description and analysis of the European dataset. Although this may obtain less diversity of the submitted isolates, it will give a better presentation of the epidemiological situation for European hospitals during the survey period.

Hospitals with comprehensive surveillance

Hospitals with comprehensive surveillance of *Acinetobacter* spp. are permitted to select isolates from their database, using Annex 10. The isolates should be from the survey period (i.e. prospective), with Form A completed for each.

National coordination of data collection and reporting

National Survey Coordinators are advised to communicate their reporting preferences to their participating hospitals and laboratories prior to the start of the study. This will simplify their collation of a national dataset for this study (see Phase 3), and any follow-up, such as data validation.

The metadata for the ECDC CRAB survey (see Annex 3, Table 7) are a minor update to the ECDC TESSy metadata AMRISO developed for the ECDC EURGen-Net CCRE survey, 2019 [8,9], and is 'back-compatible' with that data.

Survey data collection tools

National Survey Coordinators should ensure that participating laboratories and hospitals have access to the three forms for this survey: Forms A–C. These are annexes to this protocol. They are also available on the ECDC webpage for this protocol (<https://www.ecdc.europa.eu/en/publications-data/survey-protocol-ecdc-genomic-based-survey-carbapenem-resistant-acinetobacter>) as separate downloads, in both .pdf and .docx formats.

Form A (Annex 4, one page) for each isolate that meets the eligibility criteria (N≤10 per hospital)

- Its top section contains the minimal dataset ('Specimen data') that can be recorded by the clinical laboratory, preferably on the day the specimen is collected.
- Its bottom section can be completed later, also by the clinical laboratory that receives the specimen ('Microbiological data').

Form B (Annex 5, two pages) for every patient that provided an isolate that meets the eligibility criteria

- Form A and Form B are a pair; there should be the same number of each at the end of the survey.
- Completion of this form requires communication between laboratory and hospital staff, as acquiring some information, such as prior hospitalisation or travel, is likely to require a direct review of patient notes.

Form C (Annex 6, one page) should be completed for each participating hospital.

- In most countries, this form will be completed by hospital staff in each participating hospital.
- In many countries, national survey coordinators might wish to provide some data for Form C from a national database (e.g. number of beds or patient admissions). If so, consider indicating this on Form C (.docx version).

National data reporting pathways

National Survey Coordinators should communicate to participating laboratories and hospitals how they wish to receive completed Forms A–C, e.g. password protected email attachments, or upload to a secure location.

Preferred data formats for unique identifiers

Harmonising the format of unique IDs in advance should support efficient survey coordination, and help avoid errors.

Unique identifiers for institutions

This survey collects unique identifiers for hospitals (**HospitalId**; Forms A–C) and laboratories (**LaboratoryId**; Forms A & B). Both can contain ≤ 1 000 alphanumeric characters (see Annex 3, Table 7).

National Survey Coordinators should provide each participating hospital and laboratory with a HospitalId and LaboratoryId, or indicate the preferred format of these two identifiers. These might use an existing national coding system, or be specific for this survey. If a participating hospital participated in another ECDC surveillance or survey activity, such as the ECDC CCRE survey in 2019 [12], or EARS-Net surveillance [10,22], preferably use the same identifiers.

Unique identifiers for isolates/patients

This survey does not include collection of patient identifiers.

'SampleId' (Forms A & B) is a unique identifier for each specimen that may be obtained from within the laboratory's information system, to simplify follow-up. Alternatively, this can be a pseudonymised sample/isolate identifier, that can be decoded nationally. It can be $\leq 1\,000$ alphanumeric characters.

NationalRecordId is a nationally generated unique identifier for every record (i.e. for each isolate/patient) submitted to ECDC, with ≤ 80 characters (Table 7). NationalRecordId can be different from SampleId.

Identifiers for antimicrobial agents

A code for an antimicrobial agent can be provided on Form A, both for phenotypic susceptibility testing results, and also (optionally) on Form B, to record the antimicrobial agent(s) prescribed for the *Acinetobacter* infection. National Survey Coordinators should communicate their preference for the format of the antimicrobial code to participating hospitals and laboratories. Only ATC codes can be reported to ECDC.

The laboratory manual that accompanies this protocol contains the ATC codes of antimicrobial agents that are included in EUCAST and CLSI clinical breakpoints, and ESCMID and/or IDSA treatment guidelines [REF].

National Survey Coordinators may wish to note that reporting by ATC code is commonly performed by their national colleagues that report antimicrobial consumption data to ECDC, for ESAC-Net [30]. If they are unsure who their national ESAC-Net colleagues are, National Survey Coordinators, and/or their ECDC National Focal Point for Antimicrobial Resistance, are welcome to contact ECDC.

Phase 2. During the survey: actions for participating laboratories and hospitals

Isolate sampling frame

Maximum number of survey isolates

Each participating hospital should submit 10 eligible *A. baumannii* isolates, obtained during a 6-month survey period.

Hospital survey start date and end date

The survey start date for a participating hospital should be agreed with the National Survey Coordinator. The survey end date for a hospital is whichever date is first: the date when 10 samples have been collected from cases of CRAB infection (sample date), or the end date agreed with the National Survey Coordinator (e.g. after six months).

How to select and process isolates during this study

Laboratories, with their participating hospital(s), should follow steps 1, 2, and 3 below. For more information, consult the above section 'Isolate selection strategy for the survey' (page 10), which presents a summary of the below, as well as the expected situation for hospitals and laboratories in countries with high and low incidences of CRAB infections.

Step 1: Laboratories should process the first 10 eligible isolates that enter the laboratory

From the start of the survey period, **process the first 10 eligible '*A. baumannii*' isolates obtained during the survey period** (see 'Eligibility and selection criteria'), **following steps 1a–1e, for each isolate:**

Step 1a: Perform phenotypic carbapenem susceptibility testing.

Step 1b: Complete [Form A](#) (one per isolate), especially the fields specifying:

- the 'Specimen source', as either a 'Screening sample' or a 'Clinical sample'; and
- the 'Phenotypic antimicrobial susceptibility testing' result.

Step 1c: Monitor the total of processed eligible isolates in a table. Table 3 is provided as an example.

Step 1d: Store the isolate, according to best local practice, in case they are requested during 'Step 3'.

Step 1e: Complete one [Form B](#) for every Form A, using information on your laboratory information system and/or information from the sending hospital.

Table 3. Example table for laboratories to track the total number of eligible isolates obtained during the survey period

Origin of eligible isolate*	Preference	Total eligible isolates
Case of CRAB infection	Report all	(max=10)
Case of CRAB colonisation		
Case of CSAb infection		
Case of CSAb colonisation	Least preferable	
Total eligible isolates (<i>Acinetobacter</i> spp.)		(max=10)

* See 'Eligibility and selection criteria'.

Step 2: Subsequently, replace less preferable isolates with isolates from CRAb infections

If you have stored 10 eligible isolates (see Step 1d) and it is not yet the end of the survey period, identify whether all 10 isolates are from CRAb infections, by consulting your aggregate table (see Table 3).

If yes: it is the end of the survey. Inform your national survey coordinator, and proceed to Step 3.

If no: follow Steps 2a–2c until you have stored 10 eligible isolates from CRAb infections, or until the end of the survey, whichever comes first.

- **Step 2a:** if your laboratory detects a new eligible isolate from a CRAb infection from your participating hospital(s) (i.e. isolates that are from a clinical sample and phenotypically resistant to at least one carbapenem), complete one [Form A](#) and one [Form B](#), and store the isolate for Step 3, as one of your 10 stored isolates.
- **Step 2b:** For every new isolate stored during step 2a, replace a stored isolate that is not from a CRAb infection, and its Form A and Form B. The first isolates eligible for replacement by CRAb infection isolates are isolates from [CSAb colonisation](#), followed by isolates from [CSAb infection](#), followed finally by isolates from [CRAb colonisation](#).
- **Step 2c:** Store each of these isolates. Once you have 10 isolates from CRAb infections, proceed to Step 3.

Step 3: Submit isolates to the National Reference/Expert Laboratory for this survey

On request by the National Survey Coordinator and/or the National Reference/Expert Laboratory, send isolates that were stored for this survey (Step 1d and Step 2c), and the Form A and Form B for each isolate, to the location that they indicate (e.g. the National Reference/Expert Laboratory), according to their instructions.

How to complete Form A (laboratory +/- hospital staff)

On receipt of a potentially eligible sample, laboratory staff should complete at least the green box in a new Form A (Figure 3; [Annex 4](#)).

Completing the top half of Form A

'Hospital code' and 'Laboratory code' are provided by the national survey coordinator to participating hospitals and laboratories. 'Sample identifier' should match the identifier recorded in your laboratory information system.

'Patient identifier' is not recorded in the final dataset, and so it can match an identifier used locally, such as the patient ID used in a hospital information system.

Indicate whether the 'specimen source' was a clinical or screening sample. If data are available, tick one option to indicate the source of the patient sample, no matter whether it was a screening sample or clinical sample. Samples from rectal screening may be reported as 'gastrointestinal tract' rather than 'faeces'.

Figure 3. Form A: Specimen metadata (top half)

Complete for every potentially eligible sample	
Name of person completing this form:	
	<i>For internal (hospital) use only; must <u>not</u> be included in the national dataset.</i>
Patient identifier:	
	<i>For internal (hospital) use only; must <u>not</u> be included in the national dataset.</i>
Patient gender: ☐ (M / F / OTH)	Patient age: (years)
Hospital code:	
	<i>Code provided by your National Survey Coordinator.</i>
Date of sampling:	20 / / (YYYY-MM-DD)
Specimen source (TICK ONE):	
☐ Screening sample ☐ Clinical sample	
If data are available, specify the source of the screening/clinical sample (TICK ONE):	
☐ Aspirate ☐ Blood ☐ Bone marrow	☐ Catheter exit site ☐ Cerebrospinal fluid ☐ Faeces
☐ Gastrointestinal tract ☐ Lower respiratory tract ☐ Reproductive tract	☐ Skin ☐ Soft tissue ☐ Urine
	☐ Wound ☐ Other
Laboratory code:	
	<i>Code provided by your National Survey Coordinator.</i>
Sample identifier:	
	<i>Unique identifier for each sample, from your laboratory system.</i>
Date of receipt source laboratory:	20 / / (YYYY-MM-DD)
	<i>Date that this sample arrived at the laboratory for isolation.</i>

Completing the bottom half of Form A

To identify species considered to be *A. baumannii*, see 'Criteria for bacterial species and isolates' (page 10). For more technical details for the laboratory process at each step, please consult the laboratory manual that accompanies this survey protocol [1].

Laboratories should perform **phenotypic antimicrobial susceptibility testing** (AST) of clinical isolates of *A. baumannii* for at least one of the commonly available carbapenems (doripenem, imipenem, or meropenem), according to the EUCAST guidance and recommendations that are current at the time of the survey [31,32]. For example, in EUCAST 'clinical breakpoints table 14.0', carbapenem resistance is defined as a minimum inhibitory concentration (MIC) for meropenem of >8 mg/L.

Additional phenotypic antimicrobial susceptibility testing of *A. baumannii* isolates (optional)

This ECDC genomic-based survey of CRAB does not request additional AST beyond normal practice and does not include the opportunity to reimburse AST.

Participating local laboratories and reference laboratories are welcome to share additional AST results for the submitted strains that are generated for local/national purposes (Figure 4). These may include antimicrobial agents that do not have a EUCAST breakpoint, such as ampicillin-sulbactam [31,33]. There is no limit to the number of AST results that can be reported, i.e. record these separately, if the table on Form A is full.

National Survey Coordinators, in consultation with their national/expert reference laboratory, may update AST results submitted by local laboratories with AST results obtained by the national/expert reference laboratory, as per standard national practice. The metadata does not collect information on whether the AST result was generated by a local or reference laboratory, because that is beyond the scope of this survey.

Figure 4. Form A: Specimen metadata (bottom half)

Species is considered to be <i>Acinetobacter baumannii</i>, or the speciation result does not exclude <i>A. baumannii</i> ☐ Yes (eligible) ☐ No (ineligible) Gold standard species definition for this survey: NCBI taxonomy ID: 470 (NCBI:txid470 ; Bouvet and Grimont, 1986)				
Phenotypic antimicrobial susceptibility testing (at a minimum, report at least one carbapenem)				
Antimicrobial agent ATC code (preferably); or standard hospital code	AST guideline /breakpoint	AST Method	MIC (mg/L), if relevant	Disk diffusion zone diameter (mm), if relevant
	☐ EUCAST ☐ CLSI ☐ Other ☐ None/N.A.	☐ AUTOM ☐ BROTHDIL ☐ GRAD ☐ ZONE		
	☐ EUCAST ☐ CLSI ☐ Other ☐ None/N.A.	☐ AUTOM ☐ BROTHDIL ☐ GRAD ☐ ZONE		
	☐ EUCAST ☐ CLSI ☐ Other ☐ None/N.A.	☐ AUTOM ☐ BROTHDIL ☐ GRAD ☐ ZONE		
	☐ EUCAST ☐ CLSI ☐ Other ☐ None/N.A.	☐ AUTOM ☐ BROTHDIL ☐ GRAD ☐ ZONE		
	☐ EUCAST ☐ CLSI ☐ Other ☐ None/N.A.	☐ AUTOM ☐ BROTHDIL ☐ GRAD ☐ ZONE		
	☐ EUCAST ☐ CLSI ☐ Other ☐ None/N.A.	☐ AUTOM ☐ BROTHDIL ☐ GRAD ☐ ZONE		

MIC: minimum inhibitory concentration; AUTOM: Automated instrument method; BROTHDIL: Broth microdilution; GRAD: Antimicrobial gradient (E-test, etc); ZONE: Disc diffusion test; N.A.: not applicable; ATC: Anatomical Therapeutic Chemical classification, available from https://www.whocc.no/atc_ddd_index

How to complete Form B (laboratory +/- hospital staff)

Every Form A should have a paired Form B. Form B ([Annex 5](#)) contains information that may commonly be contained in patient notes, rather than on hospital/laboratory information systems.

Completing the top part of Form B (grey)

The information provided at the top of Form B should match the information provided at the top of Form A.

Completing the middle part of Form B

Within the green section '**Information on the current hospitalisation**',

- '**Origin of patient**' refers to the entire hospital stay. For example, if an eligible sample was taken in an outpatient setting (e.g. emergency department) and the patient was subsequently transferred from that outpatient setting to an inpatient setting (e.g. an infectious disease department), tick 'Admitted (inpatient)'.
- '**Date of the patient's hospitalisation or outpatient visit**' is the date of registration on an information system, i.e. the date of hospital admission or outpatient attendance.
- Within the blue section, '**previous healthcare and travel**', preferably also specify the countries, if relevant.

Completing the bottom part of Form B

- The response to '**clinical significance**' (i.e. colonisation, infection, undetermined or unknown) should, in general, mirror the response to 'specimen source' on Form A (i.e. screening sample, clinical sample). The reasons for apparently diverging responses might include a clinical designation of an infection based on signs and symptoms, following a positive result from a screening sample from a non-sterile site [18].
- If the '**date of symptom onset**' is unknown, the sample date will be used as a proxy during analysis.
- The variable '**outcome of hospital stay**' is optional, for completion during the survey period. If necessary, complete these data at the end of the survey period, e.g. 'still admitted at end of survey period'.
- The '**case origin**' is 'community-acquired' if the sample was obtained in an outpatient setting, as there were fewer than 48 hours of hospital admission. If it is not possible to identify the number of hours since admission, then 'community-onset' cases are those obtained on the day of admission (day 1) or day 2; and all other cases are 'healthcare-acquired'.
- The field to report the '**antimicrobial agents prescribed following the clinical suspicion or diagnosis of *Acinetobacter* infection**' is also optional. This is a free text variable. Preferably separate each antimicrobial code with a comma (Figure 5).

If reporting these data, use the coding system recommended by the national survey coordinator, such as ATC codes [9,34]. For convenience, the ATC codes of common treatments for *Acinetobacter* infections are listed in Tables 3 and 4 of the laboratory manual that accompanies this survey protocol [1].

Figure 5. Form B: Patient metadata (middle and bottom parts)

Additional information about the case
Clinical significance (TICK ONE): ☐ Colonisation ☐ Infection (date of symptom onset: 2 0 __ / __ / __ YYYY-MM-DD) ☐ Undetermined or unknown
Case origin (TICK ONE): ☐ Hospital-acquired (sample collected more than 48 hours post admission) ☐ Community-onset (sample collected less than 48 hours post admission).
Outcome of hospital stay (TICK ONE) <i>Optional. If necessary, complete this at the end of the survey.</i> ☐ Discharged alive (Date: 2 0 __ / __ / __ (YYYY-MM-DD)) ☐ Still admitted at end of survey period ☐ Died during the current hospitalisation, from any cause (Date: 2 0 __ / __ / __ (YYYY-MM-DD)) ☐ Unknown
Antimicrobial agents prescribed/received following the clinical suspicion or diagnosis of <i>Acinetobacter</i> infection (LIST ALL) <i>Optional. Preferably report ATC codes, available from https://www.whocc.no/atcddd/index. Alternatively, report local codes. These data will generate European-level summary statistics; and not patient-, ward-, or hospital-level analyses.</i> <i>Note: this survey obtains insufficient data to ascertain the appropriateness of individual patient care.</i>

How to complete Form C (hospital staff +/- national staff)

Complete Form C ([Annex 6](#)) according to agreements with the National Survey Coordinator. For example, some variables may be considered as optional nationally, or are available from national databases, such as denominator data.

The concept of a 'survey period' is used for every numerical variable on Form C except for 'Number of acute care beds (exclude non-acute care beds)'. The survey period is considered to be the date from the 'survey start date' until the 'planned survey end date' and is not affected by the 'date of last reported sample'.

The '**hospital denominators**' provide context to the survey data provided by participating hospitals. The 'number of occupied bed-days' can be estimated using the calculation: ([N of beds in this hospital] × [N of days in survey period] × [estimated occupancy rate; e.g. 95%]). Alternatively, if known, the number of patient-days may be reported instead. If these denominators are unavailable for the year(s) of the survey, the previous year's data may be reported.

The '**microbiological processes during the survey period**' and '**aggregate numerators during the survey period**' are useful to describe the 'pressure' on each participating hospital, and their clinical laboratories, from *A. baumannii*. This will be especially relevant in hospitals that may be experiencing an outbreak at the start of the survey period.

The optional variable under '**prevention and control during the survey period**' will be used to generate summary statistics on the 'volume' of relevant hospital-level prevention and control activities.

Submitting isolates for this survey

Detailed instructions for microbiological processing of biological samples for this survey is provided in the ECDC technical document that accompanies this survey protocol, i.e. the 'ECDC laboratory manual for the ECDC survey of carbapenem-resistant *Acinetobacter baumannii*' [1]. This section summarises that document.

Storage of original isolates

Ideally, bacterial samples should be stored for up to two years, following national best practices.

Submitting bacterial sample

The bacterial sample may be supplied as 2×1 ml overnight cultures (optical density ≥ 1 at 600 nm), expecting each culture to contain 8×10^8 cells on average) OR a pellet from equivalent cultures in 2 ml screw cap tubes; OR plated colonies on agar plates (≥ 10 colonies with a diameter ≥ 0.8 mm).

Shipment of materials

The packaging and shipment of isolates should comply with national and international shipment regulations for biohazardous material (packaging instructions P650, UN3373 [35]).

Phase 3. After the survey: actions for National Survey Coordinators

Submitting survey metadata to ECDC

Pre-survey preparation

Before the start of a national survey National Survey Coordinators are strongly encouraged to consult the section above entitled 'Phase 1: Before the start of a national survey: Actions for National Survey Coordinators', in particular the subsections 'National coordination of data collection and reporting' and 'Preferred data formats for unique identifiers'. This is essential:

- to ensure harmonised use of unique identifiers by participating laboratories and hospitals;
- to promote efficient collation of the isolate-, patient- and hospital-level metadata generated by participating laboratories and hospitals; and
- to enable correction or completion of the collated metadata, if required (e.g. missing data or impossible data values).

Data for this study can be collected on Forms A–C (see previous sections for more details). These forms are available below (Annexes 4–6) and provided separately on the ECDC webpage for this protocol, as both .pdf and .docx files.

Metadata structure

Forms A–C are directly aligned with the survey metadata, 'AMRISO' (Table 7, Annex 3). The AMRISO metadata for the ECDC CRAB survey is a minor update to the AMRISO metadata developed for the ECDC EURGen-Net CCRE survey, 2019 [8,9], and will be 'back-compatible' with those data.

The AMRISO data have three data levels, each with a one-to-many relationship. Two of these are linked and should be reported together (*AMRISO* and *AMRISO\$AST*; Table 7). *AMRDENOM* (Table 8) can be reported separately. Table 4 shows the levels, and common variables between the levels.

Tables 7 and 8 (Annex 3) presents the full AMRISO metadata variables for this survey, including their definitions and permitted data formats. In Q4 2024, these updated metadata will be included in the standard ECDC 'annual metadata revision', with direct reference to this survey protocol. This annual process proceeds towards publication and incorporation of updated/new metadata into the ECDC surveillance database ('EpiPulse Cases') in Q1 of the subsequent year. In other words, a submission in Q4 2024 is incorporated in Q1 2025.

The webpage for this protocol contains a Microsoft Excel data entry tool for the national team, to facilitate their collation of data from all the Forms A–C, using data values permitted by the metadata, for the three data levels (Annex 3; Table 4).

Table 4. Metadata data levels and linkage, ECDC CRAB survey, 2024–2025

Data level	AMRISO <i>SubjectCode</i>	Contents of 1 row of data	Shared variables with the level 'above'	Shared variables with the level 'below'
Hospital level data	<i>AMRISODENOM</i> (Table 8)	Data for one hospital, from each Form C .	Not applicable – there is no level above.	<i>HospitalId</i> .
Isolate /patient level data	<i>AMRISO</i> (Table 7)	Data from each pair of Form A (isolate level) and Form B (patient level).	<i>HospitalId</i> .	<i>NationalRecordId</i> (= <i>ParentNationalRecordId</i> from <i>AMRISO\$AST</i>).
Antimicrobial susceptibility test level data	<i>AMRISO\$AST</i> (Table 7)	Data for one antimicrobial susceptibility test, as recorded on Form A (isolate level).	<i>ParentNationalRecordId</i> (= <i>NationalRecordId</i> from <i>AMRISO</i>).	Not applicable – there is no level below.

How to submit national data to ECDC

[Annex 7](#) describes the technical process to report the collated survey data to EpiPulse Cases using ECDC metadata.

AMRISO and AMRISO\$AST need to be reported at the same time, because they are linked. AMRISODENOM can be uploaded separately.

Data processing and planned analyses and outputs

Data protection

The EU/EEA and candidate countries submitting the data act as controllers for data processing operations occurring up to the transfer of the data to ECDC. Accordingly, they must anonymise, or, where anonymisation is not possible, pseudonymise all personal data before transferring them to ECDC. They are responsible for informing the data subjects of any transfer of personal data to ECDC, as well as informing them about their rights. The EU/EEA and candidate countries submitting the data are responsible for ensuring the security of the data until the data is transmitted to ECDC.

ECDC will process all personal data received in accordance with Regulation (EU) 2018/1725. Epidemiological data and pathogen sequencing data will be stored on ECDC's digital platforms for surveillance with restricted access for a period of ten years from their collection and will be anonymised afterwards. Upon request, and in accordance with the relevant legislation on public access to documents (Regulation (EC) 1049/2001) and the *ECDC's policy on data submission, access, and use of data within TESSy*, ECDC may grant access to subsets of epidemiological data to third parties for scientific or other purposes in public interest after having priorly consulted the relevant countries.

Annex 9 includes a Controller-to-Controller agreement on the protection of personal data, which is intended to apply to this survey. By participating in the CRAB survey, the EU/EEA and candidate countries agree to comply with these terms covering the necessary data protection requirements.

Planned data analyses

ECDC will perform analysis of centrally-produced FASTQ dataset with phylogenetic analysis, species identification, characterisation of the baseline genomic population structure, cgMLST-based cluster analysis, and prediction of antimicrobial resistance and virulence from resistance/virulence gene and chromosomal point mutations. A draft material transfer agreement text is provided in Annex 8. In light of the analysis focusing on producing taxonomic descriptions of the CRAB strains, and not an investigation of gene functionality, the survey is considered outside of the scope of the Access and Benefit Sharing Regulation⁴.

A description of specific and generic analytical methodologies for WGS analysis is contained in the technical report from the European Commission project 'EURGen-RefLabCap' 'Agreed common WGS-based genome analysis methods and standard protocols for national surveillance and integrated outbreak investigations of carbapenem- and/or colistin-resistant *Pseudomonas aeruginosa* and *Acinetobacter baumannii*' [36].

Planned ECDC outputs

Report: An ECDC Technical Report will be prepared, in parallel to the article below, but published subsequently. ECDC plans to also provide country reports that summarise the findings for each country as Annex(es).

ECDC Molecular Typing Tool: This visualisation tool for genomic data is accessible to authorised national users in EpiPulse. It will contain a subset of the isolate-level data, such as the derived sequence type, the phenotypic carbapenem susceptibility testing result (SIR), and a subset of the epidemiological data, such as country, an isolate date (e.g. *DateOfReceiptSourceLab*), or infection/colonisation (*SpecimenSource*).

Article(s): All articles published by ECDC must be publicly accessible. Named co-authors will include the National Survey Coordinator. Additionally, a co-author group, with each co-author identifiable on PubMed, will contain 1-3 people/country, approved by the National Focal Point (NFP) for AMR. All co-authors must meet ICJME criteria. Draft manuscripts will be sent to co-authors to enable this, e.g. distributed to National Survey Coordinators. National Survey Coordinators and/or NFPs for AMR will be invited to list all people who should be in the acknowledgements.

National WGS data

National Survey Coordinators will receive the WGS data generated by the central sequencing laboratory, for hospitals/laboratories in their country, within about eight weeks of submission of a sample.

Nationally generated outputs

The WGS data sent to participating laboratories are not under embargo. If these data are used in publications, please acknowledge ECDC, e.g. 'Whole-genome sequencing was (partly) performed using funding from the European Centre for Disease Prevention and Control (ECDC)'.

⁴ Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union Text with EEA relevance.

References

1. European Centre for Disease Prevention and Control (ECDC). Laboratory manual for the ECDC genomic-based survey of carbapenem-resistant *Acinetobacter baumannii* in Europe - version 1.2. Stockholm: ECDC; 2024. Available at: <https://www.ecdc.europa.eu/en/publications-data/laboratory-manual-genomic-based-survey-carbapenem-resistant-acinetobacter>
2. European Centre for Disease Prevention and Control (ECDC). European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net). Date accessed: 30 November 2023. Available at: <https://www.ecdc.europa.eu/en/about-us/who-we-work/disease-and-laboratory-networks/EURGen-net>
3. European Centre for Disease Prevention and Control (ECDC). ECDC strategic framework for the integration of molecular and genomic typing into European surveillance and multi-country outbreak investigations (2019–2021). Stockholm: ECDC; 2019. Available at: <https://www.ecdc.europa.eu/en/publications-data/ecdc-strategic-framework-integration-molecular-and-genomic-typing-european>
4. Kinross P, Gagliotti C, Merk H, Plachouras D, Monnet DL, Högberg LD, et al. Large increase in bloodstream infections with carbapenem-resistant *Acinetobacter* species during the first 2 years of the COVID-19 pandemic, EU/EEA, 2020 and 2021. *Euro Surveill.* 2022 Nov;27(46):2200845. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/36398574>
5. European Centre for Disease Prevention and Control (ECDC). Antimicrobial resistance in the EU/EEA (EARS-Net) - Annual Epidemiological Report for 2022. Stockholm: ECDC; 2023. Available at: <https://www.ecdc.europa.eu/en/antimicrobial-resistance/surveillance-and-disease-data/report>
6. Hecht J, Eisefeld J, Baum JHJ, Wagner-Wiening C, Leuze D, Zimnitskaya Y, et al. An Outbreak of Carbapenem-Resistant *Acinetobacter baumannii* in Multiple Federal States in Germany. *Dtsch Arztebl Int.* 2022 Jul 25;119(29-30):508-9. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/36345584>
7. Grundmann H, Glasner C, Albiger B, Aanensen DM, Tomlinson CT, Andrasevic AT, et al. Occurrence of carbapenemase-producing *Klebsiella pneumoniae* and *Escherichia coli* in the European survey of carbapenemase-producing Enterobacteriaceae (EuSCAPE): a prospective, multinational study. *The Lancet infectious diseases.* 2017 Feb;17(2):153-63. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/27866944>
8. European Centre for Disease Prevention and Control (ECDC). ECDC study protocol for genomic-based surveillance of carbapenem-resistant and/or colistin-resistant Enterobacteriaceae at the EU level. Version 2.0. Stockholm: ECDC; 2018. Available at: <https://www.ecdc.europa.eu/en/publications-data/ecdc-study-protocol-genomic-based-surveillance-carbapenem-resistant-andor>
9. European Centre for Disease Prevention and Control (ECDC). TESSy metadata sets. 2024. Date accessed: 30 November 2023. Available at: <https://epipulse.ecdc.europa.eu/tessyhelp/index.aspx?navigation=TechnicalGuidelines>
10. European Centre for Disease Prevention and Control (ECDC). EpiPulse - the European surveillance portal for infectious diseases. Stockholm: ECDC; 2021. Date accessed: 30 November 2023. Available at: <https://www.ecdc.europa.eu/en/publications-data/epipulse-european-surveillance-portal-infectious-diseases>
11. World Health Organization (WHO). Prioritization of pathogens to guide discovery, research and development of new antibiotics for drug-resistant bacterial infections, including tuberculosis. Geneva: World Health Organization; 2017(WHO/EMP/IAU/2017.12). 2017. Available at: <https://www.who.int/publications/i/item/WHO-EMP-IAU-2017.12>
12. EURGenRefLabCap. EURGenRefLabCap (European Union Service Contract no. SC 20197401) 2021. Date accessed: 30 November 2023. Available at: <https://www.eurgen-reflabcap.eu/>
13. European Commission (EC) Implementing Decision (EU) 2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions.
14. European Commission (EC) Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (Text with EEA relevance),
15. European Centre for Disease Prevention and Control (ECDC). ECDC roadmap for integration of molecular and genomic typing into European-level surveillance and epidemic preparedness – Version 2.1, 2016-19. Stockholm: ECDC; 2016. Available at: <https://www.ecdc.europa.eu/en/publications-data/ecdc-roadmap-integration-molecular-typing-and-genomic-typing-european-level>
16. Virginia Department of Health. *Acinetobacter* infection (last updated: August 2018). Date accessed: 14 May 2024. Available at: <https://www.vdh.virginia.gov/epidemiology/epidemiology-fact-sheets/acinetobacter-infection>
17. Lötsch F, Albiger B, Monnet DL, Struelens MJ, Seifert H, Kohlenberg A, et al. Epidemiological situation, laboratory capacity and preparedness for carbapenem-resistant *Acinetobacter baumannii* in Europe, 2019. *Euro Surveill.* 2020 Nov;25(45):2001735. Available at: <https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2020.25.45.2001735>

18. Bartal C, Rolston KVI, Nesher L. Carbapenem-resistant *Acinetobacter baumannii*: Colonization, Infection and Current Treatment Options. *Infect Dis Ther*. 2022 Apr;11(2):683-94. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8960525/>
19. European Centre for Disease Prevention and Control (ECDC). Health burden of infections with antibiotic-resistant bacteria in the European Union and the European Economic Area, 2016-2020. Stockholm: ECDC, 2022. Available at: <https://www.ecdc.europa.eu/en/publications-data/health-burden-infections-antibiotic-resistant-bacteria-2016-2020>
20. Cornell University Environment HaS. *Acinetobacter baumannii* Biological Agent Reference Sheet (BARS) (Updated October 2, 2023). Date accessed: Available at: <https://ehs.cornell.edu/research-safety/biosafety-biosecurity/biological-safety-manuals-and-other-documents/bars-other/acinetobacter-baumannii#:~:text=Acinetobacter%20poses%20very%20little%20risk,in%20working%20with%20this%20agent>
21. De Blasiis MR, Sciurti A, Baccolini V, Isonne C, Ceparano M, Iera J, et al. Impact of antibiotic exposure on antibiotic-resistant *Acinetobacter baumannii* isolation in intensive care unit patients: a systematic review and meta-analysis. *The Journal of Hospital Infection*. 2024 Jan;143:123-39.
22. European Centre for Disease Prevention and Control (ECDC). Surveillance of antimicrobial resistance in the Europe EU/EEA (EARS-Net) - Annual Epidemiological Report for 2022. Stockholm: ECDC; 2023. 2023. Available at: <https://www.ecdc.europa.eu/en/publications-data/surveillance-antimicrobial-resistance-europe-2022-data>
23. Zwitter RD, Wielders CC, Notermans DW, Verkaik NJ, Schoffelen AF, Witteveen S, et al. Multidrug-resistant organisms in patients from Ukraine in the Netherlands, March to August 2022. *Euro Surveill*. 2022 Dec;27(50):2200896. Available at: <https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2022.27.50.2200896>
24. Castanheira M, Mendes RE, Gales AC. Global Epidemiology and Mechanisms of Resistance of *Acinetobacter baumannii*-*calcoaceticus* Complex. *Clinical Infectious Diseases*. 2023;76(Supplement_2):S166-S78. Available at: <https://doi.org/10.1093/cid/ciad109>
25. Chakravarty B. Genetic mechanisms of antibiotic resistance and virulence in *Acinetobacter baumannii*: background, challenges and future prospects. *Mol Biol Rep*. 2020 May;47(5):4037-46. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/32303957>
26. Noel HR, Petrey JR, Palmer LD. Mobile genetic elements in *Acinetobacter* antibiotic-resistance acquisition and dissemination. *Ann N Y Acad Sci*. 2022 Dec;1518(1):166-82. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/36316792>
27. Agyepong N, Fordjour F, Owusu-Ofori A. Multidrug-resistant *Acinetobacter baumannii* in healthcare settings in Africa. *Frontiers in Tropical Diseases*. 2023 2023-February-28;4 Available at: <https://www.frontiersin.org/articles/10.3389/fitd.2023.1110125>
28. Eurostat. NUTS - Nomenclature of Territorial Units for Statistics. 2023. Date accessed: 30 November 2023. Available at: <https://ec.europa.eu/eurostat/web/nuts/background>
29. Bouvet PJM, Grimont PAD. Taxonomy of the genus *Acinetobacter* with the recognition of *Acinetobacter baumannii* sp. nov., *Acinetobacter haemolyticus* sp. nov., *Acinetobacter johnsonii* sp. nov., and *Acinetobacter junii* sp. nov. and emended descriptions of *Acinetobacter calcoaceticus* and *Acinetobacter lwoffii*. *Int J Syst Bacteriol* [No PubMed record available]. 1986;36:228-40.
30. European Centre for Disease Prevention and Control (ECDC). European Surveillance of Antimicrobial Consumption Network (ESAC-Net). Available at: <https://www.ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/esac-net>
31. European Committee on Antimicrobial Susceptibility Testing (EUCAST). Clinical breakpoints - breakpoints and guidance. 2023. Date accessed: 26 February 2024. Available at: https://www.eucast.org/clinical_breakpoints
32. European Committee on Antimicrobial Susceptibility Testing (EUCAST). Antimicrobial susceptibility testing. Date accessed: 26 February 2024. Available at: https://www.eucast.org/ast_of_bacteria
33. Paul M, Carrara E, Retamar P, Tängdén T, Bitterman R, Bonomo RA, et al. European Society of Clinical Microbiology and Infectious Diseases (ESCMID) guidelines for the treatment of infections caused by multidrug-resistant Gram-negative bacilli (endorsed by European society of intensive care medicine). *Clinical Microbiology and Infection*. 2022 2022/04/01;28(4):521-47. Available at: <https://www.sciencedirect.com/science/article/pii/S1198743X21006790>
34. WHO Collaborating Centre for Drug Statistics Methodology. Norwegian Institute of Public Health, Oslo, Norway. Date accessed: 27 February 2024. Available at: <https://www.whocc.no/>
35. World Health Organization (WHO). Guidance on regulations for the transport of infectious substances 2021-2022. Licence: CC BY-NC-SA 3.0 IGO. WHO: Geneva; 2021. Available at: <https://iris.who.int/bitstream/handle/10665/339825/9789240019720-eng.pdf?sequence=1>
36. Bortolaia V, Rebelo AR, Coia CW, Hendriksen RS, Helwigh B, Larsen AR. EURGen-RefLabCap agreed common WGS-based genome analysis methods and standard protocols for national surveillance and integrated outbreak investigations of carbapenem- and/or colistin-resistant *Pseudomonas aeruginosa* and *Acinetobacter baumannii* (version 1.0). 2023. Available at: <https://www.eurgen-reflabcap.eu>

Annex 1. Consulted experts

This survey protocol incorporates elements from the 'ECDC study protocol for genomic-based surveillance of carbapenem-resistant and/or colistin-resistant Enterobacteriaceae at the EU level. Version 2.0', published in July 2018 [8]. Its ECDC contributing authors were Barbara Albiger, Karin Johansson, Anke Kohlenberg, Daniel Palm, Dominique Monnet, and Marc Struelens. Annex 1 also lists the panels of external experts that contributed to that protocol, during expert consultations. The expert panel for the 2018 ECDC publication 'ECDC study protocol for genomic-based surveillance of carbapenem-resistant and/or colistin-resistant Enterobacteriaceae at the EU level. Version 2.0' were Amos Adler (Tel-Aviv Sourasky Medical Center, Israel), Petra Apfalter (Elisabethinen Hospital Linz, Austria), Arta Balode (Pauls Stradins Clinical University Hospital, Latvia), Rafael Cantón (Hospital Universitario Ramón y Cajal, Spain), Ed Feil (University of Bath, UK), Christian Giske (Karolinska hospital, Sweden), Hajo Grundmann (University Medical Center Groningen, The Netherlands), Youri Glupczynski (Cliniques Universitaires UCL de Mont-Godinne, Belgium), Radosław Izdebski (National Institute of Public Health, Poland), Vincent Jarlier (Université Pierre et Marie Curie, France), Jari Javala (National Institute for Health and Welfare, Finland), Angela Kearns (Public Health England, UK), Barry Kreiswirth (Public Health Research Institute Center, New Jersey Medical School, Rutgers, USA), Frédéric Laurent (CHU Lyon, France), Romyana Markovska (Medical University of Sofia, Bulgaria), Annalisa Pantosti (Istituto Superiore di Sanita, Italy), Harald Seifert (University Hospital Cologne, Germany), Robert Skov (Serum Statens Institut, Denmark), Arjana Tambić Andrašević (University Hospital for Infectious Diseases, Croatia), Alkiviadis Vatopoulos (National School of Public Health, Greece), Neil Woodford (Public Health England, United Kingdom), Helena Žemličková (National Institute of Public Health, Czechia).

At the 'Network meeting of the European Antimicrobial Resistance Genes Surveillance Network 2023' (29–30 November 2023), the second day included discussion of the draft content for this current protocol, with nationally designated attendees. The attendees were for EU/EEA countries: Rainer Hartl (Austria); Vilain Aline (Belgium); Daniel Te-Din Huang (Belgium); Stefana Sabtcheva (Bulgaria); Arjana Tambic Andrasevic; Irina Pristas, Josip Ujevic, Marija Guzvinec, Marko Jelic (Croatia); Christos Karagiannis (Cyprus); Barbora Zapletalová, Katerina Chudejova (Czechia); Louise Roer (Denmark); Kairi Tõnsau, Liisa Lilje, Marina Ivanova (Estonia); Kati Räisänen, Santeri Soininen (Finland); Niels Pfennigwerth (Germany); Michalis Polemis, Kyriaki Tryfinopoulou (Greece); Kristján Orri Helgason (Iceland); Monica Monaco, Giulia Errico (Italy); Baiba Niedre-Otomere (Latvia); Jelena Razmuk (Lithuania); Rodianne Abela (Malta); Ørjan Samuelsen (Norway); Elżbieta Literacka, Dorota Żabicka (Poland); Manuela Caniça (Portugal); Martin Sojka (Slovakia); Helena Ribic, Mateja Pirs (Slovenia); Belén Aracil (Spain); Alma Brolund, Petra Edquist, Vilhelm Müller (Sweden); Daan Notermans, Antoni P.A. Hendrickx (The Netherlands); for Western Balkan countries: Silva Tafaj, Artan Bego (Albania); Maja Ostojic (Bosnia and Herzegovina); Arsim Kurti (Kosovo*); Ana Kaftandzieva (North Macedonia); Deana Medic, Verica Jovanovic, Violeta Rakic (Serbia); Baki Can Metin, Zekiye Bakkaloglu (Türkiye); and for the EUGen-RefLabCap project: Ana Rita Rebelo, Jette Kjeldgaard (National Food Institute, Technical University of Denmark, Denmark); Valeria Bortolaia (Statens Serum Institut, Denmark).

The 'ECDC Expert Group for microbiological aspects of the CRAB survey' was formed in February 2024, recruited from the ECDC Expert Directory in February 2024, to provide input to the 'Laboratory manual protocol for the ECDC genomic-based surveillance of carbapenem-resistant *Acinetobacter baumannii* in Europe' [1]. To enable appropriate mitigation for potential conflicts of interest, ECDC reviewed the Declarations of Interest submitted by potential Expert Group members, in accordance with the ECDC policy on scientific integrity and independence. The selected members of the Expert Group were: Silva Tafaj (Microbiology Department, University Hospital 'Shefqet Ndroqi', Tirana, Albania); Anette Marie Kühle Hammerum (National Reference Laboratory for Antimicrobial Resistance, Statens Serum Institut, Copenhagen, Denmark); Sotirios Tsiodras (Department of Medicine, Attikon University Hospital, Athens, Greece); Antoni P.A. Hendrickx (Center for Infectious Disease Control, Diagnostics and Laboratory Surveillance (IDS), National Institute for Public Health and the Environment (RIVM), Bilthoven, the Netherlands); Ørjan Samuelsen (Norwegian National Advisory Unit on Detection of Antimicrobial Resistance, University Hospital of North Norway, Tromsø, Norway); Dorota Żabicka (National Reference Centre for Susceptibility Testing, National Medicines Institute, Warsaw, Poland); Vera Manageiro (National Reference Laboratory of Antibiotic Resistance and Healthcare Associated Infections, National Institute of Health Doctor Ricardo Jorge, Lisbon, Portugal); Ana Rita Rebelo (EARS-Net EQA (ECDC contractor) and EURGen-RefLabCap; National Food Institute, Technical University of Denmark, Copenhagen, Denmark); Thierry Naas (ESGARS; Assistance Publique-Hôpitaux de Paris (AP-HP), Paris, France); Elmine Alp Meşe (ESGCIP and EUCIC; University of Verona, Italy & Faculty of Medicine, Ankara Yıldırım Beyazıt University, Türkiye); Christian Giske (EUCAST; Karolinska University Hospital and Karolinska Institutet, Stockholm, Sweden). At the time of publication, the Expert Group had held one meeting, the 'Virtual Expert Group meeting for the 'ECDC survey of CRAB 2024/2025', on 26 March 2024.

* This designation is without prejudice to positions on status, and is in line with UNSCR 1244 and the ICJ Opinion on the Kosovo declaration of independence.

The 'Virtual network meeting of the European Antimicrobial Resistance Genes Surveillance Network 2024' (26 May 2024) included discussion of the draft content for this current protocol and its accompanying laboratory manual attendees designated to attend by the National Focal Point for AMR, and the 'ECDC Expert Group for microbiological aspects of the CRAB survey'. The attendees were for EU/EEA countries Heidrun Kerschner, Rainer Hartl (Austria); Aline Vilain, Daniel Te-Din Huang (Belgium); Ivan Ivanov, Stefana Sabtcheva (Bulgaria); Christos Karagiannis (Cyprus); Kateřina Chudějová (Czechia); Sebastian Haller (Germany); Anette Hammerum (Denmark); Liidia Dotsenko, Liisa Lilje Estonia, Olga Pappa (Estonia); Sotiris Tsiodras (Greece); Maria Pérez Vázquez (Spain); Kati Räisänen, Santeri Soininen (Finland); Anaïs Potron, Katy Jeannot, Marion Opatowski (France); Arjana Tambic Andrasevic, Iva Butic, Marija Guzvinec (Croatia); Adrienn Hanczvikkel, Dániel Göbhardter, Jánvári Laura (Hungary); Christina Clarke, Martin Cormican, Susanna Frost, Umut Gurpinar, Alma Galway (Ireland); Giulia Errico, Maria Del Grosso, Monica Monaco (Italy); Ineta Pranskunaite (Lithuania); Marie Meo (Luxembourg); Andris Čakstiņš, Baiba Niedre-Otomere, Dace Rudzite (Latvia); Sarah Pace (Malta); Daan Notermans (Netherlands); Katarzyna Zacharczuk (Poland); Manueala Caniça, Vera Manageiro (Portugal); Roxana Buzila (Romania); Vilhelm Müller (Sweden); Helena Ribic, Mateja Pirs, Urška Kramar (Slovenia); Michaela Slezáková, Michaela Krenželoková (Slovakia); Kristjan Orri Helgason (Iceland); Ellen Josefsen, Ørjan Samuelsen, Torunn Annie Pedersen (Norway); for Western Balkan countries: Arsim Kurti, Silva Tafaj (Albania); Maja Ostojic (Bosnia and Herzegovina); Ana Kaftandzieva, Biljana Kakaraskoska Boceska (North Macedonia); Aleksandra Čolović Popadić, Violeta Rakic (Serbia); Hüsniye Şimşek (Türkiye); for the ECDC contractors for ECDC/2024/003: Fay Betsou, Mariana Ferrari (CRBIP Institut Pasteur, France); and the Expert Group members not listed above, for their respective countries: Ana Rita Rebelo (DTU FOOD/EURGen-RefLabCap); Thierry Naas (ESGARS); Christian Giske (EUCAST); and Emine Alp Meşe (EUCIC/ESCIP).

Annex 2. Sample size calculation

Tables 5 and 6 present the number of isolates that a participating hospital might obtain from eligible patients per week, and during a six-month surveillance period. This is based on the estimated incidence of relevant *Acinetobacter* spp. in the EU/EEA in 2019 and 2022, i.e. the years before/after the years of high incidence of healthcare-associated infections with *Acinetobacter* spp. which were concomitant with the intense healthcare response to COVID-19.

The representativeness of the survey sample to true local epidemiology will depend on several factors, including the coverage of the participating hospital for the catchment area. In 2019, there were 244 NUTS 2 areas in the EU, with a population size ranging from 86 487 (Melilla, Spain) to 12 213 447 (Île-de-France, France), and an average population size of 1.84 million [28].

Table 5. Estimated rate of detection of infections with carbapenem-resistant and carbapenem-susceptible *Acinetobacter baumannii* by sentinel hospitals participating in the ECDC CRAb survey, 2024–2025

National epidemiology of infections with <i>Acinebacter</i> spp.				Characteristics of participating sentinel hospital		
Country percentile of estimated incidence of <i>Acinetobacter</i> spp.	Estimated incidence of invasive <i>Acinetobacter</i> spp.	Estimated incidence of all CRAB infections	Average % resistance to carbapenems among <i>Acinetobacter</i> spp.	Assumed % population coverage	N of CRAB cases/week	N of CSAB cases/week
	Cases per 100 000 population per year (average of 2019 and 2022)					
Source	EARS-Net	Calculation ^a	EARS-Net	Assumption	Calculation ^b	Calculation ^b
10 th percentile	0.01	0.06	0.8	70	<1	2
25 th percentile	0.05	0.25	2.5	70	<1	2
50 th percentile	0.33	1.75	29.0	30	<1	<1
75 th percentile	3.87	20.6	76.1	30	2	<1
90 th percentile	8.24	43.85	90.0	30	4	<1
EU/EEA	2.69	14.3	55.3	NA	NA	NA

CRAb: carbapenem-resistant *Acinetobacter baumannii*; CSAb: carbapenem susceptible *A. baumannii*; EARS-Net: the ECDC antimicrobial resistance network; ECDC PPS: ECDC point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals, 2016–2017; NA: not applicable.

a: estimated from the estimated incidence of invasive infections with carbapenem-resistant *Acinetobacter* spp. in EARS-Net, and the percentage resistance of *Acinetobacter* spp. to carbapenems and the ratio of invasive infections to all HAIs in the ECDC PPS 2022–2023.

b: the calculation incorporates the estimated incidence for CRAb or CSAb, the assumed NUTS 2 population coverage of the sentinel hospital, and the mean population of a NUTS 2 level in 2019 (1.84 million).

Table 6. Estimated number of eligible isolates collected and submitted by sentinel hospitals participating in the ECDC CRAb survey, 2024–2025

Country percentile of estimated incidence of <i>Acinetobacter</i> spp.	Collected by participating hospitals				Submitted by participating hospitals	
	Isolates from CRAb infections		Isolates from CSAb infections		N of isolates from CRAb infections	N of isolates from CSAb infections
	N of weeks to collect 10 isolates	N of isolates in 6 months	N of weeks to collect 10 isolates	N of isolates in 6 months		
10 th percentile	662	1	5	49	1	9
25 th percentile	163	1	4	61	1	9
50 th percentile	54	5	22	12	5	5
75 th percentile	5	57	15	18	10	0
90 th percentile	2	120	20	13	10	0

CRAb: carbapenem-resistant *Acinetobacter baumannii*; CSAb: carbapenem susceptible *A. baumannii*; EARS-Net: the ECDC antimicrobial resistance network.

Annex 3. Metadata to collect for each submitted isolate/patient and hospital

Table 7 contains a full description of all metadata. Pages 14–16 contain a guide on how to complete the data entry forms (Forms A–C, in Annexes 4–6) that are aligned with this metadata, including a summary of the main subheadings on the data entry forms.

Table 7. Description and permitted values of AMRISO metadata for the ECDC CRAB survey 2024–2025

Collection level <i>Sublevel</i>	Variable name <i>Variable (Subject code)</i>	Variable description	Req- -uired	Variable type	Permitted values
(Standard variable)	Reporting country <i>ReportingCountry (AMRISO)</i>	The country reporting the record.	Yes	LOCATION	Country (consult the reference values in mdLocation dataset)
(Standard variable)	Health topic <i>HealthTopic (AMRISO)</i>	The code of the health topic that is being reported.	No	REF	AMRISO = Antimicrobial resistance isolate
Isolate level <i>Microbiological data</i>	National record identifier <i>NationalRecordId (AMRISO)</i>	Unique identifier for each record within and across the specified surveillance system (data source) – selected and generated by the country reporting the record.	Yes	TEXT	Max. characters: 80
Isolate level <i>Specimen data</i>	Date of sampling <i>DateOfSampling (AMRISO)</i>	Date the sample from which the isolate was derived, was taken.	No	DATE	yyyy-mm-dd (min value: 2021-03-26)
Isolate level <i>Specimen data</i>	Specimen source for human samples <i>SpecimenSource (AMRISO)</i>	Specimen source for samples from humans: clinical sample or screening sample.	No	REF	CLINICAL = Clinical sample SCREEN = Screening sample
Isolate level <i>Specimen data</i>	Specimen site <i>Specimen (AMRISO)</i>	Clinical specimen site this isolate was isolated from.	No	REF	ASP = Aspirate BLOOD = Blood BONE = Bone marrow CATH = Catheter exit site CSF = Cerebrospinal fluid FAECES = Faeces GASTR = Gastrointestinal tract LREST = Lower respiratory tract OTH = Other REPR = Reproductive tract SKIN = Skin SOFTTISSUE = Soft tissue URINE = Urine WOUND = Wound
Isolate level <i>Specimen data</i>	Sample source <i>SampleOrigin (AMRISO)</i>	Sample source: human, food, feed, animal, environment,	No	REF	HUMAN = Human

Collection level <i>Sublevel</i>	Variable name <i>Variable (Subject code)</i>	Variable description	Req- -uired	Variable type	Permitted values
Isolate level <i>Specimen data</i>	Date of sampling <i>DateOfSampling (AMRISO)</i>	Date the sample from which the isolate was derived, was taken.	No	DATE	yyyy-mm-dd (min value: 2021-03-26)
Isolate level <i>Specimen data</i>	Laboratory code <i>LaboratoryId (AMRISO)</i>	Unique identifier for each laboratory. It is recommended to keep the identifier the same across all ARHAI surveillance protocols (PPS, ICU, ESAC-Net, EARS-Net) and from one year to another.	No	TEXT	Max. characters: 1 000
Isolate level <i>Specimen data</i>	Sample identifier <i>SampleId (AMRISO)</i>	Unique identifier for each sample within the lab system, allowing to link isolates derived from the same sample. Alternatively, this can be a pseudonymised sample/isolate identifier, that can be decoded nationally.	No	TEXT	Max. characters: 1 000
Isolate level <i>Microbiological data</i>	Date of receipt source laboratory <i>DateOfReceiptSourceLab (AMRISO)</i>	Date of receipt in source laboratory, i.e. the laboratory the sample was first sent to.	No	DATE	yyyy-mm-dd (min value: 2021-03-26)
Isolate level <i>Microbiological data</i>	Pathogen <i>Pathogen (AMRISO)</i>	Species and genus of the pathogen which has been isolated from the sample.	Yes	REF	ACIBAU = <i>Acinetobacter baumannii</i> , ACISPP = <i>Acinetobacter species</i> ,
Isolate level <i>Microbiological data</i>	Date of receipt reference laboratory <i>DateOfReceiptReferenceLab (AMRISO)</i>	Date of receipt in reference laboratory or typing laboratory with reference function.	No	DATE	yyyy-mm-dd (min value: 2021-03-26)
Isolate level <i>Microbiological data</i>	Parent national record identifier <i>ParentNationalRecordId (AMRISO\$AST)</i>	The corresponding parent identifier for each record (should exist in the upper level). A record with no corresponding parent identifier will be ignored and it will not be added to EpiPulse Cases database.	Yes	TEXT	Max. characters: 80
Isolate level <i>Specimen data</i>	Antimicrobial susceptibility test (AST) record identifier <i>NationalRecordId (AMRISO\$AST)</i>	Unique identifier for each antimicrobial susceptibility test (AST) - selected and generated by the country reporting the record.	Yes	TEXT	Max. characters: 80
Isolate level <i>Microbiological data</i>	Antimicrobial agent (antibiotic) <i>AntimicrobialAgent (AMRISO\$AST)</i>	Selected antibiotic needs to be followed by either MIC and ASTMethod or DDDZ.	No	REF	consult the reference values for SubjectCode = AMRISO\$AST and Variable = AntimicrobialAgent
Isolate level <i>Microbiological data</i>	Antimicrobial susceptibility test (AST) guideline <i>ASTMethod (AMRISO\$AST)</i>	Antimicrobial susceptibility test (AST) guideline/breakpoints used for this isolate	No	REF	EUCAST = EUCAST CLSI = CLSI OTH = Other None = None or not applicable
Isolate level <i>Microbiological data</i>	Antimicrobial susceptibility test (AST) method used for each antibiotic <i>ASTMethod (AMRISO\$AST)</i>	Antimicrobial susceptibility test (AST) method that was used to determine sensitivity to an antimicrobial agent.	No	REF	AUTOM = Automated instrument method BROTHDIL = Broth microdilution GRAD = Antimicrobial gradient (E-test, etc) ZONE = Disc diffusion test

Collection level <i>Sublevel</i>	Variable name <i>Variable (Subject code)</i>	Variable description	Req- -uired	Variable type	Permitted values
Isolate level <i>Microbiological data</i>	Minimum inhibitory concentration sign <i>MICSusceptibilitySign (AMRISO\$AST)</i>	MIC sign (>, <, =).	No	REF	< = Less than <= = Less than or equal = = Equal > = Greater than >= = Greater than or equal
Isolate level <i>Microbiological data</i>	Minimum inhibitory concentration value <i>MICValueAST (AMRISO\$AST)</i>	MIC value (in mg/l). Use '.' as decimal delimiter, e.g. 0.25.	No	NUM	Min: 0 (max decimals: 6)
Isolate level <i>Microbiological data</i>	Disk diffusion zone diameter sign <i>DDZDSusceptibilitySign (AMRISO\$AST)</i>	Disk diffusion zone diameter sign, if no MIC (sign).	No	REF	< = Less than <= = Less than or equal = = Equal > = Greater than >= = Greater than or equal
Isolate level <i>Microbiological data</i>	Disk diffusion zone diameter value <i>DDZDValueAST (AMRISO\$AST)</i>	Disk diffusion zone diameter value (in mm).	No	NUM	Min: 0 (max decimals: 6)
Patient level <i>Demographic data</i>	Age <i>Age (AMRISO)</i>	Age of patient in years as received or at the date of sampling.	No	NUM	Range: 0 – 125 (max decimals: 0)
Patient level <i>Demographic data</i>	Gender <i>Gender (AMRISO)</i>	Gender of the reported case.	No	REF	F = Female M = Male OTH = Other
Hospital level <i>Hospital identifiers</i>	Hospital identifier <i>HospitalId (AMRISO)</i>	Unique identifier for each hospital – MS selected and generated. It is recommended to keep the Hospital Identifier the same across all ARHAI surveillance protocols (PPS, ICU, ESAC-Net, EARS-Net) and from one year to another.	No	TEXT	Max. characters: 1 000
Patient level <i>Hospitalisation data</i>	Date of Hospitalisation <i>DateOfHospitalisation (AMRISO)</i>	Date of hospitalisation or outpatient visit.	No	DATE	yyyy-mm-dd (min value: 2021-03-26)
Patient level <i>Hospitalisation data</i>	Origin of patient <i>PatientType (AMRISO)</i>	Patient's admission category.	No	REF	INPAT = Admitted (Inpatient) OTH = Other OUTPAT = Outpatient
Patient level <i>Hospitalisation data</i>	Hospital department <i>HospitalUnitType (AMRISO)</i>	Hospital department (at sample collection).	No	REF	ED = Emergency Department ICU = Intensive Care Unit INFECT = Infectious Disease Ward INPATIENT = Inpatient ward INTMED = Internal Medicine OBGYN = Obstetrics/Gynecology ONCOL = Haematology/Oncology

Collection level <i>Sublevel</i>	Variable name <i>Variable (Subject code)</i>	Variable description	Req- -uired	Variable type	Permitted values
					OTH = Other PEDS = Pediatrics/neonatal PEDSICU = Pediatrics/neonatal ICU PHC = Primary Health Care SURG = Surgery URO = Urology Ward ND = No data
Patient level <i>Previous healthcare/ travel</i>	Direct Hospital Transfer <i>HospitalTransfer (AMRISO)</i>	Direct transfer of patient from another hospital to the current hospital where patient is admitted.	No	REF	N = No YOTH = Yes, other country YSAME = Yes, same country ND = No data
Patient level <i>Previous healthcare/ travel</i>	Hospital transfer from country <i>CountryOfHospitalTransfer (AMRISO)</i>	Country patient was directly transferred from.	No	LOCATION	Country (consult the reference values in mdLocation dataset)
Patient level <i>Previous healthcare/ travel</i>	Prior hospitalisation <i>PriorHospitalTransfer (AMRISO)</i>	Prior hospitalisation within six months before sampling date.	No	REF	N = No YOTH = Yes, other country YSAME = Yes, same country ND = No data
Patient level <i>Previous healthcare/ travel</i>	Country of prior hospitalisation <i>CountryOfPriorHospitalisation (AMRISO)</i>	Country patient was hospitalised in within six months before sampling date.	No	LOCATION	Country (consult the reference values in mdLocation dataset)
Patient level <i>Previous healthcare/ travel</i>	Prior residence in LTCF <i>PriorResidenceInLTCF (AMRISO)</i>	Prior residence in a long-term care facility in within six months before sampling date.	No	REF	N = No YOTH = Yes, other country YSAME = Yes, same country ND = No data
Patient level <i>Previous healthcare/ travel</i>	Country of prior residence in LTCF <i>CountryOfPriorResidenceInLTCF (AMRISO)</i>	Country patient was in a long-term care facility in within six months before sampling date.	No	LOCATION	Country (consult the reference values in mdLocation dataset)
Patient level <i>Previous healthcare/ travel</i>	Travel <i>Travel (AMRISO)</i>	Having been outside the country of notification during the incubation period of the reported disease.	No	REF	N = No Y = Yes ND = No data
Patient level <i>Previous healthcare/ travel</i>	Destination of travel within the month prior to the sample date <i>TravelLocation (AMRISO)</i>	Destination of travel. Only to be recorded if yes for 'Travel'.	No	LOCATION	Country (consult the reference values in mdLocation dataset)

Collection level <i>Sublevel</i>	Variable name <i>Variable (Subject code)</i>	Variable description	Req- -uired	Variable type	Permitted values
Patient level <i>Previous healthcare/ travel</i>	Clinical significance <i>ClinicalSignificance (AMRISO)</i>	Clinical significance related to isolate: colonisation, infection, undetermined or unknown.	No	REF	COL = Colonisation INF = Infection UND = Undetermined or unknown
Patient level <i>Epidemiological data</i>	Date of Onset of Disease <i>DateOfOnset (AMRISO)</i>	Date of onset of disease. If not applicable, please use 'Unk'	No	DATE	yyyy-mm-dd (min value: 2021-03-26; UNK)
Patient level <i>Epidemiological data</i>	Hospital acquired sample <i>HospitalAcquiredSample (AMRISO)</i>	TRUE: Hospital-acquired (sample collected more than 48 hours post admission) or FALSE: community-onset (sample collected less than 48 hours post admission).	No	BOOL	TRUE/FALSE
Patient level <i>Epidemiological data</i>	Outcome of hospital stay <i>OutcomeHospital (AMRISO)</i>	Patient status at the last reported hospital discharge.	No	REF	A = Discharged alive S = Still admitted D = Died UNK = Unknown
Patient level <i>Epidemiological data</i>	Date of death <i>DateOfDeath (AMRISO)</i>	Date of death (exact date only)	No	DATE	yyyy-mm-dd (min value: 2021-03-26; UNK)
Patient level <i>Epidemiological data</i>	Date of discharge <i>DateOfDischarge (AMRISO)</i>	Date of hospital discharge (exact date only)	No	DATE	yyyy-mm-dd (min value: 2021-03-26; UNK)
Patient level <i>Epidemiological data</i> (Standard variable)	Prescribed antimicrobial agent <i>PrescribedAntimicrobial (AMRISO)</i>	Antimicrobial agents prescribed to the patient following clinical suspicion or diagnosis of <i>Acinetobacter</i> infection	No	TEXT	Preferably ATCCodes
(Standard variable)	Subject code <i>SubjectCode (AMRISO)</i>	SubjectCode is a reporting model for a disease/health topic - identifies the reporting structure and format of a record (case based or aggregate reporting).	Yes	REF	AMRISO = Antimicrobial resistance isolate
(Standard variable)	Status <i>Status (AMRISO)</i>	The Status value is used to provide the functionality for a record within EpiPulse Cases database. Default value: NEW/UPDATE. If set to DELETE, the record with the specified NationalRecordId is deleted (invalidated) from EpiPulse Cases database, if it exists. If set to NEW/UPDATE, the record is inserted into the database: If the same NationalRecordId already exists for the same data source and subject code, then the current submitted record updates (replace) the existing one.	Yes	REF	DELETE = Delete a previously reported record. NEW/UPDATE = Update a previously reported record (default).
(Standard variable)	Date used for statistics <i>DateUsedForStatistics (AMRISO)</i>	The most epidemiologically relevant date for the isolate. Equal to the date of sampling if available. If not, equal to the date of receipt in the source lab, and if that is not available, the date of receipt in the reference lab.	Yes	DATE	yyyy-mm-dd (min value: 2021-03-26)
(Standard variable; generated by ECDC)	Wgs accession identifier <i>WgsAccession (AMRISO)</i>	European Nucleotide Archive (ENA) run identifier, based on which the sequence read data can be retrieved / Sequence Read Archive (SRA) run identifier, based on which the sequence read data can be retrieved. Starts with ERR or SRR, i.e. not the sample or experiment which ERS/ERX or SRS/SRX.	No	TEXT	Max. characters: 4 000

Collection level <i>Sublevel</i>	Variable name <i>Variable (Subject code)</i>	Variable description	Req- -uired	Variable type	Permitted values
<i>(Standard variable; generated by ECDC)</i>	Wgs assembler <i>WgsAssembler (AMRISO)</i>	The assembler used for sequencing, optionally including parameter settings.	No	REF	MAP_TO_LOCI1 = Mapping to individual loci, variant 1 for IonTorrent SKESA = SKESA assembler SPADES = SPADES without read mapping and consensus calling SPADES_READMAP = SPADES either including or followed by read mapping and consensus calling VELVET = Velvet without read mapping and consensus calling VELVET_READMAP = Velvet using k-mer optimisation, and followed by read mapping and consensus calling
<i>(Standard variable; generated by ECDC)</i>	Wgs assembled genome <i>WgsAssembly (AMRISO)</i>	The assembled genome, as a gzipped FASTA file. The file contents are subsequently converted into a Base64-encoded string for inclusion into either the XML or CSV data for the isolate.	No	TEXT	Max. characters: 4 000
<i>(Standard variable; generated by ECDC)</i>	Wgs protocol <i>WgsProtocol (AMRISO)</i>	Protocol used for sequencing, limited to the sequencing technology used (today Illumina or IonTorrent) and the read length.	No	REF	HISEQ_2X100 = Illumina HiSeq 2x100 IONTORRENT = IonTorrent MINISEQ_2X150 = Illumina MiniSeq 2x150 MISEQ_2X150 = Illumina MiSeq 2x150 MISEQ_2X250 = Illumina MiSeq 2x250 MISEQ_2X300 = Illumina MiSeq 2x300 NEXTSEQ_2X150 = Illumina NextSeq 2x150 PAIRED_END_ILLUMINA = Illumina HiSeq, MiSeq, NextSeq or MiniSeq
<i>(Standard variable; generated by ECDC)</i>	Wgs raw sequence reads <i>WgsRawReads (AMRISO)</i>	The raw reads obtained from the sequencer stored as FASTQ files. Each FASTQ file is a text file which represents sequence readouts for a sample.	No	TEXT	Max. characters: 4 000

Table 8. Description and permitted values of AMRISODENOM metadata for the ECDC CRAB survey 2024–2025

Collection level <i>Sublevel</i>	Variable name <i>Variable (Subject code)</i>	Variable description	Req- -uired	Variable type	Permitted values
(Standard variable)	Reporting country <i>ReportingCountry (AMRISODENOM)</i>	The country reporting the record.	Yes	LOCATION	Country (consult the reference values in mdLocation dataset)
(Standard variable)	Health topic <i>HealthTopic (AMRISODENOM)</i>	The code of the health topic that is being reported.	No	REF	AMRISO = Antimicrobial resistance isolate
Isolate level <i>Microbiological data</i>	National record identifier <i>NationalRecordId (AMRISO)</i>	Unique identifier for each record within and across the specified surveillance system (data source) – selected and generated by the country reporting the record.	Yes	TEXT	Max. characters: 80
Hospital level <i>Hospital identifiers</i>	Hospital identifier <i>HospitalId (AMRISODENOM)</i>	Unique identifier for each hospital – MS selected and generated. It is recommended to keep the Hospital Identifier the same across all ARHAI surveillance protocols (PPS, ICU, ESAC-Net, EARS-Net) and from one year to another.	No	TEXT	Max. characters: 1 000
Hospital level <i>Hospital identifiers</i>	Hospital location - NUTS2 level <i>HospitalLocation (AMRISODENOM)</i>	NUTS2 where hospital is located.	No	LOCATION	NUTS2 (consult the reference values in mdLocation dataset)
Hospital level <i>(Hospital identifiers; generated by ECDC from the NUTS code)</i>	Hospital latitude <i>HospitalLatitude (AMRISODENOM)</i>	Hospital latitude.	No	NUM	Range: -90 – 90 (max decimals: 5)
Hospital level <i>(Hospital identifiers; generated by ECDC from the NUTS code)</i>	Hospital longitude <i>HospitalLongitude (AMRISODENOM)</i>	Hospital longitude.	No	NUM	Range: -180 – 180 (max decimals: 5)
Hospital level <i>Survey information</i>	Start date of this survey <i>PeriodStart (AMRISODENOM)</i>	Start date of the survey period (time period covered by this denominator entry).	No	DATE	yyyy-mm-dd (min value: 2021-03-26)
Hospital level <i>Survey information</i>	End date of this survey <i>PeriodEnd (AMRISODENOM)</i>	End date of the survey period (time period covered by this denominator entry).	No	DATE	yyyy-mm-dd (min value: 2021-03-26)
Hospital level <i>Survey information</i>	Date of last sample <i>DateLastSample (AMRISODENOM)</i>	Sample date of the last most recent sample submitted for this survey	No	DATE	yyyy-mm-dd (min value: 2021-03-26)
Hospital level <i>Hospital denominators</i>	Hospital Size <i>HospitalSize (AMRISODENOM)</i>	Number of acute care beds (excluding non-acute beds) in the hospital	No	NUM	Range: 0 – 3000 (max decimals: 0)
Hospital level <i>Hospital denominators</i>	Number of discharges (or admissions) during the survey period <i>NumHospSurvDischarges (AMRISODENOM)</i>	Number of hospital discharges (or admissions if discharges not available) for the specified survey period.	No	NUM	Range: 0 – 3000 (max decimals: 0)
Hospital level <i>Hospital denominators</i>	N of occupied bed-days <i>NumOccBedDays (AMRISODENOM)</i>	Number of estimated occupied bed-days during the survey period. This may be estimated by [(N of discharges) × (N of days in survey period) × (estimated % occupancy)].	No	NUM	Range: 0 – 1000000 (max decimals: 1)
Hospital level <i>Microbiological processes</i>	Hospital screens patients for the pathogen <i>HospitalScreens (AMRISODENOM)</i>	Presence of a hospital practice during the survey period to screen patients for the pathogen specified in 'Pathogen'	No	REF	N = No Y = Yes UNK = Unknown

Collection level <i>Sublevel</i>	Variable name <i>Variable (Subject code)</i>	Variable description	Req- -uired	Variable type	Permitted values
Hospital level <i>Microbiological processes</i>	Number of tested screening samples <i>NumScreeningSamples (AMRISODENOM)</i>	Number of screening samples with a microbiological test that identifies the pathogen specified in 'Pathogen'	No	NUM	Range: 0 – 1000000 (max decimals: 0)
Hospital level <i>Microbiological processes</i>	Number of tests <i>NumberOfTests (AMRISODENOM)</i>	Total number of tests during the reported period for the specified disease. If exact numbers are not available, provide estimates. Applies to all patient samples (screening+clinical) with a microbiological test that identifies the pathogen specified in 'Pathogen'	No	NUM	Range: 0 – 1000000 (max decimals: 0)
Hospital level <i>Aggregate numerator</i>	Number of colonisations <i>NumColonisations (AMRISODENOM)</i>	Total number of detected colonisations with the pathogen specified in 'Pathogen'	No	NUM	Range: 0 – 10000 (max decimals: 0)
Hospital level <i>Aggregate numerator</i>	Number of infections <i>NumInfections (AMRISODENOM)</i>	Total number of detected infections with the pathogen specified in 'Pathogen'	No	NUM	Range: 0 – 1000 (max decimals: 0)
Hospital level <i>Aggregate numerator</i>	Number of infected patients who died <i>NumInfectedDied (AMRISODENOM)</i>	Total number of patients with an infection with the pathogen specified in 'Pathogen' who died during this hospital stay, from any cause.	No	NUM	Range: 0 – 1000 (max decimals: 0)
Hospital level <i>Prevention and control</i>	Number of investigated outbreaks or clusters <i>NumInvestigatedClustersOubreaks (AMRISODENOM)</i>	Number of investigations initiated, in this hospital, during the survey period, for potential clusters or outbreaks (according to national or local definitions) of the pathogen specified in 'Pathogen'	No	NUM	Range: 0 – 100 (max decimals: 0)
<i>(Standard variable)</i>	Subject code <i>SubjectCode (AMRISODENOM)</i>	SubjectCode is a reporting model for a disease/health topic - identifies the reporting structure and format of a record (case based or aggregate reporting).	Yes	REF	AMRISODENOM = Antimicrobial resistance isolate denominator data
<i>(Standard variable)</i>	Status <i>Status (AMRISODENOM)</i>	The Status value is used to provide the functionality for a record within EpiPulse Cases database. Default value: NEW/UPDATE. If set to DELETE, the record with the specified NationalRecordId is deleted (invalidated) from EpiPulse Cases database, if it exists. If set to NEW/UPDATE, the record is inserted into the database: If the same NationalRecordId already exists for the same data source and subject code, then the current submitted record updates (replace) the existing one.	Yes	REF	DELETE = Delete a previously reported record. NEW/UPDATE = Update a previously reported record (default).
<i>(Standard variable)</i>	Date used for statistics <i>DateUsedForStatistics (AMRISODENOM)</i>	The most epidemiologically relevant date for the isolate. Equal to the date of sampling if available. If not, equal to the date of receipt in the source lab, and if that is not available, the date of receipt in the reference lab.	Yes	DATE	yyyy-mm-dd (min value: 2021-03-26)

Annex 4. FORM A: Specimen metadata (data collection tool for each eligible isolate)



FORM A: Specimen metadata ECDC CRAB survey, 2024–2025

Complete for every potentially eligible sample

Name of person completing this form: _____

For internal (hospital) use only; must not be included in the national dataset.

Patient identifier: _____

For internal (hospital) use only; must not be included in the national dataset.

Patient gender: __ (M / F / OTH) Patient age: __ (years)

Hospital code: _____

Code provided by your National Survey Coordinator.

Date of sampling: _____

20 __ / __ / __ (YYYY-MM-DD)

Specimen source (TICK ONE):

☐ Screening sample ☐ Clinical sample

If data are available, specify the source of the screening/clinical sample (TICK ONE):

☐ Aspirate ☐ Catheter exit site ☐ Gastrointestinal tract ☐ Skin ☐ Wound
☐ Blood ☐ Cerebrospinal fluid ☐ Lower respiratory tract ☐ Soft tissue ☐ Other
☐ Bone marrow ☐ Faeces ☐ Reproductive tract ☐ Urine

Laboratory code: _____

Code provided by your National Survey Coordinator.

Sample identifier: _____

Unique identifier for each sample, from your laboratory system.

Date of receipt source laboratory: 20 __ / __ / __ (YYYY-MM-DD)

Date that this sample arrived at the laboratory for isolation.

Species is considered to be *Acinetobacter baumannii*, or the speciation result does not exclude *A. baumannii*

☐ Yes (eligible) ☐ No (ineligible)

Gold standard species definition for this survey: NCBI taxonomy ID: 470 ([NCBI:txid470](https://ncbi.nlm.nih.gov/taxonomy/taxidview?id=470); Bouvet and Grimont, 1986)

Phenotypic antimicrobial susceptibility testing (at a minimum, report at least one carbapenem)

Antimicrobial agent ATC code (preferably); or standard hospital code	AST guideline /breakpoint	AST Method	MIC (mg/L), if relevant	Disk diffusion zone diameter (mm), if relevant
	☐ EUCAST ☐ CLSI ☐ Other ☐ None/N.A.	☐ AUTOM ☐ BROTHDIL ☐ GRAD ☐ ZONE		
	☐ EUCAST ☐ CLSI ☐ Other ☐ None/N.A.	☐ AUTOM ☐ BROTHDIL ☐ GRAD ☐ ZONE		
	☐ EUCAST ☐ CLSI ☐ Other ☐ None/N.A.	☐ AUTOM ☐ BROTHDIL ☐ GRAD ☐ ZONE		
	☐ EUCAST ☐ CLSI ☐ Other ☐ None/N.A.	☐ AUTOM ☐ BROTHDIL ☐ GRAD ☐ ZONE		
	☐ EUCAST ☐ CLSI ☐ Other ☐ None/N.A.	☐ AUTOM ☐ BROTHDIL ☐ GRAD ☐ ZONE		
	☐ EUCAST ☐ CLSI ☐ Other ☐ None/N.A.	☐ AUTOM ☐ BROTHDIL ☐ GRAD ☐ ZONE		

MIC: minimum inhibitory concentration; AUTOM: Automated instrument method; BROTHDIL: Broth microdilution; GRAD: Antimicrobial gradient (E-test, etc); ZONE: Disc diffusion test; N.A.: not applicable; ATC: Anatomical Therapeutic Chemical classification, available from https://www.whocc.no/atc_ddd_index

Annex 5. FORM B: Patient metadata (data collection tool for each patient with an eligible isolate)

FORM B: Patient metadata ECDC CRAB survey, 2024–2025



Complete for patients that supplied an eligible *A. baumannii* sample, if requested by the receiving laboratory

Information to ensure a matching identify of the patient and isolate

Name of person completing this form: _____

For internal (hospital) use only; must not be included in the exported national dataset.

Name (or code) of laboratory that recommended collection of this patient data: _____

Sample identifier: _____

Unique identifier for each sample, from the laboratory system.

Patient identifier: _____

For internal (hospital) use only; must not be included in the exported national dataset.

Patient gender: ____ (M / F / OTH) Patient age: ____ (years)

Hospital name and code: _____

Hospital name is recorded for internal (project) use only; must not be included in the exported national dataset.

Hospital code is provided by your National Survey Coordinator.

Information on the current hospitalisation

Origin of patient: ☐ Admitted (inpatient) ☐ Outpatient only ☐ Other

Patient's admission category

Date of the patient's hospitalisation or outpatient visit: 20 __ / __ / __ (YYYY-MM-DD)

Hospital department of the patient when the sample was taken (TICK ONE):

☐ ED ☐ ICU ☐ INFECT ☐ INPATIENT ☐ INTMED ☐ OBGYN ☐ ONCOL
☐ PEDS ☐ PEDSICU ☐ PHC ☐ SURG ☐ URO ☐ OTH ☐ No data

ED = Emergency Department, ICU = Intensive Care Unit, INFECT = Infectious Disease Ward, INPATIENT = Inpatient ward, INTMED = Internal Medicine, OBGYN = Obstetrics/Gynaecology, ONCOL = Haematology/Oncology, PEDS = Paediatrics/neonatal, PEDSICU = Paediatrics/neonatal ICU, PHC = Primary Health Care, SURG = Surgery, URO = Urology Ward, OTH = Other.

Previous healthcare and travel

Direct hospital transfer (TICK ONE):

☐ Yes, in this country ☐ Yes, from another country (Please specify: _____)
☐ No ☐ No data

Direct transfer of this patient from another hospital to this current hospital.

Hospitalisation in the last 6 months (TICK ONE):

☐ Yes, in this country ☐ Yes, in another country (Please specify: _____)
☐ No ☐ No data

Residence in a long-term care facility in the last 6 months (TICK ONE):

☐ Yes, in this country ☐ Yes, in another country (Please specify: _____)
☐ No ☐ No data

Foreign travel in the previous month:

☐ Yes (Please specify country(s): _____)
☐ No ☐ No data

If more >1 country visited, specify at least the most recent country visited >4 days before the onset of symptoms.

Additional information about the case**Clinical significance (TICK ONE):**

- ☐ Colonisation
- ☐ Infection (date of symptom onset: 2 0 __ / __ / __ YYYY-MM-DD)
- ☐ Undetermined or unknown

Case origin (TICK ONE):

- ☐ Hospital-acquired (sample collected more than 48 hours post admission)
- ☐ Community-onset (sample collected less than 48 hours post admission).

Outcome of hospital stay (TICK ONE)

Optional. If necessary, complete this at the end of the survey.

- ☐ Discharged alive (Date: 2 0 __ / __ / __ (YYYY-MM-DD))
- ☐ Still admitted at end of survey period
- ☐ Died during the current hospitalisation, from any cause (Date: 2 0 __ / __ / __ (YYYY-MM-DD))
- ☐ Unknown

Antimicrobial agents prescribed/received following the clinical suspicion or diagnosis of *Acinetobacter* infection (LIST ALL)

Optional. Preferably report ATC codes, available from https://www.whocc.no/atc_ddd_index. Alternatively, report local codes. These data will generate European-level summary statistics; and not patient-, ward-, or hospital-level analyses.

Note: this survey obtains insufficient data to ascertain the appropriateness of individual patient care.

Annex 6. FORM C: Hospital metadata (data collection tool for each participating hospital)

FORM C: Hospital metadata ECDC CRAB survey, 2024–2025



Complete one form for each participating hospital

Name of person completing this form: _____
For internal (hospital) use only; not included in the exported national dataset.

Hospital identifiers

Hospital name: _____
Recorded for internal (project) use only; not included in the exported national dataset.

Hospital code: _____
Provided by your National Survey Coordinator.

Hospital postal code: _____
Used to identify the NUTS-2 geocode of this hospital.

Survey information

Survey start date: 20__/__/__(YYYY-MM-DD) Planned survey end date: 20__/__/__(YYYY-MM-DD)

Date of last reported sample: 20__/__/__(YYYY-MM-DD)
Used as an internal consistency check.

Hospital denominators	
Number of acute care beds (exclude non-acute care beds) <i>Preferably report the number on day 1 of the survey, or otherwise on any day during the survey period.</i>	
Number of patient discharges (or admissions) during the survey period:	
Number of occupied bed-days during the survey period <i>Can be estimated using the calculation ([N of beds in this hospital] × [N of days in survey period] × [estimated occupancy rate; e.g. 95%])</i>	
Microbiological processes during the survey period (optional but recommended)	
Presence of a hospital practice to screen patients for CRAB during the survey period: ☐ Yes ☐ No ☐ Unk	
Number of screening samples with a microbiological test that identifies <i>Acinetobacter baumannii</i>	
Total number of specimens (screening + infection) processed by bacteriology, with a microbiological test that identifies <i>Acinetobacter baumannii</i>	
Aggregate numerators during the survey period (optional but recommended)	
Total number of detected cases of CRAB colonisation	
Total number of detected cases of CRAB infection	
Total number of detected cases of CRAB infection who died during this hospital stay, from any cause	
Prevention and control during the survey period (optional but recommended)	
Number of investigations initiated, in this hospital, during the survey period, for potential clusters or outbreaks (according to national or local definitions) of <i>Acinetobacter</i> spp.	

Annex 7. Reporting to TESSy under EpiPulse

In July 2023, TESSy migrated into the [EpiPulse portal](#). The application remains the same but it is now accessible via the EpiPulse URL, and with new menu names.

This section provides both an overview of the TESSy reporting process and tips on where you can find useful information.

The overall process is as follows:

- Familiarise yourself with the data collection deadlines.
- Prepare (export and transform) your data.
- Check that your data complies with the metadata.
- Check that your data source profile is up-to-date.
- Submit your file(s) to TESSy.
- Finalise and approve your submission.

Checking the data collection schedule

A link to the current data collections schedule can be found in the [Communication](#) section of the 'Documentation and Help' pages.

Preparing data

After you have exported the data from your national database, you need to ensure that the data are in a format that TESSy can accept. This applies both to the type of file submitted to TESSy (only CSV and XML files can be submitted) and to the format of the data in certain fields.

A [User Guide](#) on how to transform data to the correct TESSy format is available in the 'Guides and Training' section of the 'Documentation and Help' pages. Information on the file formats is available in the CSV Transport Protocol and XML Transport Protocol which can be found in the [Technical Guidelines & Tools](#) section of the 'Documentation and Help' pages.

AMRISO-specific guidelines for data collection and preparation for TESSy are provided in Annex 3.

Checking metadata

The metadata defines the fields and data formats that are valid as input to TESSy for a given subject.

As the requirements for data to be shared among TESSy users can change, the data changes needed to support the new requirements are identified and agreed upon between the National Surveillance Contact Points, the Network Coordination Groups and ECDC's Disease Experts. These changes are then implemented to the TESSy metadata.

In order to ensure that your data can be saved correctly in TESSy, it is important to check that the formatting is correct and in accordance with the most recent metadata set.

Changes to the metadata for the subject of this reporting protocol are described in:

- Changes to current metadata – changes since the last reporting protocol.
- Annex 1 – previous changes.

It is especially important to focus on:

- **Field formats**
Many fields require the data to be formatted in a specific way. For example, dates must be in the YYYY-MM-DD format; dates in the DD/MM/YYYY format will be rejected.
- **Coded values**
Some fields only permit the use of specific values (coded values). For example, **M**, **F**, **UNK**, or **Other** are the coded values for 'Gender' and any other value in a 'Gender' field will be rejected.

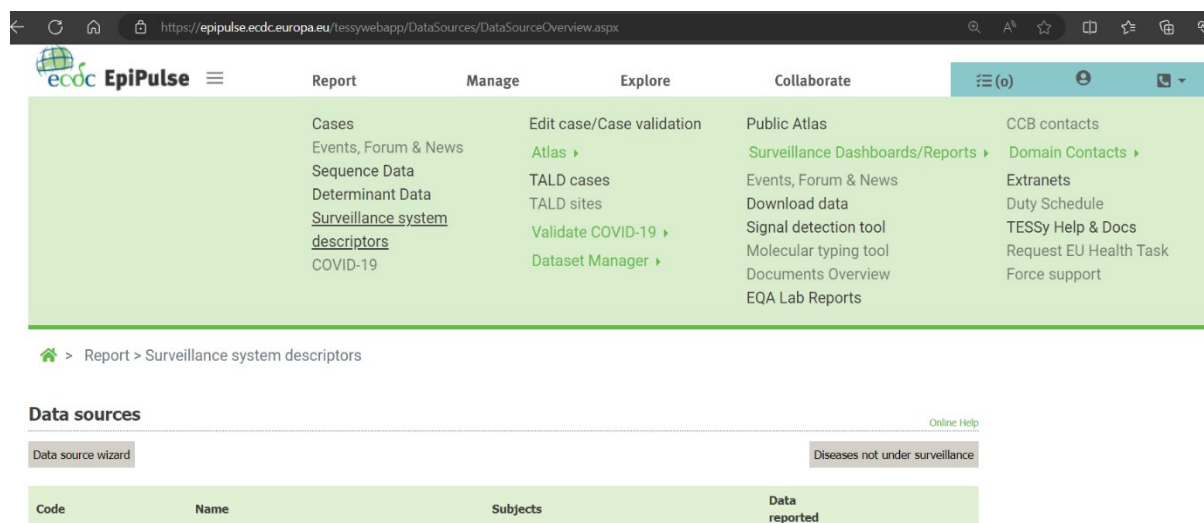
The TESSy metadata contains all the definitions and rules necessary to format data correctly for every subject (usually a disease). This can be downloaded as an Excel file from the [Technical Guidelines & Tools](#) section of the 'Documentation and Help' pages.

Filtering the fields in the file by subject will enable you to see the fields required for your subject and the rules that apply to these fields.

The [User Guide](#) provides an overview of how you work with the metadata file.

Checking your data source profile

Before submitting your file(s), please review your data source(s) in EpiPulse (in the menu, go to 'Report' -> '[Surveillance systems descriptors](#)') and update the information as necessary.



Report > Surveillance system descriptors

Data sources [Online Help](#)

Data source wizard [Diseases not under surveillance](#)

Code	Name	Subjects	Data reported
------	------	----------	---------------

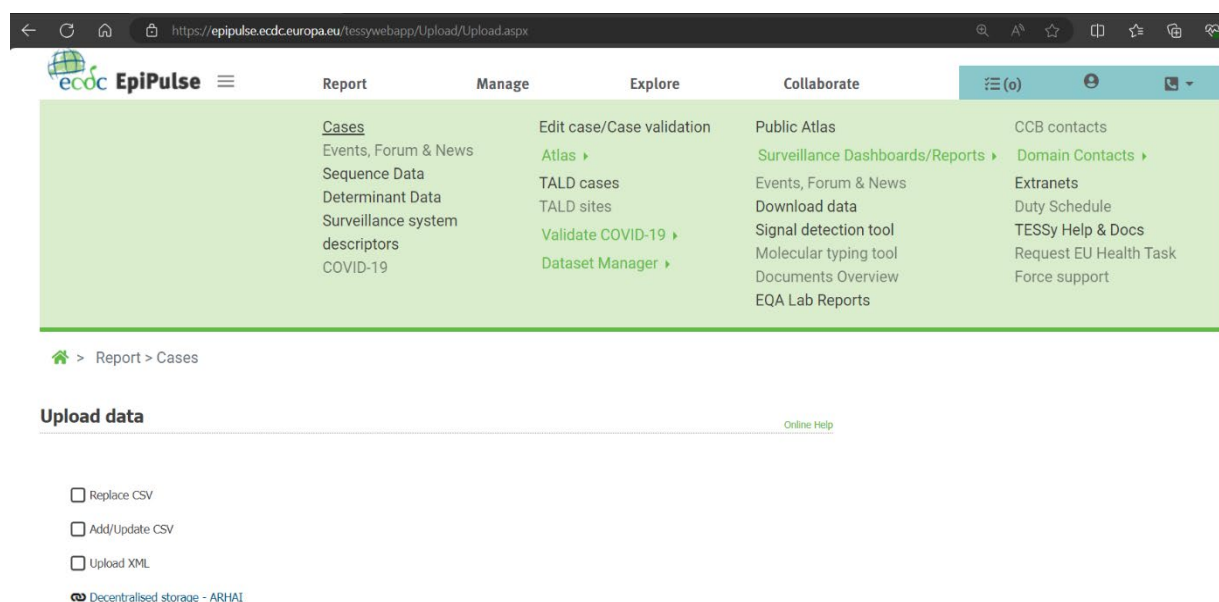
Complete and up-to-date data source information for each subject is important for improving the interpretation of data – each surveillance system has different features that need to be taken into account when comparing data at an international level.

If your data source information is out-of-date and you do not have access rights to update it, please ask your National Focal Point for Surveillance or National Coordinator to do so.

Information on data sources is available in the TESSy [User Guide](#).

Submitting your data

Data are submitted through the EpiPulse web interface (in the menu, go to Report -> [Cases](#)).



Report > Cases

Upload data [Online Help](#)

☐ Replace CSV

☐ Add/Update CSV

☐ Upload XML

[Decentralised storage - ARHAI](#)

The [User Guide](#) provides an overview of how to submit files to TESSy and in-depth descriptions of all the methods for uploading.

Finalising your submission

The compliance of your data with the validation rules in the metadata is checked automatically during the data upload process.

The result of your upload – i.e. rejected or validated – is displayed immediately after the check is concluded on the 'Validation details' webpage. Please check the result carefully.

- If your file has been rejected, there will be a message explaining each instance of non-compliance with the metadata that needs correcting.
- If your file has been validated, there might be warnings and remarks relating to possible data quality issues or potential overwriting of existing records that you should consider.

When your file has been validated and you are satisfied that all corrections have been made, please ensure prompt approval – unapproved uploads can block the approval of other uploads.

The [TESSy User Guide](#) provides information on reviewing validation results and adjusting reporting periods to avoid overwriting existing records.

EpiPulse Cases (TESSy) HelpDesk

Email: TESSy@ecdc.europa.eu

Telephone number: +46-(0)8-5860 1601

Availability: 09:00–16:00 Stockholm time, Monday to Friday (with the exception of ECDC holidays).

Annex 8. Material Transfer Agreement template

PARTIES

[Preferably the organisation of the National Survey Coordinator] (the 'Material Provider')
and
Institut Pasteur, 25-28 Rue Ru Docteur Roux, 75724, Paris CEDEX 15, France (the 'Material Receiver')

BACKGROUND

Whereas

- A. The European Centre for Disease Prevention and Control ('ECDC'), is an agency of the European Union (EU) with a mission to identify, assess and communicate current and emerging threats to human health posed by infectious diseases.
- B. The Material Receiver is the contractor of ECDC in terms of Framework Contract No. ECDC/2024/003 (the 'FWC'), whereby the contractor shall establish a temporary strain collection for multidrug-resistant bacteria, as part of ECDC's work establishing genomic-based surveillance of multi-drug resistant bacteria of public health importance. Isolates for this collection are being collected in the European-wide survey of carbapenem -resistant *Acinetobacter baumannii* (CRAB) ('the Project')
- C. The Material Provider is the National Survey Coordinator for EURGen-Net and is the party from whom the CRAB bacterial isolates to be analysed for the Project originate.
- D. The primary public health objective of the Project is to describe the occurrence and geographic distribution of CRAB strains, and/or transmissible resistance/genetic elements of critical public health importance within CRAB strains, among patients in acute care hospitals in Europe, in order to inform prevention and control activities.
- E. The secondary objectives of the Project are to support EU/EEA countries, Western Balkan countries, and Türkiye in developing technical capabilities and proficiency in genomic-based surveillance and risk assessments of CRAB, to facilitate their identification of transmission chains, to enable targeted infection control interventions; to estimate the cumulative incidence of CRAB infections in participating hospitals during the survey period, to provide additional contextual information for the genomic results; and to identify epidemiological factors for infection (or colonisation) with CRAB at clonal and sub-genomic level, to inform CRAB preparedness, prevention and control activities.
- F. Bacterial isolates (the Isolates) shall be collected from the Material Providers and processed by the Material Receiver for the DNA extraction and further on to another third party for whole-genome sequencing (WGS) and further analysis.
- G. This Material Transfer Agreement regulates the transfer of the Isolates from the Material Provider to the Material Receiver, and the use of the Isolates.

IT IS AGREED as follows:

Packaging, transport and storage of the Isolates

1. The Material Receiver shall keep the Isolates secure at the Material Receiver's laboratory and the Isolates shall not be removed from the Material Receiver's address. The Material Receiver shall ensure that no-one other than the Material Receiver and authorised co-workers have access to them. The Material Receiver undertakes to ensure that the Isolates are appropriately safeguarded to prevent theft or unauthorised access.
2. The Material Provider shall ensure compliance with protocols and any other instructions received from ECDC and all applicable laws, regulations and administrative guidelines governing the packaging and transportation of the Isolates to the Material Receiver.
3. The Material Receiver shall use the Isolates in accordance with instructions received from ECDC and/or the Material Provider, in accordance with good laboratory practice and the highest standards of skill and care and shall ensure compliance with all applicable laws, regulations and administrative guidelines governing the transportation, storage, use or disposal of the Materials, especially the applicable biosafety standards and the IATA regulations.

Ownership and use of the Isolates

4. The Material Receiver acknowledges that transfer of the Isolates from the Material Provider to the Material Receiver in no way assigns intellectual property rights to the Material Receiver or any other third party. The Material Receiver's rights of use are restricted to that permitted in terms of this agreement and as per instructions received from ECDC.
5. All Isolates transferred from the Material Provider to the Material Receiver remain the property of the intellectual property right holder which may be the Material Provider, unless the Isolates are owned by a different legal entity following, for example, an agreement. The Material Receiver will have the right to use the Isolates only for carrying out the tasks required in accordance with its contract with ECDC, concluded for the purposes of the Project. For the avoidance of doubt, the Material Receiver is expressly prohibited from:
 - a) using the Isolates for any types of testing or analysis other than as specified in the contract;
 - b) from transfers to third parties, other than those provided for in the contract;
 - c) from use of the results in any form of publication.
6. Parties to this agreement, and any third parties involved in subsequent analysis of the Isolates as part of the Project, may not apply for intellectual property rights on discoveries or inventions made through the use of the Isolates or data or information shared by Member States' competent bodies and laboratories for the purpose of the agreement.
7. If any claim is made by a third party that the provision, use or receipt of the Isolates as provided for in this agreement infringes any intellectual property rights, the Material Provider or the different legal entity shall investigate the claims made and take any reasonable remedial action necessary should the third party claims be proven valid, including return of the Isolates and termination of this agreement if required.
8. The Material Provider recognizes that use of the Isolates in the future for research purposes, in accordance with the Directive (EU) 2019/1024 on open data and the re-use of public sector information, is foreseen and is willing to engage with the Material Receiver and ECDC to agree the terms upon which such use is permitted. Any such future use shall be subject to Material Provider's express approval if required.

Data protection

9. The Parties agree to comply with all applicable data protection rules and legislation including the EU Regulation 2016/697 (General Data Protection Regulation or GDPR).
10. The Material Provider shall not provide any personal data to the Material Receiver, in particular information that would make possible the identification of individuals linked to a specific Isolate.
11. The Material Provider and the Material Receiver shall be separate controllers for any personal data processing operation that they might carry out for the implementation of this agreement and of this Project.

Data publication, transfer and release

12. The Material Receiver shall not disclose any results of any evaluations and tests carried out using the Isolates to any third party without the Material Provider's prior written consent. This section is with exception to those third parties involved in the Project, namely, ECDC and the third party hosting the WGS Platform.
13. The Material Provider shall ensure that the owners of the Isolates give their consent for the transfer of the Isolates to the Material Receiver, if such consent is required. Otherwise the Material Provider shall ensure that all applicable laws, regulations and applicable guidelines are complied with in respect of the transfer of the Isolates from the Material Provider to the Material Receiver, their storage by the Material Receiver and for further onward transfer for DNA extraction, WGS and analysis of the resulting data.
14. The Material Provider acknowledges and agrees to the transfer of the Isolates by the Material Receiver to the third party selected to perform the subsequent DNA extraction from the Isolates, and further transfer of the extracted DNA to the third party hosting the WGS Platform for WGS and analysis, subject to a separate agreement to be signed.
15. The Material Provider acknowledges and agrees to publication in accordance with the 'Survey protocol for the ECDC genomic-based survey of carbapenem-resistant *Acinetobacter baumannii* in Europe'. For the avoidance of doubt, sequence data combined with restricted meta data (year, country and phenotypic susceptibility) shall be released into the public domain in the public interest.
16. In respect of any other publications not covered by the Survey Protocol, ECDC shall consult Material Providers to obtain their consent before any publication and/or communication of data or information including that deriving from the Isolates, which have not been published before or any work reproducing or using the data. Such consultation will be undertaken unless the use and publication is specifically allowed by separate contractual

agreements or applicable legislation. Consent shall be considered implicitly given when no reply is given by a Material Provider within 14 calendar days.

17. Should a Material Provider object to the publication/communication, then ECDC shall delete the relevant sections from the publication/communication prior to its release. For the avoidance of doubt, the remainder of the publication/communication shall be released as planned. Should several Material Providers object to the publication/communication, then ECDC shall consult with each Material Provider to understand the reasons for said objections and if in agreement with objections received, cancel the publication/communication prior to release.
18. ECDC shall acknowledge the Material Provider as the source of the data and Isolates and may list the Material Provider as co-author in any publication which mentions them if the criteria for co-authorship, as provided for in ECDC's Internal Policy on authorship and acknowledgement of contribution to scientific work and related outputs, are satisfied.
19. The Material Receiver shall organise and cover the costs of transporting the Isolates from the Material Provider to the Material Receiver.

Liability

20. The Parties make no representation and give no warranty or undertaking in relation to the Isolates.
21. The Parties shall have no liability in relation to the supply of data, and the supply of the Isolates or their use or keeping or the consequences of their use, arising out of or related to this Project to the maximum extent permitted under applicable law.

Termination

22. The Parties may terminate this Agreement if one Party is in material breach of any of the terms of this Agreement and, where the breach is capable of remedy, the other Party has failed to remedy the same within one month of service of a written notice from the non-defaulting Party specifying the breach and requiring it to be remedied.
23. The Isolates stored at the Material Receiver pursuant to this Agreement shall be immediately returned to the Material Provider in the event that the Material Receiver is in breach of any of the conditions of this Agreement. Parties recognise that should the contract between ECDC and the Material Receiver be terminated or expire without renewal, ECDC shall liaise with the Material Provider and depending on outcome of these discussions, instruct the Material Receiver to either destroy the Isolates or ship the Isolates to a location to be confirmed by ECDC.

Miscellaneous

24. Any provision of this Agreement that expressly or by implication is intended to come into or continue in force on or after termination of this Agreement shall remain in full force and effect.

This Agreement has been entered into on the date it is signed by all Parties.

Signed on behalf of [Material Provider]

Signature:

Name:

Title:

Date:

Signed on behalf of the Institut Pasteur

Signature:

Name:

Title:

Date:

Annex 9. Controller-to-Controller Agreement on protection of personal data

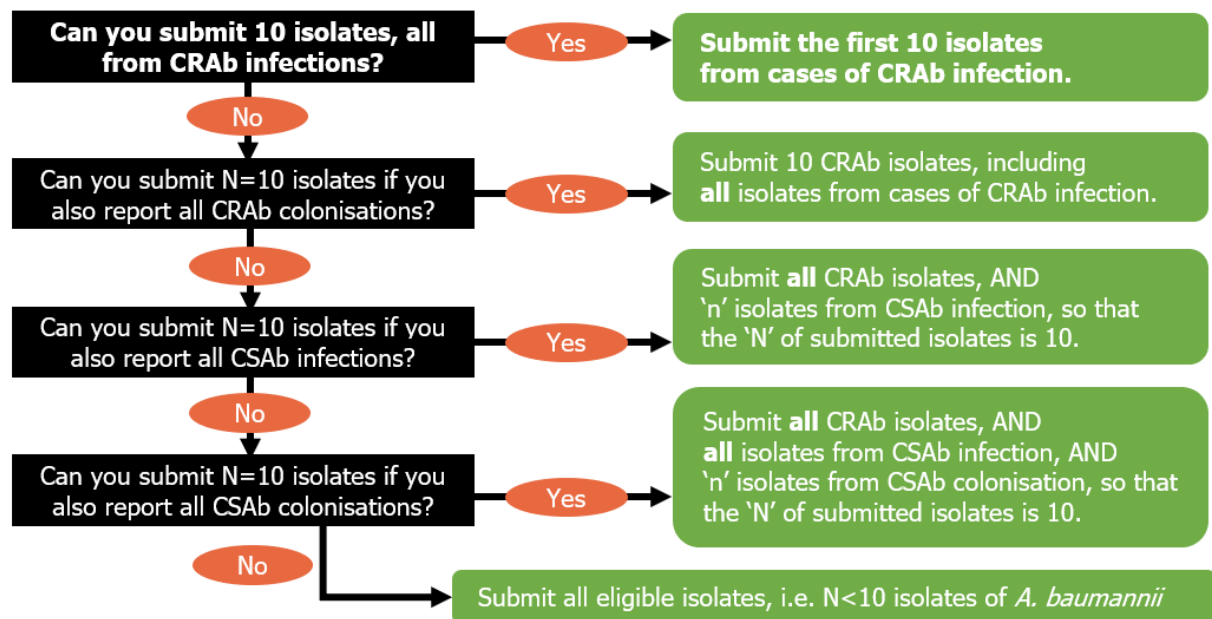
The GDPR and the EUDPR put some obligations on controllers (i.e. the entities that determine the purpose and means of personal data processing operations). This annex aims to clarify the respective roles and responsibilities of ECDC and the national reference/expert laboratories with regards to fulfilling data protection requirements stemming from the GDPR and the EUDPR.

1. ECDC shall process personal data in accordance with article 5(1) and article 10(2)(i) and 10(2)(j) of Regulation (EU) 2018/1725 and for the purposes of the CRAB Survey and for related purposes related to the fulfillment of its mandate as described in Regulation (EC) 851/2004 and Regulation (EU) 2022/2371.
2. The relevant national reference/expert laboratory shall process personal data made available to ECDC in accordance with Regulation (EU) 2016/679 and with any national law applicable.
3. ECDC and the relevant national reference/expert laboratory are acting as joint controllers for any processing of the data that is carried out jointly by the parties in the framework of the CRAB Survey, where the entities jointly determine the purpose and means of the processing operations. The relevant national reference/expert laboratory shall inform data subjects about such processing operations (including through a data protection notice) and shall act as contact points for the data subjects that want to exercise the rights conferred upon them by data protection legislation, without prejudice to the rights of the data subjects to address directly any of the joint controllers.
4. The relevant national reference/expert laboratory is controller for any processing prior to the transfer of the data to ECDC, including pseudonymisation.
5. ECDC is controller for the processing operations related to storage by ECDC of the data provided by the relevant national reference/expert laboratory, as well as for any further processing that is undertaken by ECDC to fulfil its mandate.
6. In case of personal data breach, the party where the incident occurs shall immediately (and in any case not later than 48 hours after the discovery of the breach) inform the other party whose personal data is affected. The relevant national reference/expert laboratory shall then inform the data subjects, where this is required by law taking into account the risks related to the breach. ECDC is unable to re-identify the data subjects, therefore is unable to inform them.
7. ECDC shall refrain from activities aimed at re-identifying data subjects whose data have been subject to processing for the purposes of the CRAB Survey.
8. The *ECDC's policy on data submission, access, and use of data within TESSy* includes provisions on access by third parties to data stored in ECDC's surveillance platform. Such document applies for the data covered by the CRAB Survey.
9. ECDC and the relevant national reference/expert laboratory shall designate contact points to discuss any data protection issue that might arise in the implementation of the CRAB survey, and to coordinate to ensure that data subjects can exercise their rights.

Annex 10. Decision tree to select eligible isolates, for hospitals with comprehensive surveillance of *Acinetobacter* species

This option is suitable for countries or hospitals that generate a database of *Acinetobacter* infections and colonisations via a comprehensive surveillance system. Those that do not are directed to Phase 2: During the survey: Actions for participating laboratories and hospitals.

Figure 6. Decision tree for participating laboratories to select eligible isolates to report to the national reference/expert laboratory



CRAb: carbapenem-resistant *Acinetobacter baumannii*; CSAb: carbapenem-susceptible *A. baumannii*

Annex 11. Previous versions of this document

Version 1.0

This is the internal initial version of the document, used to generate the materials presented at the virtual 'Network meeting of the European Antimicrobial Resistance Genes Surveillance Network 2023' (29–30 November 2023).

Version 1.1

The draft 'ECDC survey protocol for genomic-based surveillance of carbapenem-resistant *Acinetobacter baumannii* at the European level. Version 1.1' was circulated for comments on 15 December 2023 to NFPs for AMR, OCPs for AMRISO, and attendees of the 29–30 November meeting.

It contained minimal changes to version 1.0, including a minor edit to one of the secondary objectives, and minor language and formatting changes.

Version 1.2

The draft 'Survey protocol for the ECDC genomic-based survey of carbapenem-resistant *Acinetobacter baumannii* in Europe – Version 1.2' was emailed for national comments on 17 May 2023, to 'national survey coordinators', NFPs for AMR, and designated attendees of the virtual 'Network meeting of the European Antimicrobial Resistance Genes Surveillance Network 2023' (23 May 2024), for comments by 30 May.

The changes compared to version 1.1 included:

- An update to the sampling frame, following national comments on version 1.1, greatly simplifying the scheme.
- A re-ordering the contents of the protocol, to delineate more clearly actions before, during and after national surveys.
- An update to the sections describing the processes for identification of eligible species, AST and reporting antimicrobial consumption, following the Expert Group meeting on 23 March 2024.
- An update to the guidance for submission of samples for this survey.
- An update to Table 2, with newly published data from Eurostat regarding the number of regions per country.
- An update to text regarding Data protection, and addition of a new Annex 9, the controller-to-controller agreement.
- An update to Annex 1, including the recruitment process, and names and affiliations of the members, for the newly convened 'ECDC Expert Group for microbiological aspects of the CRAB survey'.
- An update to Annex 8, draft MTA template, following the signature of ECDC/2024/003 with CRBIP Institut Pasteur, France.
- Other updates to the text and definitions, and, when relevant, the draft survey metadata (Annex 3).
- Other minor language and formatting edits.

Version 1.3

The draft 'Survey protocol for the ECDC genomic-based survey of carbapenem-resistant *Acinetobacter baumannii* in Europe – Version 1.3' resulted from discussions at the virtual network meeting on 23 May, and national comments on version 1.2 received by 30 May. These included:

- Inclusion of clarifications to the hospital selection strategy, i.e. the recommendation of one hospital per NUTS-2 region is a guide.
- Removal of the variable for infection site from Form B.
- Updates to the text of the section 'data processing and planned analyses and outputs'.
- Addition of an introductory paragraph to 'Annex 9 – Controller-to-Controller Agreement on protection of personal data'.
- Addition or editing of text to describe variable definitions for Forms A–C, and the metadata.
- Division of Annex 3, the survey metadata from one table into two tables, for AMRISO and AMRISODENOM, respectively.
- Other minor language and formatting edits.

Updates and corrections made on 2 October 2024:

- In Table 2, the number of 'Level 2' regions for the selected EU candidate and potential candidate countries was updated, from 26 to 38. This also increased the total number of 'Level 2' regions. Box 1 is also updated, to reflect the updated number of 'Level 2' regions in eligible countries (N=291).
- Annex 3 contains minor updates. As stated in the section 'metadata structure', these metadata will be included in the annual ECDC metadata update process, so remain subject to additional changes. In Table 7, the changes include removing a duplicated row ("HospitalId"); updating a variable name ("PrescribedAntimicrobial"); and updating variable descriptions to align with the main text of this survey protocol.
- In the section 'How to complete Form C (hospital staff +/- national staff)', the definition of a survey period is now stated explicitly.
- In 'planned data analyses', a reference to an annex has been corrected, to Annex 8 rather than Annex 7.
- Annex 10 was edited so that the third green box from top contains "AND 'n' isolates from CSAb colonisation, so that the 'N' of submitted isolates is 10" rather than "AND 'n' isolates from CSAb infection, so that the 'N' of submitted isolates is 10".

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Prevention and Control (ECDC)**

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