



Antimicrobial Resistance Surveillance: Sharing industry data

Post-pilot project report
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Acknowledgement

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FOREWORD

In 2016, a number of pharmaceutical companies signed the AMR Industry Declaration (January 2016)¹ and the Industry Roadmap for Progress on Combating Antimicrobial Resistance (September 2016)², which included an industry commitment to share antimicrobial resistance (AMR) surveillance data – that is, data that reveals the extent of the resistance of bacteria to antimicrobials across the world. Specifically, the pharmaceutical companies agreed to “continue to share the surveillance data we generate with public health bodies and healthcare professionals, and work with them to improve understanding of resistance trends, inform appropriate antibiotic and vaccine use and, over time, thereby help increase surveillance capabilities globally”.

There is a clear need for the public and private sectors to share the data they gather from local and global antibiotic surveillance studies: such data reveals resistance trends, and so can guide appropriate antibiotic prescription, help set up breakpoints for antibiotics, develop local antibiotic prescribing guidelines, and encourage wider innovation in this arena.

Between November 2017 and March 2018, a 90-day pilot project – funded by a grant from Wellcome through its Drug-resistant Infections programme – was led by the Open Data Institute (ODI). There was input and advice from a steering group composed of representatives from industry (GlaxoSmithKline and Pfizer), Public Health England, Longitude 174 and researchers from University College London. The project aimed to create an online portal that openly publishes human AMR surveillance data generated and collected by the pharmaceutical industry. As the project developed, it included work to understand what human industry-led AMR surveillance data is currently available and of it what is openly accessible, either as a result of being directly published by individual pharmaceutical companies or as part of a larger platform.

As this report describes, we found that there was consistent use of standardised and quality-assured methodologies for collecting and reporting AMR surveillance data across the pharmaceutical industry, and that these datasets had significant coverage – 93 countries and 85 antimicrobials – albeit with some gaps in geographical coverage, such as in sub-Saharan Africa. Displaying these programmes within a pilot portal initially demonstrated both the practicality and the utility of providing greater access to surveillance data, as well as the gaps and challenges we currently face in epidemiology and surveillance of AMR.

A workshop was held at Wellcome’s headquarters in March 2018, with attendees from across pharmaceutical and private companies, university and public health organisations. At the workshop, outcomes from the pilot study were warmly and enthusiastically received. The workshop’s recommendations, strongly supported by the attendees, included continuing the initiative’s work and considering data-sharing approaches that have proved successful in other sectors, such as in clinical trials. There is increasing recognition that solving the shared

¹ AMR Industry Alliance. AMR Industry Declaration. amrindustryalliance.org/amr-industry-alliance-declaration/ [accessed 19 July 2018]

² Industry Roadmap for Progress on Combating Antimicrobial Resistance. ifpma.org/wp-content/uploads/2018/06/Roadmap-for-Progress-on-AMR-FINAL.pdf [accessed 14 August 2018]

challenges of AMR will require collaboration and openness, in order to maximise efforts and promote innovative approaches in data sharing across all sectors.

Both Wellcome's and ODI's experience, gained from a number of open data programmes in other sectors, shows that benefits can best be realised through structured, well-defined, independently managed efforts that promote not only the publication of open data to agreed standards but also open innovation to create useful products and services, together with the use of these approaches by decision makers.

Specifically, we have identified four key actions for furthering this initiative and making industry surveillance data open.

Key action 1: Develop a public–private partnership between industry, public health organisations and other AMR initiatives to provide a more informative, coherent and openly accessible AMR data landscape.

Key action 2: Enable open innovation and data sharing within the AMR community by encouraging reuse of AMR data shared by industry and having datasets as case studies to catalyse further data sharing.

Key action 3: Facilitate the development of common methodological and metadata standards and data governance frameworks to enable data use by the scientific and public health community and allow data comparison with existing in-country datasets.

Key action 4: Launch an online portal managed and governed by an independent party.

This work has the hallmarks of a successful and sustainable sector programme. There is both a well-defined problem that needs solving and a community of stakeholders with the determination and commitment to do so. We recommend building on this momentum to make open pharmaceutical AMR surveillance data a reality.

NINETY-DAY PILOT PROJECT

On 13 July 2017, ODI, with the support of Wellcome, hosted a workshop – ‘Making Open AMR Data Happen’ – which was attended by private and public organisations. At the workshop, participants discussed the need to share retrospective and prospective data relating to industry AMR research, and the actions required for this to happen.

The workshop had a strong focus on action and recommended a 90-day initiative to come up with short-, medium- and long-term plans for making antimicrobial surveillance data openly available. ODI, GlaxoSmithKline, Pfizer, Longitude 174 and Wellcome undertook a pilot project supported by a grant from Wellcome’s Drug-resistant Infections programme to identify key priorities and a proof-of-concept study for sharing industry surveillance data. The pilot project focused on conducting a landscape analysis of what existing AMR-related data there is within pharmaceutical companies, building an online portal gathering all findings, and developing a governance structure that would ensure the sustainability of future work in the area.

Professor Barry Cookson and Dr Liam Shaw from University College London were recruited by the project’s steering group to develop a questionnaire, aimed at capturing information on existing industry AMR surveillance programmes and data.

The questionnaire covered the following areas:

- **General information** – including name of the company, years of study activity, countries involved, antibiotics (in development and post approval), indication and microorganisms tested.
- **Methodology** – including basic demographic and clinical data (if applicable), generation, collection and transport of isolates, organism identification methods, use of internationally recognised standardised methods for susceptibility testing, and systems accreditation status of the laboratory that was used by the pharma company.
- **Dataset** – including how the data generated and/or collected was stored, managed and accessed.

The researchers sent the questionnaire, along with a description of the initiative, to 11 companies. Engagement with the initiative was positive, with responses summarised in Table 1.

Table 1. Summary of responses from companies contacted in the 90-day programme.

Companies	Response
Achaogen, GlaxoSmithKline, Johnson & Johnson, Merck, Pfizer, Shionogi	Completed questionnaires returned
Novartis, Roche, Sanofi	Engaged, but nothing to report at this stage
Allergan, The Medicines Company, Melinta Therapeutics	Engaged, but couldn't be included at this time

Preliminary work uncovered differences in the terminology used to refer to surveillance activities. For consistency, the most commonly used terms were adopted: companies have surveillance *programmes* that contain multiple *studies*.

These responses were the beginning of ongoing discussions with the companies and were used to build a pilot portal in collaboration with ODI (the portal is online at amr.theodi.org).

Figure 1. Example screenshots of the portal at amr.theodi.org. The ‘Companies’ page provides a list of companies and their programmes (left panel). Clicking on an example programme takes the user to a page (right panel) containing important information about that programme.

AMR RESEARCH INITIATIVE

A partnership between the Open Data Institute and Wellcome Trust

- About
- Project overview
- Companies**
- Programmes
- Antimicrobials

Companies

Pharmaceutical companies develop and market multiple drugs, including antimicrobials. They also conduct surveillance of antimicrobial resistance (AMR). This register contains information on six companies who conduct AMR surveillance.

Achaogen

ALERT Programme

Years active: 2014 onwards Countries: 30 Antimicrobials: 31 for plazomicin, 2017 onwards for C-Scape

GSK

SOAR 114620 Programme

Years active: 2011-2014 Countries: 15 Antimicrobials: 22

SOAR 201818 Programme

Years active: 2014-2016 Countries: 9 Antimicrobials: 13

SOAR 201910 Programme

Years active: 2015-2017 Countries: 18 Antimicrobials: 17

SOAR 114620 Programme

Conducted by GSK

Active: 2011-2014 **Studies:** 15

Regions: Thailand, India, South Korea, Singapore, Democratic Republic of Congo, Ivory Coast, Republic of Senegal, Kenya, China, Bahrain, Lebanon, Oman, UAE, Ukraine, Turkey

Primary objective
Data generation for antibiotic resistance of the main community-acquired respiratory tract infection pathogens such as *S. pneumoniae*, *H. influenzae*, *M. catarrhalis* and *S. pyogenes*.

About the data

Isolates collection method:	
Types of surveillance:	Primarily for routine clinical practice, then used for surveillance.
Organism identification:	Local labs identify microorganisms based on their routinely used methodology. Isolates were not sent to a central lab for this programme.
Methodology and breakpoints:	Gradient diffusion and disk diffusion according to CLSI guidelines.
Inclusion and exclusion criteria:	See SOAR 114620 country-specific study protocols.
Are infections hospital or community acquired?	Yes. Community-acquired is defined as <48 hrs hospitalization.
Can isolates be identified from the community?	No.

Dataset
Disclaimer: These data are provided for illustration purposes only. The data are anonymised and data from China and India only are included at this time.

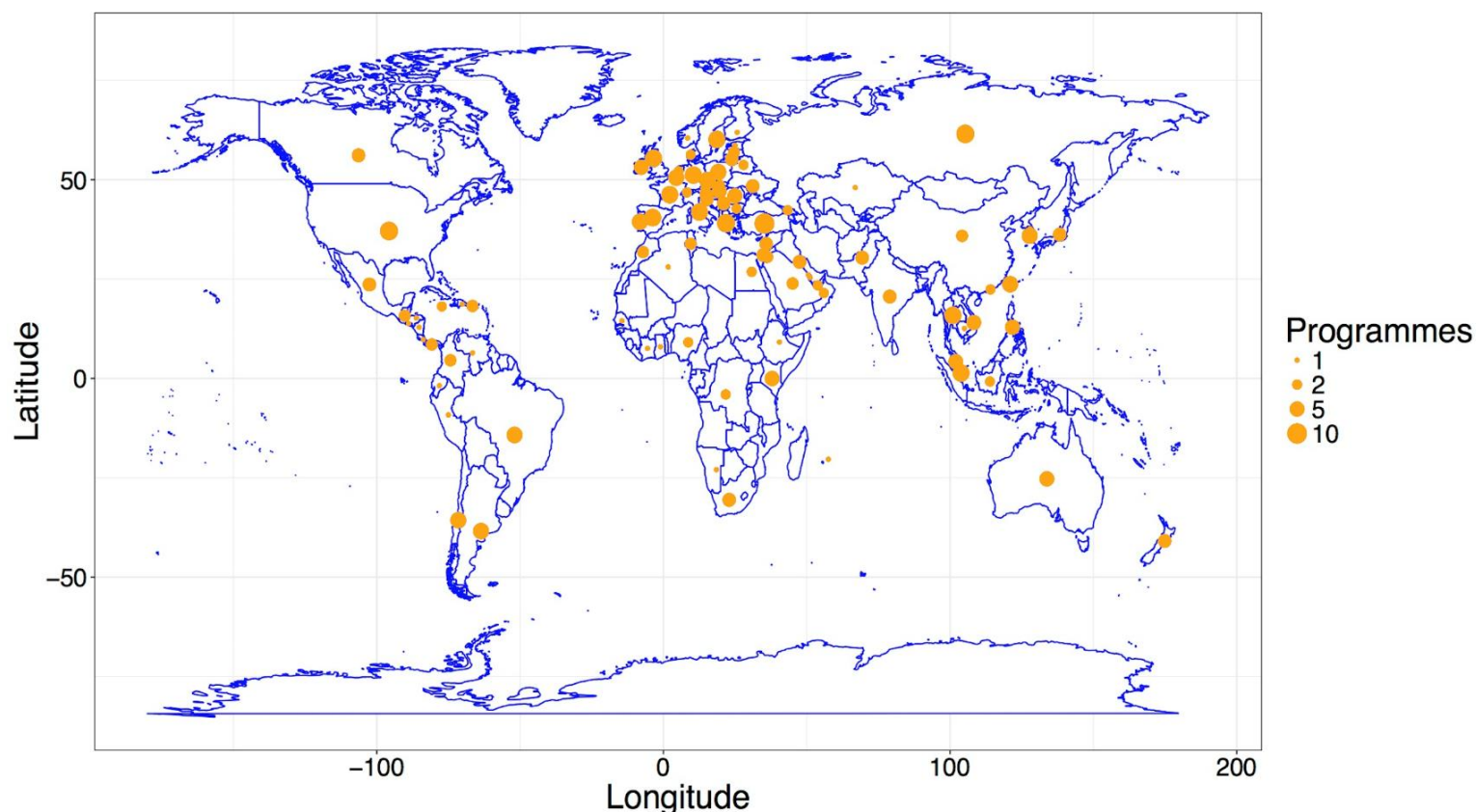
Data stored:	As an Excel spreadsheet.
Data access method:	Excel sheets (via email).
Who can access:	GSK-Global, GSK-LOCs, third party and investigators.
Data curator:	Third party.
Isolates per year:	3937
Total Isolates:	
Format:	Excel spreadsheet.
How is data from previous years added:	No.
Anonymisation instructions:	Download Download
Dataset file:	Download

Scope of datasets

A total of 12 programmes were included in the portal. Datasets held by pharmaceutical companies currently cover clinical isolates collected from local laboratories in 93 countries across the world (Figure 2).

While there is underrepresentation of certain regions (eg sub-Saharan Africa), and some countries were represented by only a single site, companies are undoubtedly making a significant contribution to global AMR surveillance. They are successfully collecting high-quality data on clinical isolates from settings where currently other robust surveillance data is limited. Even if among this data there is just one country site that has been collecting data, this represents an improvement on no data at all.

Figure 2. Countries where there are surveillance programmes conducted by pharmaceutical companies. The size of the circle indicates the number of programmes.



Although the primary aim of industry-led antibiotic surveillance programmes is to generate data for companies' own development of antibiotics, typically antibiotic panels also include other (comparator) antibiotics that are used to treat those specific infections. In total, the programmes analysed during this pilot covered 85 antimicrobials.

Companies publish scientific papers based on data from their programmes. Generally, data published in papers is in a summarised form, for instance reporting percentages susceptible/resistant to antimicrobials or showing a minimum inhibitory concentration (MIC) distribution. Additional mechanisms for sharing 'raw' MIC data for each isolate should be encouraged and enabled. Two companies, Pfizer and Merck, currently provide MIC distributions at the country level³. For instance, Pfizer's Antimicrobial Testing Leadership and Surveillance portal (ATLAS) is readily available to the public and contains over 14 years of cumulative data. The portal also represents an integration of three surveillance programmes: TEST (Tigecycline Evaluation Surveillance Trial), INFORM (International Network for Optimal Resistance Monitoring) and AWARE (Assessing Worldwide Antimicrobial Resistance Evaluation).

³ Pfizer: atlas-surveillance.com – updated every 6–9 months, anyone can access. Merck: globalsmartsite.com – dates back several years, limited public access via website.

Programme methodologies

Overall, the methods and protocols used to collect data within pharmaceutical companies' surveillance programmes had more similarities than differences. Third parties were often contracted to conduct surveillance, which further drove this standardisation in methods.

- **Isolate collection.** The majority of programmes actively collected bacterial isolates from local laboratories. These participating laboratories submit isolates from infected patients originally collected as part of routine clinical practice. Companies might also use third-party subcontractors (eg International Health Management Associates [IHMA]) to manage the study. All companies used a laboratory-based surveillance approach with quality control performed remotely through a laboratory feasibility questionnaire. Visits to hospital wards to confirm infection diagnosis were not always necessary.
- **Testing methods.** Companies used standardised methodologies, for instance breakpoints defined by the Clinical and Laboratory Standards Institute (CLSI) and/or the European Committee on Antimicrobial Susceptibility Testing (EUCAST). Laboratories were accredited and validated, with central laboratories validating all organism identification from local laboratories.
- **Infections covered.** Typically, organisms were collected from infection sites that were representative of the clinical indications for the antimicrobial (eg respiratory tract isolates for antimicrobials that treat respiratory tract infections). Some programmes limited the proportion of isolates from a particular site (eg up to 10 per cent of isolates from the urinary tract) and a type of organism (eg 50 isolates of *Klebsiella* spp.). Confirmation of infection type was left to local clinicians. Merck and GlaxoSmithKline recorded whether patients had been in a hospital or other healthcare establishment (eg a nursing home) for at least 48 hours or three nights, but other companies did not collect this information. This information is important, as it enables differentiation between hospital- and community-acquired infections; the latter are of ever-increasing importance for AMR surveillance.
- **Inclusion and exclusion criteria.** Inclusion and exclusion criteria were not defined by all pharma companies except for the exclusion of duplicate isolates from the same patient at the same time.

Data management

The research investigated the way in which the resulting data from surveillance programmes was managed and shared.

- **Format and management.** Datasets were either stored as databases (7/12) and/or spreadsheets (5/12). Data analysis and databases tended to be performed and managed by specialised companies such as the Surveillance Data Link Network (SDLN), Micron, JMI Labs or IHMA.
- **Access.** The majority of companies do not currently make their datasets publicly accessible. Investigators participating in surveillance programmes are given access to the relevant parts of datasets, either by being sent data on a disc, emailed a

spreadsheet or given access to a secure website. Pfizer and Merck have provided MIC distributions at the country level on their publicly accessible websites. Data at the site level is not provided, and data is not downloadable in machine-readable formats. While there was interest from some companies in making raw machine-readable data available, this was not achieved in the 90-day timeframe of this project. However, GlaxoSmithKline made anonymised raw MIC line-listing data available for their Survey of Antibiotic Resistance (SOAR) 114620 programme at the end of the project, demonstrating that this was possible in principle.

- **Organisational memory.** Currently there is the potential for old data to be difficult to retrieve. The detailed methodologies used for collection were also hard to locate.
- **Relationship to other surveillance data.** Different methods of surveillance contribute different (but related) data that can support global efforts to address AMR. Integrating AMR data from different datasets is often complicated and designing further approaches, such as modelling, requires ‘mixed methods’ approaches⁴. Importantly, the data collected by pharmaceutical surveillance programmes is based on priority specimens sent routinely to laboratories and therefore aligns most closely with the World Health Organization’s Global Antimicrobial Resistance Surveillance System (GLASS) protocol metric ‘Proportion of samples with growth of non-susceptible bacteria of the species and antibiotic under surveillance per specimen type’⁵.

⁴ For a discussion of mixed methods in the context of antibiotic use data, see Queenan K et al. Meeting Report: Metrics and methods for assessing antibiotic use at the granular level in humans and livestock in LMICs. London: CGIAR Research Program on Agriculture for Nutrition and Health; 2017. amr.lshtm.ac.uk/wp-content/uploads/sites/12/2018/01/LSHTM-ABU-Metrics-and-Methods-Meeting-Report-Nov17.pdf [accessed 20 July 2018].

⁵ World Health Organization. Global Antimicrobial Resistance Surveillance System: Manual for early implementation. Geneva: World Health Organization; 2015. goo.gl/nQiCiw [accessed 20 July 2018].

GOVERNANCE STRUCTURE

The 90-day initiative also proposed a possible governance framework (see Figure 3) that could be used for project sustainability. This comprised the formation of two groups working from a set of guiding principles and references. The groups and their roles were:

- **Review Committee of Technical Experts**
To discuss and make recommendations for AMR protocols and data standards and operationalise the AMR data portal.
- **Approval Authority (or Board)**
To approve work plans for AMR standards and the AMR portal; to oversee programme resourcing and make strategic decisions to enable the success of the project.

Figure 3. Proposed governance framework.

Governance Framework Preview

Guiding Principles

- Alignment to UN SDG 3
- Consensus Driven Decisions
- Fit for Purpose Solutions and Standards
- Open By Design
- One Size Fits All

References

- Open Data Charter
- ISO 38505 Governance of Data Series
- ISO Definition of Data Quality (Completeness, Uniqueness, Timeliness, Validity, Accuracy, Consistency)
- PRINCE2 Project Management Methodology



Approval Authority

Responsibilities

- Oversee Programme Funding
- Appoint Programme Manager
- Consider:
 - Legal Requirements
 - Organisational Change
 - \$ Impact
- Approve new data protocols, standards for data sharing, presentation media, data sets that can be provided as open data etc.
- Appoint members to the Expert Review Committee
- Ensure alignment to Guiding Principles

Membership

Senior Managers, Senior Researchers & Lead Policy Makers

Expert Review Committee

Responsibilities

- Address technical issues associated with data sharing
- Appoint sub committees to address specific problems e.g. development of common data protocols, presentation of open data
- Report recommendations to Approval Authority
- Report progress to Programme Manager
- Ensure alignment to Guiding Principles

Membership

Laboratory Managers Researchers
Clinical Microbiologists Policy Makers
(Members appointed by Approval Authority)

Sub Committees

Responsibilities

- Develop protocols, standards
- Investigate data presentation options
- Submit recommendations to the Expert Review Committee

Membership

As for the Expert Review Committee

WORKSHOP AND DISCUSSIONS

At the end of the research phase, a second workshop was held at Wellcome (on 27 March 2018). It discussed the results of the industry AMR surveillance analyses, lessons learned, and gaps and barriers encountered.

Session 1: Background and context

Speakers:

Tim Jinks, Head of Drug-resistant Infections, Wellcome

David Beardmore, Commercial Director, ODI

Sharon Peacock, Professor of Clinical Microbiology, London School of Hygiene and Tropical Medicine

Seamus O'Brien, Global External Scientific Affairs Lead – Anti-infectives, Pfizer

Didem Torumkune, Scientific Director – Infectious Diseases, GlaxoSmithKline

Jeremy Knox, Policy Lead – Drug-resistant Infections, Wellcome

Session focus:

- Understanding the different types of surveillance – public health-led, industry-led, both pre-launch and post-marketing.
- Exploring the different data collected through AMR surveillance and the gaps – not enough sampling, lack of metadata, lack of standardisation in data collection, selection bias, etc.
- Understanding the value of these datasets, what questions key stakeholders need to answer, and how openly sharing data helps answer those questions.
- Understanding the current policy landscape behind AMR and its surveillance.

Key messages

- A recently published landscape analysis of surveillance networks, commissioned by the Fleming Fund, highlights the extent of currently available data generated by public health organisations, academia and industry. In low- and middle-income countries, industry appears to have generated the most bacterial surveillance data since 2000⁶. Current gaps and barriers in the use of this data are also highlighted. These are mostly due to the fact that global coordination in data sharing needs to be improved.
- The pharmaceutical industry has developed programmes to routinely collect surveillance data. These programmes monitor the susceptibility of clinical isolates to marketed products and conduct pre-licence surveillance of new products to fulfil regulatory approval requirements.

⁶ Ashley EA et al. An inventory of supranational antimicrobial resistance surveillance networks involving low- and middle-income countries since 2000. J Antimicrob Chemother 2018;7:1737–49.

- There are existing difficulties related to running AMR surveillance programmes across the world, enrolling new countries (with various political contexts), and methods; these need to be understood and overcome.

Session 2: Lessons learned from the pilot project

Speakers:

Liam Shaw, Researcher,
University College London

Nandini Shetty, Consultant
Clinical Microbiologist, Public
Health England

Session focus:

- The results of the research and the online portal were presented to the audience. It was highlighted that generally high-quality data is being collected across industry studies. While this pilot engaged only with the branded-product pharmaceutical industry, there is a need to include other initiatives, public health organisations and contract research organisations to leverage useful expertise in data generation, collection, analysis, dissemination and sharing.
- The audience was then divided into groups and asked to discuss the following questions:
 - What is your perception of the extent and level of data that is currently shared as demonstrated by the 90-day programme?
 - Is this sufficient? Are there major gaps in the number of companies sharing and/or in the type and level of data?

Key messages

From a data perspective, participants agreed that:

- An online portal could potentially allow for comparison of datasets.
- It would be useful to generate standardised protocols for surveillance to be used across industry.
- There should be more incentives for sharing or opening up access to data to help companies build an internal business case.
- Different information is needed by different audiences (prescribers, policy makers, public health specialists, laboratory scientists, etc).
- Industry programmes in addition to other initiatives such as the Fleming Fund could support gaps in WHO's GLASS (eg support development of sentinel and central lab capacity).
- While detail on the origin of isolates is hugely valuable, it was agreed that protection of patient identifiable data needs to be addressed.

From a governance perspective, it was discussed that:

- an independent institution to manage the platform would be appropriate
- the portal and data therein would need to serve public health objectives.

The morning sessions concluded that AMR data should be shared. The next challenges are to: create incentives for companies to open up their surveillance data; emphasise the need to meet public commitments; and align surveillance programmes with the increasing openness of scientific research in general (for instance in clinical trials). It would help if the language used when talking about open data changed, with more emphasis placed on benefits rather than potential risks.

Session 3: Making open AMR data happen in the long term

Speakers:

Adam Dinsmore,
Programme Officer –
Open Research,
Wellcome

Francesca Chiara,
Science Officer – Drug-
resistant Infections,
Wellcome

Alison Holt, Director,
Longitude 174

Session focus:

- There is a need to nurture innovation by highlighting the availability of new open access datasets, encouraging the reuse of existing data, and promoting the development of new ideas and/or tools relevant to epidemiological and surveillance data. With that in mind, a competition with a £20,000 prize was presented, based on reusing the data gathered on the online portal.
- The workshop was then split into breakout groups to discuss specific topics and questions:
 - **Data standards.** How can the quality of surveillance data be improved?
 - **Data sharing.** What are the benefits and value of data being open, and what more can be done to make more data available?
 - **Parallel programmes and initiatives.** How to connect them better to get the most value out of the data?
 - **Data users.** How to identify and understand them better?

Key messages

- It was agreed that the quality of data from industry was good. However, standardisation could be improved by developing a protocol template and a glossary of terms.
- There were discussions around what the project could do in a future phase. Ideas included: more analysis of the data; making it more relevant to medical professionals; looking at overlaps; and inviting more companies to participate. Incentives for more companies to join could include the potential for them to optimise their R&D strategies, increase trust and transparency, as well as increase their efficiency through collaboration.
- Regarding governance, it was agreed that an independent third party with governance oversight would be needed.
- A list of potential users was discussed (healthcare professionals, government bodies, pharmaceutical companies, the public, educators, civil society organisations, the media, etc), corresponding to the different levels of understanding and thus needs in terms of access to and presentation of the data.

- This discussion focused on the value of industry surveillance data and how it can contribute to answering key AMR public health questions. The key areas of focus were:
 - Linking pathogen susceptibility and resistance prevalence data to analysis of morbidity and mortality burden and the health economic cost of AMR – eg connecting with the Global Burden of Disease initiative run by the Institute for Health Metrics and Evaluation (IHME).
 - Supplementing national-level data from low- and middle-income country programmes and supporting capability and capacity building, including at the laboratories – eg connecting with WHO's GLASS initiative and the Fleming Fund.
 - Supporting national governments' AMR action plans by sharing country-level data.
- A list of potential users was discussed (healthcare professionals, government bodies, pharmaceutical companies, the public, educators, civil society organisations, the media, etc), corresponding to the different levels of understanding and thus needs in terms of access to and presentation of the data.

Session 4: Conclusions and next steps

Speakers:

Carmem Pessoa-Silva, AMR Lead, WHO GLASS

Andy Stergachis, Associate Dean and Professor – School of Pharmacy, University of Washington

Nandini Shetty, Consultant Clinical Microbiologist, Public Health England

Sharon Peacock, Professor of Clinical Microbiology, London School of Hygiene and Tropical Medicine

Seamus O'Brien, Global External Scientific Affairs Lead – Anti-infectives, Pfizer

Andrew Freeman, Head of Medical Policy, GlaxoSmithKline

Tim Jinks, Head of Drug-resistant Infections, Wellcome

Session focus:

- The speakers and audience were asked to reflect on the discussions and explore potential next steps, with a focus on the following themes:
 - What does the public health community want to see?
 - What can the industry community do to support data sharing?

Key messages

- The workshop delegates overwhelmingly endorsed the view that more data should be shared openly.
- There was an understanding among the group that we need better standardisation of data, both for the data we already have and that which we gather in the future. In the future, techniques for data collection and templates for providing context around shared data should be improved, and done in collaboration with external parties.
- Participants also recognised the need to communicate with external users and assist them with getting the most value from the data available.

RECOMMENDATIONS AND NEXT STEPS

Access to AMR surveillance data, particularly by public health bodies and healthcare professionals, can help address the global challenge of AMR by improving understanding of resistance trends and informing appropriate antibiotic and vaccine use.

Our pilot study created the momentum to engage with pharmaceutical companies and mobilise surveillance datasets that could significantly improve the understanding of AMR. While the companies involved have made declarations and commitments to share this data more widely, the challenge remains of how to practically do so in ways that unlock the value of the data by making it as open as possible. This might be achieved through the generation of standard protocols for data collection and more transparency on the US Food and Drug Agency/European Medicines Agency requirements for surveillance studies, which are currently not broadly available.

The first phase of this initiative has been enthusiastically received. More effort is now needed to progress this area and make data available.

ODI's experience has shown that successful and sustainable data-focused change programmes require a range of complementary activities. These include:

- **Governance** – oversight of the activities required to achieve the programme's goals and the developing of success measures.
- **Policy development** and guidance, including scrutinising interaction between general data governance practices and sector norms.
- **Technology development** – creating appropriate data standards and the tools needed to support them.
- **Research** – creating case studies that help to incentivise stakeholder engagement and carrying out rigorous impact evaluation as the programme continues.
- **Training** – enabling data publishers to understand how to make data available and data reusers to understand how it can be exploited.
- **Competitions and acceleration** programmes to foster innovation in the sector and drive reuse of published data.
- **Building communities** within the sector and communicating clearly with them to ensure activities are integrated with existing initiatives.

The following four key action recommendations draw on Wellcome's and ODI's experience of unlocking value from data and creating sustainable sector-focused data transformation programmes.

Key action 1: Develop a public–private partnership between industry, public health organisations and other AMR initiatives to provide a more informative, coherent and openly accessible AMR data landscape.

Key action 2: Enable open innovation and data sharing within the AMR community by encouraging reuse of AMR data shared by industry and having datasets as case studies to catalyse further data sharing.

Key action 3: Facilitate the development of common methodological and metadata standards and data governance frameworks to enable data use by the scientific and public health community and allow data comparison with existing in-country datasets.

Key action 4: Launch an online portal managed and governed by an independent party.

Key action 1

Develop a public–private partnership between industry, public health organisations and other AMR initiatives to provide a more informative, coherent and openly accessible AMR data landscape.

Develop incentives and work with others

The success of a data transformation programme within a sector relies on engaging its stakeholders and others with a common goal. Although the desire to disclose datasets for antibiotics in development could be a barrier, this initiative has already successfully engaged several pharmaceutical companies, as well as public health bodies and nongovernmental organisations. This engagement should now be extended, and incentives should be created for more industry partners to share their data. For instance, a portion of the AMR surveillance conducted by pharmaceutical companies is currently operated by third parties, who could bring expertise in conducting surveillance studies and managing the resulting datasets to the initiative.

This initiative should also complement and integrate with other AMR surveillance initiatives, both globally (such as WHO's GLASS initiative) and at a national level. There is scope to create a public–private partnership to deliver on this aim. It would also be beneficial to link data generated by industry with data collected from national surveillance systems. The public health benefits from this approach are obvious: surveillance data would be used to indicate the burden of disease and AMR in a country. At the same time, industry could utilise this data to inform and shape R&D strategy by targeting areas of research where the needs (including for cost-effectiveness) are greatest.

The Surveillance and Epidemiology of Drug-resistant Infections Consortium (SEDRI), a global initiative newly created by Wellcome, is aimed at fostering coordination and uptake of best practices in AMR surveillance and data use and sharing, and so will sustain these efforts by providing in-country links and access to a network of experts⁷.

Key action 2

Enable open innovation and data sharing within the AMR community by encouraging reuse of AMR data shared by industry and having datasets as case studies to catalyse further data sharing.

Launch a data reuse prize as proof of concept

The full value of access to AMR surveillance data will be unlocked when mechanisms for data sharing and data reuse have been widely implemented and can inform the decisions of public health bodies, healthcare professionals and pharmaceutical companies. While an online portal could address some needs, others could be met through open innovation, eg through analysis and visualisation of data.

Data and the relevant protocols that underpin it could be shared more openly and consistently than currently. Companies do share data in the form of MIC distributions in scientific publications and/or on dedicated websites. But additionally, 'raw' MIC data for each isolate could be made available on a dedicated platform under an open licence that permits access to others. The use and sharing of surveillance data would enable a broad range of visualisation and analysis to take place. Molecular AMR data would add value and could be included in the future database.

There are concerns about providing surveillance data at the site level as it has potential ramifications for participating hospitals. We recommend creating guidance on the appropriate aggregation and anonymisation of surveillance data to enable it to be opened up where possible and shared in secure ways where necessary.

⁷ Information on SEDRI is available at wellcome.ac.uk/what-we-do/our-work/surveillance-and-epidemiology-drug-resistant-infections-consortium [accessed 20 July 2018].

There are some areas where the data collected could be more standardised, and an independent group of industry experts is needed to consider how best to do this so that the proposals are owned by companies.

In the immediate next phase of this project, we will launch a data reuse prize to encourage the AMR community to reuse surveillance datasets.

The prize is the first step towards meeting the following goals:

- evaluating the utility of surveillance data and identifying barriers to its use
- resting and improving the standards developed as part of this pilot
- providing examples of the reuse of AMR data to inform public health initiatives.

Key action 3

Facilitate the development of common methodological and metadata standards and data governance frameworks to enable data use by the scientific and public health community and allow data comparison with existing in-country datasets.

Develop methodological, data and metadata standards

Standardisation makes it easier to compare and integrate data from different sources. This reduces the time and resources needed to analyse and understand data and therefore makes it more useful.

Standards are useful at the methodological level (how data is collected and values calculated), at the data level (the machine-readable formats it is shared in) and at the metadata level (what additional information is provided along with the data).

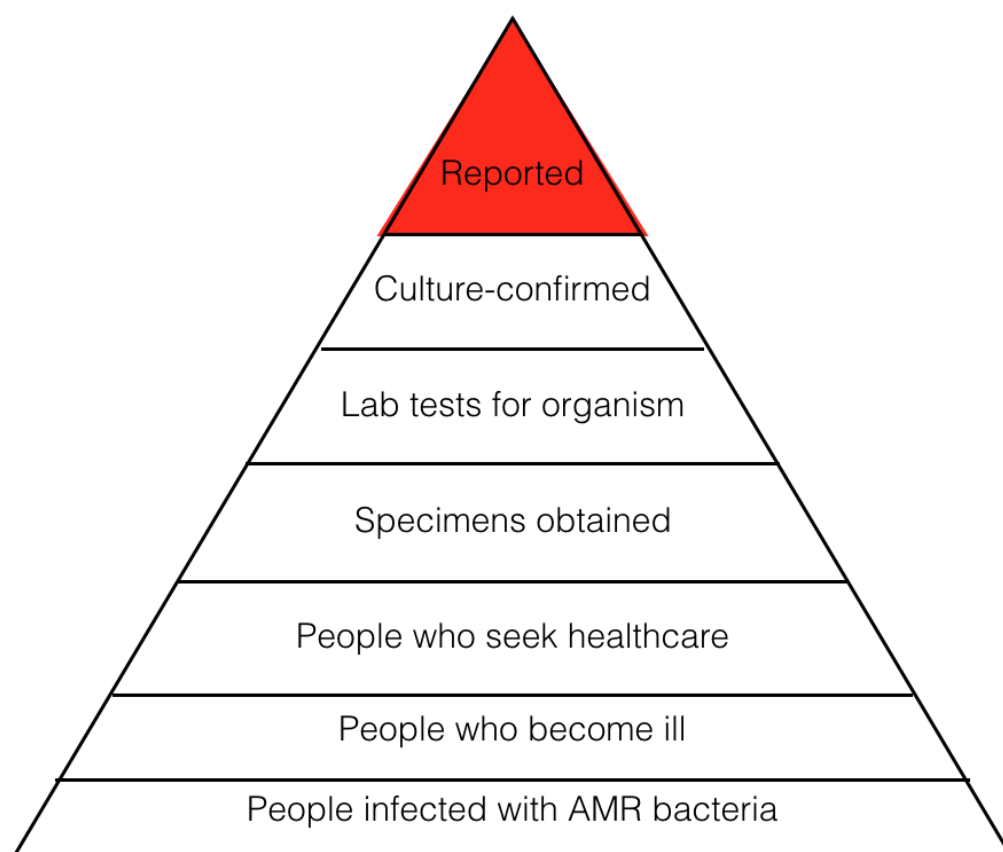
Methodological standards

Overall, there is already a high level of standardisation and quality in the methodological aspects of industry surveillance programmes. There is a very strong foundation on which to build the level of standardisation and interoperability required for more advanced uses of surveillance data.

However, some methodology of surveillance programmes is not as standardised, reducing comparability between datasets. For example, studies report the proportion of resistant isolates, but what this proportion represents can be different in different datasets due to different breakpoints (eg per organism or per infection site).

Furthermore, denominator data for the wider population is not currently routinely collected or reported. Data from surveillance sits at the top of a 'surveillance pyramid' (Figure 4). Without denominator data, surveillance data cannot be used to infer general rates of AMR: rates based on the proportion of clinical samples collected do not translate into resistance rates at the general population level.

Figure 4. AMR surveillance pyramid.



These points are *not* arguments for not releasing data. There are methodological approaches, routinely used when interpreting public health datasets, that can deal with data collected using different methods. Rather, they are points to bear in mind when using currently available data and designing future study methodologies.

Data standards

Standards for exchanging data specify common formats and shared rules that lead to consistent data. A good standard for data exchange solves a specific problem and provides tools to check that data has been properly structured. These reduce the workload of data reusers.

A data exchange standard for AMR surveillance data should define a common format for data that describes how data should be serialised or structured for sharing. It should combine commonly understood formats (such as CSV) and shared term definitions and vocabularies to make it easier for the same tools to be used to analyse data no matter the surveillance programme it originated from.

Metadata standards

Surveillance data cannot be understood without contextual information about the methods used to generate it. In order to be integrated with other datasets, methods of collection,

analysis and study protocols have to also be shared. For example, during industry clinical trials, protocol summaries are made publicly available at the outset of trials, and after completion study results are made publicly available. It is also common practice for clinical trial documents such as protocols to be made available. A similar approach should be explored for AMR studies. Rather than sharing full protocols, reduced summaries based on agreed standards of disclosure could be shared instead.

Key action 4

Launch an online portal managed and governed by an independent party.

Launch an online portal

Discussions during workshops identified a range of potential users for online services providing access to integrated surveillance data: prescribers, policy makers, public health specialists, laboratory scientists, pharmaceutical companies themselves, and so on.

It is unlikely that any single portal will satisfy all the needs of all these stakeholders. One advantage of an open data approach is that different solutions can be created to satisfy different needs. However, continuing to prototype an online portal would be beneficial as:

- a way of delivering immediate insights and value from published data
- a concrete motivating example to help engage other stakeholders
- a test environment for the utility of data and metadata standards.

It is necessary in the next phase of the research to identify an independent organisation able to host and further develop the portal. An adequate governance framework, as suggested in this paper, should be also put in place to ensure that data collection, sharing and use are maximised.

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Wellcome's Drug-resistant Infections Program is exploring global solutions to tackle antimicrobial resistance.

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