



Public Health
England

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Mandatory Healthcare Associated Infection Surveillance: data quality statement

October 2020

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Introduction

This document describes many of the aspects of quality assurance (QA) surrounding the routine publication of the results from the mandatory surveillance of bacteraemia and *C. difficile* infection (CDI).

Public Health England will update this statement annually after the close of every financial year.

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Accessibility

All mandatory surveillance outputs are published on GOV.UK.

All data tables are produced and published in a non-proprietary format (.ods). All commentaries are published as PDFs with accompanying data tables being made available as .ods files.

A comprehensive list of all current mandatory surveillance outputs and their location on GOV.UK can be found in appendix 1.

Background and history of mandatory surveillance of bacteraemia and CDI

Public Health England (PHE) has been managing the mandatory surveillance of *Staphylococcus aureus* bacteraemia in England since April 2001. Mandatory surveillance was originally instigated in response to increasing rates of MRSA bacteraemia across the English NHS and has subsequently been rolled out for other HCAs where there was a perceived issue or problem.

It has been mandatory for NHS acute trusts to report all cases of Meticillin-resistant *Staphylococcus aureus* (MRSA) bacteraemia since April 2004. In October 2005, surveillance was enhanced to include patient-level data. Enhanced surveillance involves collecting patient details such as NHS number, hospital number, date of birth and sex, as well as information concerning the patient's location, date of admission, consultant specialty, and associated care details. All information is collected by acute trusts and reported to PHE via a real-time web-based surveillance system (Healthcare Associated Infection Data Capture System (HCAIDCS)). In January 2011, this scheme was extended to include surveillance of Meticillin-sensitive *Staphylococcus aureus* (MSSA) bacteraemia.

Surveillance of *Clostridioides difficile* (previously *Clostridium difficile*) infection (CDI) was originally introduced in 2004 for patients aged 65 years and over. This was then extended to include all cases in patients aged 2 years and over in April 2007. Reports are submitted using the same real time web-enabled system that is used to collect enhanced MRSA and MSSA bacteraemia data. A similar enhanced dataset is collected. *Escherichia coli* (*E. coli*) bacteraemia surveillance was introduced in June 2011 following observed year-on-year increases via PHE voluntary surveillance and a recommendation from the Advisory Committee on Antimicrobial Prescribing, Resistance and Healthcare Associated Infection (APRHAI). Surveillance is again undertaken via the HCAI DCS.

Between April 2013 and April 2018, all NHS organisations reporting positive cases of MRSA bacteraemia were required to complete a Post Infection Review (PIR)¹. This process was introduced to support the delivery of zero tolerance on MRSA bacteraemia, as set out by NHS England Planning Guidance². A PIR was undertaken on all reported MRSA bacteraemias with the purpose of identifying how a case occurred and to identify actions which would prevent reoccurrences. It also enabled identification of the organisation best placed to ensure necessary improvements are made. From April 2018, only trusts with MRSA rates in the top 15% of trusts were required to undertake PIRs for any MRSA cases. In addition, trusts which breach the threshold in the course

¹ <https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2014/02/post-inf-guidance2.pdf>

² <https://webarchive.nationalarchives.gov.uk/20161104031123/https://www.england.nhs.uk/everyonecounts/>

of a year will be expected to commence the PIR process for the remainder of the year. From this point, PIR became a local process and was not reported to PHE³. From April 2017 all NHS acute trusts were required to undertake surveillance of *Klebsiella* spp. and *Pseudomonas aeruginosa* bacteraemia. Alongside ongoing *E. coli* bacteraemia surveillance these additional requirements are to support progress against the Government's ambition to reduce the number of Gram-negative bloodstream infections by 50% by the end of financial year (FY) 2020/21.

Relevant Chief Medical Officer/Chief Nursing Officer letters detailing the introduction of the various mandatory surveillance schemes can be found below:

Implementation of mandatory HCAI surveillance:

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Professionalletters/Chiefmedicalofficerletters/DH_4003782

MRSA bacteraemia mandatory surveillance:

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Professionalletters/Chiefmedicalofficerletters/DH_4112588

NHS Improvement guidance on PIR

<https://improvement.nhs.uk/resources/mrsa-guidance-post-infection-review/>

CDI surveillance (patients aged 65 and over):

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Professionalletters/Chiefmedicalofficerletters/DH_4125069

CDI surveillance (patients aged 2 and over):

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Professionalletters/Chiefmedicalofficerletters/DH_073767

MSSA bacteraemia:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215835/dh_123292.pdf

³ https://improvement.nhs.uk/documents/2512/MRSA_post_infection_review_2018_changes.pdf

E. coli bacteraemia:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215619/dh_126221.pdf

The ambition to halve healthcare associated Gram-negative bloodstream infections is outlined in the NHS Improvement Provider Bulletin (15 March 2017).

This includes a link to a letter from the NHS Improvement National Director for Infection.

Prevention and Control providing and overview of the intention to the mandate the reporting of *Klebsiella* spp. and *P. aeruginosa* BSI.

<https://improvement.nhs.uk/news-alerts/provider-bulletin-15-march/#infections>

Purpose

Mandatory HCAI surveillance outputs are used to monitor progress on controlling key health care associated infections and for providing epidemiological evidence to inform action to reduce them. Data are unavailable from any other source and provide unique information on infection levels.

Data are used to support the NHS objective of improving the quality and safety of services and promoting patient choice by providing access to information on NHS performance.

Data are used nationally for benchmarking purposes and for the performance management of MRSA bacteraemia and CDI objectives set by NHS Improvement⁴.

Data/outputs are also routinely used to answer relevant Parliamentary Questions.

These data are also used to inform patient choice via the NHS Choices website⁵.

NHS acute trusts and CCGs use these data to monitor progress against these objectives and to help inform action to reduce these infections locally. Mandatory surveillance outputs are routinely used to appraise local/regional NHS management of infection levels within their area.

The *Klebsiella* spp. and *P. aeruginosa* bacteraemia surveillance outputs will form an integral part of NHS Improvement's strategy for the 50% reduction in Gram-negative bacteraemia by the end of FY 2020/21⁶.

⁴ <https://improvement.nhs.uk/resources/clostridium-difficile-infection-objectives/>

⁵ <http://www.nhs.uk/service-search/Hospital/se1/Results/3/-0.0926785692572594/51.4953231811523/7/0?distance=25&metricGroupId=479&ResultsOnPageValue=10&isNational=0>

⁶ <https://improvement.nhs.uk/news-alerts/provider-bulletin-15-march/#infections>

Relevance, user need and perception

Users' needs

Data and outputs from the mandatory surveillance of bacteraemia and CDI are used for a variety of purposes, by a range of organisations across the health service. Details of key stakeholders and associated data users are outlined below.

National users

Public Health England – data/outputs are used to:

- undertake epidemiological analyses at national/regional/local level
- provide relevant response to Parliamentary Questions (PQs) as/when required

Department of Health (DH) – data/outputs are used to:

- routinely brief ministers on numbers/rates of HCAI (nationally and regionally) for all infections reported via mandatory surveillance (MRSA, MSSA, *E. coli*, *Klebsiella* spp. and *P. aeruginosa* bacteraemia and CDI)
- inform/identify national level targets for interventions/reduction strategies

NHS England & NHS Improvement – data/outputs are used to:

- identify/establish performance management/improvement methodologies
- set national/local/organisational level performance management targets/objectives
- assess performance against target/objective

My NHS – data/outputs are used to:

- make comparisons for most recent 3 months to the same period in the preceding year

Local users

NHS England Local Offices – data/outputs are used to:

- assess NHS trust/CCG Performance against targets/objectives at a local level

Local Public Health England (Field Epidemiology Service) / Public Health England Centres – data/outputs used to:

- assist in outbreak investigation as/when necessary

- inform public health initiatives/reports at a local level

NHS acute trusts – data/outputs are used to:

- inform trust boards of the current organisational position in terms of key HCAIs (MRSA, MSSA and E. coli bacteraemia and CDI)
- monitor progress against performance management objectives/targets

Clinical Commissioning Groups – data/outputs are used to:

- monitor progress against performance management objectives/targets
- assist in the commissioning of services from relevant acute level providers

User satisfaction

A routine 'Stakeholder Engagement Forum' is held every 3 months. This meeting includes representation from a wide range of national level stakeholders as well as from local NHS organisations such as CCGs and acute trusts.

Standing items on the meeting's agenda include:

- recent publications
- experiences
- improvements
- future developments/updates

Following the meeting a summary of the discussion/outcomes is produced and is available on the GOV.UK website.

This summary covers:

- currently known uses of data/outputs
- user experiences (including changes/updates/improvements)
- stakeholder opinion of proposed/upcoming changes

Meeting feedback is used to improve/enhance ongoing engagement. It is also used to inform future development and to ensure that data users remain central/integral to the process.

Summary information from these meetings is routinely made publicly available.

Timeliness and punctuality

Timeliness

Mandatory HCAI surveillance data is published in as timely a manner as possible. Data is signed off by acute trust Chief Executives 15 days after the end of each month (eg sign off for each month is required by the 15th of the following month). Data is published on a monthly, quarterly and annual basis according to a pre-announced publication schedule published on GOV.UK. Dates are included for an entire 12-month period.

The [PHE official statistics publication calendar](#) is available online.

The mandatory [HCAI surveillance specific announcements](#) for 2020 is available online.

Monthly data tables

Monthly data is processed and analysed before being published on the first Wednesday of the following month. This occurs between 2 and 6 weeks following the end of a given month (depending on how the month falls). For example, January 2017 data was signed off on 15 February 2017 and then published on 1 March 2017. This is 2 weeks from sign off to publication.

Decreasing the amount of time between data sign off and monthly publication has been investigated. It is, however, believed that adhering to these set sign off and publication dates ensures transparency in terms of deadline/table production/publication without reference to a changing schedule of dates. This far outweighs any minor benefits that could be achieved by changing timings during months with longer lead times.

Quarterly epidemiological commentary

The QEC is published approximately 2 months following sign-off of the last full month of data for inclusion. Publication occurs on the second Thursday of the final month of the following quarter. For example, data up to and including December 2016 was signed off on 15 January 2017 and was published on 9 March 2017.

Decreasing the amount of time between sign off and publication has been considered. However, doing so would not allow enough time to undertake relevant data quality checks on either the data used for preparing the report or the report itself. Hence the benefit of using the current publication schedule far outweighs any minor benefit that might be achieved in reducing the lead time for the QEC publication.

Annual data tables and annual epidemiological commentary (AEC)

Annual data tables and the accompanying AEC is published in early July each year. This is approximately 3 months following the end of the financial year (FY) and the associated sign off deadline of March data (15 April).

The annual data tables include counts and rates for both acute trusts and CCGs. Rate calculation and associated quality assurance considerably increases the time required for table production.

The AEC represents the most substantial HCAI mandatory surveillance output produced/published each FY. The lead time necessary for analysis/compilation of data cannot be underestimated. The document in its entirety includes in excess of 20 analyses from 2019 for all 6 infections subject to mandatory surveillance.

Punctuality

All published data outputs are published at 09:30 on the pre-announced publication date. To date there have been 2 occasions where publication was delayed.

On 10 July 2014 publication of the annual data and accompanying Annual Epidemiological Commentary (AEC) was delayed by approximately 30 minutes as a result of unforeseen delays in the process used by Online Services for uploading statistics to the external website. Further information on this delay is available on the UKSA website⁷.

In the financial year 2018/19, there was a 1-hour delay in publishing monthly tables on 01 August 2018. This occurred as a result of human error in the publishing process.

⁷ UKSA website

https://uksa.statisticsauthority.gov.uk/wp-content/uploads/2015/12/images-healthcareassociatedinfectionshcaistatistic_tcm97-44590.pdf

Routine comparison/quality assurance of HCAI DCS data with voluntary laboratory surveillance data (SGSS)

The Second Generation Surveillance System (SGSS) is a voluntary surveillance data capture system used by laboratories to report cases of microbial infection from various samples, eg blood, urine and faeces etc. Information on antibiotic and antifungal susceptibility is also submitted where relevant. Although primarily an internal system used by healthcare professionals, the data reported via this system is routinely compared to the mandatory data collected via the mandatory surveillance database - HCAI DCS. This routine comparison between surveillance systems provides a data quality check of the ascertainment of cases reported to the HCAI DCS.

The following summary provides the results of this comparison for financial year 2018/19.

NB: Testing for *C. difficile* is a 2-stage process, the second stage identifies *C. difficile* toxin. Only *C. difficile* toxin-positive cases are reportable to the mandatory surveillance system. It is not currently possible to differentiate reported *C. difficile* cases which have tested positive for *C. difficile* toxins from those which have not, to an acceptable degree of accuracy on SGSS. This is due to data quality and reporting issues in SGSS. Therefore, it is not currently possible to include *C. difficile* data in the routine HCAI DCS/SGSS comparison as information on *C. difficile* cases is not comparable.

Figure 1 compares the overall trends of MRSA and MSSA bacteraemia reported to the mandatory (HCAI DCS) and voluntary (SGSS) surveillance schemes between financial years (FY) 2011/12 and FY 2018/19. Figure 2 shows the same comparison between HCAI DCS and SGSS for *E. coli*, *Klebsiella* spp. and *P. aeruginosa* bacteraemia.

Figure 1: Number of *E. coli*, MRSA and MSSA bacteraemia cases reported via the mandatory surveillance and voluntary surveillance schemes: 2011/12 to 2018/19

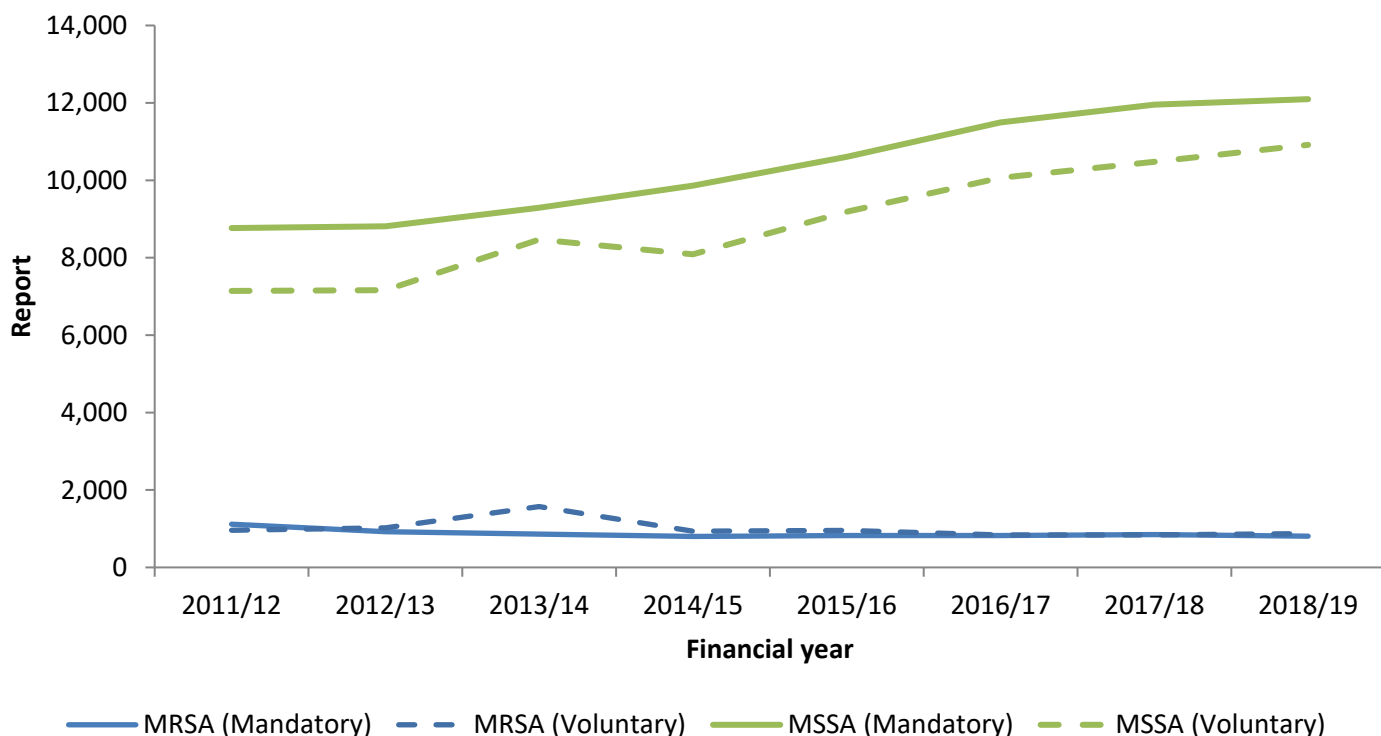
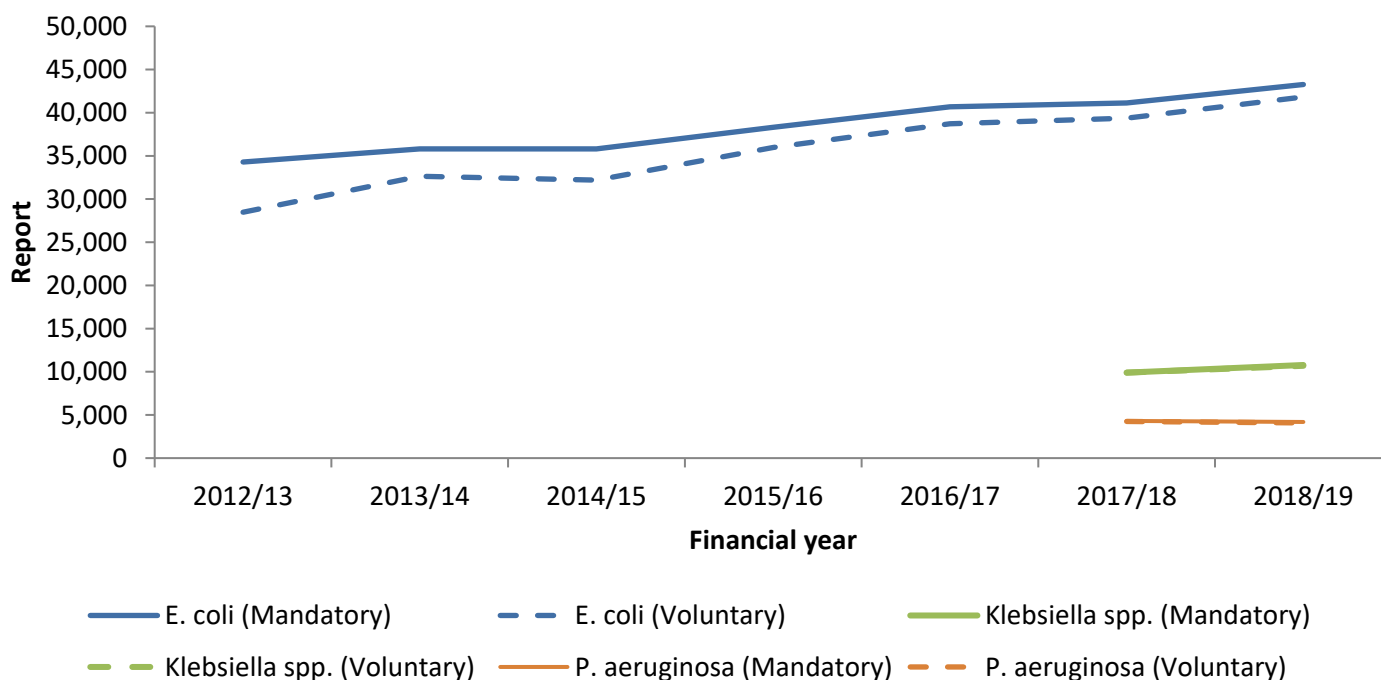


Figure 2: Number of *E. coli*, *Klebsiella* spp. and *P. aeruginosa* bacteraemia cases reported via the mandatory surveillance and voluntary surveillance schemes: 2012/13* - 2018/19



*Mandatory reporting of *E. coli* bacteraemia began in June 2011 while mandatory reporting of *Klebsiella* spp. and *P. aeruginosa* began in April 2017.

In general, these show that more cases are captured via mandatory surveillance than via voluntary surveillance however, the overall trends of cases reported to both surveillance schemes remain the same. Interpretation of the comparisons in case numbers for MRSA and MSSA bacteraemia should be done with care. Meticillin resistance in the mandatory surveillance is reported by NHS acute trusts after susceptibility testing. However, for this report meticillin resistance in the voluntary system, was determined by selecting the most severe susceptibility results from patients' blood cultures within a 14-day period. This difference is a contributory factor to the apparent over-ascertainment of the voluntary MRSA reports in some financial years.

HCAI DCS and SGSS matching process

Not all cases reported to SGSS will be subject to reporting in the mandatory HCAI DCS. Therefore, for datasets to be comparable, cases from SGSS have been limited based on certain criteria. These include:

- MRSA: All reported *S. aureus* bacteraemia from blood culture which are not susceptible to meticillin, oxacillin, ceftazidime or flucloxacillin
- MSSA: All reported *S. aureus* bacteraemia from blood culture which are susceptible to meticillin, oxacillin, ceftazidime or flucloxacillin
- *E. coli* bacteraemia: All reported cases of *E. coli* from blood cultures
- *Klebsiella* spp. bacteraemia. All reported cases of *Klebsiella* spp. (including *Enterobacter aerogenes*) from blood cultures
- *P. aeruginosa* bacteraemia. All reported cases of *P. aeruginosa* from blood cultures

Cases were then matched between surveillance systems on a case by case basis using a number of ordered steps. SGSS cases within 14 days of the earliest cases from a patient were excluded as duplicate episodes (see appendix 2 for details).

Table 1: Total number of cases reported to the mandatory and voluntary surveillance schemes, 2018/19.

| Organism causing bacteraemia | Voluntary | Mandatory | Ascertainment (%) |
|-------------------------------------|------------------|------------------|--------------------------|
| <i>S. aureus</i> * | 12,628 | 12,904 | 98 |
| MRSA | 875 | 807 | 108 |
| MSSA | 10,916 | 12,097 | 90 |
| Not known | 837 | - | - |
| <i>E. coli</i> | 41,823 | 43,264 | 97 |
| <i>Klebsiella</i> spp. | 10,687 | 10,785 | 99 |
| <i>P. aeruginosa</i> | 4,075 | 4,186 | 97 |
| Total** | 68,376 | 71,139 | 96 |

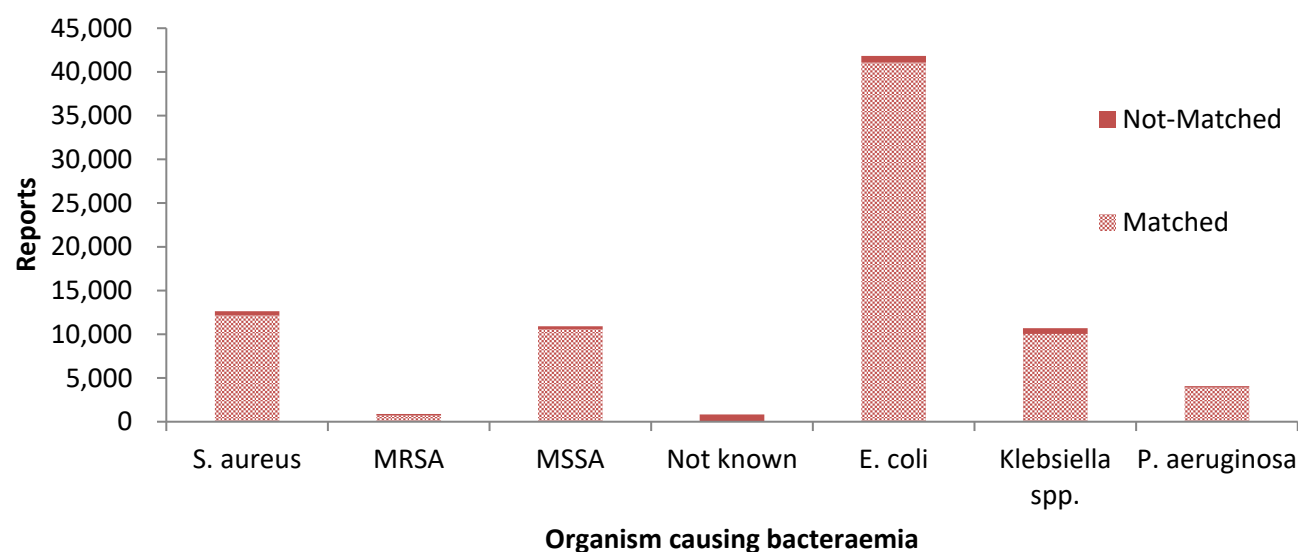
* Includes 895 *S. aureus* cases with unknown meticillin susceptibility

** Excludes 895 *S. aureus* cases with unknown meticillin susceptibility

Number of cases from voluntary surveillance (SGSS) found in the mandatory surveillance scheme (HCAI DCS)

Reports have been matched this way to demonstrate the effectiveness of the HCAI DCS in capturing all cases of Gram-negative bacteraemia, *Staphylococcus aureus* bacteraemia, which are eligible for mandatory reporting. Figure 3 and Table 3 shows the number of cases reported via voluntary surveillance (SGSS) that were also captured via mandatory surveillance (HCAI DCS).

Overall 66,236 (97%) cases reported via SGSS and mandatory surveillance were identified in the HCAI DCS. The number of *E. coli*, *Klebsiella* spp., *P. aeruginosa*, MRSA and MSSA bacteraemia cases reported to the voluntary surveillance scheme which were identified in the mandatory surveillance scheme were 41,059 (98%), 10,035 (94%), 3,905 (96%), 696 (80%) and 10,541 (97%) cases respectively.

Figure 3: Ascertainment of cases reported the voluntary surveillance scheme which were identified in the mandatory surveillance scheme**Table 2: Ascertainment of cases reported to the voluntary surveillance scheme which were identified in the mandatory surveillance scheme**

| Organism causing bacteraemia | Matched (%) | Not-Matched (%) | Total (%) |
|------------------------------|-------------|-----------------|--------------|
| <i>S. aureus</i> * | 12,132 (96) | 496 (4) | 12,628 (100) |
| MRSA | 696 (80) | 179 (20) | 875 (100) |
| MSSA | 10,541 (97) | 375 (3) | 10,916 (100) |
| <i>E. coli</i> | 41,059 (98) | 764 (2) | 41,823 (100) |
| <i>Klebsiella</i> spp. | 10,035 (94) | 652 (6) | 10,687 (100) |
| <i>P. aeruginosa</i> | 3,905 (96) | 170 (4) | 4,075 (100) |
| Total** | 66,236 (97) | 2,140 (3) | 68,376 (100) |

* Includes 895 *S. aureus* cases with unknown meticillin susceptibility

** Excludes 895 *S. aureus* cases with unknown meticillin susceptibility

The apparent under-ascertainment of MRSA and MSSA cases compared to other data collections is an artefact of how cases of both data collections have been reported from the mandatory and voluntary surveillance schemes. When comparing *S. aureus* cases as a whole – MRSA, MSSA and those with unknown meticillin susceptibility (n= 837), only 4% (n= 496/12,628) of all *S. aureus* cases were not identified in the HCAI DCS.

Number of cases from the mandatory surveillance scheme (HCAI DCS) found in the voluntary laboratory surveillance scheme (SGSS)

Reports were matched on a case by case basis in order to identify the proportion of individual cases that are captured via the mandatory surveillance scheme (HCAI DCS)

but are not reported via the voluntary laboratory surveillance scheme (SGSS). This is opposed to the comparison of overall/total cases undertaken above.

Table 2 shows the percentage of cases reported via the HCAI DCS that were also identified in SGSS. Overall 66,674 (94%) cases reported to the HCAI DCS were also reported in SGSS. The number of *E. coli*, *Klebsiella* spp., *P. aeruginosa*, MRSA and MSSA cases identified in SGSS were 41,178 (95%), 10,196 (95%), 3,197 (94%), 696 (86%) and 10,687 (88%) respectively. This suggests that approximately 6% infection currently captured by the mandatory surveillance could not be found in voluntary surveillance. This demonstrates the importance of both the mandatory surveillance scheme and of the system used for data collection (HCAI DCS). Further benefits are outlined in Strengths and weaknesses.

Table 3: Ascertainment of cases reported to the mandatory surveillance scheme which were identified in the voluntary surveillance scheme FY 2018/19

| Organism causing bacteraemia | Matched (%) | Not Matched (%) | Total (%) |
|------------------------------|-------------|-----------------|--------------|
| <i>S. aureus</i> * | 12,304 (95) | 600 (5) | 12,904 (100) |
| MRSA | 696 (86) | 111 (14) | 807 (100) |
| MSSA | 10,687 (88) | 1,410 (12) | 12,097 (100) |
| <i>E. coli</i> | 41,178 (95) | 2,086 (5) | 43,264 (100) |
| <i>Klebsiella</i> spp. | 10,196 (95) | 589 (5) | 10,785 (100) |
| <i>P. aeruginosa</i> | 3,197 (94) | 269 (6) | 4,186 (100) |
| Total cases** | 66,674 (94) | 4,465 (6) | 71,139 (100) |

* Includes 895 *S. aureus* cases with unknown meticillin susceptibility

** Excludes 895 *S. aureus* cases with unknown meticillin susceptibility

Resolution of unmatched cases from the voluntary surveillance scheme

As part of the routine laboratory data check, laboratories with cases reported to the voluntary surveillance scheme but not identified in the HCAI DCS (mandatory scheme) are contacted for feedback on those cases. The cases are closed if:

- The unmatched case is subsequently identified in the HCAI DCS,
- The unmatched case is added to the HCAI DCS as a new record, or
- There is a legitimate reason for it not being reported to the HCAI DCS (eg post mortem blood cultures).

The highest percentage of open unmatched cases from voluntary surveillance was observed in MRSA (97%; 173/179), *Klebsiella* spp. (94%; 611/652) and *P. aeruginosa* bacteraemia (92%; 156/170). The highest percentage of closed cases was observed in the unmatched reports of *E. coli* bacteraemia (12%; 89/764) and MSSA bacteraemia (10%; 39/375). About half (n= 418) of the open *S. aureus* cases with unknown meticillin susceptibility have been resolved.

Table 4: Follow-up for unmatched cases

| Organism causing bacteraemia | Number of cases unmatched | Number of cases resolved (%) |
|------------------------------|---------------------------|------------------------------|
| <i>S. aureus</i> | 496 | 104 (21) |
| MRSA | 179 | 6 (3) |
| MSSA | 375 | 39 (10) |
| Not known | 837 | 418 (50) |
| <i>E. coli</i> | 764 | 89 (12) |
| <i>Klebsiella</i> spp. | 652 | 41 (6) |
| <i>P. aeruginosa</i> | 170 | 14 (8) |
| Total | 2,140 | 189 (9) |

Expected number of reports not captured by the mandatory surveillance scheme

Assuming all currently open cases remain open, an expected number of cases eligible for mandatory reporting which haven't been captured by the HCAI DCS can be estimated. For example, the results of this routine laboratory data check show that overall 94% (n = 66,674) (Table 2) of cases reported to the HCAI DCS are captured on SGSS. It can be assumed that the total number of open cases from SGSS (n = 1,951) represents 94% of an expected number of unmatched cases which should be reported to the HCAI DCS; therefore, we could expect up to 2,082 reports, across all organisms, which are not included in the mandatory surveillance scheme. Using this, an ascertainment of cases reported to the mandatory surveillance system compared to total number of cases eligible for mandatory reporting can be calculated as follows:

$$\left(\frac{\text{Total number of cases on the HCAI DCS}}{\left(\frac{\text{Total number of cases on the HCAI DCS} + \text{expected number of unmatched cases from SGSS}}{\text{}} \right)} \right) \times 100$$

$$\left(\frac{66,674}{66,674 + 2,082} \right) \times 100 = 97\%$$

Using this method, the ascertainment of *E. coli*, *Klebsiella* spp., *P. aeruginosa*, MRSA and MSSA bacteraemia cases reported to the mandatory surveillance system compared to the estimated total number of cases of these bacteraemia eligible for mandatory reporting are 98%, 94%, 96%, 80%, and 97%, respectively. This demonstrates that the HCAI DCS has an extremely high level of coverage.

Summary/conclusion

Identifying cases from the mandatory surveillance scheme (HCAI DCS) which were also reported to the voluntary surveillance scheme (SGSS) demonstrates the percentage of Gram-negative, MRSA and MSSA bacteraemia which are not captured by SGSS (Table 2):

- overall 97% (n=66,674) of all cases reported to the HCAI DCS can be accounted for in SGSS
- of the 3% (n= 2,140) of cases not captured by SGSS. 47% (n= 2,086) are *E. coli* bacteraemia, 13% (n= 589) are *Klebsiella* spp. bacteraemia, 6% (n= 269) are *P. aeruginosa* bacteraemia, 2% (n= 111) are MRSA bacteraemia and 32% (n= 1,410) are MSSA bacteraemia
- this demonstrates the necessity of the mandatory surveillance scheme; relying on voluntary surveillance alone would mean that an estimated 7% of the total burden of infection across the organisms currently subject to mandatory surveillance would be missed

Identifying cases from SGSS which were also reported to the HCAI DCS demonstrates the effectiveness of the HCAI DCS as a surveillance system responsible for capturing Gram-negative, MRSA and MSSA bacteraemia eligible for mandatory surveillance. (Table 3):

- overall 97% (n= 66,236) of all cases reported to SGSS are also accounted for in the HCAI DCS
- the highest ascertainment of SGSS cases found in the HCAI DCS, was observed in *E. coli* (95%, n= 41,178) and *Klebsiella* spp. (95%, n=10,196)
- the apparent under-ascertainment of MRSA (86%, n=696) and MSSA (88%, n= 10,687) is due to different data collection methods for cases from the mandatory and voluntary surveillance schemes (the ascertainment of *S. aureus* cases as a whole - MRSA and MSSA is 95% (n=12,304))

Taking into account the open cases identified in the voluntary surveillance scheme, the HCAI DCS is capturing an estimated 98%, 94%, 96% and 95% of *E. coli*, *Klebsiella* spp., *P. aeruginosa* and *S. aureus* bacteraemia cases, respectively, which are eligible for mandatory reporting.

In conclusion, the vast majority of data reported via PHE's voluntary surveillance system (SGSS) can be found in data reported to mandatory surveillance (HCAI DCS). This suggests that the HCAI DCS can indeed be seen to provide an accurate national picture of the overall burden of infection across the 3 bacteraemia under mandatory surveillance in England.

Accuracy and reliability

Under mandatory surveillance guidelines all laboratory confirmed cases should be reported. Data should not be subject to sampling error, as the data collection is a census of all infections rather than a sample (ie all laboratory-confirmed cases of these infections in England are mandated to be reported to Public Health England). However, there is the potential for non-sampling error.

Coverage error

Infection cases are reported by NHS acute trusts. As part of the verification process these data are signed off on a monthly basis by the CEO of the acute trust by the 15th of the following month (as outlined in Timeliness). This sign-off process provides formal assurance that the data are accurate and complete. Published statistics; therefore, include details of all cases for the reported time period.

On occasion; however, a notification is received that an amendment is required (undertaken via the update process outlined in Practice area 2: Communication with data supply partners). This may occur when sign off is required prior to full laboratory results being available. This may result in additional cases being added following laboratory confirmation. Alternatively, deletions may be required. An acute trust may have entered case information for what they thought was an MSSA bacteraemia, but further laboratory information may confirm the case to actually be an MRSA bacteraemia. In this situation, a CEO must request the deletion of the MSSA bacteraemia episode and the addition of an MRSA episode (for the same time period).

NHS acute trusts or external agencies eg the Care Quality Commission may also perform audits of local infection data. This can result in requests to add infection episodes that had not previously been entered. Finally, an NHS trust may ask to delete a case, if it is found to be a duplicate of a case reported from another trust (please see the Mandatory HCAI Surveillance Protocol, section 9.2 for further detail on what constitutes a duplicate).

NHS acute trusts may request to alter their data in order to improve the CCG attribution of a given infection record. The algorithm for CCG attribution is as described in the associated Mandatory HCAI Surveillance Protocol (section 13.6, appendix 6). This process is undertaken via an 'unlock' of the HCAI DCS. Further detail of the unlock process can be found in the 'Data-Specific Policy for Revisions/Amendments to MRSA bacteraemia, MSSA bacteraemia, *E. coli* bacteraemia & *Clostridioides difficile* Infection

Mandatory Surveillance Data⁸. NB: This policy will be updated to include *Klebsiella* spp. and *P. aeruginosa* over coming months.

A total of 91 (62%) acute trusts requested an unlock of at least 1 case across all organisms affecting data in financial year 2018/19 This equated to 769 cases that were unlocked. 53% of these unlocks were to add additional cases to a locked time period (n=413), 39% were amendments (n=298) and 8% (n=58) were to delete records (Table 4).

Compared to the previous financial year (2017/18) there has been a 4% decrease in the number of trusts that requested unlocks to change their data; with a 41% increase in the total number of unlocks. Deletion of data however have remained relatively stable. The number of unlock requests to add a case increased from 301 to 413 requests. The number of unlock requests to amend cases increased from 213 to 298 requests. The number of deleted cases increased from 31 to 58 requests.

Table 5: Number of unlocked cases by data collection and unlock reason, for financial year 2018/19

| Reason for unlock request | Data Collection | | | | | | Total |
|---------------------------|-----------------|------|------|----------------|------------------------|----------------------|-------|
| | CDI | MRSA | MSSA | <i>E. coli</i> | <i>Klebsiella</i> spp. | <i>P. aeruginosa</i> | |
| Add | 48 | 5 | 33 | 129 | 170 | 28 | 413 |
| Amend | 66 | 3 | 25 | 181 | 19 | 4 | 298 |
| Delete | 16 | 13 | 11 | 12 | 5 | 1 | 58 |
| Total | 130 | 21 | 322 | 322 | 194 | 33 | 769 |

The HCAI DCS includes facilities to assist NHS acute trusts to identify duplicate infection episodes within their organisation. A pop-up for potential duplicates at case entry is available in order to determine that no duplicates have been entered for a designated time period. Following sign off, as the CEO of an acute trust has verified their data as being accurate, data used for statistical publications are not altered by the PHE mandatory surveillance team to remove potential duplicate records. This may result in multiple listings of the same infection episode in the dataset.

As the mandatory surveillance of healthcare associated infections dataset is a national-level data collection, there is no over coverage; however, there is a possibility that some cases may not be reported to the HCAI DCS, resulting in under coverage. In order to ascertain the level and to rectify this, a consistency study is performed comparing

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https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/509316/HCAI_Mandatory_Surveillance_Data_Specific_Revisions_and_Corrections_Policy_March_2016.pdf

voluntary reported laboratory information for England with the mandatory surveillance scheme dataset.

See Routine comparison/quality assurance of HCAI DCS data with voluntary laboratory surveillance data for more information.

Data changes between releases are highlighted in each publication, so that users are made aware of any changes to historical data between publications. Further information on this process is available on the caveats page of each routine publication.

Measurement error

All mandatory HCAI surveillance data is collected via the HCAI DCS. The appendices of the mandatory HCAI surveillance protocol detail definitions/guidance on each field in the data collection. Therefore, there should be little concern over the interpretation of the questions by different users, although it should be noted that some questions are subjective in nature, asking the clinical opinion of the treating physicians.

Non-response error

Item non-response

The bulk of data used to produce the mandatory HCAI surveillance outputs are from mandatory questions in the data capture system. This means that a response is required in order to save the infection episode. Therefore, there will be only a marginal effect of non-response error in the statistical outputs. The exceptions are the data collected on risk factors for bacteraemias presented in the Annual Epidemiological Commentary (AEC), as the risk factor/source of bacteraemia questions are not mandatory fields. However, there are accompanying statements in the relevant sections of the AEC on the level of response for these data, as well as, mention in the discussion of potential bias caused by missing data.

Unit non-response

While item non-response is extremely low, unit non-response (ie individual NHS acute trusts who have not entered data and/or signed off data) is present. All outputs highlight such non-responders. Non-responders are furthermore referred to NHS England for follow up/resolution.

Processing error

Data entry

Processing errors may occur during the data entry stage. The data collected via the HCAI DCS is either entered by hand or partially uploaded (key questions required to save an infection episode) using the healthcare associated infections data capture system upload wizard. Data entry errors may occur, either because the source data at the acute trust is incorrect or missing, or in the transcription process.

While it is not possible to provide a level or direction of bias through processing errors for the entire data collection, it is possible to estimate the collective level of processing errors for 2 key variables (date of birth and NHS number), which can be used as an indicator for the full data collection. Section 13.6 (appendix 6)⁹ of the associated Mandatory HCAI Surveillance Protocol details the process of CCG attribution. This is done through the use of both NHS number and date of birth entered onto the healthcare associated infections data capture system. If either the date of birth or NHS number is incorrect or missing, a match will not be made and we will not receive necessary patient data from the NHS Spine. Assessing the percentage of all cases which could not be attributed via a match with the NHS Spine provides an indication of data entry errors.

For FY 2018/19 Less than 2% of all cases are not attributed to a CCG through a match with the Spine, where neither NHS number nor date of birth are missing. Thus, we are confident in the data entered onto the healthcare associated infections data capture system. Data entry errors may occur, either because the source data at the acute trust is incorrect or missing, or in the transcription process.

Data processing

As mentioned in Timeliness and punctuality, the accuracy of the data submitted to the mandatory surveillance of healthcare associated infections scheme is assured by the CEO of all of the reporting acute trusts via the monthly sign off process. Data is not amended after data entry. Data is; however, processed in order to produce the statistics. All statistical processing is performed independently by 2 scientists and then is cross-checked to verify that the data are correct. In addition, when rates are

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https://hcaidcs.phe.org.uk/ContentManagement/LinksAndAnnouncements/HCAIDCS_Mandatory_Surveillance_Protocol_v4.2.pdf

calculated for our quarterly commentaries and annual data tables and commentary, we also independently process the data used for denominators (occupied overnight bed days (KH03 return) from NHS England and population data from the Office of National Statistics).

Mandatory HCAI Surveillance Data in NHS performance management

NHS Improvement sets annual objectives for the continued improvement of CDI in England and there has been a zero-tolerance policy for MRSA since April 2013. Organisations which exceed their objectives are liable for financial penalties (up to and including 31 March 2014 for CCGs and to date for acute trusts).

Additionally, the secretary of state for health set an ambition to reduce Gram-negative bloodstream infections by 50% by 2021.

While PHE are not responsible for either the setting of these objectives, or the imposition of financial sanctions, data collected, produced and published (as National Statistics) by PHE are used by NHS England to set objectives for, and the performance management of, Gram-negative bloodstream infection, CDI and MRSA bacteraemia incidence rates.

As such, there is the potential for the introduction of bias into the statistics, as one of the organisation types who are subject to targets (acute trusts) are responsible for reporting infection numbers to PHE. Therefore, there could be a potential conflict between the use of statistics for both epidemiology/public health and for performance management.

Speculation of potential 'gaming' in NHS acute trusts, through the empirical treatment of suspected cases of CDI or MRSA bacteraemia without seeking microbiological confirmation of the diagnosis (whereby cases are only reportable to the surveillance scheme if they are laboratory confirmed) led PHE to investigate whether there was any evidence to corroborate such concerns.

A separate data set, (the Quarterly Mandatory Laboratory Returns) which includes the numbers of *C. difficile* toxin tests performed by laboratories in England between 2008 and 2013, was queried to ascertain if there were any changes in the testing of *C. difficile* toxin over a 6 year period in England. In brief, while there has been an overall decline in the count and rate of *C. difficile* toxin testing in England over this time period, there has been a much greater decline in the count and rate of CDI, with a much higher ratio of toxin tests performed per case of CDI identified in 2013 than in 2008, leading to the conclusion that there is little evidence of large-scale changes in testing practices over time and that 'gaming' by NHS acute trusts to avoid exceeding CDI objectives and

incurring financial penalties, has not been a major factor in the reduction of CDI in England.¹⁰

Furthermore, the number of deaths involving CDI or MRSA in England, where MRSA or CDI were mentioned on death certification – a data source not related to the mandatory surveillance scheme - have decreased in recent years¹¹, providing further confidence in the trends reported in HCAI Official Statistics as they are borne-out in other data sources.

Finally, data provided in Routine comparison/quality assurance of HCAI DCS data with voluntary laboratory surveillance data, comparing the mandatory NHS acute trust reported data with voluntary laboratory reported data indicates that the mandatory surveillance scheme, from which Official Statistics are produced, is capturing cases in a similar order of magnitude to the voluntary scheme and overarching trends overtime between the 2 datasets are conserved.

Together, these alternative data sources provide us with confidence in the reliability of the data.

Strengths and weaknesses

The mandatory surveillance scheme has several strengths; the surveillance is at patient-level and in real-time, including both risk factor data and information on both date of positive specimen and date of inpatient admissions which allow for timing of detection to be ascertained. These enhanced data provide a platform to identify potential interventional targets, which could not be garnered from other surveillance schemes in place in England.

In addition, the surveillance scheme is a census of all microbiologically confirmed episodes of bacteraemias and CDI, which provides up to 3%¹² greater ascertainment than comparative voluntary surveillance schemes (see Routine comparison/quality assurance of HCAI DCS data with voluntary laboratory surveillance data). Such rich surveillance is unrivalled across much of the world. The structured nature of the

¹⁰ Gerver et al., 2015. *Clostridium difficile* toxin testing by National Health Service (NHS) acute Trusts in England: 2008-2013.

Clinical Microbiology and Infection 21(9):850. Accessed via:

<http://www.sciencedirect.com/science/article/pii/S1198743X15004243>

¹¹ Deaths Involving *Clostridium difficile*, England and Wales: 2012

<https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsinvolvingclostridiumdifficileenglandandwales/2013-08-22>

¹² Excluding CDI cases, due to issues with voluntary surveillance described in **Error! Reference source not found.**

surveillance scheme provides for robust local and national data, with the potential for benchmarking of the data and comparison within organisations and regions over time.

Well-completed patient identifiers allow for the utilisation of other data sources through direct linkage, allowing for a fuller dataset without duplication of effort in the resource-restricted NHS. For example, data can be linked from the mandatory surveillance scheme with data from the voluntary laboratory reports to access antimicrobial susceptibility information, or to Hospital Episode Statistics for comorbidity information or prior healthcare interactions.

Live reporting from the HCAI DCS, for registered users, is available, covering the statistics and other tabulations/graphical representations of these data as well. While regular pre-defined statistical publications provide the timely reporting of data, with extensive stratification of the data by organisation type and time periods on a website accessible to both healthcare professionals and the general public.

However, even with the ability to link the mandatory surveillance data with other datasets, the completion of the data return takes time and in the resource-restricted NHS, this leads to variable field completion for the non-mandatory fields, which in turn restricts what the data can be used for. In addition, there is the potential conflict between the use of these data for epidemiological purposes by PHE and performance management/audit by others. While the effect on data validity is not currently of great concern, as discussed in Mandatory HCAI Surveillance Data in NHS performance management, the emphasis on performance management surrounding reductions in MRSA bacteraemia and CDI could lead to an emphasis on the infection prevention and control of these infections over others and, as we know, that interventions developed to tackle MRSA bacteraemia and CDI have not had a similarly reductive impact on other healthcare associated infections.

Comparison with devolved administrations

There are several differences between the English mandatory HCAI surveillance scheme and the surveillance undertaken by the devolved administrations. These include case definitions/protocols for diagnosing the infections, definitions re: inpatient episode vs. trust apportioned/assigned episodes, age groups included in the surveillance schemes and the way in which data are presented (i.e. time periods provided).

Ignoring differences in the case definitions used for the surveillance schemes, the population sizes of the devolved administrations are quite different to England; therefore, crude counts of infections cannot be compared between countries in the United Kingdom. Furthermore, as the population demographics between the devolved administrations differ, as do the denominators used to calculate any infection rates,

these are also not directly comparable. Therefore, the data provided in the published reports from Public Health Agency Northern Ireland, Public Health Wales and Health Protection Scotland are not directly comparable with the data published by Public Health England. Data on healthcare associated infections from the devolved administrations can be found using the following web links:

Wales: <http://www.wales.nhs.uk/sites3/home.cfm?orgid=379>

Northern Ireland: <https://www.publichealth.hscni.net/directorate-public-health/health-protection/healthcare-associated-infections-antimicrobial-resistanc>

Scotland: <https://www.hps.scot.nhs.uk/data/healthcare-associated-infection-quarterly-epidemiological-commentary/>

Comparability over time

MRSA bacteraemia

Although data are comparable over time, and can be displayed as a time series there have been 2 recent changes to the published MRSA bacteraemia outputs:

NHS England adopted a 'zero tolerance' approach to MRSA bacteraemias in April 2013. In parallel all organisations reporting an MRSA bacteraemia were required to undertake a Post Infection Review (PIR) (outlined in the PIR toolkit¹³ and History). The way in which MRSA bacteraemia data was published was subsequently changed to incorporate the PIR outcome (ie 'assignment'). This has resulted in changes to how MRSA bacteraemia data is presented in routine outputs. Attempts have; however, been made to retain published data trends through the continued inclusion of historical data series (trust apportioned cases) in parallel with the new methodologies (trust assigned cases) until the new time series is well established. This approach has been taken in both the QEC and AEC.

In April 2014, the PIR process was amended, to include the additional assignment option of 'Third Party'. This option encompasses cases where the case was deemed intractable or the patient received care at another facility and it was at this other facility where there were learning outcomes identified (see PIR toolkit and History for further detail). This has meant that there have been further breaks in the MRSA bacteraemia time series. As such, we present trust

¹³ Guidance on the reporting and monitoring arrangements and post infection review process for MRSA bloodstream infections from April 2014 (version 2) <https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2014/02/post-inf-guidance2.pdf>

assigned data for financial year 2013/14 separately to trust assigned data from financial year 2014/15 onwards, as the options for assignment were not identical.

In April 2018, the PIR process was further amended¹⁴ and ceased to be part of the national surveillance as performed by PHE. Instead, the PIR process is performed locally and only among trusts with the highest rates of MRSA infection.

In 2019, responding to improved understanding of the phylogeny of *S. aureus*, the surveillance was changed so that *S. aureus* was a complex consisting of *S. aureus*, *S. schweizeri* and *S. argenteus*.

CDI

A change in the guidance on the laboratory testing algorithm for *C. difficile* detection in 2012 may have had an effect on the CDI time series. Based upon an NHS Centre for Evidence Based Purchasing report in 2009.¹⁵

The DH commissioned a study to review the effectiveness of many test kits available to detect *C. difficile* toxin in order to identify the combination of tests which produced the most reliable results. Based on these results, a 2-stage testing algorithm¹⁶ has been recommended. The DH has estimated, that if all acute trusts had adopted the new testing algorithm compared to the single test algorithm between October 2010-September 2011, then a 17% reduction in the total number of CDI episodes would have been expected.¹⁷

Therefore, it is likely that a small proportion of the reduction in CDI seen in England between 2010 and 2012 may be due to the gradual change in laboratory testing from the former testing algorithm to the more accurate 2-stage algorithm. However, it is worth noting that any potential reduction caused by this change in testing, will have only occurred once (ie at a single time point) for each reporting.

¹⁴ Update on the reporting and monitoring arrangements and post-infection review process for MRSA bloodstream infections https://improvement.nhs.uk/documents/2512/MRSA_post_infection_review_2018_changes.pdf

¹⁵ *Clostridium difficile* toxin detection assays CEP08054

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216192/dh_127743.pdf

¹⁶ Guidance on the reporting and monitoring arrangements and post infection review process for MRSA bloodstream infections from April 2014 (version 2) <https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2014/02/post-inf-guidance2.pdf>

¹⁷ Updates Guidance on the Diagnosis and Reporting of Clostridium Difficile.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215135/dh_133016.pdf

Data collection and associated quality assurance

The administrative data source used for collection of the data included in all the mandatory HCAI surveillance outputs is the HCAI DCS. This is a real-time web-enabled system that facilitates the collection of all mandatory HCAI surveillance data from NHS acute trusts. The HCAI DCS is managed by the Healthcare Associated Infection & Antimicrobial Resistance (HCAI & AMR) division at PHE. The HCAI & AMR division are also responsible for the production of the mandatory surveillance outputs.

NHS acute trusts are required to report all episodes of MRSA bacteraemia, MSSA bacteraemia, *E. coli* bacteraemia, *Klebsiella* spp. bacteraemia, *P. aeruginosa* bacteraemia and CDI that test positive within their trust laboratories and fulfil associated case definitions to the HCAI DCS. Further organism specific requirements for the submission of cases can be found in the [Mandatory HCAI Surveillance Protocol](#).

Quality Assurance of the HCAI Data Capture System

The HCAI DCS has been assessed in line with the Risk/Profile matrix included in the UKSA 'Administrative Data Quality Assurance Toolkit'¹⁸ and has been judged as follows:

- high risk of data quality concerns due to complex data collection processes that are hard to independently verify
- high public interest profile as the data represents an important public health issue that has historically received substantial media coverage

Such an assessment/judgement demands assurances across a variety of practice areas. The assurances currently in place are believed to ensure that the quality of information held on the HCAI DCS is sufficient for the production of the Official Statistic outputs relating to mandatory HCAI surveillance.

Practice area 1: Operational context and administrative data collection

The following assurances are in place across this practice area:

¹⁸ Administrative Data Quality Assurance Toolkit https://www.statisticsauthority.gov.uk/wp-content/uploads/2015/12/images-qualityassurancetoolki_tcm97-44368.pdf

As outlined above there is a protocol in place for the organisms covered by Mandatory HCAI Surveillance. This protocol spells out in detail the exact processes/requirements for data suppliers (NHS acute trusts) in terms of data provision/transfer from NHS acute trusts to PHE (HCAI DCS).

The mandatory HCAI surveillance protocol provides background on both the surveillance processes and the mechanism employed for data collection (HCAI DCS). Details of exactly what should be reported (surveillance inclusion criteria, core data set etc.) are also provided for each organism under surveillance. Information on monthly reporting deadlines (as outlined in Timeliness) is also provided.

The HCAI DCS is also supplemented by a complete and comprehensive set of user guides. These guides provide system users with detailed information on all aspects of the system: <https://hcaidcs.phe.org.uk/WebPages/InternalContentPage.aspx>

All infection episodes are entered onto the HCAI DCS by the NHS acute trust responsible for testing the specimen. Acute trust CEOs are required to sign off the infection data across all 6 infections collected via the HCAI DCS on the 15th of each month (see Monthly data tables for further detail). CEO sign off constitutes formal agreement/assurance that a given month of data is complete and correct. Acute trust CEO sign off is as mandated by the Chief Medical Officer (CMO) June 2005: NHS acute trusts that have failed to sign off their data for 3 or more months in a row are highlighted in all published data tables. The public reporting of organisations that repeatedly fail to sign off serves the dual purpose of increasing awareness of potential data quality issues and of highlighting those organisations that are failing to adhere to their mandatory responsibilities. Further information on this process is provided in the relevant data tables and their associated caveats.

Routine comparison/quality assurance of HCAI DCS data with voluntary laboratory surveillance data details the routine comparisons that are undertaken between data collected on the HCAI DCS and that collected via the voluntary surveillance system (Second Generation Surveillance System). This routine audit not only enables us to assess the completeness of the mandatory datasets but also enables us to identify/investigate any differences that may exist in terms of the collection/recording of data by region/geography, age, sex etc.

Accuracy and reliability provides a detailed investigation/assessment of the accuracy/quality of surveillance data reported via the HCAI DCS. This section includes assessment of potential sources of bias and error as well as discussion on the impact that NHS performance management may have on reported data

Practice area 2: Communication with data supply partners

The following assurances have been implemented across this practice area:

There are established/maintained collaborative relationships in place between PHE and NHS acute trusts (data suppliers). These are maintained via regional PHE colleagues.

PHE also routinely gauge the extent of interest from NHS colleagues in attending the quarterly Mandatory HCAI Surveillance National Stakeholder Engagement Forum (outlined in User satisfaction). If there is found to be significant interest in attending such a forum an event specifically for NHS colleagues will be convened.

The HCAI DCS includes a facility for direct communication with system users. This enables news items and other announcements/areas of interest to be communicated to system users on an ad-hoc basis as/when required.

The PHE mandatory surveillance team routinely uses Granicus (formerly GovDelivery) to deliver relevant communications to specific/targeted user/stakeholder groups. Use of this methodology ensures the timely dissemination of information whenever required.

As outlined above there is a protocol in place for the organisms covered by Mandatory HCAI Surveillance. This protocol spells out in detail the roles and responsibilities of NHS acute trusts as data suppliers. It also includes detail on the process of data supply/transfer from reporting NHS organisations to the PHE-managed HCAI DCS as well as associated sign off requirements. The underlying requirements are as mandated by the CMO. More detailed information on the various CMO mandates for undertaking mandatory HCAI surveillance can be found in History

Organisationally PHE has a published 'Official Statistics Corrections and Revisions Policy':

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/383416/PHE_Revisions_and_Corrections_Policy_V01.00_Nov14.pdf

This is supplemented by a 'Data Specific Revisions and Corrections Policy' which provides additional information relating specifically to mandatory HCAI surveillance:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/509316/HCAI_Mandatory_Surveillance_Data_Specific_Revisions_and_Corrections_Policy_March_2016.pdf

This additional guidance accounts for the nuances of the real time surveillance undertaken by the HCAI DCS. It also provides information/signposts for how data suppliers can request/undertake an update to reported information.

The HCAI DCS adheres to PHE requirements for security and confidentiality. These arrangements are documented in detail in Confidentiality and disclosure control

NB: The PHE mandatory surveillance team is responsible for both the administration of the HCAI DCS and for the publication of the various outputs. This means that there is significant overlap between the QA steps/assurances undertaken taken in terms of both the administrative source (HCAI DCS) and the published outputs.

Practice area 3: QA principles, standards and checks applied by data suppliers

The following assurances are in place across this practice area:

The Mandatory HCAI Surveillance Protocol provides information on data collected via the HCAI DCS. This is the definitive data entry guide for data providers (NHS acute trusts) and helps to ensure that all organisations are adhering to a well-defined and exhaustive set of definitions. Furthermore, certain fields/options are only triggered when a certain response to a previous question is given. By linking questions in this manner data quality is ensured – it is not possible for reporting organisations to input/save inconsistent information. Further information on all data items collected and the linkage/triggering of subsequent questions can be found in appendix 1 of the [Mandatory HCAI Surveillance Protocol](#).

Mandatory HCAI Surveillance Data in NHS performance management provides discussion on the potential impact that the application of these data for performance management purposes may have on reporting.

Routine comparison/quality assurance of HCAI DCS data with voluntary laboratory surveillance data outlines the routine comparisons undertaken between HCAI DCS data and data collected via the voluntary surveillance system (SGSS) for FY 2018/19. This routine audit enables assessment of the completeness of the mandatory datasets.

Practice area 4: Producer's QA investigations and documentation

The following assurances are in place across this practice area:

Routine comparisons between HCAI DCS data and data collected via the voluntary laboratory surveillance system (SGSS) are undertaken. This has previously been outlined/discussed under practice area 3. Further detail can be found in Routine comparison/quality assurance of HCAI DCS data with voluntary laboratory surveillance data.

Assessment on the impact of the use of these data for performance management purposes may have on reporting has been undertaken (previously outlined under

practice area 3). Further detail can be found in Mandatory HCAI Surveillance Data in NHS performance management

Strengths and weaknesses provides an overview of the major strengths and weaknesses of the data and of the associated administrative data source (HCAI DCS). This includes detail on the issues inherent in the use of the data for published statistics/data outputs.

Cost and burden

Cost

All mandatory HCAI Surveillance Outputs are produced from data collected via the HCAI DCS. Data collected via this system are primarily for epidemiological purposes.

The Official Statistics outputs are by-products of this process and as such incur very little in the way of additional cost.

In terms of the overall data collection process PHE are obliged to submit information on the burden of assessment to the NHS Digital Challenging Burden Service (CBS). The CBS assesses burden and provides associated recommendations to minimise burden.

Further information on CBS can be found on the [NHS Digital website](#).

Burden

The HCAI DCS was relaunched in October 2015. Several changes/improvements have been incorporated to reduce the burden placed upon data suppliers (NHS acute trusts).

Recent improvements/developments include:

The addition of a data upload wizard which enables data providers to batch upload infection data. Historically information had to be manually entered on a case-by-case basis. Further details on the data upload process is available in the associated user guide:

https://hcaidcs.phe.org.uk/ContentManagement/LinksAndAnnouncements/HCAIDCS_Data_Upload_Wizard_UserGuide_v4.0.pdf

The inclusion of easily accessible organisation specific summary information via the dashboards functionality. This enables HCAI DCS system users to see their summary position at a glance. Historically it was only possible to glean this information via multiple different reports.

Further information on the various dashboards is available in the associated user guides:

Summary Dashboard:

https://hcaidcs.phe.org.uk/ContentManagement/LinksAndAnnouncements/HCAIDCS_Dashboard_Summary_Dashboard_UserGuide_V3.0.pdf

Benchmarking Dashboard:

https://hcaidcs.phe.org.uk/ContentManagement/LinksAndAnnouncements/HCAIDCS_Dashboard_Benchmarking_Dashboard_UserGuide_V2.0.pdf

Data Completeness Dashboard:

https://hcaidcs.phe.org.uk/ContentManagement/LinksAndAnnouncements/HCAIDCS_Dashboard_Data_Completeness_Dashboard_UserGuide_V2.0.pdf

Data flows have been updated to enable more fluid/intuitive data entry. By ensuring that relevant questions are only triggered as/when required by a previous response, ambiguity in data entry is mitigated. This ensures that data entry is streamlined wherever possible.

Confidentiality and disclosure control

Confidentiality and disclosure control underpins all statistical/data driven work undertaken by PHE and is governed by organisational level guidance/policies. Local policies/procedures supplement this guidance as/when necessary.

Organisational level policies/procedures

PHE has a range of organisational policies/procedures in place to ensure statistical confidentiality and to avoid the unauthorised disclosure of data/individuals:

PHE has a Personal Information Charter which sets out the standards PHE staff are required to comply with when handling personal information:

<https://www.gov.uk/government/organisations/public-health-england/about/personal-information-charter>

PHE also has well defined organisation level 'Caldicott Policy' which sets out the framework through which PHE implements the recommendations of the 'Caldicott Report on the Protection and Use of Patient Information' (1997)¹⁹. There is also an 'Information Risk Management Policy'²⁰. Both these documents are available to staff via the PHE intranet

PHE follows the 'Anonymisation Standard' devised by the NHS Digital and approved by the Information Standards Board, which provides a standard approach and a set of tools to anonymise information to ensure that, as far as it is reasonably practicable, information published does not identify individuals. This standard is a statutory requirement for all public bodies publishing health and social care data²¹

PHE has adopted an internal Standard Operating Procedure for disclosure control which is consistent with the GSS disclosure control policy²²

All PHE staff, including temporary and contract staff, with access to personal or confidential information are required to complete mandatory, information governance

¹⁹ The Caldicott Committee Report on the Review of Patient-Identifiable Information

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4068404.pdf

²⁰ Information Risk Management Policy

<http://phenet.phe.gov.uk/Policies-and-Procedures/Policy%20Documents/Information%20risk%20management%20policy.pdf>

²¹ Anonymisation Standard for Publishing Health and Social Care Data Specification

<http://content.digital.nhs.uk/media/18876/1523202010spec/pdf/1523202010spec.pdf>

²² Disclosure control policy for tables

<http://www.ons.gov.uk/ons/guide-method/best-practice/disclosure-control-policy-for-tables/index.html>

training upon recruitment and then every year thereafter. This training gives guidance to staff on how to protect and share information safely and appropriately

PHE terms and conditions of employment include confidentiality clauses which apply to those staff employed on PHE terms and conditions. Similar clauses are included in the contracts of those staff employed on NHS contracts

Mandatory HCAI surveillance output level policies/processes

As well as the previously outlined organisational level policies/procedures. There are a number of processes undertaken at the output level to ensure confidentiality and disclosure control:

All mandatory HCAI Surveillance data is collected and processed in accordance with the Data Protection Act (1998)²³. Patient level data is not published.

Disclosure control methods are always adhered to ; published statistics are tabular outputs, which are always at an aggregate level (ie tabulation by acute trust or Clinical Commissioning Groups or larger geographies) meaning that the risk of disclosure is extremely low.

All published outputs take into account the need to protect patient confidentiality whilst At the same time ensuring that there is public access to official data and that it meets requirements to assist the Secretary of State to undertake their function in relation to the health service; in accordance with the Statistics and Registration Service Act 2007 s42.²⁴

HCAI DCS system specific policies/controls

The HCAI DCS applies a strong password policy to user passwords as well as ensuring that users of the system only have access to information relevant to their roles.

All PHE computers are connected to a local area network that is protected by firewalls operating to accepted NHS standards, and are protected by PHE standard anti-virus software.

Unauthorised access to the HCAI DCS will be prevented as the access to the networked drive and data on the PHE server, is controlled through a centralised directory at organisational level.

Access to the database is controlled through username and passwords issued to identified and authorised users. Passwords are encrypted and follow the guidelines for using and handling passwords as set out in the Centre for Protection of National Infrastructure (CPNI) Password

²³ Data Protection Act 1998

<http://www.legislation.gov.uk/ukpga/1998/29/contents>

²⁴ Statistics and Registration Service Act 2007

<http://www.legislation.gov.uk/ukpga/2007/18/contents>

Guidance²⁵. The user is required to configure 3 security questions as part of the registration process:

- access to patient level data within the application, with or without Patient Identifiable Information (PII), is restricted based on the organisational hierarchy.
- national users have access to patient level data for all cases entered on the system (full or pseudo-anonymised depending on organisation)
- sub-national users (CCGS, NHS Local Offices, PHE Centres etc.) have patient level access for cases mapped to their organisation
- NHS acute trusts only have patient level access to the specific records that they entered
- system administrators have access to PII for routine administrative work.
- access to these PII is granted on a need to know basis as identified by the System Owner and would include NHS number, forename, initials, Soundex and date of birth

Further information on roles and permissions can be found in the '[Overview of Roles and Permissions](#)' user guide.

No PII is transmitted beyond PHE secure networks by PHE staff. Standard Operating Procedures are in place regarding dissemination of data from the system to ensure data are aggregate only with all PII removed prior to transmission beyond PHE. Exceptions must be signed off by the Director of the Centre or Division to which the data transfer applies and, where necessary, the Director will be responsible for ensuring appropriate legal advice and guidance is sought.

External support colleagues will have access to anonymised data only, contained in a separate support environment.

HCAI DCS backups are held in secure offline locations to which access is restricted. Backups are never held on the live system and are encrypted. HCAI DCS data is stored in a secure GIS approved location. All data is suitably encrypted using appropriate algorithms. When the database is no longer required the storage is released back to the ICT Storage Team for reuse within the storage system. All physical IT infrastructure is disposed of in line with agreed PHE procedures. Backup tapes are disposed of by the Storage/Networking and Security teams in line with their procedures.

²⁵ Centre for the Protection on National Infrastructure - Password Guidance

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/458857/Password_guidance_-_simplifying_your_approach.pdf

Appendix 1: Current mandatory HCAI surveillance outputs

Monthly counts of cases

Monthly counts by NHS acute trust and Clinical Commissioning Group (CCG), published as .ods and .xlsx documents on a monthly basis.

Monthly data tables include data for a rolling 13-month period and provide MRSA bacteraemia, CDI, MSSA bacteraemia and *E. coli* bacteraemia, *Klebsiella* spp. bacteraemia and *P. aeruginosa* bacteraemia counts by both acute trust and by Clinical Commissioning Group.

Bacteraemia caused by MRSA, MSSA, *E. coli*, *Klebsiella* spp. or *P. aeruginosa*

Counts of cases by onset status and prior trust exposure, for trusts and CCGs

MRSA: <https://www.gov.uk/government/statistics/mrsa-bacteraemia-monthly-data-by-attributed-clinical-commissioning-group>

MSSA: <https://www.gov.uk/government/statistics/mssa-bacteraemia-monthly-data-by-attributed-clinical-commissioning-group>

<https://www.gov.uk/government/statistics/escherichia-coli-e-coli-bacteraemia-monthly-data-by-attributed-clinical-commissioning-group>

Klebsiella spp.: <https://www.gov.uk/government/statistics/klebsiella-species-bacteraemia-monthly-data-split-by-location-of-onset-by-ccg>

P. aeruginosa: <https://www.gov.uk/government/statistics/p-aeruginosa-bacteraemia-monthly-data-split-by-location-of-onset-by-ccg>

C. difficile infection

Counts of cases by prior trust exposure, for acute trusts and CCGs:

<https://www.gov.uk/government/statistics/clostridium-difficile-infection-monthly-data-by-attributed-clinical-commissioning-group>

Quarterly Epidemiological Commentary

Provides national aggregated counts and rates of cases by financial year quarter for MRSA, MSSA, *E. coli*, *Klebsiella* spp., *P. aeruginosa* and CDI.

<https://www.gov.uk/government/statistics/mrsa-mssa-and-e-coli-bacteraemia-and-c-difficile-infection-quarterly-epidemiological-commentary>

Annual outputs

Annual counts and rates of cases are reported by acute trust and CCG. These are accompanied by an epidemiological commentary detailing trends in rates, by age, sex and region as well as infographics and short summaries per organism.

Appendix 2: Patient and laboratory information used for the matching process

Cases bacteraemia reported to the voluntary surveillance scheme (via SGSS) and the mandatory surveillance scheme (via HCAI DCS) were identified based on the following ordered steps:

1. NHS number, Date of Birth (DoB)
2. NHS number
3. Hospital number, DoB, Soundex
4. Hospital number
5. Specimen number, Laboratory Code, DoB, Soundex, sex, forename initial
6. Specimen number, Laboratory Code, sex, forename initial
7. Specimen number, DoB and forename initial or Soundex
8. Specimen number, DoB
9. Specimen number, Fuzzy DoB²⁶, forename initial or Soundex

Subsequently, matching episodes²⁷ were identified were an episode from the same patient was identified in both SGSS and HCAI DCSw

²⁶ The fuzzy matching of DOB is an NHS Digital accepted method of matching records to account for subtle differences in the records that would originate from a data entry error. It assumes that the records belong to the same patient if only 1 component (ie day, month or year) of the date of birth is different, while all other parts of the DOB and the NHS no. are the same

²⁷ Specimen dates ± 14 days were used as an episode of bacteraemia is defined as 14 days