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Assessment of real-world evidence data sources for carbapenem resistance

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Summary

- Using a systematic approach, this analysis has identified various real-world evidence data sources that provide patient-level data relating to carbapenem resistance (CR) in the EU5 countries (France, Germany, Italy, Spain, and the UK), Canada, and the USA.
- Our analysis showed that many of the identified evidence sources collected microbiological and clinical data relating to CR but that there was a lack of economic data.
- There is a need for patient-level cost and resource use data on patients with carbapenem-resistant infections.
- Closer collaboration between researchers and greater leverage of existing real-world evidence are encouraged and may assist research on the burden of CR.

Introduction

- Antibiotic-resistant bacteria have been estimated to cause approximately 2 million infections in patients in the USA and 2.5 million infections in individuals in Europe annually.[1]
- Carbapenems are often used to treat infections resistant to other antibiotics; consequently, growing resistance to carbapenems is a significant concern.
- A recently developed global 'priority pathogens' list of antibiotic-resistant bacteria published by the World Health Organization rates carbapenem-resistant strains of bacteria as a top (critical) priority.[2]

Objective

- The objective of this study was to identify real-world evidence data sources reporting patient-level data relating to CR to enable better characterization of the burden of resistant infections on, and unmet needs of, patients and healthcare systems.

Methods

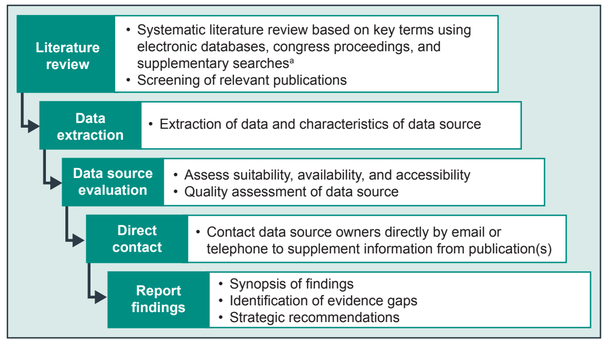
SURE™ (Systematic Understanding of Real-World Evidence)

- The SURE™ process systematically identifies, analyses, and summarizes real-world evidence data sources relevant to a specific disease or treatment area (Figure 1).

Literature review and data extraction

- The MEDLINE®, Cochrane and Embase® electronic databases were searched for relevant publications up to March 2016. Publications were screened according to the 2015 Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) guidelines.[3]
- Manual searches of relevant congress proceedings for the period 2014-2016 were performed, and Google advanced searches and manual searches of national strategy policy documents were also carried out.
- Search strings were devised to identify real-world studies related to CR that included patient-level data and a named data source.
- Data sources reporting isolate-only CR data were excluded at screening.
- To ensure focus on contemporary data sources, sources from which no data were published after 2011 were excluded at full-text review.
- Only data sources reporting patient-level data in the EU5 countries, Canada and the USA were analysed.
- Of 4360 screened publications, 111 publications referring to 68 data sources from the countries of interest were identified (Figure 2).

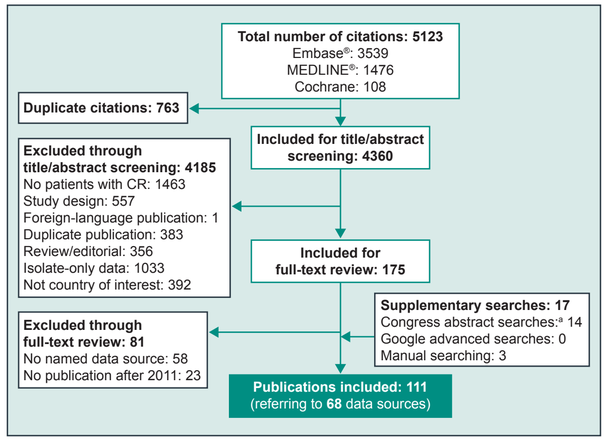
Figure 1. The SURE™ process.



[a]The systematic review process is fully compliant with the 2015 PRISMA-P guidelines.[3]
PRISMA-P, Preferred Reporting Items for Systematic review and Meta-Analysis Protocols; SURE™, Systematic Understanding of Real-World Evidence.

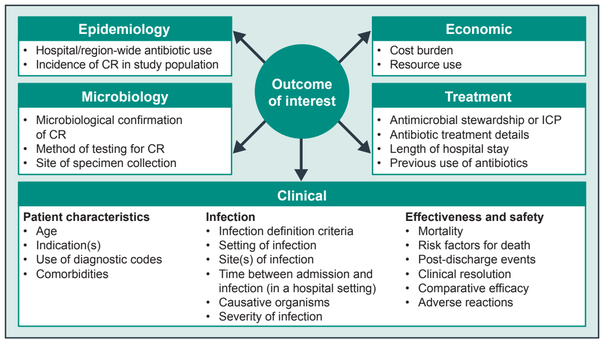
- General information about each data source and the outcomes of interest that were available within the data source were extracted from the 'Methods' and 'Results' section of each publication (Figure 3).
- To gain a comprehensive understanding beyond the details provided in the published literature, a subset of the data sources identified through the systematic search was prioritized for further investigation through direct contact with data source owners/administrators.

Figure 2. PRISMA flow diagram.



[a]Annual European Congress of ISPOR, Annual US Congress of ISPOR, ASM Microbe (formerly known as the Interscience Conference on Antimicrobial Agents and Chemotherapy), European Society of Clinical Microbiology and Infectious Diseases congresses, IDWeek and International Congress on Infectious Disease, 2014-2016.
ASM, American Society for Microbiology; CR, carbapenem resistance; ISPOR, International Society for Pharmacoeconomics and Outcomes Research; PRISMA, Preferred Reporting Items for Systematic reviews and Meta-Analyses; US, United States.

Figure 3. Outcomes of interest extracted for each data source.



CR, carbapenem resistance; ICP, infection control programme.

Data source evaluation and direct contact

- To understand the quantity and quality of the available data, each source was graded as 'good', 'moderate', or 'poor' based on the number of reported data points within each outcome of interest; the same grading criteria were applied to all identified data sources.
- After evaluation of the identified data sources, 45 were considered to be of particular interest and were prioritized for direct contact.
- Owners/administrators of these data sources were sent a questionnaire to gather additional information not available in publications.

Results

Data source locations

- Of the EU5 and North American countries, the USA had the highest number of identified data sources, followed by Italy and Spain (USA, n = 33; Italy, n = 11; Spain, n = 8; France, n = 5; Germany, n = 3; Canada, n = 3; UK, n = 2; multinational, n = 3) (Figure 4).
- Most of the identified data sources were either electronic medical records (n = 25) or retrospective observational studies (n = 20). Other sources were prospective observational studies (n = 15), disease registries (n = 5), administrative/claims databases (n = 2), and a surveillance report (n = 1).

Figure 4. Number of identified data sources in the countries of interest.

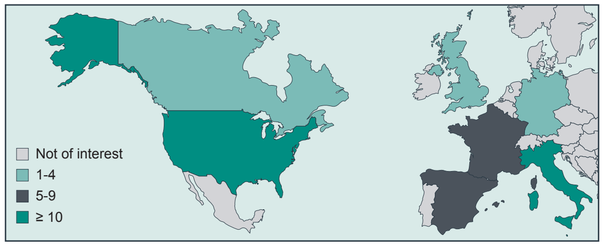
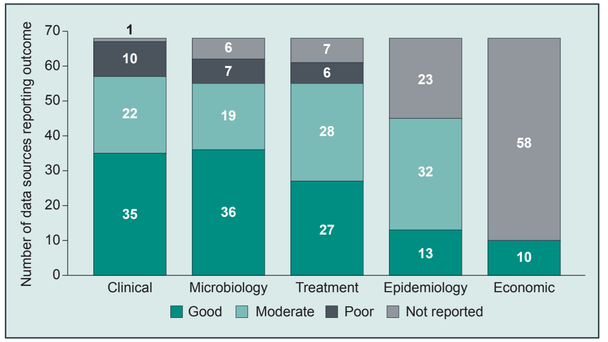


Figure 5. Outcomes reported in the 68 identified data sources.



Outcomes reported

- Most identified data sources were graded as 'good' or 'moderate' when considering the comprehensiveness of data on the outcomes of interest (Figure 5).
- The most comprehensive data sources were from the USA; two data sources had published data on all outcomes of interest.
- In total, 45 data sources were prioritized and contacted for further information. Of these, 3 provided the requested information, 2 responded positively (requiring further follow-up), 7 declined to provide information, and 33 have not yet responded to direct contact.

Conclusions

- This systematic analysis of real-world evidence identified 68 separate data sources reporting predominantly clinical, microbiology, and treatment outcomes of patients with carbapenem-resistant infections.
- Few data sources included economic outcomes data.
- Real-world evidence detailing the impact of CR on patients and its economic impact in the clinical setting is needed to enhance understanding of the CR burden in specific countries and settings.
- Closer collaboration between researchers and greater leverage of existing real-world evidence are encouraged, and may assist research into the burden of CR.

Disclosures

Obaro Evuarherhe and Polly Field are paid employees of Oxford PharmaGenesis, Oxford, UK. Eilish McCann is a paid employee of Merck & Co., Inc., Kenilworth, NJ, USA. Merck & Co., Inc., Kenilworth, NJ, USA provided funding for this study to Oxford PharmaGenesis.

Acknowledgements

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References

1. Sievert DM *et al. Infect Control Hosp Epidemiol* 2013;34:1-14.
2. World Health Organization. February 2017. Available from: http://www.who.int/medicines/publications/global-priority-list-antibiotic-resistant-bacteria/en/ (Accessed 3 March 2017).
3. Moher D *et al. Syst Rev* 2015;4:1.

http://tinyurl.com/h3y53sm