Public Health England

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English Surveillance Programme for Antimicrobial Utilisation and Resistance (ESPAUR): Validation protocol for NHS Acute Trust Antimicrobial Consumption Data

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339

Contents

Executive summary

Antimicrobial resistance (AMR) occurs when microbes, such as bacteria, change in ways that render the medications used to cure the infections they cause ineffective. This is a major concern because a resistant infection may kill, and imposes huge costs to individuals and society.

It is important to measure the extent of antibiotic use since AMR is facilitated by the use of antibiotics. Currently, data on antibiotics dispensed by NHS Acute Trust pharmacies are collected by two independent companies. This protocol aims to determine the accuracy of the reported data held in these systems and the main reasons for discrepancies identified.

Worksheets will be sent by PHE to a nominated contact in Acute Trusts. Each Trust will be requested to review locally held data and summarise reasons for discrepancies identified. Each Trust is allocated a time period to analyse their data and return to PHE.

Completion of this data forms part of NHS-England quality premium for Clinical Commissioning Groups. PHE will publish details of the Acute Trusts who have completed the validation work in April 2016.

The aims of this protocol are:

- to validate antimicrobial consumption data and develop a standardised reporting output for Acute NHS Trusts in England
- to determine which antibiotics can be accurately measured using current surveillance systems
- to utilise this data to improve the information systems currently in operation
- to utilise this data to determine antibiotic quality measures for each Acute NHS Trust

Introduction

The development of antimicrobial resistance (AMR) is linked to antimicrobial use; responsible use is therefore pivotal to reduce the threat of AMR (Goossens 2009; Moreira et al.2013). The clinical, economic and public health implications of antimicrobial resistance present a major threat to future healthcare.

In 2014, data for antibiotic consumption in hospitals and primary care in England was published by the English Surveillance Programme for Antimicrobial Utilisation and Resistance (ESPAUR) for the first time. This report highlighted that from 2010 to 2013, there was considerable variability in both antibiotic resistance and antibiotic prescribing across England. Furthermore, areas of high antimicrobial prescribing were frequently associated with relatively high levels of resistance.

Rx-info and IMS Health are commercial organisations specialising in the provision of information, services and technology for the healthcare industry including the NHS. IMS Health provided the secondary care antibiotic consumption data for the ESPAUR report. Both IMS Health and Rx-info have in-house quality assurance processes; however the datasets have not been externally validated.

NHS England included validation of Acute Trust prescribing data as part of the antimicrobial quality premium for clinical commissioning groups in the 2015/16 financial year. Acute NHS Trusts are asked to validate their antibiotic prescribing data using this Public Health England (PHE) validation protocol. PHE will publish details of the Acute Trusts who have validated the data in April 2016.

Validation studies of national surveillance systems are rarely performed because of cost and methodological difficulties (Fabry et al. 2007). In England, The UK Clinical Pharmacy Association Pharmacy Infection Network completed a proof of concept research project concerning the validation of antibiotic consumption data in a small number of Acute hospital Trusts in England. This work identified discrepancies between the datasets held by IMS Health, Rx-Info and Trust Pharmacy Systems (FIS Conference 2013 and 2014). Data specifically relating to pre-packed antibiotics and manufacturing units contributed to some of the variations.

The aims of this protocol are

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Methods

An Excel file containing five spreadsheets specific to each Trust will be sent by email to a nominated person within each organisation. Ideally this will be the antimicrobial or lead pharmacist.
A description of the contents of each of worksheets A to E is as follows:

A. **Total breakdown**: Contains a breakdown of **1st April 2013 to 31st March 2014** consumption data (inpatient plus outpatient) for a selected group of antibiotics. Each line splits each antibiotic into the drug molecule, strength, formulation and pack size. The respective quantity as processed by IMS Health is entered into column B. See appendix 1 for a worked example of these variables. Trust data are to be entered into column C.

B. **Inpatient breakdown**: Contains a breakdown of consumption data for selected antibiotics dispensed only for hospital inpatients (see 'data entry' below) **for the financial year 2013/14**. This details the molecule, the strength, the formulation, the pack size and formulation for each antibiotic for total inpatient dispensing for the Trust. Trust data is to be entered into column C.

C. **Raw data**: Each organisation is requested to insert their raw antibiotic data for the 2013/14 financial year into this worksheet. Data should be extracted from the Trust pharmacy system. These data should not be manipulated in anyway. Trusts should simply provide an Excel download of data for items dispensed from section 5.1 of the BNF.

D. **Trust DDD calculator**: This worksheet is provided to Trusts so that they can return translation table(s) or calculators to PHE. This does not necessarily have to be for the selected antibiotics. It is possible the Trust does not use any such calculation tables, if this is the case; this sheet is to be left blank. If the calculator is not in Excel format, it should be emailed to espaur@phe.gov.uk as an additional attachment, along with the validation worksheets.

E. **Summary**: Trusts do not need to enter any data here. This is for Trust information and use only. It contains a summary of total antibiotic use and consumption. Antibiotic data is expressed as Defined Daily Dose (DDD)[1] for financial years 2011/12, 2012/13 and 2013/14 and DDD/100 admissions [2] for 2013/14. The consumption data has been provided by IMS Health and admissions data extracted from Hospital Episode Statistics (HES) database for the 2013/14 financial year.

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[1] The ATC/DDD system is as a tool for presenting drug utilization statistics with the aim of improving drug use: http://www.whocc.no/use_of_atc_ddd/

[2] The use of admission rather than bed-day denominator was favoured to reflect hospital activity. This is consistent with the 2014 ESPAUR report which will allow hospitals to compare their data with the published data in the ESPAUR report: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/362374/ESPAUR_Report_2014__3_.pdf

Data entry

The different definitions for data entry are as follows:

- **total use:** Defined as all cost centres currently in use within the Trust (including accident and emergency, Acute clinical units, urgent care centres etc.). NOTE: Issues from franchised units to cost centres in the Trust *are* to be included unless this data is _**not**_ reported by IMS Health. NOTE: Issues to other organisations, manufacturing units and between pharmacy stores must be excluded. See FAQ for more information

- **in-patient use:** Defined as items dispensed as ward stock (including theatre and day units), in-patient supply, one-stop dispensing and TTA supply only. A&E is _**not**_ included in this section

All data entered must be provided as unit packs dispensed. For example, the number of packs or bottles of liquid. Some pharmacy systems may report these data as individual units dispensed (eg number of individual capsules). Such data must be converted into dispensed packs before submission. **See appendix 1 for a worked example.**

There may be more than one entry for what appears to be the same strength and pack size of a drug. This occurs when different brands of the same product are used within a Trust. If the Trust system does not split use in this way, simply enter the data into a relevant row as it appears from the Trust system. PHE analysis will account for these apparent discrepancies. See appendix 1 for a worked example.

Please note that the data submitted should be extracted directly from the Trust's pharmacy system and should be independent to that used for submission to or obtained from other data bases (such as IMS Health, Rx-info).

Where Trust data shows the use of one or more of the selected antibiotics but it has not been reported by the IMS Health, please make an entry at the end of the relevant spreadsheet.

Table 1: The antibiotics that will be validated are

Amikacin	Amoxicillin
Amoxicllin / clavulanic acid	Cephalosporins (BNF section 5.1.2.1)
Ciprofloxacin	Clarithromycin
Clindamycin	Daptomycin
Doxycycline	Ertapenem
Erythromycin	Flucloxacillin
Gentamicin	Imipenem with cilastatin
Levofloxacin	Linezolid
Meropenem	Moxifloxacin
Nitrofurantoin	Ofloxacin
Penicillin G	Penicillin V
Piperacillin / tazobactam	Teicoplanin
Temocillin	Tigecycline
Trimethoprim	Vancomycin

Exclusions to data provided - The following data must be excluded from any consumption data that each Trust reports. See FAQ for more information.

- antibiotics dispensed to manufacturing units and between one pharmacy store and another
- antibiotics dispensed to other Trusts and hospitals that would stock take independently at patient or ward level dispensing

Validation process / Next steps

Analysis

Data submitted by each Trust will be formally analysed and compared against that acquired from the IMS Health and Rx-info databases.

Sign off of validation completion

Column D will automatically determine the percentage discrepancy between Trust and IMS data. Column E (comments) in worksheets A and B must be used to explain discrepancies between Trust and IMS data. Trusts will be expected to have completed reasonable investigations to explain reasons for a discrepancy of 3% or greater for each strength and formulation of drug. If there the reason for the discrepancy cannot be identified, the Trust should enter 'reason for discrepancy unknown' into the relevant cell in column E. **See appendix 1 for a worked example.**

Ethical approval and permissions

The data used has been provided to Public Health England by IMS Health; 99% of hospitals in England contribute to the IMS dataset. As part of the development of the ESPAUR programme, all Acute NHS Trusts in England have given permission for PHE to access the data held by both IMS Health and Rx Info (Define®) for the purpose of data validation.

No patient identifiable data is included.

Frequently Asked Questions (FAQs)

1. **How do I get the data you are asking for?**
Different Trusts have different IT systems. Furthermore these systems may be configured differently. If you do not know how to get the required data from your system, please contact the technical help desk of the manufacturer of your specific pharmacy IT system. They will guide you through the process of data extraction. For example:

   For JAC call 01268416348 (select option 1)
   For Ascribe call 08451232297 (select option 2)

2. **When do I need to return my data to you?**
There is a set timetable for all Acute Trusts in England set out in appendix 2; data must be returned by the date specified there. This excludes those Acute Trusts who have returned their data as part of the pilot validation process.

3. **How can a CCG know what dates the Trusts that we commission services from should return their data?**
If you are a commissioner of services, the timetable in appendix 2 outlines when Acute Trusts should return their data. If you wish to know if a specific Trust has returned data in an appropriate timeframe, please email ESPAUR@phe.gov.uk with 'validation protocol' in the subject heading. We ask that you allow at least four weeks after the expected data return date to request more information.

4. **I would like to validate my data but I do not have the resources to dedicate to this project.**
Validation of antimicrobial prescribing data in acute Trusts forms part of the NHS 2015-16 quality premium with CCGs. Acute Trusts should discuss resources with their commissioners. However, Trusts may be incentivized to reduce their antibacterial consumption in 2016-17, and accurate data validation will support this activity. Accurate baseline data is essential and Trusts are encouraged to take this opportunity to validate their data.

5. **How long will it take me to obtain and submit my own data?**
During the pilot validation process we have found that the time taken has varied considerably between one organisation and another. We suggest that it should take between 4-7 hours in total. Approximately 2-3 hours for an individual to extract the relevant data from the pharmacy system and between 2 and 4 hours to manipulate and enter the data into the validation worksheets. If you think it will take considerably longer than this, we suggest you contact the manufacturer of your pharmacy IT system for guidance (see FAQ 1). We anticipate this will reduce the time you will need to spend on data extraction.

6. When I enter my own data, do I enter the number of individual doses or packs?

The feedback we have received to date suggests that it is more convenient to enter the data as *whole packs*. For this reason we request that data is entered as packs dispensed *not* individual units. See appendix 1 for a worked example.

7. Why exclude data relating to manufacturing units and stock transfers between pharmacy stores?

In our provisional validation work we found that the transfer of medication to and from manufacturing units or between pharmacy stores can result in 'double counting'. For this exercise we are concerned only with the consumption of medication ie that which is supplied to patients. We therefore ask that data between pharmacy stores or manufacturing units are not included in your analysis.

8. How should I report returned or expired stock?

Stock that has either been returned or expired should be subtracted from the total. In general your pharmacy system will count these transactions as negative values and will effectively do this calculation for you.

9. Why have you used DDD per 100 admissions rather than per 100 bed-days?

The most appropriate denominator to use for measuring antimicrobial consumption is subject to debate. The use of DDD/100 admissions as a measure of consumption is consistent with that used in the 2014 ESPAUR report and previous work by ARHAI sub-committees.

10. Why do I need to send you data in worksheets A and B if I am sending you the raw data anyway?

We are not familiar with how the different pharmacy systems report their data. By manipulating your own data into worksheets A and B (ie into a format that we can recognise) we hope to be able to work through discrepancies between the data sets. If we cannot do this by looking at the data in the worksheets we will try and understand more about your data by reviewing your raw data.

11. There appears to be more than one entry for the same product. Where do I enter my data?

IMS Health has more than one entry for apparently identical products. Below is a worked example for 100ml bottles of amoxicillin 250mg/5ml oral liquid. Here, data that has been submitted to IMS suggests 2 different brands (rows 8 and 11) of this product have been used. Where Trust data has a single entry for that product, data should be entered into one of the rows in column C and 0 in the other. In this same example, rows 13 and 15 correspond to two different brands of a sugar free formulation of this same product.

	Formulation|Strength|Pack Size	Number of packs dispensed IMS 2013/2014	Number of packs dispensed Trust 2013/2014
1			(Inpatient + outpatient)
2			
3			
5	AMOXICILLIN		
6	SACHETS SF 2 3 G		
7	SACHETS SF 3 G 2		
8	SUSP 250 MG 1 100 ML	240	341
9	SUSP PAED 125 MG 1 100 ML	7	
10	SYRUP 125 MG 1 100 ML	118	
11	SYRUP 250 MG 1 100 ML	101	0
12	SYRUP SF 125 MG 1 100 ML	75	
13	SYRUP SF 250 MG 1 100 ML	27	173
14	SUSP SF 125 MG 1 100 ML	0	
15	SUSP SF 250 MG 1 100 ML	146	0
16	VIAL 250 MG 10		

Figure 1: examples of multiple entries (FAQ no.11)

12. What if I have further questions?

Please email ESPAUR@phe.gov.uk with 'validation protocol' in the subject heading. We will endeavour to email you back within 2 working days.

References

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Moreira MR, Guimarães MP, Rodrigues AA de A, Gontijo Filho PP. Antimicrobial use, incidence, etiology and resistance patterns in bacteria causing ventilator-associated pneumonia in a clinical-surgical intensive care unit. Rev Soc Bras Med Trop. 2013 46(1):39–44.

NHS England. NHS England » The Forward View into action: Planning for 2015/16 [Internet]. 2014 [cited 2015 Jan 5]. Available from: http://www.england.nhs.uk/ourwork/forward-view/

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Fabry J, Morales I, Metzger M-H, Russell I, Gastmeier P. Quality of information: a European challenge. J Hosp Infect [Internet]. 2007 Jun [cited 2015 Jan 5];65 Suppl 2:155–8. Available from: http://www.sciencedirect.com/science/article/pii/S0195670107600358

APPENDIX 1: Worked example of data entry for validation worksheet

	A	B	C	D	E	F
1	Example NHS Trust		Inpatient Breakdown (Inpatient only			
2						
3						
4	Formulation|Strength|Pack Size	Number of packs dispensed IMS 2013/2014	Number of packs dispensed Trust 2013/2014	Calculated % difference	Comments	
5	AMIKACIN					
6	AMPS 100 MG /2ML 5 2 ML	22	22	0%		
7	VIAL 500 MG /2ML 5	44	43	-2%		
8	AMOXICILLIN					
9	CAPS 250 MG 15	4	4	0%		
10	CAPS 250 MG 21	291	503	73%	Dicrepancy possibly due to manufacture of pre-packs	
11	CAPS 500 MG 21	2688	5254	95%	Reason for discrepancy unknown	
12	SUSP 250 MG 1 100 ML	141	201	43%	Single entry for 250mg	
13	SYRUP 250 MG 1 100 ML	61	0	-100%	Single entry for 250mg	
14	SYRUP 125 MG 1 100 ML	119	115	-3%	Single entry for 125mg	
15	SUSP 125 MG 1 100 ML	2	0	-100%	Single entry for 125mg	
16	VIAL 250 MG 10	95	96.5	2%		
17	VIAL 500 MG 10	2060.3	2486.3	21%	Supply to CIVAS ?	
18	AMOXICILLIN/CLAVULANIC ACID					
19	DISPERS TABS 375 MG 21	0				

The pack size is critical to how you report your own Trust data. The feedback we have received suggests that it will be quicker and easier for Trusts to provide data in whole packs rather than individual units.

- **in the above example:** IMS Health data suggest 44 **outer boxes** containing 5 vials of amikacin 500mg/2ml were dispensed in the 2013/14 financial year. This represents 220 vials in total. The data entered into column C, in this case 43, must be in this same format. Ie number of boxes not individual vials
  row 9 shows 4 **packs** of 15 capsules of amoxicillin 250mg were dispensed
- row 14 shows 119 **bottles** of 100ml amoxicillin 125mg/5ml suspension were dispensed
- reasons for discrepancies of 3% or greater in magnitude must be investigated. The possible explanation for these differences is to be entered in the appropriate cell of column E

APPENDIX 2: Timetable for data analysis

Data will be handled in three groups. Data must be returned by the date specified in the following tables.

Group 1:

For the following Trusts, data will be provided by PHE 01 April 2015 and must be returned by 15 May 2015 via ESPAUR@phe.gov.uk Subject: AMC data validation

Aintree University Hospital NHS Foundation Trust	Countess Of Chester Hospital NHS Foundation Trust
Airedale NHS Foundation Trust	Croydon Health Services NHS Trust
Alder Hey Children's NHS Foundation Trust	Dartford And Gravesham NHS Trust
Ashford And St Peter's Hospitals NHS Foundation Trust	Derby Hospitals NHS Foundation Trust
Barking, Havering And Redbridge University Hospitals NHS Trust	Doncaster And Bassetlaw Hospitals NHS Foundation Trust
Barnet And Chase Farm Hospitals NHS Trust	Dorset County Hospital NHS Foundation Trust
Barnsley Hospital NHS Foundation Trust	Ealing Hospital NHS Trust
Barts Health NHS Trust	East Cheshire NHS Trust
Basildon And Thurrock University Hospitals NHS Foundation Trust	East Kent Hospitals University NHS Foundation Trust
Birmingham Children's Hospital NHS Foundation Trust	Frimley Park Hospital NHS Foundation Trust
Birmingham Women's NHS Foundation Trust	Gateshead Health NHS Foundation Trust
Blackpool Teaching Hospitals NHS Foundation Trust	George Eliot Hospital NHS Trust
Bolton NHS Foundation Trust	Gloucestershire Hospitals NHS Foundation Trust
Bradford Teaching Hospitals NHS Foundation Trust	Great Ormond Street Hospital For Children NHS Foundation Trust
Brighton And Sussex University Hospitals NHS Trust	Great Western Hospitals NHS Foundation Trust
Burton Hospitals NHS Foundation Trust	Guy's And St Thomas' NHS Foundation Trust
Calderdale And Huddersfield NHS Foundation Trust	Hampshire Hospitals NHS Foundation Trust
Cambridge University Hospitals NHS Foundation Trust	Harrogate And District NHS Foundation Trust
Central Manchester University Hospitals NHS Foundation Trust	Heart Of England NHS Foundation Trust
Chelsea And Westminster Hospital NHS Foundation Trust	Heatherwood And Wexham Park Hospitals NHS Foundation Trust
Chesterfield Royal Hospital NHS Foundation Trust	Homerton University Hospital NHS Foundation Trust
Colchester Hospital University NHS Foundation Trust	

Group 2:

For the following Trusts, data will be provided by PHE 01 May 2015 and must be returned by 15 June 2015 via ESPAUR@phe.gov.uk Subject: AMC data validation

Hull And East Yorkshire Hospitals NHS Trust	Northern Lincolnshire And Goole NHS Foundation Trust
Ipswich Hospital NHS Trust	Northumbria Healthcare NHS Foundation Trust
Isle Of Wight NHS Trust	Nottingham University Hospitals NHS Trust
James Paget University Hospitals NHS Foundation Trust	Oxford University Hospitals NHS Trust
Kettering General Hospital NHS Foundation Trust	Pennine Acute Hospitals NHS Trust
King's College Hospital NHS Foundation Trust	Plymouth Hospitals NHS Trust
Kingston Hospital NHS Foundation Trust	Poole Hospital NHS Foundation Trust
Lancashire Teaching Hospitals NHS Foundation Trust	Portsmouth Hospitals NHS Trust
Liverpool Heart And Chest Hospital NHS Foundation Trust	Queen Victoria Hospital NHS Foundation Trust
Liverpool Women's NHS Foundation Trust	Royal Berkshire NHS Foundation Trust
Maidstone And Tunbridge Wells NHS Trust	Royal Brompton & Harefield NHS Foundation Trust
Medway NHS Foundation Trust	Royal Devon And Exeter NHS Foundation Trust
Mid Cheshire Hospitals NHS Foundation Trust	Royal Free London NHS Foundation Trust
Mid Essex Hospital Services NHS Trust	Royal Liverpool And Broadgreen University Hospitals NHS Trust
Mid Staffordshire NHS Foundation Trust	Royal National Hospital For Rheumatic Diseases NHS Foundation Trust
Mid Yorkshire Hospitals NHS Trust	Royal National Orthopaedic Hospital NHS Trust
Milton Keynes Hospital NHS Foundation Trust	Royal Surrey County Hospital NHS Foundation Trust
Moorfields Eye Hospital NHS Foundation Trust	Royal United Hospital Bath NHS Trust
North Tees And Hartlepool NHS Foundation Trust	Salford Royal NHS Foundation Trust
North West London Hospitals NHS Trust	Salisbury NHS Foundation Trust
Northampton General Hospital NHS Trust	Sheffield Children's NHS Foundation Trust
Northern Devon Healthcare NHS Trust	

Group 3:

For the following Trusts, data will be provided by PHE 01 June2015 and must be returned by 15 July 2015 via ESPAUR@phe.gov.uk Subject: AMC data validation

Sheffield Teaching Hospitals NHS Foundation Trust	The Royal Orthopaedic Hospital NHS Foundation Trust
Shrewsbury And Telford Hospital NHS Trust	The Royal Wolverhampton NHS Trust
South Devon Healthcare NHS Foundation Trust	The Walton Centre NHS Foundation Trust
South Tees Hospitals NHS Foundation Trust	The Whittington Hospital NHS Trust
South Tyneside NHS Foundation Trust	United Lincolnshire Hospitals NHS Trust
South Warwickshire NHS Foundation Trust	University Hospital Of North Staffordshire NHS Trust
Southend University Hospital NHS Foundation Trust	University Hospital Of South Manchester NHS Foundation Trust
St Helens And Knowsley Hospitals NHS Trust	University Hospital Southampton NHS Foundation Trust
Stockport NHS Foundation Trust	University Hospitals Birmingham NHS Foundation Trust
Tameside Hospital NHS Foundation Trust	University Hospitals Bristol NHS Foundation Trust
Taunton And Somerset NHS Foundation Trust	University Hospitals Coventry And Warwickshire NHS Trust
The Christie NHS Foundation Trust	University Hospitals Of Morecambe Bay NHS Foundation Trust
The Clatterbridge Cancer Centre NHS Foundation Trust	Warrington And Halton Hospitals NHS Foundation Trust
The Dudley Group NHS Foundation Trust	West Suffolk NHS Foundation Trust
The Hillingdon Hospitals NHS Foundation Trust	Western Sussex Hospitals NHS Foundation Trust
The Newcastle Upon Tyne Hospitals NHS Foundation Trust	Weston Area Health NHS Trust
The Princess Alexandra Hospital NHS Trust	Wirral University Teaching Hospital NHS Foundation Trust
The Queen Elizabeth Hospital, King's Lynn, NHS Foundation Trust	Worcestershire Acute Hospitals NHS Trust
The Robert Jones And Agnes Hunt Orthopaedic Hospital NHS Foundation Trust	Wrightington, Wigan And Leigh NHS Foundation Trust
The Rotherham NHS Foundation Trust	Yeovil District Hospital NHS Foundation Trust
The Royal Bournemouth And Christchurch Hospitals NHS Foundation Trust	York Teaching Hospital NHS Foundation Trust
The Royal Marsden NHS Foundation Trust	