

RAPID RISK ASSESSMENT

Carbapenem-resistant Enterobacterales – fourth update

18 November 2026

Summary

ECDC is publishing this rapid risk assessment due to a worsening epidemiological situation for carbapenem-resistant Enterobacterales (CRE) in the European Union (EU)/European Economic Area (EEA) which is leading to an increasing loss of treatment options. At the same time, the estimated incidence of bloodstream infections (BSIs) by carbapenem-resistant *K. pneumoniae* for the EU/EEA continues to increase. In this document, ECDC assesses the situation and proposes recommendations to EU/EEA countries. This assessment is intended for national public health authorities and healthcare providers in the EU/EEA.

Epidemiological situation

Recent EURGen-Net[1] investigations and the survey of carbapenem-resistant Enterobacterales 2025 (CRE25 survey) show a further worsening epidemiological situation for CRE in the EU/EEA. This includes a shift in carbapenemases in *Klebsiella pneumoniae* with an increasing proportion of NDM carbapenemases, increasing acquisition of the virulence factors yersiniabactin and aerobactin in *K. pneumoniae*, as well as increasing dissemination of *Escherichia coli* carrying $bla_{\text{OXA-244}}$. Based on these findings, the probability of further spread with escalating transmission of CRE in healthcare and community settings in the EU/EEA is high.

Risk assessment

Carbapenem-resistant Enterobacterales BSIs are associated with a high level of attributable mortality, primarily due to delays in administering effective antimicrobial therapy and the limited number of alternative treatment options. Novel beta-lactam/beta-lactamase inhibitor combinations have been approved for use in the EU since 2016. However, the increasing proportion of NDM carbapenemases in carbapenem-resistant *K. pneumoniae* has rapidly reduced the number of effective new treatment options. Simultaneously, an increase in virulence markers in carbapenem-resistant *K. pneumoniae* may favour prolonged colonisation, a higher probability of infection and potentially more severe infections.

The impact of the spread of CRE can be mitigated by appropriate awareness, coordinated action at the national level, early laboratory detection and characterisation, enhanced infection prevention and control (IPC) measures, and antimicrobial stewardship. However, the continued increase of CRE will not only result in negative treatment outcomes for individuals but can also negatively impact the quality and sustainable delivery of healthcare, resulting in a very high risk to patients requiring healthcare in the EU/EEA.

[1] https://www.ecdc.europa.eu/en/about-us/who-we-work/disease-and-laboratory-networks/EURGen-net

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Recommendations

The following enhanced efforts are required to control and reduce harm related to the spread of CRE in the EU/EEA:

- Strengthen national coordination of CRE control measures and develop a national strategy for CRE control. This includes a national CRE management team and action plan for CRE.
- Improve IPC measures in healthcare facilities. Hand hygiene remains one of the most effective measures to interrupt transmission and should be prioritised alongside screening, contact precautions, communication, and training. Detailed IPC measures are outlined in the full Recommendations section below.
- Establish adequate laboratory capacity for rapid detection and characterisation of CRE, including phenotypic antimicrobial susceptibility testing and identification of carbapenemase genes, to enable targeted use of newly-approved antimicrobials.
- Strengthen genomic surveillance, including whole genome sequencing, as close as possible to real time, accompanied by systematic metadata to guide IPC measures by identifying sources of CRE outbreaks and delineating transmission chains.
- Apply antimicrobial stewardship to decrease selection pressure and preserve the effectiveness of the carbapenems and the newly approved antimicrobials. This includes national treatment guidelines and audits of their implementation. Ensure access to antimicrobials effective against NDM-producing Enterobacterales.
- Strengthen investment in research, including innovative approaches for CRE treatment and control.

What is new?

Revised risk assessment based on the latest European genomic surveillance results on carbapenem-resistant *K. pneumoniae* and *E. coli* from the recent CRE25 survey and related strengthened recommendations.

Epidemiological situation

Over the past 12 years, European genomic surveillance of carbapenem-resistant Enterobacterales (CRE) has been conducted through structured surveys, including the European survey of carbapenemase-producing *Enterobacteriaceae* (EuSCAPE) 2013-2014 [1,2], the survey of carbapenem- and/or colistin-resistant Enterobacterales (CCRE survey) 2019 [3-5] and the survey of carbapenem-resistant Enterobacterales 2025 (CRE25 survey).

Carbapenem-resistant *Klebsiella pneumoniae*

Change in carbapenemase distribution

Carbapenem-resistant (R)/carbapenem-susceptible, increased exposure (I) *K. pneumoniae* species complex (SC) isolates (from all sample types) from the CRE25 survey (n=1 700) and the CCRE survey (n=1 261) were compared for 29 European countries: Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Kosovo[2], Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden. This comparison revealed a marked shift in carbapenemase distribution. The largest increase (28.1%) was observed among isolates carrying bla_{NDM}, either alone or together with other carbapenemase genes, most commonly in combination with bla_{OXA-48} (Figure 1A). In contrast, bla_{KPC}, the most common carbapenemase gene group in the 2019 CCRE survey, decreased by 23%.

The geographic distribution of bla_{NDM}-positive isolates also expanded substantially, with the proportion of nomenclature of territorial units for statistics level 2 (NUTS-2) regions with at least one bla_{NDM}-positive isolate increasing from 44.7% to 84.3%. This trend is concerning, as NDM carbapenemases confer resistance to several antibiotics recently introduced in the European Union (EU)/European Economic Area (EEA) for the treatment of CRE infections. Furthermore, although bla_{NDM-1} remained the predominant variant among carbapenem-R/I *K. pneumoniae* SC isolates with bla_{NDM} genes, a substantial shift within the NDM variants was observed, with an increase of the proportion of bla_{NDM-5}, and a decrease of the proportion of bla_{NDM-1}.

Acquisition of virulence markers

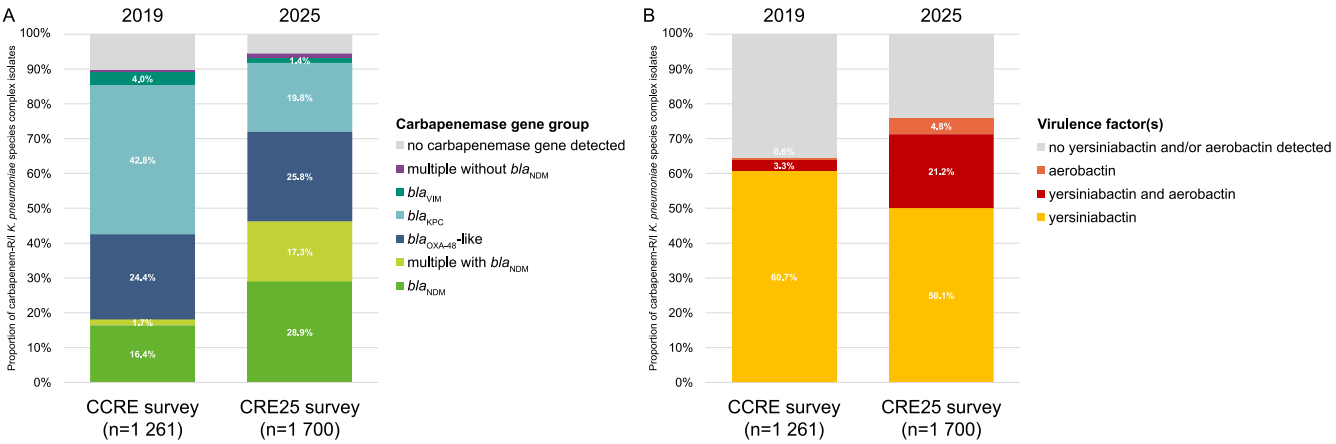
Convergence of multidrug resistance and virulence in *K. pneumoniae* poses an increased threat for patients [6]. Both healthcare-adapted carbapenem-resistant high-risk lineages acquiring virulence factors [7-11] and community-associated hypervirulent *K. pneumoniae* (hvKp) acquiring carbapenemase genes [7,12,13] have been reported in the EU/EEA. While hvKp were previously rarely observed in the EU/EEA, sustained healthcare-associated spread of hvKp ST23 carrying carbapenemase genes had been reported in Ireland [13]. However, it is the acquisition of yersiniabactin and aerobactin by circulating carbapenem-resistant high-risk lineages that is currently driving the increase of virulence markers in carbapenem-R/I *K. pneumoniae* in Europe.

[2] *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.*

Between the CCRE and CRE25 surveys, the proportion of carbapenem-R/I *K. pneumoniae* SC isolates carrying both yersiniabactin and aerobactin increased from 3.3% to 21.2% (Figure 1B). Their geographic distribution also expanded substantially, with the proportion of NUTS-2 regions reporting at least one isolate carrying both virulence factors increasing from 12.4% to 60.9%. The increase of aerobactin is related to the rapid spread of plasmids carrying aerobactin alone or together with a carbapenemase gene, such as *bla*$_{OXA-48}$ or *bla*$_{NDM}$, as well as by the spread of *K. pneumoniae* high-risk lineages that have acquired these plasmids. A recent investigation of the European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net) documented cross-border spread of a mosaic plasmid carrying both resistance (*bla*$_{OXA-48}$) and virulence (aerobactin) determinants [14].

In European healthcare settings, yersiniabactin and aerobactin may enhance the ability of *K. pneumoniae* to colonise humans and potentially cause an increase of infections in patients who are already severely ill and have frequent healthcare exposure. Both virulence factors are siderophores enhancing iron acquisition and bacterial survival in iron-restricted host environments. Yersiniabactin contributes to virulence in pulmonary infections [15] while aerobactin enhances growth and survival in human ascitic fluid and serum [16]. Although clinical data are missing, the increasing prevalence of yersiniabactin and aerobactin among carbapenem-R/I *K. pneumoniae* may elevate the number and severity of *K. pneumoniae* infections in Europe.

Figure 1. Distribution of carbapenemase gene groups (A) and the virulence factors yersiniabactin and aerobactin (B) in carbapenem-R/I *Klebsiella pneumoniae* species complex isolates in 29 countries that submitted data for the CCRE and the CRE25 surveys



Sequence types and cross-border clusters

The increase in the proportion of isolates with *bla*$_{NDM}$ is driven by several developments: the continued spread of previously circulating *K. pneumoniae* high-risk lineages carrying *bla*$_{NDM}$ (e.g. sequence type (ST) 147), the emergence of *bla*$_{NDM}$-positive lineages that were absent (e.g. ST6260, ST6668) or rare (e.g. ST383, ST395) in previous European genomic surveys, and the acquisition of *bla*$_{NDM}$ by lineages previously associated with other carbapenemase genes such as ST258/512 carrying *bla*$_{KPC}$. Evidence of cross-border dissemination was observed in the *K. pneumoniae* SC CRE25 survey dataset, where 97 of 270 genomic clusters included isolates from more than one country. One example of these cross-border clusters from the CRE25 survey described in more detail is the rapid dissemination of carbapenemase-producing *K. pneumoniae* ST6668 [17] within the EU.

Increasing estimated incidence of bloodstream infections

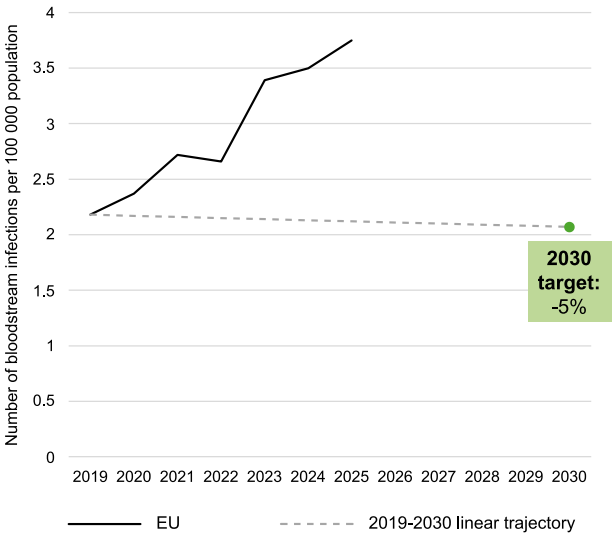
For *K. pneumoniae*, data from the European Antimicrobial Resistance Surveillance Network (EARS-Net) for 2025 show large variability in the national percentages of carbapenem (imipenem or meropenem) resistance in isolates from invasive infections, mostly bloodstream infections (BSIs), ranging from 0% to 69.7%. In 2025, six countries reported national percentages of carbapenem resistance above 25% (Bulgaria, Croatia, Cyprus, Greece, Italy, and Romania) [18]. The population-weighted mean percentage for the EU/EEA showed a significantly increasing trend from 11.7% in 2021 to 12.0% in 2025 [19]. Significantly increasing national trends in carbapenem resistance percentages were observed in invasive isolates of *K. pneumoniae* from 2021 to 2025 for Bulgaria, Cyprus, Czechia, Finland, Hungary, Latvia, Lithuania, the Netherlands, Poland, Portugal, Slovenia and Sweden [18].

The estimated incidence of BSIs by carbapenem-resistant *K. pneumoniae* for the EU/EEA increased from 2.15 in 2019 to 3.70 per 100 000 population in 2025, which corresponds to an increase of 72% [19]. Moreover, in the last five years (2021-2025) it increased from 2.69 to 3.70 per 100 000 population. This trend runs in the opposite direction to the EU target to reduce the total incidence of BSIs with carbapenem-resistant *K. pneumoniae* by 5% by 2030 compared with 2019 levels (Figure 2) [20]. Based on 2025 data, only five EU Member States (Austria, France[3], Ireland, Luxembourg, and Malta) have reached their national reduction target, while all others reported an increase or no change. The latest 2025 results showed five countries having an estimated national incidence of BSIs by carbapenem-resistant *K. pneumoniae* equal to or above 10 per 100 000 population (Bulgaria, Cyprus, Greece, Italy, and Romania) [18]. Notably, the overall incidence of *K. pneumoniae* BSIs, including both

[3] *Due to changes in the surveillance network in 2020 the progress toward the target should be interpreted with caution.*

carbapenem-resistant and carbapenem-susceptible cases, increased from 19.3 to 26.1 per 100 000 population (35%) during 2021–2025.

Figure 2. Estimated incidence of bloodstream infections with carbapenem-resistant *Klebsiella pneumoniae*, EU, 2019–2025



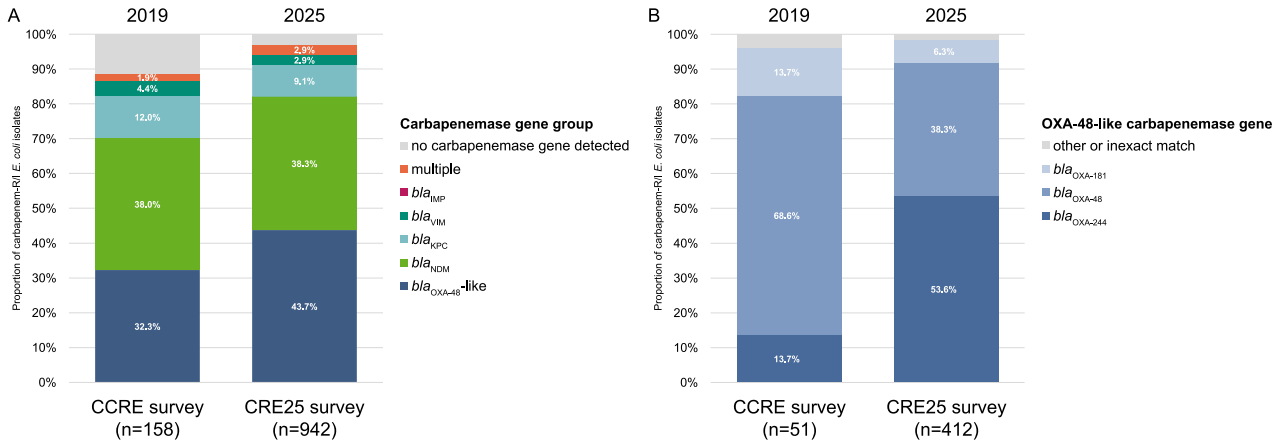
Carbapenem-resistant *Escherichia coli*

Change in carbapenemase distribution

The carbapenemase gene distribution also changed when comparing carbapenem-R/I *Escherichia coli* isolates between the CCRE survey (n=158) and CRE25 survey (n=942) in 29 countries that participated in both surveys. The proportion of isolates carrying *bla*$_{\text{OXA-48}}$-like genes alone increased from 32.3% to 43.7%, while *bla*$_{\text{NDM}}$ remained largely stable and *bla*$_{\text{KPC}}$ decreased from 12.0% to 9.1% (Figure 3A). Among the 412 CRE25 survey isolates carrying *bla*$_{\text{OXA-48}}$-like genes, *bla*$_{\text{OXA-244}}$ was the predominant variant (53.6%), followed by *bla*$_{\text{OXA-48}}$ (38.3%) and *bla*$_{\text{OXA-181}}$ (6.3%). This contrasted with the CCRE survey, where *bla*$_{\text{OXA-48}}$ predominated (68.6%), while both *bla*$_{\text{OXA-244}}$ and *bla*$_{\text{OXA-181}}$ accounted for only 13.7% of isolates each (Figure 3B).

OXA-244 has weaker carbapenem-hydrolysing activity than other OXA-48-variants and is often associated with only slightly decreased carbapenem susceptibility and therefore challenging to detect for clinical laboratories [21]. This increases the risk for undetected transmission in community settings. Although there is a lack of data on treatment outcomes for infections with OXA-244-producing *E. coli*, OXA-48-like carbapenemases have been linked to compromised clinical efficacy of carbapenem treatment [21,22]. The European Committee on Antimicrobial Susceptibility Testing (EUCAST) recommends avoiding carbapenems for treating carbapenemase-producing Enterobacterales even if isolates are categorised as susceptible (S) or I, due to a potentially impaired clinical response to treatment [23].

Figure 3. Distribution of carbapenemase gene groups (A) and OXA-48-like carbapenemase gene variants (B) in carbapenem-R/I *Escherichia coli* isolates in 29 countries that submitted data for the CCRE and the CRE25 surveys



Sequence types and cross-border clusters

The spread of carbapenem-R/I *E. coli* carrying *bla*$_{OXA-244}$ was polyclonal, with detections across major multidrug-resistant and extraintestinal pathogenic *E. coli* (ExPEC) lineages, including in descending order ST131 and its single locus variant ST13730, followed by ST38, ST69 and ST10. ExPEC can be transmitted in both healthcare and community settings via the faecal-oral, household, sexual or food-borne routes [24] and are therefore difficult to control. Furthermore, 100 of 155 genomic clusters identified in the CRE25 survey *E. coli* dataset were cross-border clusters, highlighting ongoing international dissemination.

Estimated incidence of bloodstream infections

EARS-Net data for 2025 show a lower overall EU/EEA population-weighted mean percentage of 0.2% for carbapenem (imipenem or meropenem) resistance in invasive *E. coli* than *K. pneumoniae* isolates [19], with national percentages ranging from 0% to 2.4% [18]. Between 2021 and 2025, a slightly increasing trend was observed for the EU/EEA population-weighted mean of national percentages, and the estimated incidence of carbapenem-resistant *E. coli* BSIs increased from 0.07 to 0.15 per 100 000 population [19]. However, the low carbapenem resistance proportions documented by EARS-Net should be interpreted cautiously. EARS-Net monitors proportions of *E. coli* isolates resistant to imipenem and meropenem. Therefore, it can underestimate the proportion of carbapenemase-producing isolates, especially those carrying OXA-48-like carbapenemases which might impair clinical response to carbapenems, but not result in imipenem or meropenem resistance as defined by EUCAST clinical breakpoints [23].

Treatment options for CRE

Carbapenemase production results in resistance to carbapenems or potentially impaired response to carbapenem treatment even if tested susceptible. Carbapenemase-producing isolates are frequently also resistant to aminoglycosides, fluoroquinolones and trimethoprim-sulfamethoxazole, resulting in multidrug-resistance [25,26]. Historically, colistin, fosfomycin and tigecycline showed *in vitro* activity against many CRE. However, concerns remain regarding their clinical effectiveness, frequent adverse effects, rapid development of resistance during treatment and increasing resistance globally. Additionally, fosfomycin and tigecycline have inadequate activity against *K. pneumoniae,* reflected by the lack of EUCAST clinical breakpoints.

Since 2016, several new antimicrobials with varying activity against CRE have been authorised in the EU, including ceftazidime-avibactam (2016) [27], meropenem-vaborbactam (2018) [28], imipenem-relebactam (2020) [29], cefiderocol (2020) [30], cefepime-enmetazobactam (2024) [31] (currently only recommended for infections with extended spectrum beta-lactamase-producing Enterobacterales [32]), and aztreonam-avibactam (2024) [33]. Eravacycline has also been approved [34] but only has breakpoints for *E. coli* and indication for complicated intraabdominal infections [23]. The activity of ceftazidime-avibactam, cefepime-enmetazobactam, meropenem-vaborbactam, imipenem-relebactam depends on the type of carbapenemase present, as the beta-lactamase inhibitors in these combination antimicrobials do not inhibit metallo-beta-lactamases (MBLs) including NDM, IMP and VIM. In contrast, aztreonam is stable against MBLs but is hydrolysed by many co-produced beta-lactamases [35]. Combined with avibactam, aztreonam retains broad activity against MBL-producing CRE. Although susceptibility to aztreonam-avibactam remains high [36], resistance mechanisms have already been described, mainly in *E. coli* through modification in penicillin-binding protein 3 (PBP3) [37-39].

Cefiderocol is a siderophore cephalosporin with activity against CRE that exploits iron uptake to enter the bacterial cell [40]. Resistance may arise through multiple mechanisms, including modification in PBP3, beta-lactamase variants, porin mutations, siderophore receptor mutations and efflux pump overexpression [41]. Cefiderocol resistance data vary due to selection bias of tested collections and ongoing challenges with phenotypic susceptibility testing, but the highest resistance proportions have been observed in NDM-producing CRE [42]. With the increasing proportion of carbapenem-R/I *K. pneumoniae* SC isolates carrying *bla*$_{NDM}$ genes in Europe, access to cefiderocol and aztreonam-avibactam is critically important for treating CRE. There are currently no other approved antimicrobials (per November 2026) that are consistently effective for treating NDM-positive CRE.

Antimicrobial consumption

The combined consumption of newly approved antimicrobials with activity against CRE, including ceftazidime-avibactam, imipenem-relebactam, meropenem-vaborbactam, cefiderocol, aztreonam-avibactam has increased in the EU/EEA up to 2025. Nevertheless, data from the European Surveillance of Antimicrobial Consumption Network (ESAC-Net) indicate that their consumption is much lower than that of polymyxins, primarily colistin (Table 1). The high polymyxin consumption suggests limited access to newer, more effective and better tolerated antimicrobials. Factors that might impact the use of newer antimicrobials are differences in national treatment guidelines, national availability and high costs. Another contributing factor may be the limited use of rapid tests to identify carbapenemase genes, which is required to guide treatment with newly approved antimicrobials. While the newly approved antimicrobials should be used carefully and primarily for definitive therapy, the present usage patterns suggest they are underutilised for CRE infections where they would be more effective than polymyxins. The use of carbapenems for infections with CRE should be avoided, even in the case of *in vitro* susceptibility.

Table 1. Comparison of consumption of newly approved antimicrobials with activity against carbapenem-resistant Enterobacterales, polymyxins and carbapenems, EU/EEA, 2025*

Name	EU/EEA consumption volume (number DDD)	EU/EEA consumption rate***** (DDD per 1 000 inhabitants per day)
Newly approved antimicrobials with activity against CRE**	873 653	0.00543
Polymyxins***	4 485 587	0.02761
Carbapenems****	14 339 418	0.08843

DDD – defined daily doses; EEA – European Economic Area; EU – European Union.
**Including 29 EU/EEA countries reporting data for antibacterials for systemic use (ATC J01) in 2025 (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia and Spain).*
***Newly approved antimicrobials included in the calculation for this table are aztreonam-avibactam (ATC J01DF51), ceftazidime-avibactam (J01DD52), meropenem-vaborbactam (J01DH52), imipenem-relebactam (J01DH56) and cefiderocol (J01DI04).*
****Polymyxins include colistin (ATC A07AA10, J01XB01) and polymyxin B (A07AA05, J01XB02).*
***** Carbapenems included all carbapenems in ATC group J01DH, with the exception of the newly approved combinations meropenem-vaborbactam and imipenem-relebactam, which are included with newly approved antimicrobials.*
******Population-weighted mean rate among EU/EEA countries that reported data to ESAC-Net for 2025. Population coverage data for hospital sector consumption from ESAC-Net was used to calculate consumption rates.*

ECDC risk assessment for the EU/EEA

This assessment is based on evidence available to ECDC at the time of publication. It follows the ECDC rapid risk assessment methodology, where the overall risk is determined by a combination of the probability of infection and the impact of the disease on affected populations [43]. ECDC will continue to monitor the event and reassess the risk based on future developments and the response measures implemented.

Recent EURGen-Net investigations, and the CRE25 survey show a further worsening of the epidemiological situation regarding CRE, including:

- a changing pattern of carbapenemase types in *K. pneumoniae,* with an increasing proportion of NDM carbapenemases and an increase of isolates co-producing two carbapenemases;
- increasing acquisition of the virulence markers yersiniabactin and aerobactin in circulating carbapenemase-producing high-risk lineages of *K. pneumoniae*;
- spread of *E. coli* producing OXA-244.

These findings add to the warning signs listed in the third update of ECDC's rapid risk assessment on CRE in 2025 [44], including:

- the increasing incidence of carbapenem-resistant *K. pneumoniae* BSIs in EU/EEA countries;
- genomic evidence of continued transmission and outbreaks of high-risk lineages of carbapenemase-producing *K. pneumoniae* in hospitals in the EU/EEA [45];
- examples of convergence of virulence and resistance in *K. pneumoniae* including healthcare-associated spread of hvKp ST23 in the EU/EEA [13];
- newly emerging Enterobacterales species carrying carbapenemase genes [46,47];
- increasing evidence of plasmid-mediated spread of major carbapenemase genes through intra- and inter-species horizontal gene transfer, causing outbreaks within hospitals and across healthcare networks [48];
- increasing detection of high-risk lineages of *E. coli* carrying carbapenemase genes in the EU/EEA, with a risk for transmission in the community [25,49].

Based on the findings above, the probability of further spread with escalating transmission of CRE in healthcare and community settings is considered high.

CRE infections are associated with a high level of attributable mortality, primarily due to delays in administering effective antimicrobial therapy and the limited number of alternative treatment options [50,51]. Novel antimicrobials or combinations have been approved for use in the EU in the last decade. However, the increasing proportion of NDM carbapenemases in carbapenem-resistant *K. pneumoniae* narrows the treatment options, as ceftazidime-avibactam, cefepime-enmetazobactam, imipenem-relebactam and meropenem-vaborbactam are not effective against NDM-positive CRE. The continued high consumption of colistin, an antimicrobial that has significant nephrotoxicity and lower efficacy than beta-lactam antibiotics, suggests that many hospitals in the EU/EEA experience difficulties in providing effective treatment for CRE and other multidrug-resistant Gram-negative bacteria. Simultaneously, an increase in virulence markers in carbapenem-resistant *K. pneumoniae* may favour prolonged colonisation, a higher probability of infection and potentially more severe infections.

The impact of CRE infections on patients can be mitigated by national and local action, appropriate awareness, early laboratory detection and characterisation, and timely expert advice on infection management. Consistently applied infection prevention and control (IPC) measures, as well as antimicrobial stewardship can be effective to reduce the spread of CRE. However, the accelerating dissemination of CRE observed over a period of 12 years shows that implementation of control measures has been insufficient to stop their spread in the EU/EEA. Various factors might contribute to the continued spread of CRE including challenges with implementing IPC measures in resource-constrained and understaffed acute care and long-term care facilities, and spread in community settings with related difficulties for detection and control. The increase of CRE will not only result in negative treatment

outcomes for individuals with CRE infections but can also negatively impact the quality and sustainable delivery of healthcare. The impact is therefore expected to be high. When considered together, the probability of spread and impact result in a very high risk to individuals requiring healthcare in the EU/EEA and to the sustainable delivery of healthcare in the EU/EEA.

ECDC recommendations

1. National strategy for CRE prevention and control

Countries should:

- Establish a dedicated multidisciplinary **National CRE Prevention and Control Team (NCPT)**, where not already in place, to lead and coordinate CRE prevention and control activities. This team should be integrated into existing national structures for the prevention and control of AMR and healthcare-associated infections where applicable. The NCPT can be replicated with respective teams at regional and local level where relevant.
- Develop and implement a **CRE National Action Plan (CRE NAP)**, preferably as part of the antimicrobial resistance National Action Plan or an action plan on multidrug-resistant organisms (MDROs).. The CRE NAP can be complemented by respective plans at regional and local level.

The CRE NAP should define clear objectives, responsibilities, timelines, indicators and targets for monitoring implementation and progress. Key elements of a national CRE strategy include:

- **Governance**: The NCPT should be established within the Ministry of Health, National Public Health Institute, or another appropriate national authority and include participation of other relevant national institutions such as the National Medicines Agency. NCPT should lead national coordination, monitor implementation of the CRE NAP, support outbreak response, oversee surveillance systems, and ensure accountability for aprevention and control efforts across healthcare facilities and regions.
- **Multidisciplinary expertise:** The NCPT should include expertise in infectious diseases, IPC, clinical pharmacy, antimicrobial stewardship, laboratory detection and characterisation, phenotypic and genomic surveillance. Representation from both national-level experts and professionals working in healthcare facilities (public and private, as applicable) ensures that recommendations are feasible, practical and adaptable to different healthcare settings.
- **Mandate and responsibilities**: The NCPT should be mandated and adequately resourced to:
  - Coordinate, oversee and monitor implementation of the CRE NAP across all types of healthcare facilities, including acute-care hospitals, long-term care facilities, rehabilitation facilities;
  - Ensure surveillance systems (automated or laboratory-based) provide timely, complete and accurate phenotypic and genomic data, and analyse these data to inform prevention and control actions;
  - Facilitate timely communication and sharing of surveillance data, alerts, lessons learned and best practice among healthcare facilities, laboratories and public health authorities nationally and internationally;
  - Promote awareness and knowledge sharing for appropriate patient and IPC management between healthcare facilities on the regional and local level;
  - Identify and address gaps in surveillance systems and control measures;
  - Coordinate and support outbreak investigations, related communication and response activities;
  - Develop and update national CRE guidance on laboratory detection, screening, IPC and clinical management;
  - Support, monitor and evaluate the implementation of national guidance in healthcare facilities;
  - Monitor, assess and report challenges related to access and availability of antimicrobials for CRE infections and contribute to national and international initiatives addressing these challenges [52,53];
  - Promote distribution of independent antimicrobial product information to physicians and reduce their exposure to potentially inaccurate promotional material;
  - Improve national preparedness for large-scale transfers of military or civilian patients who may carry CRE or other multidrug-resistant pathogens, including standard operating procedures, designated referral centres, and surge capacity for safe clinical management of highly drug-resistant infections and IPC (isolation capacity, infectious disease competence, immediate access to last line antimicrobials).
- **Dedicated resources:** Adequate and sustainable resources, including funding, workforce capacity, laboratory and information systems should be secured at the national, regional and healthcare facility level to support the implementation of the CRE NAP. Strong commitment and accountability from the highest level of healthcare authorities and healthcare leadership is essential to ensure that the infrastructure, staffing, training, surveillance and IPC capacities required for effective implementation are in place and maintained.
- **Awareness and engagement:** National awareness and engagement activities should promote understanding of CRE among healthcare workers, healthcare leaders and relevant stakeholders. These activities should emphasise that CRE transmission is preventable and that sustained reductions require coordinated action across laboratories, clinical services, IPC programmes and healthcare management. Communication strategies should empower healthcare workers by highlighting the effectiveness of evidence-based IPC measures and demonstrate how improvements in implementation and compliance can reduce CRE transmission.

- **Monitoring and evaluation mechanisms**: Progress against defined objectives, indicators and targets should be monitored and reported annually, using both proportion of resistance and estimated incidence of resistance, at national and local levels. Public reporting can support accountability, maintain stakeholder engagement and increase awareness of CRE prevention and control efforts.
- **Innovation and access to antibiotics and other medical countermeasures (MCM):** In addition, Member States can consider measures to ensure innovation and access to antibiotics and other MCM necessary to combat CRE. To support this effort, the Commission is developing a MCM preparedness roadmap against CRE, which aims to map current gaps, as well as potential actions to stimulate research and innovation, support the development and uptake of new and existing antibiotics and other MCM, and strengthen their availability and accessibility across the EU.

ECDC will continue to support prevention and control of CRE via its surveillance networks, development of guidance and tools and country support activities. National authorities are invited to contact ECDC for specific support on CRE NAPs and implementation of related control measures.

2. Healthcare facility infection prevention and control

Reducing transmission within and between healthcare facilities is the cornerstone of CRE prevention and control. The continued increase in CRE incidence in several countries, together with evidence of ongoing transmission within and between healthcare facilities, indicates that existing IPC measures are often insufficiently implemented or monitored. The importance of preventing transmission is further reinforced by reports of carbapenem-resistant *K. pneumoniae* lineages combining resistance and virulence determinants, potentially increasing the risk of prolonged colonisation, infection and adverse patient outcomes. Hand hygiene remains one of the most effective measures to interrupt transmission and should be strongly prioritised alongside screening, contact precautions, environmental cleaning and antimicrobial stewardship [54,55]. Support from hospital leadership is essential to ensure the availability of the necessary human, material and financial resources required for sustained implementation, monitoring and continuous improvement [56].

Effective measures to prevent transmission of CRE include:

- **Hand hygiene is a core intervention** for preventing CRE transmission. Healthcare facilities should implement multimodal hand hygiene improvement programmes consistent with international guidelines, including the WHO Five moments for hand hygiene [57]. Compliance should be routinely monitored, with regular and timely feedback to healthcare workers. ECDC's digital hyFive Hand Hygiene Tool supports structured observation, analysis and feedback on hand hygiene practices that enable monitoring and quality improvement at unit and facility level.
- **Appropriate glove use:** Glove use should follow standard and transmission-based precaution recommendations and should not replace hand hygiene. Unnecessary glove use should be actively reduced, as it may decrease hand hygiene compliance, increase transmission risk and unnecessary consumption of resources. Healthcare facilities should monitor glove use practices and provide regular feedback to healthcare workers. ECDC's hyFive tool also includes a dedicated glove-use module that supports structured monitoring of glove use practices and feedback to healthcare workers.
- **Standard precautions**, including hand hygiene, should be applied consistently to all patients, given that CRE colonisation may go undetected.
- **Contact precautions** for patients who are colonised or who have a CRE infection including placement in a single room with dedicated toilet facilities where available, or cohorting of patients, staff and equipment when single rooms are limited; appropriate use of personal protective equipment (e.g. gloves and gowns); limitation of patient movement and transport; use of dedicated or disposable patient-care equipment; and prioritisation and monitoring of environmental cleaning and disinfection [58].
- **Coordinated outbreak investigation and control measures** should be promptly initiated in healthcare facilities upon increasing detection of CRE cases, and include a rapid epidemiological and genomic investigation of cases, CRE screening in affected wards, contact tracing, strict implementation of contact precautions, training on and monitoring of hand hygiene practices, antimicrobial stewardship support, investigation and control of environmental reservoirs when suspected, as well as appropriate internal and external communication.
- **Communication** of CRE infection or colonisation during patient transfer and transport, including documentation in patient administration systems and/or medical records.
- **Screening** strategies should be tailored to the local epidemiology of CRE and available human, technical, and financial resources. For screening of CRE colonisation, rectal or faecal samples should be collected. Healthcare facilities should consider pre-emptive isolation and contact precautions for patients at increased risk of CRE carriage while awaiting screening results.
  - In countries where CRE acquisition is uncommon, screening may focus on patients with travel history and/or healthcare exposure during the previous 12 months in countries or facilities with known high CRE prevalence or documented outbreaks. Global data on carbapenem resistance among *K. pneumoniae* and *E. coli* bloodstream and urinary tract infections are available through the Global Antimicrobial Resistance and Use Surveillance System (GLASS) dashboard.
  - In countries with endemic CRE, consider admission and periodic screening of high-risk patients (e.g. immunosuppressed, dialysis-dependent) and patients admitted to high-risk units (e.g. ICUs, transplant, burn, and haematology/oncology units).

  - In settings with a high CRE burden or ongoing transmission, repeated point-prevalence surveys may be considered to monitor transmission and evaluate the impact of control measures.
  - Consider environmental cultures only when a persistent environmental reservoir is suspected (e.g. sinks, toilets, showers or drains). Remove (where possible) or thoroughly disinfect identified environmental reservoirs of CRE.
- **Environmental cleaning and disinfection and management of environmental reservoirs:** Healthcare facilities should ensure routine and terminal cleaning and disinfection of rooms occupied by patients who are colonised or who have a CRE infection, with particular attention to high-touch surfaces, shared patient-care equipment and bathrooms. Monitoring and feedback should be used to support consistent implementation. Regular maintenance of sinks, drains and associated wastewater plumbing which can act as environmental reservoirs should be performed, as well as promotion of practices that reduce splash and environmental contamination.
- **Staff engagement and training**: Healthcare workers should receive regular training on CRE epidemiology including feedback on local surveillance data and trends, transmission and prevention. Training should emphasise that CRE transmission is preventable and that all staff have a role in reducing transmission through consistent implementation of IPC measures.
- **Accessible information on CRE** should be given to patients, families and friends, with details on what IPC measures are expected while hospitalised and their role in reducing the risk of CRE transmission. Information on CRE colonisation or infection should accompany patients throughout the continuum of care to ensure appropriate prevention and control measures are maintained across healthcare settings.
- **Leadership and accountability:** Healthcare facility leadership should ensure adequate staffing, infrastructure, training, surveillance and IPC resources and establish clear accountability for implementation and monitoring of CRE prevention and control measures. Healthcare facility leadership should receive immediate communication on outbreaks to inform decision-making and the provision of adequate resources for IPC action.
- **Monitoring and feedback**: Systematic monitoring, auditing and feedback of IPC practices should be implemented in all healthcare facilities. Monitoring should include hand hygiene, appropriate use of personal protective equipment, environmental cleaning and implementation of transmission-based precautions. Results should be regularly communicated to frontline staff, clinical leaders and hospital management, and used to guide targeted improvement actions, including feedback, training and system adjustments to facilitate desired IPC behaviours. Monitoring should focus on both process indicators (e.g. compliance with IPC practices) and outcome indicators.
- **Behaviour change approaches** should be incorporated into IPC training activities (See Proposal for EU guidance on the establishment and implementation of infection prevention and control programmes in healthcare [55] for further guidance on behaviour change to strengthen IPC practices.

In residential care settings, including long-term care facilities, all reasonable IPC measures and antimicrobial stewardship activities should be implemented to reduce the risk of CRE spread, taking into consideration the entirety of residents' care needs and potential harm associated with extended isolation.

3. Laboratory capacity and surveillance

For Enterobacterales isolated from diagnostic samples, standardised quality-assured AST based on EUCAST guidance is required to detect carbapenem resistance and to inform timely treatment decisions. Effective control of CRE in the EU/EEA also requires active surveillance to detect asymptomatic carriers. EUCAST guidance indicates that meropenem provides the optimal balance between sensitivity and specificity for detecting CRE that produce carbapenemases using the screening cut-off values (MIC >0.125 mg/L or zone diameter <28 mm) [59]. Implementation of national CRE carriage screening programmes for patients in healthcare facilities should be supported with sufficient funding and laboratory capacity.

Following the detection of reduced carbapenem susceptibility, it is important to determine whether the isolate produces a carbapenemase and, if so, to identify the carbapenemase family. This can be achieved using supplementary phenotypic or molecular methods, including several commercial assays suitable for routine diagnostic laboratories. Differentiation between the major carbapenemase families (NDM, VIM, IMP, KPC and OXA-48-like) is essential for both surveillance and treatment decisions. Information on the carbapenemase family should be included into the laboratory reporting to clinicians. The use of rapid tests can significantly improve the timely detection of CRE infections and asymptomatic colonisation and requires adequate reimbursement. Laboratories should also be able to test susceptibility to the new antimicrobial agents with activity against CRE. The emergence of acquired resistance calls for conducting phenotypic AST for these agents, in addition to the differentiation of carbapenemase families described above. Enterobacterales isolates that are carbapenem-resistant or suspected to produce carbapenemases should be referred to the national reference laboratory (NRL) for confirmatory testing and further characterisation.

Countries should continue to reinforce and maintain the central role of NRLs in characterising the CRE population structure, carbapenemase, virulence and other clinically relevant resistance genes. NRLs also require the capacity to provide technical guidance to local laboratories and support the interpretation of laboratory and surveillance results for IPC teams, clinicians and public health authorities. WGS enables high-resolution investigation of transmission events and outbreaks to guide IPC interventions. It also supports monitoring of the emergence and spread of high-risk CRE clonal lineages and mobile genetic elements, including plasmids, within and between countries. CRE control therefore requires appropriate and sustained financing of sequencing capacities at the NRL.

Genomic surveillance is required to detect virulence genes that might be associated with hvKp and other high-risk *K. pneumoniae* lineages, including the increasing proportion of yersiniabactin and aerobactin among carbapenem-R/I *K. pneumoniae*. Continued surveillance will also be required to monitor other CRE species as well as plasmids carrying carbapenemase and/or virulence genes, which are contributing to the dissemination of antimicrobial resistance and virulence. If the number of isolates exceeds national WGS capacity, representative sampling schemes should be defined based on the specific surveillance objectives and consistently implemented. Although the direction and relative contribution of the different transmission pathways remain uncertain, CRE and carbapenemase genes may circulate between humans, animals, food and the environment, highlighting the need for integrated One Health surveillance.

Guidance on WGS-based genome analysis methods and standardised protocols for national CRE surveillance and outbreak investigations is available from the EURGen-RefLabCap project [60]. Additionally, European NRLs are encouraged to engage in EURGen-Net and in the phenotypic and genomic capacity-building activities of the European Reference Laboratory for Public Health on Antimicrobial Resistance in Bacteria (EURL-PH-AMR) [61] and participate in related external quality assessments and genomic proficiency testing.

4. Antimicrobial stewardship programmes

The implementation of comprehensive antimicrobial stewardship programmes (ASP) in hospital and community settings is essential to prevent and control the emergence and spread of CRE and of other MDROs. Rational use of antimicrobials should be promoted using the AWaRe classification [62], including measures to restrict the use of antibiotics classified as not recommended [63]. Increased awareness among clinicians of the challenge of detecting and treating CRE infections, and access to timely expert advice on infection management are also important. ASP should include efforts to reduce carbapenem consumption in hospitals by implementing carbapenem-sparing strategies using antibiotics such as piperacillin-tazobactam and temocillin as alternatives [64,65].

National guidelines for the treatment of severe CRE infections should be developed considering the epidemiological situation of CRE and predominant carbapenemase genes in the country. They should also specify indications for the most appropriate newly approved antimicrobials. National authorities need to ensure timely access to antimicrobials listed in the national guidance, including newly approved antimicrobials; monitor and audit their use in accordance with the national guidance, and perform surveillance of resistance to newly approved antimicrobials. Of note, effective treatment of infection with CRE producing MBLs such as NDM requires access to aztreonam-avibactam or cefiderocol. Adequate reimbursement of hospitals for treatment of patients with CRE infections is required to ensure sustainable management of patients.

Antimicrobial stewardship programmes need to be informed by behavioural and implementation science that applies interventions tailored to the barriers and facilitators identified [66]. General good practice recommendations for the treatment of CRE infections include optimal dosing schemes with attention to adverse effects, optimisation of dosing and administration by pathogen and indication, use of EUCAST recommended dosing, source control, step-down targeted treatment and follow-up cultures [67]. Diagnostic stewardship interventions are useful to improve the process of ordering, performing and reporting microbiological testing with the aim of reducing antimicrobial use and AMR [68]. For ceftazidime-avibactam, meropenem-vaborbactam, imipenem-relebactam, cefiderocol and aztreonam-avibactam, the EU Summary of Product Characteristic (SmPC) (which describes the properties and the officially approved conditions of use in the EU) specifies that these newly approved antimicrobials should be used to treat infections in patients 'with limited treatment options', and 'only after consultation with a physician experienced in the management of infectious diseases' [27-30,33].

5. Measures to prevent spread of CRE into the community

In shared public environments, standard personal hygiene rules should be applied to prevent person-to-person transmission, as well as good hygiene practice to prevent food contamination from handlers who are colonised with CRE. In addition, antimicrobial-resistant bacteria, including CRE, can spread from humans who are colonised to the animal population through a variety of routes (wastewater, human/animal contact, etc.). It is important that measures are in place to address such transmission routes to minimise the potential spillover of CRE from humans to food-producing animals.

It is also important to avoid the potential transmission of CRE via the food chain using a One Health approach [69]. The harmonised monitoring programme for antimicrobial resistance in 'food-producing animals and food thereof' stipulates that CRE should be monitored in broilers, fattening turkeys, fattening pigs and bovine animals (less than one year of age), and in meat derived thereof every second year on a routine basis [70]. Continued prohibition of the use of carbapenems in food-producing animals should be maintained [71]. As genes encoding carbapenemases are mostly plasmid-mediated, and co-resistance may be an important issue in the spread of such resistance mechanisms, decreasing the frequency of antimicrobial usage in animal production within the EU in accordance with prudent use guidelines is also a high priority [71].

A multifaceted, integrated approach to minimising antimicrobial use in food-producing animals is recommended, and further options related to this are outlined in the 'EMA and EFSA Joint Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety' [72]. Recommended options include: establishing targets for antimicrobial use reduction, use of on-farm health plans, increasing the availability of rapid diagnostics, improving husbandry and management procedures for

disease prevention and control, rethinking livestock production systems to reduce inherent disease risk. Finally, some studies provide robust evidence of alternatives to antimicrobials that positively influence animal health parameters [72].

6. Measures to prevent cross-border spread

Healthcare facilities should:

- Obtain a travel history and relevant healthcare exposure for all patients upon admission, where feasible;
- Screen patients at risk for CRE carriage and implement pre-emptive contact precautions pending screening results using a screening strategy tailored to the local epidemiology of CRE, and the availability of human, technical, and financial resource, as outlined in recommendation 2 above;
- Ensure effective communication during patient transfers. For direct inter-facility transfers, verbal and written communication should clearly indicate a patient's CRE-positive status (colonisation or infection) to enable appropriate IPC measures in the receiving facility;
- Notify relevant public health authorities of CRE cases or events in accordance with national reporting requirements.

National and public health authorities should:

- Establish mechanisms for timely notification, risk assessment, and coordinated response to CRE cases or events with potential cross-border implications;
- Report relevant events to international surveillance and alert systems. For the EU/EEA and candidate countries, these include the Early Warning and Response System (EWRS), when reporting criteria are met and the European surveillance portal for infectious diseases (EpiPulse) for timely information sharing on events with potential cross-border relevance to facilitate situational awareness, risk assessment, and coordination among countries.

7. Research and innovation

Sustained control and effective treatment of CRE will require investment into integrated data infrastructure to target control measures, research to address outstanding questions and innovative treatment and control approaches. Priority areas for research and innovation include:

- CRE transmission dynamics including spread of mobile genetic elements and spread of carbapenemase-producing *E. coli* in community settings;
- Clinical impact of CRE carrying additional virulence markers and potential implications for management;
- Optimised screening and detection strategies;
- Effectiveness of control measures and barriers for their implementation;
- Development of new antimicrobials;
- Development of alternative treatment approaches to antibiotics such as bacteriophage therapy, monoclonal antibodies or virulence inhibitors;
- New preventive strategies including vaccines targeting Enterobacterales.

Guidance documents

For details on control measures for CRE and for the treatment of CRE infections, please refer to the following:

- ECDCs proposal for EU guidance on the establishment and implementation of infection prevention and control programmes in healthcare [55];
- hyFive Hand Hygiene Tool: https://www.ecdc.europa.eu/en/publications-data/hyfive-hand-hygiene-tool;
- ECDC's guidance on IPC measures and tools for the prevention of the entry of carbapenem-resistant *Enterobacteriaceae* into healthcare systems [73];
- WHO's guidelines for the prevention and control of carbapenem-resistant *Enterobacteriaceae*, *Acinetobacter baumannii* and *Pseudomonas aeruginosa* in healthcare facilities [58];
- WHO's implementation manual to prevent and control the spread of carbapenem-resistant organisms at the national and healthcare facility level [56];
- European Society of Clinical Microbiology and Infectious Diseases (ESCMID) guidelines for treatment of infections caused by multidrug-resistant Gram-negative bacilli, for the management of infection control measures to reduce transmission of multidrug-resistant Gram-negative bacteria in hospitalised patients and for the decolonisation of carriers of multidrug-resistant Gram-negative bacteria [67,74,75];
- WHO's guide to antimicrobial stewardship interventions [76] and the WHO AWaRe (Access, Watch, Reserve) antibiotic book [62];
- National guidelines of EU/EEA countries, as listed in the ECDC directory of online resources for the prevention and control of AMR and HAI [77].

Limitations

The field of antimicrobial resistance is evolving, and new evidence may become available at short notice. In particular, any information related to treatment options for CRE infections, indications for specific antimicrobials and their safety should be considered as a general indication of potential use at this time. Individual prescribing decisions should be made in the context of the current SmPC, the individual patient context and other relevant information. At the time of writing, information on newly approved antimicrobials and resistance to them was limited. In addition, antimicrobial resistance percentages varied between studies. It is therefore important to bear in mind that resistance percentages are always strongly influenced by the bacterial collection selected for testing. Expected resistance to the newly approved antimicrobials was estimated based on genomic data for carbapenemase gene distribution. Furthermore, there is limited information on treatment outcomes and adverse effects for the newly approved antimicrobials.

External reviewers

Austria: Julia Weber (Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection, Vienna); Belgium: Pierre Bogaerts, Te-Din Huang (National Reference Centre for Antimicrobial-Resistant Gram-Negative Bacilli, CHU UCL Namur); Croatia: Arjana Tambić Andrašević (University Hospital for Infectious Diseases, Zagreb); Denmark: Anette Hammerum, Barbara Holzknecht (Statens Serum Institut); France: Laurent Dortet (Associated French National Reference Centre for Antibiotic Resistance: Carbapenemase-Producing *Enterobacteriaceae*, Le Kremlin-Bicêtre); Germany: Felix Reichert (Robert Koch Institute, Berlin); Greece: Sophia Hatzianastasiou, Ioanna Spiliopoulou (National Public Health Organisation, Athens); Hungary: Ágnes Hajdu (National Center for Public Health and Pharmacy, Budapest); Ireland: Ruth Waldron (Galway University Hospital, Galway); Italy: Maria Del Grosso, Giulia Errico, Monica Monaco (Istituto Superiore di Sanità, Rome); Latvia: Baiba Niedre-Otomere (National Microbiology Reference Laboratory, Riga); Malta: Michael A. Borg (Mater Dei Hospital, Msida); The Netherlands: Antoni Hendrickx, Daan Notermans (National Institute for Public Health and the Environment, Bilthoven); Norway: Ørjan Samuelsen (Norwegian Centre for Detection of AMR, University Hospital of North Norway): Poland: Ewa Gabińska, Dorota Żabicka (National Medicines Institute, Warsaw); Portugal: Vera Manageiro (National Institute of Health Doutor Ricardo Jorge, Lisbon); Romania: Gabriel A. Popescu (Carol Davila University of Medicine and Pharmacy, Bucharest); Slovakia: Martin Sojka (Public Health Authority, Bratislava); Spain: María Pérez Vázquez (Instituto de Salud Carlos III, Madrid), Sweden: Hanna Billström, Alma Brolund, Petra Edquist, Inga Fröding, Birgitta Lytsy, Barbro Mäkitalo, Vilhelm Müller, Stephan Stenmark (Public Health Agency of Sweden, Solna).

European Food Safety Authority: Ernesto Liébana, Beatriz Guerra.

European Medicines Agency: Radu Botgros.

European Union Reference Laboratory for Public Health on Antimicrobial Resistance (EURL-PH-AMR) in Bacteria: Valeria Bortolaia, Louise Roer, Camilla Wiuff Coia.

DG-HERA: Marta Monteiro Fernandes.

Disclaimer

ECDC issues this risk assessment document based on an internal decision and in accordance with Article 20 of Regulation (EU) 2022/2371 on serious cross-border threats to health, Article 7(1) and 8a of Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control (ECDC). In the framework of ECDC's mandate, the specific purpose of an ECDC risk assessment is to present different options on a certain matter. The responsibility on the choice of which option to pursue and which actions to take, including the adoption of mandatory rules or guidelines, lies exclusively with the EU Member States and EEA countries. In its activities, ECDC strives to ensure its independence, high scientific quality, transparency and efficiency. This report was written with the coordination and assistance of an internal response team at the ECDC. All data published in this risk assessment are correct to the best of our knowledge at the time of publication. Maps and figures published do not represent a statement on the part of ECDC or its partners on the legal or border status of the countries and territories shown.

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