National hospital data for intussusception: Data linkage and retrospective analysis to assess quality and use in vaccine safety surveillance

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ABSTRACT

Objectives: To assess the quality of national Hospital Episode Statistics (HES) data for intussusception, and evaluate this routinely collected database for rotavirus vaccine safety surveillance by estimating pre-vaccination trends in intussusception hospitalisation.

Methods: Data linkage was performed between HES and prospective intussusception data from the British Paediatric Surveillance Unit (BPSU), followed by capture–recapture analysis to verify HES data quality. Inclusion criteria were infants aged less than 12 months and admitted for intussusception to National Health Service (NHS) hospitals in England from March 2008 to March 2009. To estimate pre-vaccination incidence rates of intussusception, we performed a retrospective analysis of HES data. Infants aged less than 12 months and admitted for intussusception to NHS hospitals in England between 1995 and 2009 were included.

Results: Data linkage between 254 cases of intussusception identified in HES data and 190 cases reported via the BPSU resulted in 163 cases common to both data sources. Of remaining 91 cases in HES, 37 had confirmed intussusception. HES data accuracy was 78.7% (200 confirmed/254 cases) and completeness for intussusception was 86% (163 matched/190 BPSU cases) compared to 81.5% (163 matched/200 HES cases) for BPSU. A total of 233 (95% CI: 227.4 to 238.8) intussusception cases were estimated for the infant population (2008 to 2009). For retrospective analysis, of 6462 intussusception admissions in HES data (1995 to 2009), 1594 (24.7%) were duplicate admissions. A declining trend in intussusception incidence was observed in the infant population, from 86/100,000 in 1997 to 34/100,000 in 2009 (60% reduction, $P < 0.001$). Cosinor modelling showed an excess of cases among infants in winter and spring ($P < 0.001$, $n = 4957$, 1995 to 2009).

Conclusion: National hospital data capture the majority of admissions for intussusception and should be considered for the post-implementation surveillance of rotavirus vaccine safety in England.

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1. Introduction

Routinely collected healthcare data can be used to evaluate medical products and interventions and directly influence patient care in the very systems that generated the data [1]. In the UK,

Hospital Episode Statistics (HES) contain details of all admissions, outpatient and A&E attendances to National Health Service (NHS) hospitals in England [2]. The HES database has been used for a wide range of healthcare purposes such as: deriving patient safety indicators [3], monitoring the use of new health devices and procedures [4], as well as studying hospital admission trends for whooping cough [5], bacterial pneumonia and empyema [6], and acute anaphylaxis [7]. A recent systematic review on the accuracy of routinely collected datasets versus case notes in Great Britain, which included datasets from single/multiple hospitals in England, reported an overall median accuracy of 83.2% (IQR: 67.3–92.1%). Accuracy, in this review, was defined as the percentage agreement

between coding recorded in the routinely collected dataset compared to that allocated through independent assessment of hospital notes or discharge summaries [8].

For vaccine safety, a recent study used HES to evaluate the risk of narcolepsy associated with influenza vaccine in England [9]. This database however was used as a supplementary means of case ascertainment since clinical management of narcolepsy does not necessarily require hospital admission. In addition to risk evaluation, the availability of population-based background rates of adverse events following immunisation has become increasingly important for vaccine safety assessment. Background rates assist in distinguishing legitimate vaccine safety concerns from events that are temporally associated with, but not caused by, vaccination [10,11]. For monitoring of rotavirus vaccine safety, intussusception has been a prime focus. In addition to the risk of intussusception associated with a previous rotavirus vaccine leading to vaccine withdrawal in the United States [12], recent studies also have shown a small intussusception risk associated with the newer rotavirus vaccines [13–19]. Some population-based studies have suggested a decline in the background incidence rates due to intussusception [20–27], with the greatest reduction occurring within the first six months of life [20,21]. Although reasons for the decline in intussusception remain unclear, hypotheses include improvements in hygiene and sanitation [22], changes in dietary factors [28,29], or in some studies in the United States, a possible reduction in case recording in inpatient discharge databases as a result of treatment shifts from hospital admissions to outpatient systems [23,30].

For the first time, we assessed the quality of routinely collected HES data for intussusception by performing data linkage and capture–recapture analysis—between HES and prospective intussusception data previously obtained via the established British Paediatric Surveillance Unit (BPSU) system [31], for the infant population in England (2008 to 2009). We examined whether existing HES data can be used for rotavirus vaccine safety surveillance by estimating incidence rates, including any seasonal variation of intussusception among infants in England from 1995 to 2009—prior to vaccine (Rotarix®) introduction into the routine UK immunisation programme in July 2013.

2. Methods

2.1. Data linkage and capture–recapture analysis for HES data quality assessment and case validation (2008 to 2009)

In addition to validating the previously reported intussusception incidence for England [31], the quality (accuracy and completeness) of routinely collected HES data was verified using data linkage and capture–recapture methodology [32]. We linked the HES data source to previous intussusception data obtained via the British Paediatric Surveillance Unit (BPSU) [31]. The BPSU was established in 1986 for prospective active surveillance of uncommon childhood disorders in the UK and Republic of Ireland, including recent studies on adverse events following immunisation (AEFI) [33]. In our previous study, baseline incidence rates of intussusception (prior to rotavirus vaccine introduction) were estimated for all four UK countries, including the Republic of Ireland, by clinicians reporting cases to the BPSU (from 2008 to 2009) [31]. For this study, intussusception cases were validated against HES for the same BPSU study time-period but for England only, since this database contains all admissions to NHS hospitals in England.

Consistent with previously reported BPSU intussusception study criteria [31], data linkage and capture–recapture analysis involved analysing the HES database for infants admitted with intussusception to NHS hospitals in England from March 2008 to March 2009 and aged less than 12 months at the time of admission. The International Classification of Diseases, 10th revision (ICD-10) intussusception codes K56.1 or K38.8 (intussusception of appendix) were used for case definition in HES. We contacted relevant National Health Service (NHS) organisations and mapped hospital names, including type of intervention, against the corresponding HES codes [34,35]. A unique identifier, the NHS number, was used to identify duplicate admissions; where the NHS number was missing, the following sequence of variables was used: patient's date of birth, gender, dates of admission and discharge, dates of start and end of HES episode (patient under care of a specific consultant), healthcare provider (NHS hospital), type of intervention, admission method (how patient was admitted to hospital), district postcode and ethnic group. In case of patient transfer from paediatric medical to paediatric surgical speciality, the surgical episode was retained as the primary episode since this was more likely to contain the definitive diagnosis of intussusception (based on enema reduction and/or laparotomy). We excluded all readmissions.

The R computing environment (version 2.11.1, *Record Linkage* package) was used for data linkage [36]. Variables common to both data sources (match key) consisted of the patient's NHS number, date of birth, gender, NHS hospital, dates of admission and discharge. For deterministic linkage, the number of cases that matched between HES and BPSU data sources (matched pairs) was obtained via step-wise elimination of matching variables. We used probabilistic record matching to complement the deterministic method as probabilistic matching uses information on a greater number of matching variables, taking into account coding errors for example errors in data entry of the NHS number. A manual/clerical review was carried out to confirm the status of matched/possibly matched pairs between HES and BPSU data sources (details are available from authors).

The capture–recapture method estimates the extent of incomplete case ascertainment using information from two or more reporting systems, which allows an estimate of the total number of cases in a population [32]. For capture–recapture analysis, HES cases, which did not match against those reported using BPSU, were identified as extra with case status subsequently confirmed by paediatric surgeons via case notes review. In addition, the diagnosis confirmation process involved identifying cases in the HES data source that matched with definite intussusception cases prospectively obtained from the previous BPSU study (i.e. BPSU data source for England, 2008 to 2009) using Brighton Collaboration's definite case criteria [31,37]. The accuracy of HES data was measured as the proportion of ICD-10 coded cases of intussusception, which had a confirmed diagnosis. HES data completeness was calculated as the proportion of confirmed intussusception cases reported via BPSU, which were common to HES. The Lincoln–Petersen estimate was calculated to obtain the total number of intussusception cases for the study population [32,38].

To calculate the validated incidence rates for England, including those by month of life, denominator data were obtained from the Office for National Statistics (ONS). For month of life, the denominator comprised of babies born in March 2008 (<1 month) and included follow-up data for this cohort for subsequent months [39]. The validated pre-vaccination incidence rates were annualised and expressed per 100,000 live births with 95% confidence intervals.

2.2. Retrospective HES data analysis for estimation of trends in intussusception incidence (1995 to 2009)

To evaluate HES for rotavirus vaccine safety surveillance, we analysed this database to estimate trends in hospitalisations due to intussusception in the infant population in England from 1995