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Bespoke linkage of Public Health England laboratory data on gastrointestinal infections to the Clinical Practice Research Datalink: Ethics approval and a study proposal

Esan, Oluwaseun[1*], Fanshawe, Thomas[1], Violato, Mara[1], McCarthy, Noel[2], and Perera-Salazar, Rafael[1]

[1]University of Oxford
[2]University of Warwick

Objectives

Gastrointestinal (GI) infections are common. Most infections are self-limiting, with some people developing long-term sequelae following their GI infection. Currently, the surveillance of GI infections such as Campylobacter and Salmonella is primarily based on laboratory data held by Public Health England (PHE). Information on symptoms severity, treatment of infection and subsequent complications is not captured by this data source.

Electronic Health Records (EHR) provide a platform to assemble cohorts for long-term follow-up at relatively low costs. Record linkage of existing EHR provides a powerful resource to estimate the burden of complications following gastrointestinal Infections (GI) and the associated risk factors such as treatment of the primary GI infection.

A range of ethical and data governance approvals processes, motivated to protect patients and patient data, are required to allow use of routine and linked data for research. The aim of this project is to establish a bespoke linkage of PHE laboratory data on Campylobacter, non-typhoidal Salmonella (NTS) and verocytotoxin producing Escherichia coli (VTEC) to the Clinical Practice Research Datalink (CPRD, primary care records), hospital records and other secondary datasets in order to estimate the burden of complications following GI infections.

Approach

Linkage of laboratory data, primary care data, hospital records, deaths and deprivation index were proposed following an initial data completeness check of laboratory data on Campylobacter spp., NTS and VTEC over a ten year (2004-2014) period. Linkage plans were discussed with all relevant organisations. Finalised study protocols were completed and application for approval for linkage was submitted to the Independent Scientific Advisory Committee (ISAC) and the NHS Research Ethics Committee. An additional application was sent to the Confidential Advisory Group (CAG) to comply with section 251 of the UK NHS Act 2006 on accessing patient identifiable information.

Results

ISAC approval for CPRD linkage is dependent on CAG approval. Completion of data linkage will allow the measurement of complications following GI infections to be estimated more accurately than is possible using routine, unlinked population-level data. It allows the implementation of designs such as the case-crossover design for the investigation of patient-level risk factors such as use of antibiotics and their association with complications.

Conclusion

Bespoke record linkage to CPRD can allow the measurement of risk of long-term sequelae following acute infections. Considerable time should be built into research timelines to allow completion of all ethical, governance and data access procedures.

*Corresponding Author:
Email Address: oluwaseun.esan@kellogg.ox.ac.uk (O. Esan)

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