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An evaluation of the electronic reporting system for the enhanced surveillance of carbapenemase-producing Gram-negative bacteria in England

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SUMMARY

Background: An electronic reporting system (ERS) for the enhanced surveillance of carbapenemase-producing Gram-negative bacteria (CPGNB) was launched by Public Health England in May 2015.
Aim: This evaluation aimed to assess uptake, timeliness and completeness of data provided and explore potential barriers and facilitators to adopting the system.
Methods: The evaluation comprised a retrospective analysis of surveillance data and semi-structured interviews with ERS users.
Findings: The proportion of organisms referred for investigation of carbapenem resistance via ERS increased over the first 12 months post-implementation from 35% to 73%; uptake varied widely across regions of England. Completeness of enhanced data fields was poor in 78% of submitted isolates. The median number of days to report confirmatory test results via ERS was 1 day for the regional service and nine days for the national reference laboratory, which additionally conducts phenotypic testing to confirm carbapenemase negativity. Hindrances to ERS utility included: a lack of designated, ongoing resource for system maintenance, technical support and development; uncertainty about how and when to use ERS and workload. Incomplete data prevented gaining a better understanding of important risk factors and transmission routes of CPGNB in England.
Conclusion: The ERS is the only surveillance system in England with the potential to gather intelligence on important risk factors for CPGNB to inform public health measures to control their spread. Although the ERS captures more information on CPGNB than other

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surveillance systems, timeliness and completeness of the enhanced data require substantial improvements in order to deliver the desired health benefits.

Introduction

Infections resulting from bacteria expressing carbapenem resistance as a result of acquired carbapenemases have increased globally over the past decade [1—3]. With limited therapeutic options available to treat infections caused by carbapenem-resistant Gram-negative bacteria (CRGNB), attributable death rates are 26% to 44% higher than in patients with comparable carbapenem-susceptible infections [4] and costs and morbidity related to consequent prolonged hospital stays are commensurately higher [5]. Preventing the spread of CRGNB is therefore a global public health priority.

Surveillance plays an important role in identifying emerging antimicrobial resistance and detecting outbreaks [6]. Epidemiological analysis of microbiological reports in England from 2010 to 2011, for instance, found alarming proportions of multi-resistant *Acinetobacter baumannii* isolates (77.2%) with resistance to imipenem or meropenem, as well as year-on-year increases in the number of cases of carbapenem-resistant *Klebsiella* spp. [7]. In response to the increasing detection of CRGNB in England, Public Health England (PHE) implemented an electronic reporting system (ERS) for these bacteria. This free-to-use, national system was launched in May 2015 with two goals: firstly, to offer a system for laboratories to electronically request confirmation and characterization of acquired carbapenemase production in Gram-negative bacteria; and secondly, to collect additional risk factor information from hospitals on patients infected or colonized by confirmed carbapenemase producers in order to understand the underlying epidemiology in England [8] and better inform control measures. The ERS request form was based on the paper version of the form used by the national reference laboratory prior to the implementation of the ERS. The enhanced surveillance fields were initially developed by a sub-group of the national incident control team and following piloting in the North West of England final fields were agreed by experts as part of the work of the national incident control team. The ERS surveillance system is not mandatory and therefore requires the voluntary support of microbiologists and hospital infection prevention and control teams.

Patient-level data capture is needed to determine risk factors such as foreign travel history, prior hospital admissions, patient provenance, admission type, sample details (clinical or screening) and potential contact with other patients known to be infected and/or colonized with carbapenemase-producing Gram-negative bacteria (CPGNB). Prior to the ERS there was no ongoing structured national surveillance for CPGNB in England and consequently a paucity of information on their epidemiology. The ERS is a novel approach integrating diagnostic laboratory referral practices and electronic data capture to rapidly respond to an emerging resistance threat. It is therefore important to evaluate and disseminate the lessons learnt from implementing the ERS.

This evaluation aimed to examine uptake and coverage of the ERS for enhanced surveillance of CPGNB in England and to assess its provision of timely and complete data. In addition, potential barriers and facilitators to adopting the system were explored.

Methods

Evaluation approach

The evaluation incorporated a retrospective analysis of surveillance and laboratory data [9,10] and stakeholder interviews with ERS users.

Data

Data were extracted from the ERS for the period May 2015 to April 2017, and from the Antimicrobial Resistance and Healthcare Associated Infections (AMRHAI) Reference Unit's laboratory information management system for the period May 2015 to December 2016. Data periods differ as data for the period January 2017 to April 2017 were not available from AMRHAI at the time of this evaluation. Data on all Gram-negative bacteria entered in the ERS were extracted, including bacteria for confirmation of carbapenemase production sent to either a specialist PHE laboratory or to AMRHAI, and cases where local molecular test results were entered. Data extracted from AMRHAI were for all Gram-negative bacteria with requests for confirmation of carbapenemase production sent via ERS, plus aggregated data for total monthly requests.

Outcome measures

Number of registered users was evaluated as a count of those registering to use ERS over the evaluation period for each of the following: microbiology laboratory users, National Health Service (NHS) acute hospital Trust users and regional specialist laboratory users. Trust users were infection prevention and control (IPC) team members, microbiology users were laboratory personnel responsible for referring organisms to PHE reference laboratories, or recording the results of local molecular tests; and regional specialist laboratory users were microbiology users who are located in a specialist laboratory offering a service for the confirmation of carbapenemase producers.

Uptake was evaluated as the number of Gram-negative bacteria received by AMRHAI for acquired carbapenemase testing via the ERS divided by the total number of Gram-negative bacteria sent to AMRHAI for confirmation of acquired carbapenemase production per month, for the period May 2015 (launch date) to the end of December 2016 (20 months).

Coverage was evaluated as the number of Gram-negative bacteria received by AMRHAI for acquired carbapenemase testing via the ERS divided by the total number of Gram-

negative organisms sent to AMRHAI for confirmation of acquired carbapenemase production by region of England from May 2015 to December 2016.

Completeness of data was measured as the percentage of missing responses for each data field on the ERS form (see Appendix A) from January 2016 to December 2016 (12 months). Data from the first six months was excluded to allow for an implementation period and one full year of data used to assess this measure in order to facilitate future comparative evaluation of data completeness. An average completion rate was calculated using a sub-set of data fields from the ERS form including: 'overseas travel' (yes/no answers only), 'overseas health care' (yes/no answers only), 'admission date', 'patient screened', 'clinical speciality', and 'admission from'. Capture of these data is vital to meeting the ERS objectives: to describe patients infected and/or colonized by time, place and person; to monitor transmission events within and between healthcare facilities; and to assess key risk factors. Five completion rate categories were derived: very good (80–100% complete), good (50–79% complete), poor (20–49% complete), very poor (<20% complete) and none (0% complete).

Timeliness was based on ERS records and expressed as confirmatory testing turnaround-time (TAT) and calculated separately for regional and national laboratories. Regional laboratory TAT consisted of the median number of days from 'create date' (when Portable Document Format (PDF) file is created on ERS) to 'results date' (when records are made available). Data for organisms referred to Birmingham regional PHE laboratory were used for the period May 2015 to December 2016. National laboratory TAT consisted of the median number of days from 'date sample sent to AMRHAI' (a proxy date used to indicate intention to submit a sample with receipt usually at one to two days or more after this) to 'national laboratory result' (the date results were uploaded onto the ERS). National laboratory TAT was calculated for the period from when an automated process was implemented to deliver AMRHAI results to ERS, July 2016 to April 2017. Only isolates sent directly to AMRHAI were included as isolates sent via local specialist PHE laboratories would take longer and skew results. National laboratory TAT incorporates the time taken to perform additional phenotypic testing to confirm carbapenemase negativity and is therefore not comparable to regional laboratory TAT. To avoid large overestimations of TAT, outliers were excluded from calculations and defined as >31 days for results to become available.

Data analysis

All extracted data were cleaned and analysed using Microsoft Excel 2010 and Stata version 13 [11]. Descriptive statistics were used to explore the main characteristics of the data.

Stakeholder interviews

Stakeholder interviews were designed to explore the potential barriers and facilitators to adopting the system as set out in the study aim. Stakeholders were purposively sampled to include both ERS users (microbiology laboratory users and NHS acute hospital Trust users) and data end users (PHE epidemiologists and data analysts who use ERS data). Semi-structured interviews were conducted by one researcher (D.J.) using a topic guide to explore possible barriers to ERS participation, acceptability and usefulness. Interviews were recorded and analysed using good-practice guidelines for qualitative data analysis [12–14]. Initial coding themes were developed *a priori* based on the evaluation objectives. The final coding framework was developed iteratively incorporating both *a priori* and newly emerging themes from the analysis of recorded interviews.

Ethics approval

The evaluation protocol was reviewed by the PHE Research Ethics and Governance Group and assessed as not requiring ethical approval.

Results

Did laboratories use the system of electronic referral?

Number of registered users

From its launch in May 2015 to April 2017 a total of 761 individuals registered as ERS users. Of these, 71% (N=538) registered as microbiology laboratory users, 26% (N=196) as NHS acute hospital Trust users and 3% (N=27) as regional specialist laboratory users. ERS microbiology users (N=538) represented 95% (124/131) of laboratories in England. The number of laboratories (N=131) varied slightly across the study period due to reconfiguration of services. The number of microbiology users per laboratory ranged from 1 to 21. Trust users represented 51% (79/155) of NHS acute hospital Trusts.

Uptake

Over the first 12 months following the launch of the ERS (May 2015 to April 2016) the number of bacteria recorded on ERS was 1517 nationally, which represented 35% of the total number of Gram-negative bacteria sent to AMRHAI for confirmation of acquired carbapenemase production (N=4313). In the eight months following (May 2016 to December 2016) the number of bacteria increased to 73% (296/404) of the total number of bacteria sent to AMRHAI for confirmation of acquired carbapenemase production (Figure 1).

The steepest rise in the proportion of organisms referred using the ERS occurred between November 2015 and January 2016 (from 25% to 65%). Isolates not linked with ERS records (35%) in 2016 were submitted using paper request forms of which 26% came from laboratories that had registered ERS users.

Coverage

Regional variations in the proportion of organisms referred to AMRHAI using the ERS (coverage) for the period from May 2015 to December 2016 are shown in Figure 2. There was marked regional variation in coverage, ranging from 90% in the West Midlands to the 23% in the South-East of England. Manchester data are not included in these results because it was undertaking its own confirmatory testing and for logistical reasons was unable to upload these results to the system.

Were risk factor data collected?

Completeness of data

Eighty-nine laboratories reported Gram-negative bacterial isolates (N=2711) via ERS during the period January 2016 to

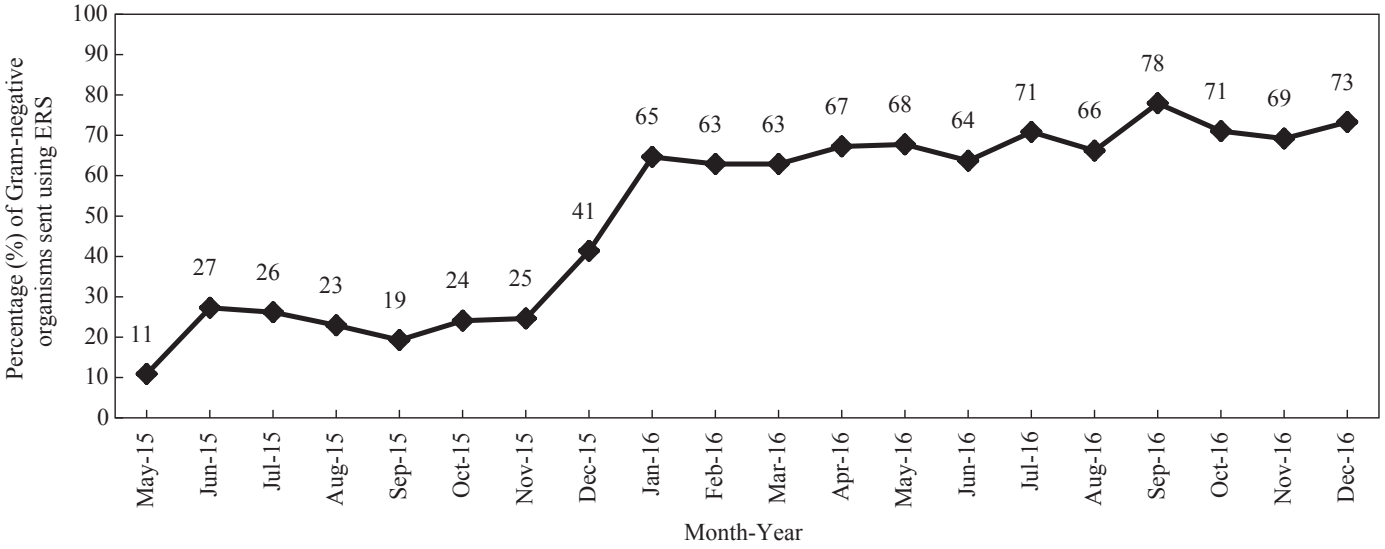

Figure 1. The proportion of all Gram-negative bacteria sent for confirmation of acquired carbapenemase production by month from the launch of the electronic reporting system (ERS) on 5th May 2015 to 31st December 2016. Data from the North West; Greater Manchester (GM) were excluded from the analysis as they were not available for the entire reporting period.

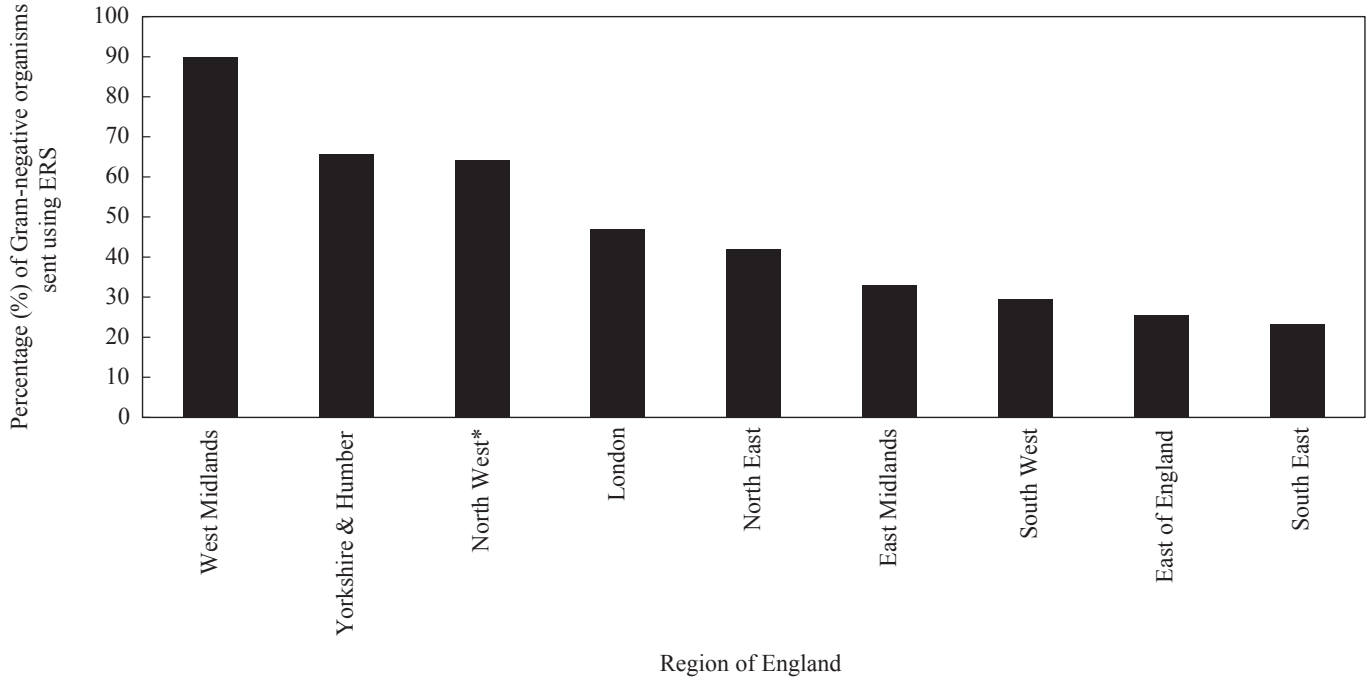

Figure 2. The proportion of Gram-negative bacteria sent to AMRHAI using the ERS by region of England from the launch of the electronic reporting system (ERS) on 5th May 2015 to 31st December 2016. Data from the North West; Greater Manchester (GM) were excluded from the analysis as they were not available for the entire reporting period.

December 2016 (Table I). Completion rates for core data fields were good (50–79% complete) with the exception of those that included an option 'unknown', such as 'overseas travel', or were not mandatory, such as 'hospital number', for which completion rates were poor (<49% completed). For the enhanced data fields, very good completion rates (80–100% completed) were only achieved for a very small proportion of isolates (1.4%), whilst the majority of isolates (78%) were either poor (20–49% completed) or very poor (<20% completed) completion rates.

Timeliness

The regional laboratory median testing TAT for confirmation of carbapenemase-producing Gram-negative bacteria was one

Table I
Completion rates for the enhanced dataset items, 2016

Item completion rate*	Number of laboratories (*N*=89)	Number of isolates reported (*N*=2710)	Proportion of isolates (%)
Very good (80–100%)	6	37	1.4
Good (50–79%)	19	533	19.7
Poor (20–49%)	29	1127	41.6
Very poor (<20%)	27	980	36.2
None (0%)	8	34	1.3

* Fields included: 'overseas travel', 'overseas health care', 'admission date', 'patient screened', 'clinical speciality', 'admission from'.

day (range: 1–18 days) for the period from May 2015 to the end of April 2017 and did not vary across the reporting period (Table II). This calculation excluded three outliers.

The national laboratory (AMRHAI) median TAT for confirmatory testing and full characterization was nine days (range: 2–31 days) during the period July 2016 to April 2017. This calculation excluded four outliers.

Stakeholder views on ERS

Ten semi-structured interviews were conducted including four microbiology laboratory staff and six PHE epidemiologists. Key issues highlighted by the different stakeholders are summarized below.

Barriers to implementation

Lack of designated, ongoing resource for system maintenance, technical support and development was highlighted as a barrier to effective utility of the ERS. The ERS was originally set up as an interim solution and although the service is free to use the resources allocated for maintenance and support were short-term. Users highlighted the need for sustained effort and resourcing across healthcare and public health organizations including administrative and technical support.

Unclear communication about the ERS was experienced by both microbiology and end-users. They wanted clarification about their roles and responsibilities around ERS and use of the system within laboratories and acute NHS hospital Trusts.

Duplication and increased workload for reference laboratory staff resulted from the use of different electronic data resources within their work context. They frequently needed to manually extract data from the ERS website and enter it onto other data systems.

Motivation to continue providing additional data on confirmed carbapenemase producers to the ERS was decreasing partly because of the lack of timely and useful feedback received about the data.

The ERS data entry system was described as 'clunky' and time consuming to use. System failures such as inconsistent automatic requests for enhanced data were noted.

Usefulness

Length of time to receipt of reports with respect to delays and frequency of ERS reports affected the perceived usefulness of the ERS data to inform public health actions.

Incompleteness of enhanced data was a limitation to the usefulness of the data for epidemiological analysis to inform public health action and to determine risk factors and transmission routes. To date, epidemiologists have only been able to identify 'hotspots' of CPGNB using the ERS data.

Discussion

The coverage of the ERS increased over the period of the evaluation and captured local, regional and national confirmatory test results. From its launch in May 2015 to April 2016, 35% of laboratories had used the ERS and this rose to 73% by the end of December 2016. There were a number of laboratories that did not submit isolates using the ERS and this varied considerably by region of England. Regional variations in coverage may partly be explained by differing local protocols, local leadership and championing of the system and availability of PHE reference or regional laboratory services. Additionally, a number of NHS acute hospital Trusts use private laboratory services, which historically have not been encouraged to participate in routine surveillance.

The completeness of risk factor data collected using the ERS has not been adequate to meet the core objective of collecting person-level data on patients infected or colonized by confirmed CPGNB to determine important risk factors and transmission routes. Although there were large numbers of isolates submitted using the ERS, a relatively small proportion of

Table II
Confirmatory testing* turnaround-time for Electronic Reporting System users at regional and national levels

Laboratory	Median number of days	Standard deviation	Range (days)
Regional laboratory (reporting period)			
First 6 months (5th May 2015 to 5th November 2015)	1	2.5	1–18
Last 6 months (1st July 2016 to 31st December 2016)	1	1.7	1–10
Entire period (5th May 2015 to 31st December 2016)	1	2.0	1–18
National AMRHAI laboratory			
Last quarter of the 2016	10	5.9	2–31
First quarter of the 2017	9	5.4	2–28
Entire period (1st July 2016 to 26th April 2017)	9	5.6	2–31

* Only including isolates sent directly to national AMRHAI laboratory.

these had very good completion rates for the enhanced data fields. There was evidence that this may partly be due to system failures to alert Trust users to complete patient risk factor data, which in turn may be linked to a lack of sustainable investment for the ongoing maintenance and administration of the system.

The prevention and control of CPGNB requires rapid detection that poses an ongoing challenge for microbiology laboratories [15—17]. TATs using the ERS were a median of one day for the regional laboratory and nine days for the national laboratory across the reporting period. Timeliness of reporting from the national reference laboratory was expectedly longer due to the additional time required for MIC determination (used as a comparator method to rule out carbapenemase activity) and differences between laboratory date data capture. More recently, NHS laboratories in England, particularly those with higher prevalence of carbapenemase producers, have increasingly been performing local molecular confirmation tests to support the timely control of these bacteria. Commercial polymerase chain reaction (PCR) tests offer testing times of between 30 and 50 min [18] and are a positive development to enhance the provision of timely results. With an increasing number of local laboratories able to identify carbapenemase-producing bacteria, a new approach to surveillance is required to ensure the comprehensive capture of cases. Work is underway to adapt PHE routine national laboratory surveillance system to accept locally confirmed CPGNB. Future work will therefore involve linkage of laboratory and hospital data to allow us to identify patient groups at greater risk and focus control and prevention efforts.

The evaluation highlighted regional variations in uptake by using national microbiological data and enhanced data from the ERS. However the use of different data sources resulted in differing time periods across outcome measures due to data availability. The study would be strengthened by using comparative data periods across all outcome measures although in practice this is often not possible [19]. The median TATs for the regional and national laboratories were not comparable and comparison with non-ERS-user TATs would have helped to contextualize these results.

The ERS relies on the goodwill of laboratory and healthcare staff to complete data entry voluntarily. Microbiology users acknowledged being demotivated due to a lack of visible and useful outputs emanating from the system while epidemiologists highlighted the need to improve coverage and completeness of key fields before comprehensive outputs can be developed. System users wanted timely access to the data they input in order to inform local policies and procedures and to identify local risk factors and transmission routes. Meeting this requirement offers an opportunity to improve the engagement of laboratories and NHS acute hospital Trust staff in data provision and form a perpetuating cycle that meets the needs of both data providers and users.

The ERS system has not adequately met its objectives to support laboratories with electronic confirmation and characterization of acquired carbapenemase production in Gram-negative bacteria, or to collect sufficient additional risk factor information on patients infected or colonized by confirmed CPGNB in order to understand the underlying epidemiology in England. This public health need remains unmet.

Despite its limitations, the ERS is the only surveillance system that seeks to provide intelligence on CPGNB throughout England. Although the current enhanced surveillance system has increased the information available on carbapenemases in England, it is not yet sufficient to deliver the public health benefits sought. A long-term sustainable approach is required that seeks to build the surveillance process into routine workflows and minimize duplication of data collection to facilitate comprehensive and efficient ascertainment. Enhanced data capture may be better incorporated into existing laboratory reporting systems. In addition, alternatives to the ERS such as data linkage or sentinel surveillance to provide risk factor data are options being explored and considered. Consideration is needed for the processes and resource requirements of NHS acute hospital Trusts to facilitate timely and accurate completion of clinical risk factor data to inform epidemiological analysis. To improve timeliness of testing results, resources could be targeted to support NHS laboratories to perform local molecular confirmation tests to inform the control of these bacteria locally.

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Conflict of interest statement

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Author contributions

D.J. and I.O. designed the study and D.J. analysed the data and conducted and analysed the qualitative interviews. C.M.C. assisted in the design and conduct of the qualitative interviews and wrote the manuscript. I.O., D.I., P.C., B.M.-P., R.H., S.H., R.P., R.F., K.L.H., A.P.J. and NW contributed to the conduct of the study. All authors contributed to the manuscript development and agreed the final version.

Appendix A. Core and enhanced data fields captured on electronic reporting system (ERS).

Core data fields	Enhanced data fields*
Purpose of submission	Has the patient travelled overseas in the past 12 months?
Patient demographics	Specify all countries visited in previous 12 months, if applicable
Electronic reporting system ID	Has the patient received any healthcare overseas in the past 12 months?
NHS number	Specify all countries in which healthcare has been received in the previous 12 months
Date of birth	Date admitted
First name	Select healthcare facility patient admitted to
Surname	Hospital/site name
Gender	Clinical specialty at time of specimen collection
Hospital number*	Was the patient on a private ward?
Normal residence	Was the patient admitted for this infection episode
Country of residence	Nature of admission
Residential postcode	Where was patient admitted from?
Specimen details	Specify if admitted from another healthcare facility (NHS or Private)
Laboratory name	Specify whether patient admitted from an overseas country
Type of sample	Was the patient screened for carbapenemase-producing Gram-negative bacteria on admission?
Specimen number	If patient was screened, indicate result
Specimen date	Was the patient in possible contact with carbapenemase-producing Gram-negative bacteria during this admission, before the specimen was taken?
Specimen type	Has the patient been in close contact with another case outside of a healthcare facility?
Bacterial ID	
Were supplemental and/or confirmatory tests performed on this isolate?	
Did supplemental tests performed indicate the presence of a carbapenemase?	
Do you require this isolate to be typed?	
Which laboratory is the isolate being referred to?	
Patient location at time of specimen collection	
Specific healthcare facility if patient was an inpatient, outpatient or in A&E at time of specimen collection	

* Fields are not mandatory.

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