

Protecting and improving the nation's health

Electronic Reporting System

Enhanced surveillance of carbapenemase-producing Gram-negative bacteria

NHS trust and microbiology laboratory user guide

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

Public Health England Wellington House 133-155 Waterloo Road London SE1 8UG

Tel: 020 7654 8000 www.gov.uk/phe Twitter: @PHE_uk

Facebook: www.facebook.com/PublicHealthEngland



You may re-use this information (excluding logos) free of charge in any format or medium, under the terms of the Open Government Licence v3.0. To view this licence, visit OGL or email psi@nationalarchives.gsi.gov.uk. Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned. Any enquiries regarding this publication should be sent to Hcai.Amrdepartment@phe.gov.uk.

Published: July 2016

PHE publications gateway number: 2016141



Contents

Background	4
Referral of isolates to specialist microbiology and the national reference laboratories	6
Reporting locally confirmed carbapenemase-producing Gram-negative bacteria	8
Microbiology laboratory users	9
Registration:	9
Making requests on the ERS	12
Viewing results	15
Reporting locally confirmed carbapenemase producers	17
When to release records to NHS trust users	18
Downloading data extracts	19
NHS trust <u>u</u> sers	21
Registration	21
Entering enhanced surveillance data	22
Downloading data extracts	24
Further information	25
References	26
Appendix 1: data capture tool for enhanced surveillance of carbapenemase-producir	ng
Gram-negative hacteria	27

Background

Antimicrobial resistance is of increasing concern in the UK. In the Chief Medical Officer's 2011 Annual Report it was recommended that surveillance of infections occurring in the healthcare setting should be expanded; specifically, there is a need for the surveillance of carbapenem resistance in Gram-negative bacteria (1). In addition, the 'UK Five Year Antimicrobial Resistance Strategy 2013 to 2018' emphasised the need for surveillance systems that can rapidly identify new threats or changing patterns in resistance (2).

Carbapenem resistance in Gram-negative bacteria results from one or more different cellular mechanisms, including the production of acquired carbapenemases. Acquired carbapenemases are included among the Ambler β -lactamase classes A, B and D. Ambler class A β -lactamases include the *Klebsiella pneumoniae* carbapenemases (KPC), one of the most frequently isolated carbapenemase families (3;4). New Delhi metallo- β -lactamases (NDM) belong to the Ambler class B carbapenemases, as also do the VIM and IMP families of carbapenemases. The final class of carbapenemases, known as the carbapenem-hydrolysing class D β -lactamases (CHDLs), are most frequently found in *Acinetobacter* spp. However, recently there has been increasing instances of OXA-48 and OXA-48-like enzymes detected among the Enterobacteriaceae (5).

In May 2015, Public Health England (PHE) launched a national programme for the enhanced surveillance of carbapenemase-producing Gram-negative bacteria. Enhanced surveillance of carbapenemase-producing Gram-negative bacteria requires use of the web-based Electronic Reporting System (ERS). The ERS serves three main functions: (i) a system for laboratories to request full characterisation of Gram-negative bacteria where expression of an acquired carbapenemase is suspected; (ii) a system to report locally confirmed carbapenemase producers and (iii) a system for NHS trusts to submit enhanced surveillance data. The ERS has been upgraded and includes new functionality – this new version of the user guide describes new processes and functionality available.

The ERS collects information on patient demographics, submitting laboratory (including specimen) details, healthcare setting and risk factors. Some of this information must be provided at the time of isolate referral (core dataset). All other information should be provided within seven days of the isolate being confirmed as a carbapenemase-producer by a PHE specialist microbiology laboratory or the Antimicrobial Resistance and Healthcare Associated Infections (AMRHAI) reference unit (enhanced dataset). The "core" and "enhanced" sections in the ERS are as follows, on the next page:

Core dataset:

- purpose of data submission
- patient demographics
- specimen details
- patient location at time of specimen collection

Enhanced dataset (all patients):

foreign travel

Enhanced dataset (admitted patients):

- admission details
- screening
- potential contact with carbapenemase-producing Gram-negative bacteria

Full details of all data to be captured can be found in 'Electronic Reporting System; Enhanced surveillance of carbapenemase-producing Gram-negative bacteria: data collection manual'. All data submissions should occur via the ERS however, a paper-based data capture tool has been created which may aid the collection of data required (Appendix 1).

This guidance document describes:

- · which isolates should be referred for full characterisation
- which isolates should be reported via the ERS
- how NHS trust users and microbiology laboratory users register for the ERS
- how microbiology laboratory users make a request via the ERS
- how microbiology laboratory users report locally confirmed carbapenemaseproducing Gram-negative bacteria via the ERS
- how microbiology laboratory users access and manage test results
- how microbiology laboratory users release records to NHS trust users
- how and when enhanced surveillance data should be provided
- downloading data extracts from the ERS

Referral of isolates to specialist microbiology and national reference laboratories

Laboratory methods for the detection of bacteria-producing carbapenemases can be found in the 'UK Standards for Microbiology Investigations: Laboratory Detection and Reporting of Bacteria with Carbapenem-Hydrolysing β-lactamases (Carbapenemases)' (6).¹ Laboratories should refer isolates to the AMRHAI reference unit when resistance due to the presence of an acquired carbapenemase is suspected. The AMRHAI unit therefore wishes to receive:

- all Enterobacteriaceae suspected to produce a carbapenemase.
- all Pseudomonas sp. suspected to produce a carbapenemase ie isolates
 resistant to carbapenems, ceftazidime and piperacillin-tazobactam that also
 show strong imipenem-EDTA synergy (irrespective of susceptibility or
 resistance to aztreonam); there is no need to send isolates resistant only to
 carbapenems and susceptible to other β-lactams
- all *Acinetobacter* sp. suspected to produce a metallo-carbapenemase, ie with strong imipenem-EDTA synergy
- representatives of any carbapenem-resistant Gram-negative strains that are associated with clusters or outbreaks of infection or colonisation

Organisms exhibiting carbapenem resistance due to the expression of intrinsic resistance mechanisms do not need to be sent to AMRHAI, unless associated with clusters or outbreaks of infection or colonisation.

All organisations referring isolates will be required to make requests for confirmatory testing via the ERS and submit enhanced surveillance data. Core surveillance data should be provided via the ERS for all isolates referred to AMRHAI; the core dataset must be completed before sending the isolate.

AMRHAI wishes to receive isolates from the same patient if the same organism has been isolated from *different* clinical sites. A new referral request should be generated via the ERS in these instances. Submission of subsequent isolates of the same organism from the same patient isolated from the same site is only necessary in the instance of therapeutic failure, or if the sending laboratory suspects a change in the organism's antibiogram. In these instances, enhanced surveillance data will not be requested.

¹ Laboratories should submit isolates as detailed in the most recent version of the document

It is recognised that some PHE specialist microbiology laboratories offer confirmatory testing and molecular tests for suspected carbapenemase producers. Therefore, some local microbiology laboratories may wish to refer isolates to a specialist microbiology laboratory in the first instance. Again, laboratories should make requests via the ERS, and the core dataset should be provided at the time of isolate referral. Following testing at a specialist microbiology laboratory, isolates may be referred on to AMRHAI if further testing is required. The process for referring isolates to PHE specialist microbiology laboratories and/or AMRHAI is presented in Figure 1.

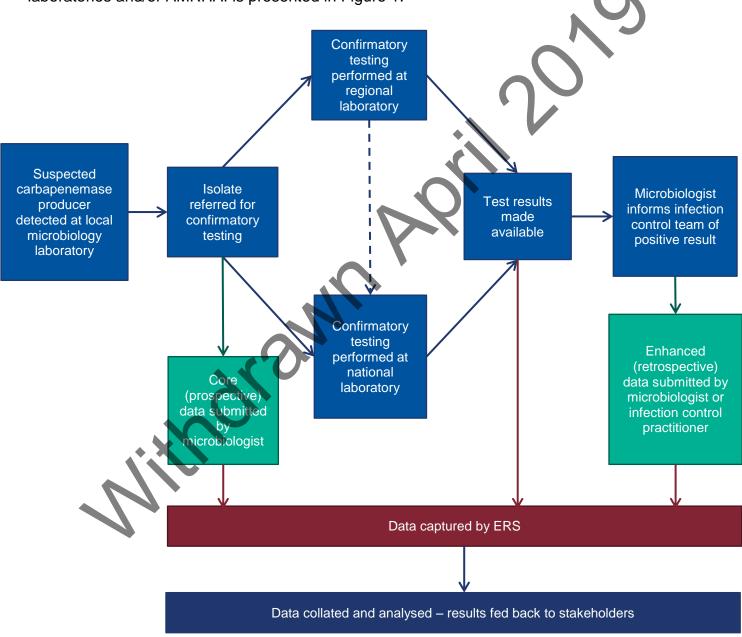


Figure 1: Summary of process for referral of isolates to PHE specialist microbiology laboratories and/or AMRHAI

Reporting locally confirmed carbapenemase-producing Gram-negative bacteria

PHE is aware that a number of local microbiology laboratories have introduced molecular methods to detect carbapenemase-producing Gram-negative bacteria. To ensure that a complete epidemiological picture is achieved, we request that microbiology users to report locally confirmed isolates via the ERS and ask that enhanced surveillance data is provided for these isolates, too.

To maintain consistency with laboratories referring isolates for testing at either PHE specialist microbiology laboratories and/or AMRHAI, we request that the following isolates be reported:

- first identification of a carbapenemase producer from any body site (clinical or screening)
- subsequent identification of an organism from the same body site if different from that previously reported
- subsequent identification of a resistance mechanism from the same body site if different from that previously reported

There is no need to report the same organism/mechanism combination if identified several times from the same body site, unless any of the following is true:

- the antibiogram has changed
- there is suspected treatment failure
- this is a new/recurrent infection/colonisation on for a separate hospital admission

Microbiology laboratory users

This user group refers to those that work in local microbiology laboratories and are responsible for requesting full characterisation of Gram-negative bacteria where production of a carbapenemase is suspected, or reporting locally confirmed carbapenemase producers.

NOTE: users are now able to register and access the system as a microbiology laboratory user and an NHS trust user

Registration

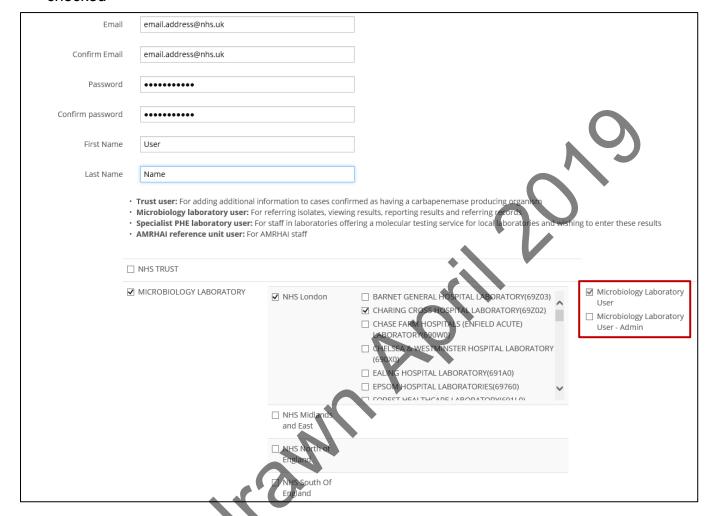
To register:

- go to the ERS website (https://cro.phe.nhs.uk/) and click on the "Register" menu item
- enter your email address (must be an NHS or PHE email account), password and name



select "MICROBIOLOGY LABORATORY"

- select your Region and Lab from the dropdown menus
- the "Microbiology Laboratory User" box on the right-hand side of the screen will be checked



- NOTE: there is a tickbox to indicate if you should be assigned as a local administrator ("Microbiology Laboratory User – Admin"); you should only tick this box if you are going to act as the local system administrator for the selected laboratory (further instructions for local administrators are detailed below)
- after you have completed all the registration fields, click on "Register"; you will
 receive an email to the email account that you registered with, please confirm that
 you have registered with the correct email address by clicking on the link in the email
- an account request will be sent to your local administrator to review your request and activate your account. You will receive an email to the account you registered with when your account has been activated
- **NOTE:** if you work for several different NHS organisations, you will be able to register multiple for organisations as a microbiology laboratory user. To do this, select the relevant laboratories from the list when you register

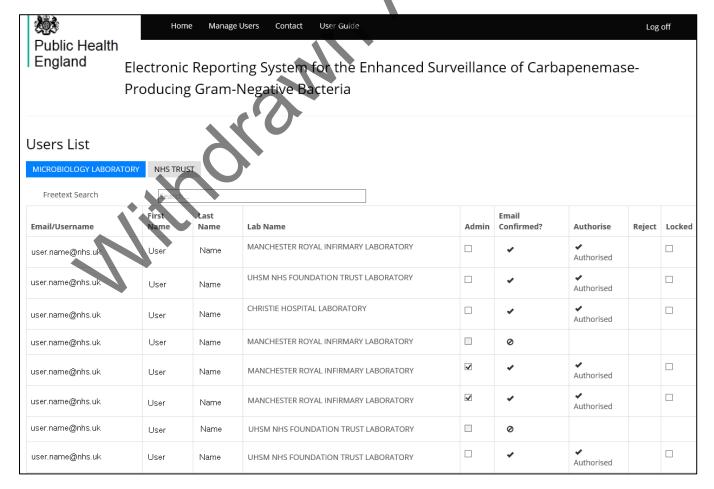
Local administrators

Microbiology Laboratory Users with local administrator rights will have the ability to authorise Microbiology Laboratory Users assigned to the laboratory that they act as the administrator for. They are also able to authorise accounts for NHS Trust Users associated with the laboratory.

NOTE: local administrators are responsible for granting access to person identifiable information stored on the system. Local administrators need to ensure that staff given access to the ERS are aware and compliant with Caldicott principles. Local administrators will need to actively manage the accounts for their organisations by removing/locking accounts when staff leave the organisation or change to a role where ERS access is no longer required

Local administrators should only authorise accounts when they are certain that the request that has been made is genuine and appropriate.

Local administrators are able to manage account requests under the "Manage Users" menu on their home page.



On the "Manage Users" page, administrators have the ability to authorise requests by clicking on "Authorise User" and then unchecking the box under the "Locked" column. Administrators are also able to reject the user's request by clicking on "Reject User". (Accounts can be locked by the administrator after the account has been authorised.)

Please note, you will only be able to authorise an account after the requester has confirmed their email address.

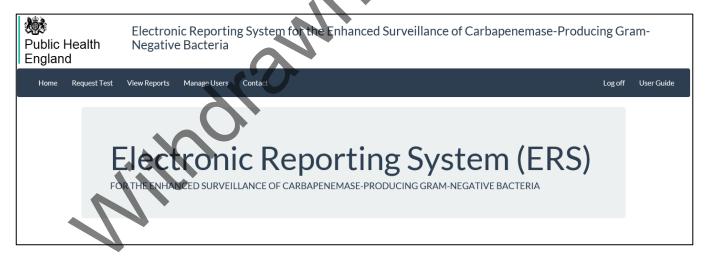
Local administrators are also able to assign administrator rights to other users when this is deemed to be necessary.

Making requests on the ERS

After your account has been authorised you can make requests for full characterisation of Gram-negative bacteria where expression of an acquired carbapenemase is suspected.

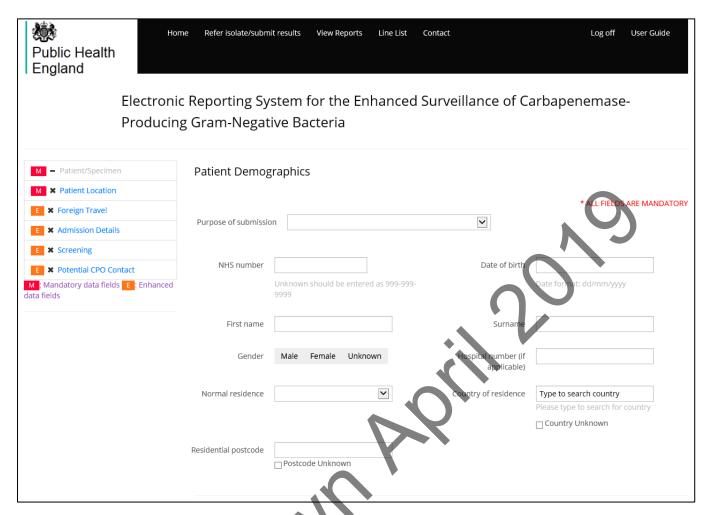
To do this:

- go to the ERS website (https://cro.phe.nhs.uk/) and click on the "Login" menu item
- enter your registered email account and password and click on the "Login" button
- select "Refer isolate/submit results" from the menu bar



Data entry is divided into a number of pages, listed down the left hand side of the screen (see below).

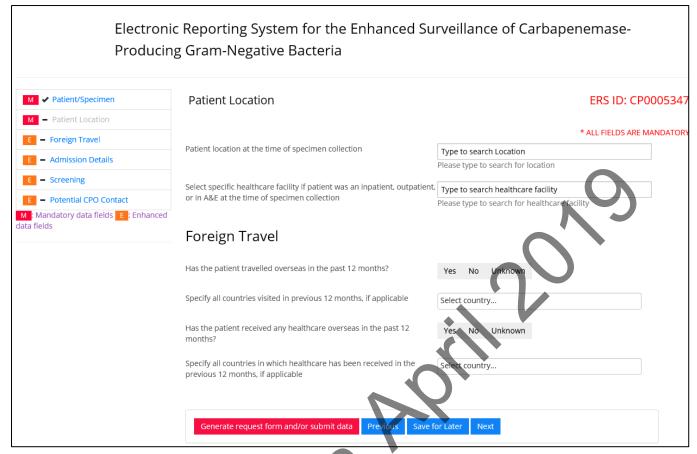
It is possible to navigate using the list on the left-hand side of the screen. However, if you navigate away from a page in this way data entered will not be saved.



To make an electronic request for referral, please provide patient demographic information, specimen details and the patient's location at time of specimen collection. All mandatory fields on the first two pages must be completed before a request can be made.

If possible, please provide any travel information available at time of isolate referral. This information will be printed on the PDF request form (if provided) and can help inform testing.

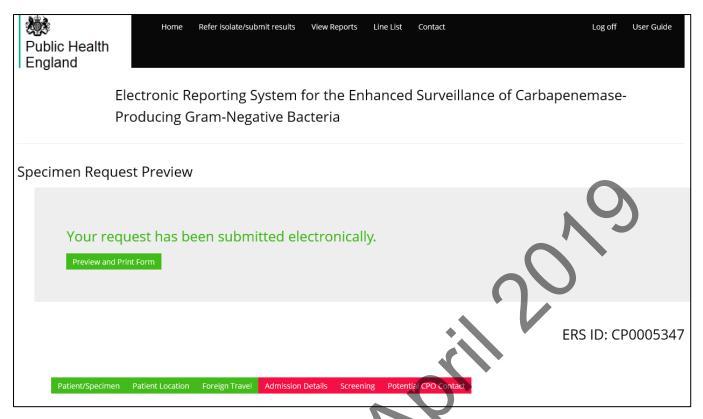
NOTE: clicking "Save for Later" will save what you have entered so far. All data fields on a page must have a response before the data is saved (you can make use of the "Unknown" options and complete these questions when the data becomes available. Information "saved for later", in this way, can be retrieved when needed by going to the "Incomplete records" tab on the "View Reports" page.



After all required information has been entered, click on "Generate request form and/or submit data".

Review the information provided on the "Specimen Request Preview" page. If you are happy with the information displayed on-screen, click on the "Generate request form and/or submit data" button at the bottom of the page. This will submit the request via the system.

NOTE: no further changes can be made to the information entered on the first two screens after the form has been generated



After the request has been submitted you will need to print the form by clicking on "Preview and Print Form" and send this with the isolate to the laboratory you selected under "Which laboratory is the isolate being referred to?"

Please note, the option to select a PHE specialist microbiology laboratory will only be made available if that laboratory is performing regional confirmatory duties. If your PHE specialist microbiology laboratory is not performing confirmatory duties, isolates should be referred directly to the AMRHAI reference unit, PHE Colindale.

After the request process has been completed, the record will be located on the "View Reports" page, under "Specimens submitted". Records will progress from "Specimens submitted" to "Specimens pending results" after they have been checked-in by the receiving laboratory.

You can access any of the records on the system by clicking on the ERS ID.

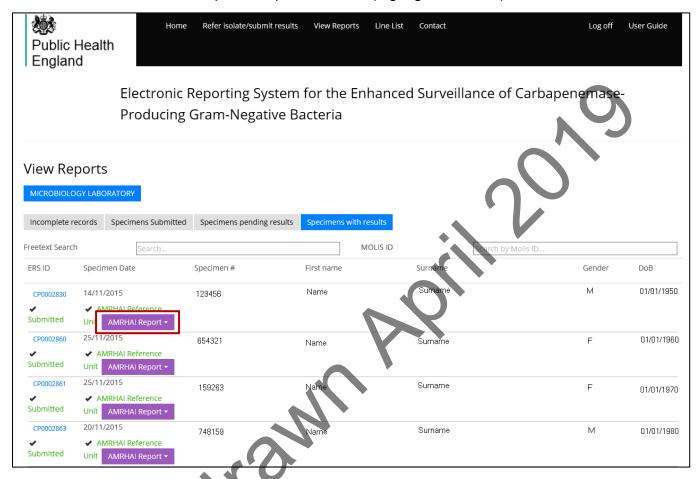
For information, laboratory request forms associated with the isolate are viewable within the record, on the left-hand side of the screen.

Viewing results

Results are made available on the ERS after they have been validated and released by the laboratory performing confirmatory testing. You will receive an email when results become available; you will need to log on to the ERS to view the results.

To view results:

- click on the "View Reports" menu
- click on the "AMRHAI Report" dropdown menu (highlighted below)



Where the result has been made available by a PHE specialist microbiology laboratory, but the isolate has been sent on to AMRHAI for further testing, the AMRHAI result will show as pending.

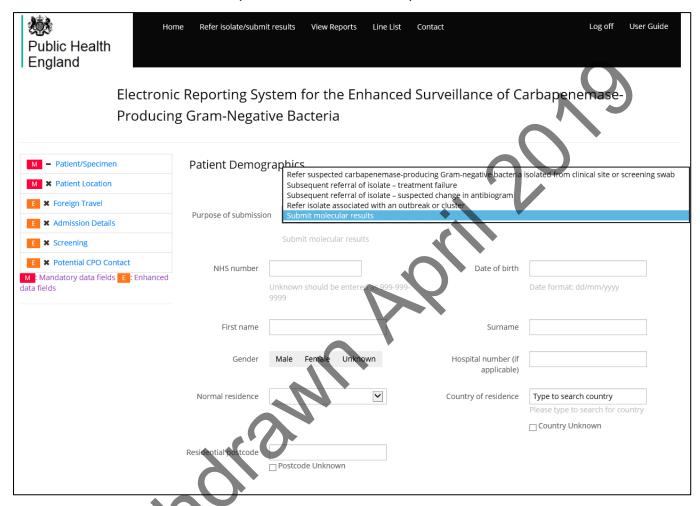
Results from AMRHAI may become available in stages and are contained in the "AMRHAI Report" dropdown menu (see above). Each time a new set of results becomes available an updated version of the PDF will appear on the system (you will also be notified of the update by email). Previous versions of the report will be listed in a dropdown menu for that record on the "Specimens with results" tab.

For information, laboratory results associated with the isolate are also viewable within the record, on the left-hand side of the screen.

You can search for records using the "Freetext Search" feature. You can search based on ERS ID, specimen date, specimen number, first name, surname and date of birth.

Reporting locally confirmed carbapenemase producers

To report a locally confirmed carbapenemase producer, select "Refer isolate/submit results" from the menu bar. On the Patient Demographics screen, select "Submit molecular results" from the "Purpose of submission" dropdown menu.



Enter patient demographic data and specimen details.

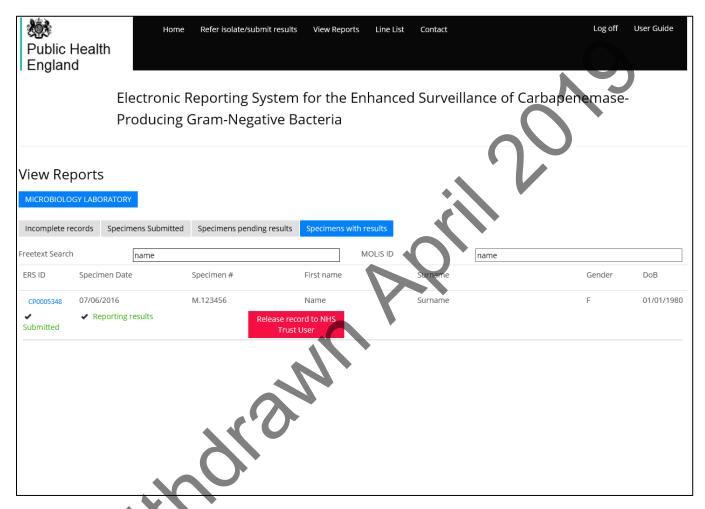
When you get to the question "Which laboratory is the isolate being referred to?" select "Reporting results" from the dropdown menu.

After all required information has been entered on the Patient/Specimen and Patient Location screens, including molecular results, click on "Generate request form and/or submit data".

Review the information you have provided; if you are happy with the information displayed on-screen, click on the "Generate request form and/or submit data" button at the bottom of the page. This will submit the request via the system.

NOTE: no further changes can be made to the information entered on the first two screens after the data has been submitted

Go to the "Review Reports" tab; as the results have already been entered, the record will appear under the "Specimens with results" tab. From here, the record can be released to the appropriate NHS trust user for provision of enhanced surveillance data.



When to release records to NHS Trust Users

If the patient was in an acute NHS trust at the time of specimen collection, the result may be released to the respective NHS trust users for completion of enhanced surveillance data.

Records should be released to NHS trust users when you receive molecular test results indicating that a carbapenemase was detected (from either a PHE specialist microbiology laboratory or AMRHAI) or if you have identified carbapenemase production locally using molecular confirmatory methods.

You do not need to release records for isolates where carbapenemases were not detected. Also, you do not need to release records if the isolate was a "Subsequent referral of isolate" for any reason, as enhanced surveillance data is not required in this instance.

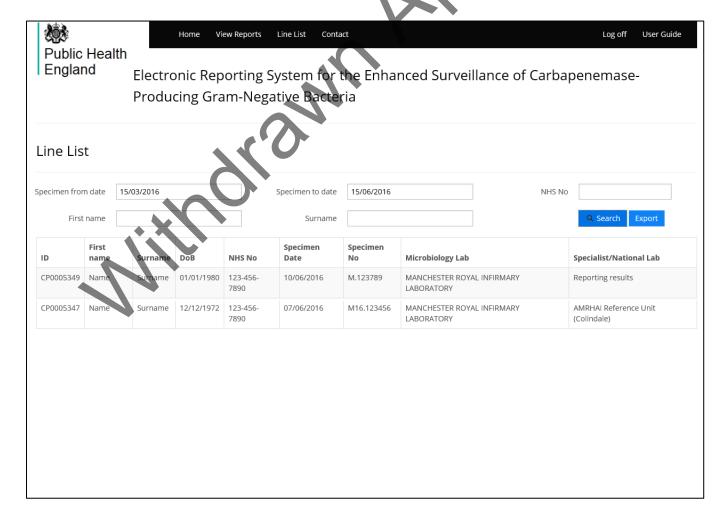
To release a record, click on "Release record to NHS Trust User". This will send an email to the corresponding NHS Trust Users notifying them that the record has been released, and will display the record in their system.

After clicking on "Release record to NHS Trust User" the text box colour will change to green to indicate that the record has been released.

NOTE: microbiology laboratory users can also provide enhanced surveillance data

Downloading data extracts

To access a line list of reports, click on "Line List" at the top of the screen. You will then be able to specify the time frame for your extract. You can also search for patients using name and NHS number on this page.



After clicking on "Export" you will be able to open an Excel spreadsheet containing all the data fields and your responses for isolates that have been referred or reported via the ERS for your laboratory.



NHS trust users

The completion of the core dataset by the laboratory requesting confirmatory testing or reporting of a locally confirmed carbapenemase-producing organism will create a record in the ERS. The laboratory is therefore responsible for providing the core dataset at time of isolate referral/reporting. The laboratory should be supported by other NHS trust colleagues, such as members of the Infection Prevention and Control Team (IPCT), in the provision of enhanced surveillance data.

NOTE: users are now able to register and access the system as a microbiology laboratory user and an NHS trust user.

Registration

To register:

- go to the ERS website (www.cro.phe.nhs.uk/) and click on the "Register" menu item
- enter your email address (must be an NHS or PHE email account), password and name



- check the "NHS TRUST" box
- select your Region and Trust using the appropriate tick boxes

- select your Primary Microbiology Lab after you have selected your trust from the list; this is the laboratory that performs the majority of the trust's microbiology testing and will determine which local system administrator receives your request for an account
- after you have completed all the registration fields, click on "Register"; you will
 receive an email to the email account that you registered with, please confirm that
 you have registered with the correct email address by clicking on the link in the email
- an account request will be sent to your local administrator to review your request and activate your account – you will receive an email to the account you registered with when your account has been activated
- NOTE: if you work for several different NHS organisations, you will be able to register for multiple organisations as a NHS trust user. To do this, select the relevant Trusts from the list when you register

Entering enhanced surveillance data

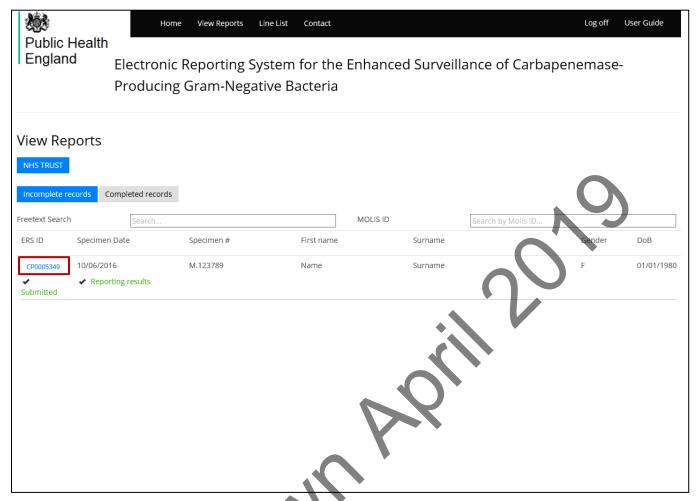
After your account has been authorised you can log on to the system and enter enhanced surveillance data for patients found to be infected or colonised with carbapenemase-producing Gram-negative bacteria.

To do this:

- go to the ERS website and click on the "Login" menu item
- enter your registered email account and password and click on the "Login" button

Records requiring enhanced surveillance data will be in "View Reports", under the "Incomplete records" tab.

These records will appear on your system after they have been released by the microbiology laboratory user. We request that you enter the enhanced surveillance data within seven days (you will receive an email when the record has been released by the microbiology laboratory user asking you to log on to the ERS).



To enter enhanced surveillance data for a record, click on the ERS ID for that record (highlighted above).

It is not possible to make amendments to information provided by the microbiology laboratory user on the first two pages. However, Foreign Travel details can be updated if these have become available since isolate submission or reporting.

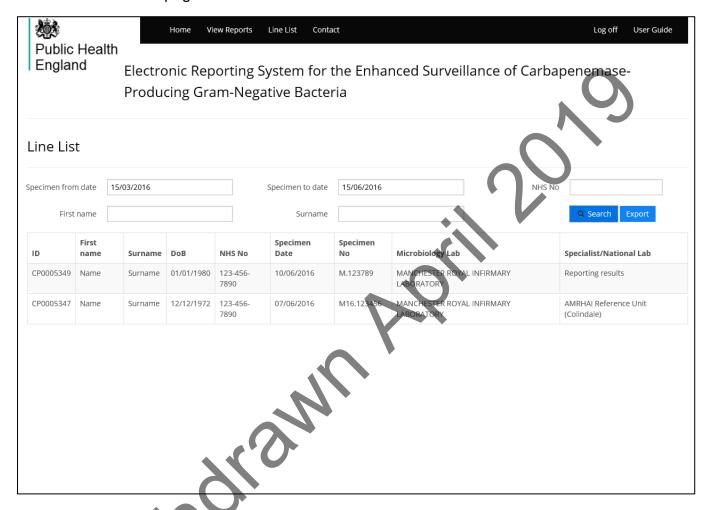
Information can be entered into any of the enhanced surveillance pages. Please complete Foreign Travel for all patients. Please complete Admission Details, Screening and Potential Contact with Carbapenemase-Producing Bacteria for patients that were admitted at the time of specimen collection.

When you have provided all available information, click "Complete" on the final page. Clicking on this button indicates that you have provided all the information available to you and the record is complete; this will progress the record to the "Complete records" tab.

You can search for records using the "Freetext Search" feature. You can search based on ERS ID, specimen date, specimen number, first name, surname and date of birth.

Downloading data extracts

To access a line list of reports, click on "Line List" at the top of the screen. You will then be able to specify the time frame for your extract. You can also search for patients using name and NHS number on this page.



After clicking on "Export" you will be able to open an Excel spreadsheet containing all the data fields and your responses for isolates that have been referred or reported via the ERS for your Trust.

Further information

For system support and further information, contact details can be found under the "Contact" menu item.



For enquiries relating to sending specimens to either your PHE specialist microbiology laboratories or AMRHAI, please refer to the relevant contact details on the ERS website (indicated above).

For enquiries relating to system support, please contact: ers@phe.gov.uk

References

- (1) Department of Health: annual Report of the Chief Medical Officer (Volume Two) Infections and the rise of antimicrobial resistance. London, UK: 2013
- (2) Department of Health: UK Five Year Antimicrobial Resistance Strategy 2013 to 2018. London, UK; 2013
- (3) Nordmann P, Cuzon G, Naas T. The real threat of Klebsiella pneumoniae carbapenemase-producing bacteria. *Lancet Infect Dis* 2009; **9**: 228-36
- (4) Woodford N, Turton JF, Livermore DM. Multiresistant Gram-negative bacteria: the role of high-risk clones in the dissemination of antibiotic resistance. FEMS Microbiol Rev 2011; 35: 736-55
- (5) Mathers AJ, Hazen KC, Carroll J, Yeh AJ, Cox HL, Bonomo RA, *et al.* First clinical cases of OXA-48-producing carbapenem-resistant Klebsiella pneumoniae in the United States: the "menace" arrives in the new world. *J Clin Microbiol* 2013; **51**, 680-3
- (6) Public Health England: UK Standards for Microbiology Investigations, laboratory detection and reporting of bacteria with carbapenem-hydrolysing β-lactamases (Carbapenemases). London, UK; 2014

Appendix 1: Data capture tool for enhanced surveillance of carbapenemase-producing Gram-negative bacteria

Core dataset: To be completed for all suspected carbapenemase-producing Gram-negative bacteria referred to a PHE specialist microbiology laboratory or AMRHAI for further testing.

Enhanced dataset: To be completed for all isolates confirmed as carbapenemase-producers by a PHE specialist microbiology laboratory or AMRHAI (information to be provided within 7 days of positive result).

Patient demographics (core dataset)		
NHS number:	Date of birth://	
First name:	Surname:	
Gender: Male □Female □Unknown □	Normal residence:	
Hospital number:(if applicable)	Country of residence:	
Specimen details (core dataset)		
Laboratory name:	Type of sample: Screening □Clinical □Unknown □	
Specimen number:	Specimen date:/	
Specimen type:	Organism:	
Were supplemental and/or confirmatory tests performed on this isolate?		
Yes □ No □ Unknown □		
If yes, please state the type of test(s) performed?		
Did supplemental/confirmatory tests performed indicate the presence of a carbapenemase?		
Yes □ No □ Unknown □ N/A □		
Patient location (at time of specimen) (core dataset)		
Patient location (healthcare facility) at time of specimen collection:		
Specify if "Other":		
Specify NHS trust (Acute, Community or Mental Health) if hospital inpatient, outpatient or in A&E at time of specimen collection:		

Foreign travel (enhanced dataset – all patients)		
Has the patient travelled overseas in the last 12 months?		
Yes □ No □ Unknown □		
If yes, please list all countries visited in last 12 months:		
Has the patient received any healthcare overseas in the last 12 months?		
Yes □ No □ Unknown □		
If yes, please list countries where healthcare received:		
in yes, prease her sealthines mene headinesis reserved.		
	-0	
IF HOSPITAL INPATIENT (NHS or PRIVATE)	PLEASE COMPLETE FOLLOWING SECTIONS	
Admission details (enhanced dataset – admitted patients)		
Data de la	Was the patient admitted for this infection episode?	
Date admitted:/	Yes □ No □ Unknown □	
NHS trust admitted to:	Nature of admission:	
Hospital name:		
Prospital Hame.	Where was the patient admitted from?	
Clinical specialty at time of specimen collection:		
	If another healthcare facility, please specify:	
Was the patient on a private ward?		
Yes □ No □ Unknown □	If admitted from an overseas country, please specify:	
Screening (enhanced dataset – admitted patients)		
	ram-negative bacteria (includes carbanenemase-producing	
Was the patient screened for carbapenemase-producing Gram-negative bacteria (includes carbapenemase-producing Enterobacteriaceae) on admission?: Yes □ No □ Unknown □		
If yes, was the result: Positive □ Negative □ This is the screening specimen □ Unknown □		
Potential contact with carbapenemase-producing bacteria (enhanced dataset – admitted patients)		
Was the patient in possible contact with carbapenemase-producing Gram-negative bacteria during this admission, before the specimen was taken?		
☐ Yes, patient was on the same ward at the same time	☐ Possibly, other patient(s) known to be infected or	
as other patient(s) who were known at the time to be infected or colonised	colonised in hospital at same time	
☐ Yes, patient was on the same ward at the same time	☐ No, patient not known to have contact with other patient(s) infected or colonised	
as other patient(s) who were later found to be infected or	□ Unknown	
colonised		
Has the patient been in close contact with another case outside of a healthcare facility? Yes □ No □ Unknown □		