



PHE Gateway Number: 2018513



Welcome to the latest issue of what has previously been *AMRHAI News*. In April we launched our restructured National Infection Service (NIS), which includes infection-related and cross-cutting divisions each led by a Deputy Director under the leadership of Derrick Crook as Director, NIS. We have reconfigured our HCAI and AMR service with Susan Hopkins as its Deputy Director, and I have become Deputy Director of NIS Laboratories ('NIS Labs'). Susan and I work closely, and NIS Labs will deliver HCAI and AMR reference services that reflect the changing needs of our organisation and its customers. As Lord Jim O'Neill highlighted in his **2016 report**, tackling AMR needs a multidisciplinary approach, and the breadth of expertise in our new HCAI and AMR service provides this for NIS and PHE. The scope of this newsletter has therefore been broadened to reflect the interests of our entire HCAI and AMR service. We hope you will (continue to) enjoy it.

Neil Woodford

Deputy Director NIS Laboratories

Introduction from Susan Hopkins, Deputy Director of National Infection Service for HCAI & AMR Division.



The Division of HCAI & AMR is one of four topic-specific divisions and is developing an integrated, scientifically-led structure. We are bringing together expertise including infectious diseases epidemiologists, infection specialists, antimicrobial pharmacists, microbiologists, infection prevention and control specialists, statistical and mathematical modellers, and other allied disciplines including health psychologists.

Our mission is to protect people from healthcare-associated and antimicrobial resistant infections, through world-leading public health microbiology, outbreak response, surveillance, research and interventions. Our three core functions are:

- surveillance - delivering national programmes that collect epidemiological data, focusing on antimicrobial use and resistance, streptococcal and healthcare-associated infections;
- microbiology - providing clinical microbiological advice and diagnosis, complex reference services, methodology development, microbial epidemiology and investigation and management of national and uncommon outbreaks
- interventions - undertaking research and producing interventions to improve prevention, control and management of infections and promote effective use of microbiology laboratory services

We work closely with staff from the NIS Field Services and NIS laboratories to assist in local outbreaks and take a lead on national outbreaks and incidents. We can be contacted at this email address: [**Hcai.Amrdepartment@phe.gov.uk**](mailto:Hcai.Amrdepartment@phe.gov.uk).

Susan Hopkins

Deputy Director HCAI & AMR

Update on *Candida auris* within the UK

To date, 2018 has been a relatively quiet year for *Candida auris* within the United Kingdom, if not internationally, where ever more countries report case detections for the first time, with ongoing outbreaks in several continents. A review of the UK incident response to date has been undertaken, identifying both specific and structural areas for how better to respond to a novel, emerging pathogen. Sporadic cases continue to be introduced into English hospitals, with many having seen one-off isolates in 2018. These have been recognised early, and through case isolation, enhanced infection prevention and control measures, and wider screening have been self-contained. Only one hospital that has previously seen a large-scale outbreak has had a smaller recrudescence of new transmissions, this time with another lineage of *C. auris*, which demonstrates a new introduction into the hospital. Whole genome sequencing has shown that within lineages it is difficult to distinguish newly introduced cases from transmission events, though further work is ongoing to better characterise this within the UK.

Colleagues at Porton Down continue to add to the international literature through ongoing testing of different disinfectants and cleansing agents, to determine which have greatest efficacy against *C. auris*. The Mycology Reference Laboratory remains committed to collaborating with local hospitals, industry, and international bodies to further diagnostic testing and novel antifungal testing. Various members of the incident management group have participated in national and international events to help define an ongoing action plan to address the many unanswered questions about transmission dynamics, outbreak prevention, individual case management, and drug resistance.

PHE staff from the HCAI/AMR division and NIS laboratories in Colindale, Biosafety Unit at Porton and Mycology Reference Laboratory in Bristol, successfully collaborated with clinicians at Oxford University Hospitals NHS Foundation Trust and researchers at the University of Oxford to identify environmental reservoirs of *Candida auris* in a tertiary neurosurgical unit outbreak. Despite enhanced infection prevention and control measures, this outbreak proved very difficult to control until a potential point source of contaminated ancillary temperature probes was identified and removed. A mixture of fungal sequencing, case control data, and environmental control are presented in an article published this month in the New England Journal of Medicine

https://www.nejm.org/doi/full/10.1056/NEJMoa1714373?query=featured_home.

Colin Brown

AMRSTI Section participate in G-ToG randomised control trial

The Antimicrobial Resistance in Sexually Transmitted Infections (AMRSTI) Section were responsible for the microbiological component of the recent randomised controlled trial 'Gentamicin compared with ceftriaxone for the treatment of gonorrhoea (G-ToG)' (ISRCTN51783227). The trial was led by Prof. Jonathan Ross at Birmingham University Hospital and compared gentamicin 240 mg plus azithromycin 1 g with the current first-line treatment for gonorrhoea (ceftriaxone 500 mg and azithromycin 1 g). The primary endpoint was clearance of *Neisseria gonorrhoeae* using a molecular test two weeks post treatment. The study revealed that gentamicin, in combination with azithromycin, had a lower cure rate (91%) than the current first-line treatment of gonorrhoea (98%). For those administered gentamicin, clearance was better for those with a genital infection (94%), compared with the clearance rates with gentamicin for pharyngeal (80%) and rectal (90%) gonorrhoea. Unfortunately the trial data showed that gentamicin is not an appropriate alternative first-line treatment for gonorrhoea. However, gentamicin could be considered as an alternative for genital infection particularly in patients with beta-lactam allergies or for those who harbour a genital ceftriaxone-resistant isolate. The full results have been submitted for publication and further analysis of MICs and treatment outcomes is on-going.

This project was funded by the National Institute for Health Research Health Technology Assessment Programme (project number 12/127/10). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Health Technology Assessment Programme, NIHR, NHS or the Department of Health.

Michelle Cole

How to cap an escalating MIC service (part two)?

Back in [issue 6](#) of this newsletter the AMRHAI Reference Unit announced that we would no longer determine MICs for confirmed CPE from rectal/faecal screens (i.e. gut colonisation) if requested. However, you may have continued to receive MIC reports from us for rectal/faecal isolates because interpretation of the antibiogram to infer the underlying resistance mechanism was used to help infer the absence of carbapenemase activity in all PCR-negative isolates.

Since January 2018 we have been using a CE-marked real-time PCR to seek genes for class A (KPC, IMI/NMC-A, GES, FRI and SME), class B (GIM, IMP, NDM, SIM, SPM and VIM) and class D (OXA-48-like) carbapenemases in all isolates referred for investigation of carbapenem resistance. Although no method is 100% sensitive or specific for detecting carbapenemase activity, this assay detects all carbapenemase families identified amongst >14,000 CPE submitted to AMRHAI from UK laboratories since 2000. We are therefore stopping all MIC determination on isolates from sites indicating gut colonisation and will monitor for the emergence of novel carbapenemases not covered by our PCR assay by more detailed investigation of PCR-negative isolates from other specimen types.

Katie Hopkins

Carbapenem-resistant and carbapenemase-producing Enterobacteriaceae

Carbapenem-resistant Gram-negative bacteria, particularly carbapenemase-producing Enterobacteriaceae (CPE), are a matter of national and international concern. Infections caused by these bacteria are associated with an increase in morbidity, attributable mortality, and healthcare costs. Treatment options are limited and resistance can emerge even to new antibiotics.

The AMRHAI Reference Unit provides national reference facilities for confirmation and further characterisation of Gram-negatives suspected of producing a carbapenemase. Enhanced surveillance data for confirmed CPE is provided by hospital Trusts via the [Electronic Reporting System \(ERS\)](#), and PHE monitors and publishes the trends in CPE infections in the annual [ESPAUR Report](#). PHE has also produced CPE toolkits to provide practical advice for [acute trusts](#) and [non-acute and community settings](#) with the aim of helping prevent or reduce the spread of CPE within these sectors. While the overall burden of infections caused by CPE currently forms a small proportion of overall infections, the difficulty in detecting and treating CPE, added to their potential for spread, make CPE a significant concern.

PHE is currently developing an updated action plan in relation to clinical and laboratory testing surveillance and feedback; and infection prevention and control and antimicrobial stewardship interventions.

In April 2018 the AMRHAI Reference Unit introduced charging for detection of the 'big 4' carbapenemase families (KPC, OXA-48-like, NDM and VIM) for NHS laboratories. Later this year, we will produce a report evaluating the current assays available for the molecular detection of the 'big 4' carbapenemases in UK. We hope this will help diagnostic laboratories to make an informed decision about the cost-effective assays available to implement based on their local circumstances.

Karen Shaw and Rifat Soyfoo

New custom-made LENTICULE discs containing the 'big five' carbapenemase families

In collaboration with the AMRHAI Reference Unit, the National Collection of Type Cultures (NCTC) has developed a custom-made LENTICULE disc product that can be used as a 'five-in-one' positive control for multiplex real-time and conventional PCR assays targeting the 'big five' carbapenemase families, which are most commonly seen in the UK: KPC, OXA-48-like, NDM, VIM and IMP.

Each LENTICULE disc contains:

- NCTC 13438 *Klebsiella pneumoniae* KPC-3
- NCTC 13442 *Klebsiella pneumoniae* OXA-48
- NCTC 13443 *Klebsiella pneumoniae* NDM-1
- NCTC 13437 *Pseudomonas aeruginosa* VIM-10
- NCTC 13476 *Escherichia coli* IMP-type (unsequenced)

Each carbapenemase gene family is easily identifiable from the melt curve and results have been shown to be standardised and consistently reproducible in internal laboratory testing at AMRHAI.

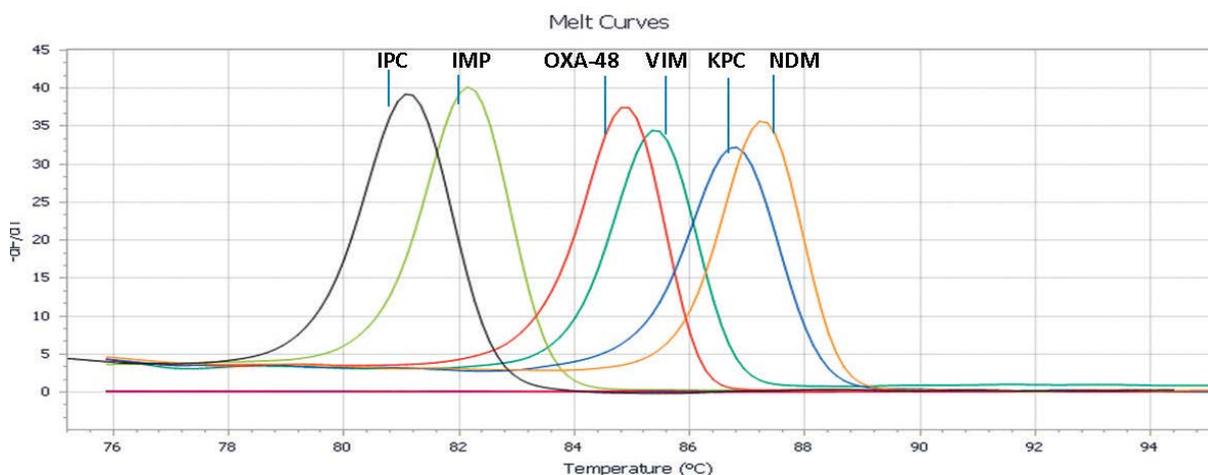


Figure 1: Melt curves showing easy differentiation between each carbapenemase gene

Control failure has a big impact on efficient laboratory working and use of LENTICULE discs can help to reduce the risk of assay failure and the need to re-test batches of samples.

Viability: format reduces damage due to freezing

Stability: no need to passage, therefore characteristics are not lost

Sterility: single use, reduces risk of contamination

Use of LENTICULE discs could also help laboratories that are screening bacterial cultures to meet ISO15189 section 5.6.2.2, which states: "The laboratory shall use quality control materials that react to the examining system in a manner as close as possible to patient samples."

To register your interest in this new product, please go to:

www.phculturecollections.org.uk/AMRcontrols.

Ayuen Lual

Reporting of antimicrobial susceptibility testing results on groups of organisms or agents for which there are no EUCAST breakpoints

The AMRHAI Reference Unit frequently receives requests to determine MICs for bacterial groups and antimicrobial agents for which EUCAST has not published breakpoints. In these instances, service users may notice changes in the ways that these MICs are reported. EUCAST guidance is that, where available, PK-PD non-species related breakpoints should be used to interpret MIC values. These are listed in the **EUCAST clinical breakpoints** document, along with the dosage on which each PK-PD breakpoint is based.

In cases where no PK-PD breakpoint has been established, susceptibility testing results must be interpreted by referring to the **EUCAST MIC distributions website** and determining whether the MIC is in the wild-type (i.e. the organism lacks mechanisms of resistance to the antimicrobial) or non-wild-type range for the species or related species. In either situation reporting as S, I or R should be avoided as such categorisation should be reserved for organism-antimicrobial agent combinations where specific breakpoints have been defined. Further information can be found in the EUCAST document ‘**Antimicrobial susceptibility tests on groups of organisms or agents for which there are no EUCAST breakpoints**’. Any feedback regarding changes to the reporting of MICs should be sent to amrhai@phe.gov.uk.

Katie Hopkins

‘Treating your infection: urinary tract infections’ leaflet for older adults and those who care for them



The primary care unit develops resources and interventions to improve the diagnosis and treatment particularly outside hospitals. Recent work has focused on improving patient knowledge on how to prevent UTIs, how UTIs develop, how they are diagnosed and managed, and providing advice on self-care and when to re-consult. These resources aim to reduce recurrent infections, *E. coli* bacteraemia, hospital admissions and improve older adults’ health and wellbeing. We know how busy prescribers are, and how important it is to use precious consultation time efficiently. Therefore, we have developed a leaflet to share with older adults and their relatives or carers when they have urinary symptoms or with those who may be at risk of future UTIs.

The leaflet has been developed following extensive needs assessment with general practitioners, care home staff, care home residents and their relatives, and a variety of stakeholders. The older adult leaflet was developed based on the original TARGET TYI-UTI leaflet for uncomplicated UTIs, and underwent iterative modifications after each interview or

focus group. Data collection was informed by the Theoretical Domains Framework in order to explore all behavioural determinants.

The leaflet can be used in several ways. To provide information on UTIs to those at risk, care staff may wish to share this leaflet with older adults in their care and/or their relatives. The leaflet may also be used during primary care consultations to facilitate dialogue between a patient and their GP on specific topics like treatment or safety netting. It is important that the leaflet is used as a tool to interact with patients, rather than as a 'parting gift'.

We are happy to receive constructive comments on how the leaflet can be improved. Please contact the TARGET team via TARGETantibiotics@phe.gov.uk.

Leah Jones

Best Small Exhibition Stand – Infection Prevention Society 2018



The TARGET and e-Bug teams from the Primary Care Unit (PCU), HCAI & AMR Division have been busy at the Annual Infection Prevention Conference in Glasgow. The team exhibited the TARGET resources for primary care professionals to optimise prescribing and the e-Bug resources for schools and community groups. The PCU team came away with the award for Best Small Stand! They also delivered an interesting oral presentation on UTI in older adults, three fantastic poster talks on education and antimicrobial stewardship, as well as an interactive symposium on the TARGET and e-Bug projects. A very successful conference!

Charlotte Eley, TARGET and e-Bug teams

Ceftazidime-avibactam resistance identified in carbapenem-resistant Enterobacteriaceae in England

Ceftazidime-avibactam (CAZ-AVI), a β -lactam/diazabicyclooctane β -lactamase inhibitor combination, was launched in Europe in 2016. CAZ-AVI is active against most Ambler class A and C, and some class D β -lactamases, therefore it is recommended for the treatment of infections due to carbapenem-resistant Enterobacteriaceae (CRE) that harbour either KPC or OXA-48-like non-metallo-carbapenemases (but not metallo-carbapenemases such as IMP, VIM or NDM), or where resistance is due to ESBL and/or AmpC activity together with impermeability.

AMRHAI Reference Unit data from the first 12 months of routine susceptibility testing with CAZ-AVI revealed that susceptibility rates exceeded 95% for Enterobacteriaceae harbouring class A or OXA-48-like carbapenemases, and also those with carbapenem resistance due to ESBL or AmpC enzymes and impermeability. Subsequently, we have observed borderline resistance to CAZ-AVI (MICs 8 – 16 mg/L) in a cluster of *Klebsiella*

pneumoniae ST512 isolates harbouring both KPC-3 and OXA-181 carbapenemases from patients with no prior exposure to CAZ-AVI (Taori et al. 28th ECCMID ePoster #O0582).

Resistance to CAZ-AVI has been reported elsewhere, with the underlying mechanism(s) of resistance identified as mutant KPC-2 or KPC-3 enzymes, differences in CAZ-AVI susceptibility depending on the KPC variant, mutant CTX-M ESBLs or mutation in the OmpK36 outer membrane protein. In response, the European Centre for Disease Prevention and Control (ECDC) recently published a rapid risk assessment on the emergence of CAZ-AVI in CRE.

AMRHAI's findings have been shared with ECDC's Epidemic Intelligence Information System (EPIS) and the WHO's Emerging Antimicrobial Resistance reporting (GLASS EAR) scheme. The HCAI & AMR Division is undertaking an investigation of CAZ-AVI resistance among reference laboratory referrals and as reported by diagnostic laboratories via the Second Generation Surveillance System. This study will include an analysis of CAZ-AVI usage in secondary care and will make recommendations to inform public health practice. Enterobacteriaceae isolates determined as resistant to CAZ-AVI based on local susceptibility testing, but not known to produce a metallo-carbapenemase, should be referred to the AMRHAI Reference Unit for confirmation of resistance.

Rachel Freeman, Berit Muller-Pebody and Katie Hopkins

Update on e-Bug

PHE's Primary Care Unit has teamed up with the Public Health Agency (PHA) to disseminate the e-Bug educational materials to schools across Northern Ireland. e-Bug (www.e-bug.eu) is an evidence-based resource that educates children about microbes, the spread and prevention of infection, antibiotics and antibiotic resistance.

On the 12th and 13th June, PHE and PHA trained almost 100 educators on the innovative educational materials through interactive workshops and activity demonstrations at the W5 Science centre in Belfast and Cookstown, Northern Ireland. All trainees left with a full set of e-Bug resources, including a newly developed microbe top trumps card game 'Microbe Mayhem'. Both primary and post primary educators attended the training and will take the messages back to their schools across Northern Ireland.

Some highlights of the training were the popular 'snot gun' activity, demonstrating the importance of using a tissue when we sneeze, and an interactive group activity to show the effect of herd immunity in practice.

PHE collected data on the knowledge of educators and their confidence in delivering the topics included in the e-Bug materials before and after the training. Understanding teachers' own knowledge and confidence in teaching challenging health topics such as antibiotic resistance can help us to develop new resources and adapt our training to meet teachers' needs as well as improve the messages taught to children who are our future generation of antibiotic users and prescribers.

Over the next year PHE and PHA will evaluate the delivery of the materials to students. Please contact us if you have any questions on the materials at e-Bug@phe.gov.uk

e-Bug Team, Primary Care Unit, HCAI & AMR

Fighting antibiotic resistance together: working with industry and academia

The antimicrobial resistance 'crisis' demands a sustainable pipeline of new antibiotics and innovative diagnostics to support appropriate prescribing, improving outcomes for individuals and antibiotic stewardship. NIS Labs holds extensive collections of well-characterised resistant bacteria from infections, which include representatives of the major clonal lineages and resistance mechanisms of public health importance (e.g. diverse carbapenemase genes). Using customised challenge panels of bacteria we are able to

compare the *in vitro* activity of new, developmental compounds vs. comparator antibiotics. We can also investigate early stage (pre-clinical) compounds for antibacterial activity to aid lead selection.

We also evaluate the analytical potential of novel diagnostics targeting specific species or resistance mechanisms and are also able to evaluate diagnostic performance of novel diagnostics in laboratories by directly testing on clinical specimens through NIS Laboratories. We work with industrial, academic and other partners to obtain funding for developing concepts and new technologies and are able to offer independent scientific advice on development strategies and product profiles, seeking to ensure that new solutions address clinical problems.

If you would like to explore using our contract research services then please contact us at amrhai@phe.gov.uk.

Katie Hopkins, Shazad Mushtaq, Mark Sutton and Neil Woodford

Growth of the ICU Surveillance programme

The ICU voluntary bloodstream infection surveillance programme was set up by the 'Infection in Critical Care Quality Improvement Programme (ICCQIP)' in early 2016. Initially the surveillance was run in 27 Trust (48 ICU) pilot sites, but in November 2016 it was opened up to all Acute Trusts. The programme has generated much interest and has grown to 102 Trusts (162 ICUs).

In early 2018, the Care Quality Commission (CQC) included participation in the ICCQIP ICU surveillance programme as a quality indicator, and forms part of CQCs 'Well Led' Audits.

ICCQIP are working with Getting It Right First Time, to promote both participation in the surveillance programme and use of data from it. Further collaborative work is also being developed with the Intensive Care National Audit and Research Centre (ICNARC), Paediatric Intensive Care Audit Network (PICANET) and the Neonatal Data Analysis Unit (NDAU), especially around use of data linkage to case mix adjust the infection data and reduce or possibly remove the need for bespoke data collection.

Increased participation allows more meaningful analysis and interpretation of ICU bloodstream infections (ICU-BSI) data. Quarterly reports are produced on the data and feedback is given to allow units to monitor their infection rates within their ICU against a background of those in other ICUs. Various counts, rates and plots are available in the report, including BSI, ICU-BSI (Figure 2), CVC-associated BSI and CVC-related BSI, amongst others.

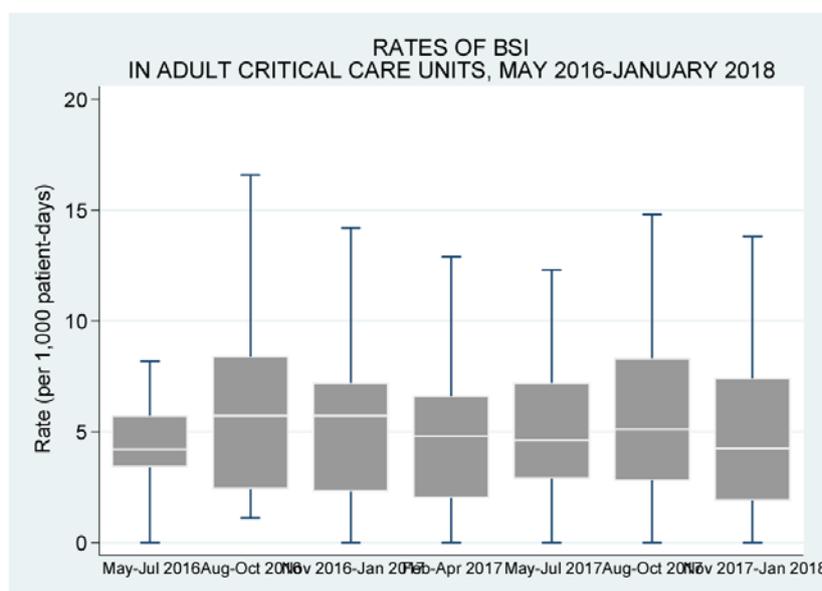


Figure 2: Rate of ICU associated BSI by unit by quarter, May 2016 to Jan 2018.

In addition, other meaningful data can be extrapolated for example the most common species isolated from BSIs in ICUs (see Figure 3).

Looking ahead, we hope to continue building on the programme’s current success. We are currently in the process of a launching a new more enhanced data capture system, which facilitates data upload and on-demand reports.

Dimple Chudasama

Invasive staphylococcal disease: Improving PWID status data capture

Analysis of the first year of the MRSA bacteraemia whole genome sequencing/Mandatory Surveillance integrated dataset is underway. See [here](#) for the interim analysis of the first six months of data; the overall findings will be disseminated later this year as an annual report. Most importantly, thank you for your continued contribution to this initiative - the study runs until the end of March 2019, so please continue to send us your MRSA bacteraemia isolates!

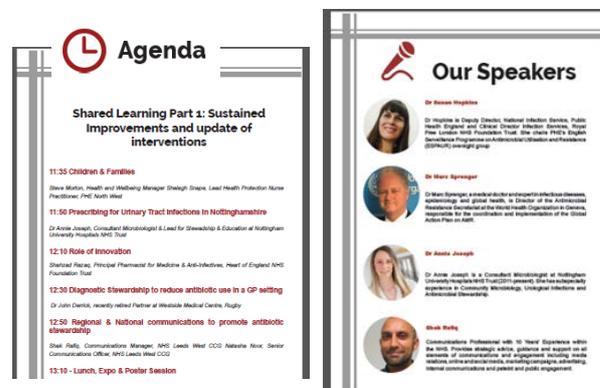
Clonal shifts in MRSA over time are well recognised and we have noted a particular clone of MRSA commonly associated with people who inject drugs (PWID). We have observed this clone predominantly in the South of England and, following review of our archives, it is likely that this clone has been circulating among PWID since around 2012. Furthermore, the latest **“Shooting up” report** highlights an increase in the proportion of bacteraemia cases between 2011 and 2016 from PWID, rising from 6.9% to 13% for MSSA and from 1.6% to 8.1% for MRSA. However, this is likely to be an underestimate as risk factor information is missing for a large proportion of MRSA and MSSA bacteraemias reported.

To improve our understanding of the epidemiology of invasive MSSA/MRSA infections in this ‘at risk’ group, we would be grateful if you could:

- make efforts to include PWID status on referral forms of any *S. aureus* (MSSA and MRSA) referred to us for analysis
- complete the PWID status field when reporting MSSA or MRSA bacteraemia cases using the mandatory reporting system

Angela Kearns, Bruno Pichon, Laura Bubba, Peter Staves, Olisaeloka Nsonwu, Simon Thelwall, Russell Hope

2018 Antibiotic Guardian Conference and Awards



The 2018 Antibiotic Guardian conference and Awards took place 27 June. The conference provided guidance, resources and information for practitioners on topics associated with tackling antimicrobial resistance. The theme of the day was “Shared Learning” with the day beginning with a focus on sustained improvements and dissemination. The presentations

from the conference are available via the following link

(<http://antibioticguardian.com/Meetings/ag-conference-and-awards-2018/>).

The third Antibiotic Guardian awards, which champions organisations and individuals who have demonstrated achievement in tackling antimicrobial resistance at a local, regional, national and international level took place the evening of the 27th. The guest speaker for the awards was Chief Medical Officer for England, Dame Professor Sally Davies.

The awards were jointly presented by Dr Diane Ashiru-Oredope (lead for the Antibiotic Guardian campaign and Lead Pharmacist for the AMR Programme at Public Health England); Dr Susan Hopkins (Deputy Director, HCAI & AMR Division, National Infection Service) and Dr Bruce Warner (Deputy Chief Pharmaceutical Officer for England).

Awards were given out in 10 categories across both human and animal health including; Agricultural & Food; Diagnostic stewardship; Infection prevention and control; and Innovation & Technology. Sixty-two entries were shortlisted. Additionally, the Das Pillay Antimicrobial Stewardship Memorial award was given for the first time at the 2018 Awards, in recognition of innovation in the field of antimicrobial stewardship (AMS) at a junior level. To find out more about the shortlisted entrants please visit the Antibiotic Guardian website (<http://antibioticguardian.com/shared-learning/>).

Overall, the ability to learn from those within both the human and animal sectors was found to be very valuable.

Diane Ashiru-Oredope

Save the date!

International Infection Prevention and Control Week (14-20 October), World Antibiotic Awareness Week (WAAW) (12-18 November) and European Antibiotic Awareness Day (EAAD) (18 November) 2018 provide an excellent opportunity to engage with healthcare professionals (HCPs) and the public on the issue of AMR.

Ahead of the week, choose your Antibiotic Guardian pledge and register your organisation's planned local activities by 17 November via the online registration form

<http://antibioticguardian.com/organisations/> (this will take less than five minutes). Last year over 294 organisations registered their local activities to support WAAW. Activities can include displaying Keep Antibiotics Working campaign materials, education and training sessions, including AMR information on websites, internal/external newsletters or social media activities. A resources toolkit

(<https://www.gov.uk/government/collections/european-antibiotic-awareness-day-resources>) is available.

Diane Ashiru-Oredope

Contact us

General enquiries

amrhai@phe.gov.uk

Reference services; placements and visits; infection prevention and control, and site visits; R&D opportunities; commercial opportunities

Bacteriology Triage; Tel 020-8327-7887

Specimen / result / report queries

Hcai.Amrdepartment@phe.gov.uk

national surveillance programmes for antibiotic use, resistance, bloodstream infection and *Clostridium difficile* surveillance, surgical site infections antimicrobial prescribing and IPC interventions in primary and secondary care

Consultant Microbiologists

colindalemedmicro@phe.gov.uk; Tel 020-8327-6736

Advice on medical management of cases. This service is not to access laboratory results.