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Validation of administrative data to estimate vaccine impact: Audit of the Fiji hospital admissions electronic database, 2007–2011 & 2014–2015

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ABSTRACT

Objectives: Post-licensure studies to evaluate vaccine impact are an important component of introducing new vaccines. Such studies often rely on routinely collected data but the limitations to these data must be understood. To validate administrative data for use in 10-valent pneumococcal conjugate and rotavirus vaccine impact evaluations we have audited the two electronic database capturing hospital admissions in Fiji for completeness and consistency.

Methods: Hospital admission data for one week per year between 2007–2011 and 2014–2015 was collected from ward registers for selected hospitals. Ward registers were defined as the reference standard and compared to data captured in electronic databases. Data quality was assessed for completeness of admissions data (percentage of admissions in the electronic database, expressed as sensitivity), consistency of complete reporting (determined by identifying variables associated to complete reporting), and completeness of coding (percentage of admissions in the electronic database with an assigned ICD-10-AM code).

Results: Over all hospitals and years, the sensitivity for completeness of admission data was 83% (95% CI: 81.3, 84.6). Consistency of complete reporting varied and was highest at tertiary hospitals using the electronic database (sensitivity: 89.1%, 95% CI: 87.4, 90.7). The overall completeness of coding at tertiary hospitals was 90.8% (95% CI: 90.5, 91.1) with annual and hospital variation.

Conclusion: The administrative data in the electronic databases in Fiji are of reasonable quality for the vaccine impact evaluation. This quantification of the missing data can be used to adjust the vaccine impact estimates.

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1. Background

Post-licensure studies to evaluate vaccine impact on hospital admissions are an important component of introducing new vaccines as there is often a substantial difference between the benefit demonstrated in vaccine clinical trials and that which can be achieved in routine practice [1–4]. There are many factors which may contribute to this difference including study design, completeness of reporting, vaccination coverage and schedules, and differences in strains of target organisms. In addition, the wider health benefits to the unvaccinated community, through indirect effects, can usually only be described following the introduction of a vaccine into a large population.

Vaccine impact evaluations estimate change in incidence of disease outcomes following the introduction of a vaccine [5]. The detection of changes in disease epidemiology requires quality longitudinal data over prolonged periods of time, both pre- and post-vaccine introduction. These data may be sourced either from large observational studies or surveillance systems in a representative sample population [6], which require significant investment and planning prior to vaccine introduction. Effective routine surveillances systems may be lacking in low- and middle- income

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countries where vaccines have the potential to have the biggest impact due to the high burden of disease.

Routinely collected administrative hospitalisation data constitute an important source of health information of potential value in large observational studies. Collection of administrative data are generally not designed to answer specific research questions, so the dataset suffers from specific limitations which must be understood and described prior to use [7]. Data quality has previously been categorised according to: Completeness-presence of the necessary data [7–11]; validity, accuracy or correctness-closeness of agreement between a data value and the true value [7–13]; and consistency-relevant uniformity in data across clinical investigation sites, facilities, departments, units within a facility, providers, or other assessors [7].

In Fiji, a number of studies have been designed to evaluate vaccine impact on hospital admissions following the introduction of two new infant vaccines, the 10-valent pneumococcal conjugate (PCV10) and rotavirus (RV) vaccines [14]. Where surveillance systems were lacking, national hospital admission data was used to assess vaccine impact on all-cause pneumonia, meningitis, sepsis and diarrhoea. In order to ensure reliability of the vaccine impact evaluations, here we assess the quality of the administrative data and describe how this can be used to adjust an estimate of vaccine effect. We aim to describe the completeness and consistency of Fiji's national hospital admission data captured in two electronic databases in comparison to the reference standard of paper-based hospital ward registers.

2. Methods

2.1. Study site

Fiji is the third largest Pacific Island country. The population was 837,271 in the 2007 national census [15]. There is good access to healthcare services and services are provided free of charge. Three tertiary hospitals (Colonial War Memorial (CMWH), Lautoka and Labasa) and 18 secondary hospitals capture all public hospital admissions.

All admissions in Fiji are captured within two electronic database systems: the Fiji Patient Information System (PATISplus) and manual reports for hospitals not using PATISplus. PATISplus was introduced in January 2012 and replaced the older version PATIS which was based on a Health Information System developed in Fiji with support from United States Agency for International Development (USAID) in 1997. The PATIS system (PATIS or PATISplus) assigns a unique patient identifier referred to as the National Health Number (NHN), and creates an electronic copy of the patient data for future care which improves continuity of care [16]. The PATIS system has been available at all three tertiary hospitals (CWMH, Lautoka, Labasa) from 2007 until present. PATIS was available at Nadi and Nabouwalu Sub-Divisional Hospital between 2007 and 2011, in 2012 human resources were no longer available to enter into PATIS on site, and these hospitals switched to the manual database system. The two databases, the PATIS system and manual, record similar data on individual patient admissions, and are both stored at the central level Health Information and Research Analysis Unit (HIRA), Ministry of Health and Medical Services (MoHMS), Suva.

2.2. Generation of admission data

Upon admission to any hospital in Fiji, patients' details are recorded into the ward registers by a nurse. Doctors generate clinical data, including discharge diagnosis, and record data in paper-based individual patient medical records. The ICD-10-AM code is assigned using the discharge diagnosis by medical coders. Medical coders are certified in elementary or intermediate ICD-10-AM coding and elementary or intermediate Medical Terminology, from the Health Information Management Association of Australia (HIMAA). HIMAA training was delivered in Fiji by The University of Queensland between May 2006 and 2008. The HIMAA training included elementary requirements for ICD 10 AM coding (2006), comprehensive medical terminology (2007) and introduction to ICD 10AM (2008).

For hospitals using the PATIS system, individual patient admission details from patient medical records are entered into the PATIS system database on site by medical coders and administrative assistants. Administrative assistants are unable to assign the ICD-10-AM code so enter all variables except for the ICD-10-AM code, which is referred to a medical coder for coding at a later time. Medical coders and the information technology team from HIRA conduct site visits to hospitals using the PATIS system to provide onsite refresher training and assist in assigning ICD-10-AM codes to uncoded admissions.

For all hospitals not on the PATIS system, a carbon copy or photocopied version of the individual patient admission details is generated from the paper-based patient medical records. The carbon copy or photocopied version is sent to the HIRA by the record administration staff, for coding and entry by medical coders into an electronic 'Manual report' database. Entered data includes; date of birth, age in years, age in months, age in days, ethnicity, sex, date of admission, date of discharge, ICD-10-AM code and discharge type (discharged/transferred/died).

2.3. Sample selection

The hospitals chosen for this study collectively capture approximately 80% of all admissions in Fiji. Private hospitals and specialist hospitals were excluded as the admissions are few, particularly for the outcomes of interest in the vaccine evaluation study. Selected hospitals were all three tertiary hospitals (CWMH, Lautoka, Labasa); the two largest secondary hospitals using the PATIS system (Nadi, Nabouwalu); and the two largest hospitals using manual reporting (Ba, Tavua). The percentage of national admissions between 2007 and 2015 by hospital were; 37% CMWH, 19% Lautoka, 11% Labasa, 5% Nadi, 1% Nabouwalu, 4% Ba, 2% Tavua. All wards admitting cases of pneumonia, meningitis, sepsis or diarrhoea of any age were selected. These wards included: paediatric, paediatric intensive care, neonatal intensive care, women's medical, men's medical, acute medical, intensive care, coronary care, surgical, trauma, and tuberculosis wards. All-cause admissions on selected wards during the designated time period were included in the audit. Admissions occurring in one designated week during the peak pneumonia season, without a public holiday, were selected for audit for each year of the vaccine evaluation study (2007–2011, 2014 and 2015). Either the week of 20–26th of April or 1–6th of May was chosen, dependent on excluding the public holidays for that year.

2.4. Data collection

Ward registers for the selected wards and audit period were located by the study team. If the patient register was missing the closest week temporally, without a public holiday and within the same year was taken. Ward registers were reviewed and all admission data entered into an Excel database on site by trained research assistants. Recorded variables included; hospital, ward, NHN, patient name, ethnicity, sex, age, date of admission, date of discharge, admission type (new admission/transfer), discharge type (discharged/transferred/died) and suspected diagnosis.

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