

Leveraging the Road to Health booklet as a unique patient identifier to monitor the prevention of mother-to-child transmission programme

A Haeri Mazanderani,^{1,2} MB ChB, MMed, FCPATH (SA) Viro, Dip HIV Man (SA); G G Sherman,^{1,3,4} MB BCh, MMed (Haem), PhD; F Moyo,^{1,4} MSc; A E Goga,^{5,6} MB ChB, DTM&H, DCH, MSc MCH, MSc Epidemiology, FCPaed (SA), PhD; U Feucht,^{6,7} MB ChB, FCPaed (SA), MMed (Paed), Dip HIV Man (SA), CAHM, PhD

¹ Centre for HIV and STIs, National Institute for Communicable Diseases, National Health Laboratory Service, Johannesburg, South Africa

² Department of Medical Virology, Faculty of Health Sciences, University of Pretoria, South Africa

³ Department of Paediatrics and Child Health, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa

⁴ Paediatric HIV Diagnostics Syndicate, Wits Health Consortium, Johannesburg, South Africa

⁵ Health Systems Research Unit, South African Medical Research Council, Cape Town, South Africa

⁶ Department of Paediatrics and Child Health, Faculty of Health Sciences, University of Pretoria, South Africa

⁷ Tshwane District Clinical Specialist Team, Pretoria, South Africa

Corresponding author: A Haeri Mazanderani (ahmadh@nicd.ac.za)

Background. Currently there is no unique patient identification system in the South African public health sector. Therefore, routine laboratory data cannot effectively be de-duplicated, thereby hampering surveillance of laboratory-diagnosed diseases such as mother-to-child transmission of HIV.

Objectives. To determine the uptake of Road to Health booklet (RTHB) identifiers at HIV polymerase chain reaction (PCR) birth test and describe their performance in linking follow-up test results in the early infant diagnosis programme.

Methods. Between May 2016 and May 2017, Tshwane District Clinical Services implemented a unique patient identifier pilot project in which a sticker-page of unique, readable, barcoded patient identifiers was incorporated in the patient-retained immunisation record (the RTHB) before distribution. Uptake of RTHB identifiers at birth was calculated as the proportion of HIV PCR tests in infants aged <6 days registered with an RTHB identifier over the total number of registered HIV PCR tests. Descriptive analysis of demographic details was performed among infants with two registered HIV PCR tests linked by the RTHB identifier, and performance of the National Health Laboratory Service Corporate Data Warehouse (NHLS CDW)-linking algorithm in matching RTHB-linked results was calculated using a 2 × 2 table.

Results. A total of 5 309 HIV PCR birth tests registered with an RTHB identifier were extracted from the NHLS CDW over the 13-month period of the pilot project. The number of registered RTHB identifiers increased from 24 (2% of birth PCR tests) in May 2016, peaking at 728 (56% of birth PCR tests) in May 2017. Among infants with a registered RTHB identifier at birth, 635 (12%) had a subsequent linked HIV PCR test, as indicated by the same RTHB number registered for a later specimen. Demographic details at the time of birth and subsequent PCR test were compared, demonstrating that <4% of infants had exact matches for name, surname, date of birth and sex; 74% of birth tests had variations such as 'born to' or 'baby of' in place of a first name; surnames matched exactly in 61% of cases; 18% ($n=116$) of infants had both tests performed at the same facility, of which only 27% ($n=31$) had the same patient folder number on both test results.

Conclusions. Leveraging RTHBs as unique patient identifiers, even if used temporarily until linkage to other future national unique identifiers, promises to be an effective scalable approach to laboratory-based surveillance, facilitating healthcare provider access to all test results from birth.

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Accurate patient identification is an essential requirement for safe, continuous medical care. In low- and middle-income settings, multiple unrelated patient identifiers and folder numbers are frequently used within different health facilities and across different health information systems, including primary healthcare clinics, hospitals, pharmacies and laboratories. The introduction of a unique healthcare identification number is often proposed as the most efficient way of connecting a patient with their medical records, thus reducing inefficiencies and errors, saving costs and facilitating monitoring of national health programmes.

South Africa (SA)'s National Department of Health has developed a Health Patient Registration System (HPRS) for the creation and

allocation of a unique patient identification number for all patients seen in the public health sector, although it has yet to become operational across the country. The first step in the implementation of the HPRS is to register primary patient identifiers within the system and link these to the HPRS-created unique patient identification number (also referred to as the Master Patient Index (MPI)), and thereafter to link electronic health records. The national SA identification number and alternative positive identification numbers from official documentation (e.g. asylum seeker permits and passports) are being used as the primary patient identifiers in the HPRS (M Wolmarans, chief director, Strategic Planning, National Department of Health – personal communication, March 2017).

This raises several important questions regarding the ability of the HPRS to assist with national disease surveillance, especially within programmes that monitor disease incidence among newborn infants, such as the prevention of mother-to-child transmission (PMTCT) of HIV programme (which monitors and acts on infant HIV test results from birth). The infrastructural requirements needed to generate national identity numbers for all newborn infants, and parental indecision regarding a newborn's name and surname, are likely to delay registration and assignment of a national identity number prior to discharge. Furthermore, in healthcare settings with a high proportion of migrants, use of national identity numbers as a requirement for access to healthcare can represent an important obstacle towards achieving equity in the healthcare system. Even if MPIs were to be provided without identification numbers, it is unclear how these could be generated before neonatal testing at all obstetric units across the country.

In contrast to national identification number documents, infant immunisation records are readily available at birth and handed to each mother at the time of delivery, regardless of race, ethnicity, nationality or health facility. Furthermore, they are free of cost and have the potential to play an important role in tracking and documenting immunisation status and other childhood health services received.^[1] They are therefore well positioned to be leveraged as a vehicle to provide newborn infants with a unique patient identifier. In SA, the patient-retained immunisation record, referred to as the Road to Health booklet (RTHB), is a comprehensive child health document that includes health-promotion information, as well as growth and developmental monitoring tools and the ability to track adherence to the PMTCT programme. Early infant diagnosis (EID) of HIV, an essential component of the PMTCT programme, includes routine HIV polymerase chain reaction (PCR) testing at birth and 10 weeks of age for all HIV-exposed infants – ~260 000 infants per annum in SA.^[2] Hence, the RTHB has a pivotal role in improving communication between health workers and caregivers, empowering caregivers, enhancing continuity and co-ordination of care, as well as having the potential to assist with monitoring of national public health programmes, such as the PMTCT programme.^[3] Although the World Health Organization (WHO) recommends that patient-held immunisation records be issued with a unique identifier,^[1] SA's RTHBs are currently not issued with identifiers, despite being printed and distributed centrally.

In May 2016, Tshwane District Clinical Services implemented a unique patient identifier pilot project in which unique, readable barcoded patient identifiers were incorporated in the RTHBs and distributed within the district. We report on the use of these identifiers and describe their performance in linking follow-up test results within the HIV EID programme.

Methods

Setting

Tshwane District is a large metropolitan area in SA's Gauteng Province. There are ~50 000 live births per annum in the district's public health sector; 12 000 (24%) of these infants are born to HIV-infected mothers (L Bamford, National Department of Health – personal communication, July 2017). National guidelines for EID recommend that all HIV-exposed infants have routine HIV PCR testing at birth, at 10 weeks of age and 6 weeks after cessation of breastfeeding, with confirmatory testing of infants who test positive or indeterminate using the same assay on a subsequent specimen.^[4,5] On account of this, and the lack of a national unique patient identifier, routine laboratory data cannot effectively be de-duplicated, thereby

hampering surveillance efforts, such as estimating mother-to-child transmission rates. To address these challenges, various probabilistic patient-linking algorithms are used that employ demographic details, including first name, surname, sex and date of birth, to link all laboratory results to an individual patient. The algorithm currently used by the National Health Laboratory Service Corporate Data Warehouse (NHLS CDW) has a reported sensitivity of 73% and positive predictive value of 83% among adult patients,^[6] while performance among infants is unknown.

Road to Health booklet identifiers

The RTHB is a standardised patient-retained health record issued at birth to all infants born in the SA public health sector, and documents an infant's immunisation, growth and PMTCT status. Between May 2016 and May 2017, RTHBs distributed within Tshwane District were pre-issued with a unique patient identifier. To avoid stigma, these were issued to infants, regardless of nationality or HIV-exposure status. An identifier product, custom designed for the purpose of this pilot project, comprised a page of 30 readable barcoded stickers, with a separate laminated barcoded peel-out card, as well as adhesive strips to facilitate manual insertion in the RTHBs (Fig. 1). Initially, 70 000 unique RTHB identifiers were printed at ZAR4.57 per identifier. Identifiers were prefixed with the letters RTHB, followed by a unique combination of four numerals and four alphas, so as to distinguish them from all other identifiers/barcodes used in the public health sector. Clinical staff working in the district were requested to place an RTHB sticker on the laboratory request form each time clinical specimens were submitted to the laboratory, and laboratory personnel were requested to capture the RTHB identifiers within a specific searchable field (alternate reference number) available on the laboratory information system and not currently used within the district. An additional column populating the RTHB identifiers was also incorporated in the consolidated HIV PCR results (Results for Action Reports) routinely distributed in the district on a weekly basis, thereby allowing continuous monitoring of uptake and usage of RTHB identifiers in all public health facilities in the district.

Analysis

All HIV PCR results taken from health facilities in Tshwane District and registered between 1 May 2016 and 31 May 2017 were extracted from the NHLS CDW. Uptake of RTHB identifiers at birth was calculated as the proportion of HIV PCR tests among infants aged <6 days, registered with an RTHB identifier over the total number of registered HIV PCR tests among this age group. Descriptive analysis was performed and median and interquartile ranges (IQRs) were calculated for duration between birth and subsequent testing. As a means of validating the performance of the NHLS patient-linking algorithm among newborn infants, we measured the ability of this linking algorithm against the RTHB unique patient identifier issued to link HIV PCR laboratory results at birth (defined as infants aged <6 days) to subsequent registered HIV PCR results. Performance of the NHLS CDW-linking algorithm in identifying RTHB numbers was calculated using 2×2 tables. Analysis of first names and surnames among RTHB-linked results was performed manually by a single researcher, and coded into one of three categories: names that were recognisably similar (with character differences counted), names that were considered distinctly different, and names that were prefixed (or followed) by an indication that the patient had yet to be named (e.g. 'baby of' or 'born to'). Data were extracted in Microsoft Excel, and all statistical analysis was performed using STATA version 14 (StataCorp., USA).

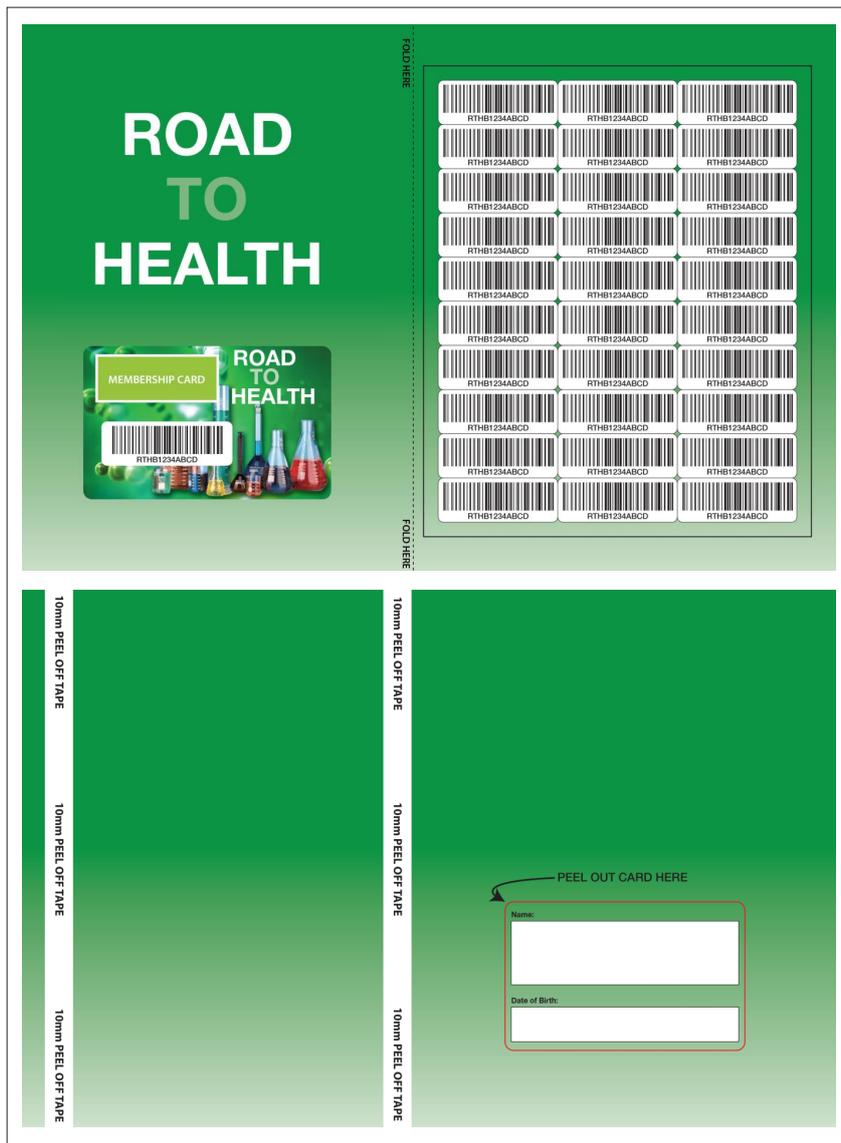


Fig. 1. Road to Health booklet unique patient identifier.

Results

Among 13 499 HIV PCR birth tests extracted from the NHLS CDW over the 13-month study period, 5 309 (39%) had a registered RTHB identifier. The number and proportion of birth tests with an RTHB identifier increased from 24 (2%) in May 2016 to 727 (56%) in May 2017 (Fig. 2). Among the 5 309 infants with an RTHB identifier captured at birth, 635 (12%) were found to have had a second HIV PCR test, as indicated by the same RTHB identifier registered for a later specimen, with 25 (0.5%) infants having a third test. The median age at first PCR test was 1 day (IQR 1 - 1) and at second test 73 days (IQR 70 - 81). Unfortunately, the coverage of PCR testing after birth in the district is unknown on account of the inability to effectively de-duplicate routine laboratory data. However, HIV PCR testing volumes

within Tshwane District among infants aged between 8 and 14 weeks approximated two-thirds of the testing volume at birth during the study period.

Of the 635 infants with ≥ 2 RTHB-linked tests, birth HIV PCR results were as follows: 6 (0.9%) were positive, 7 (1.1%) indeterminate, 604 (95%) negative and 18 (3%) rejected. Among the 6 infants with a positive result at birth, 5 tested positive and 1 indeterminate on the second test, whereas of the 7 infants who had an indeterminate result at birth, 5 tested negative and 2 positive on the second test. Only 1 of the 5 infants with an indeterminate-negative result had a third HIV PCR test, which was positive. Hence, 9 of 635 (1.4%) infants could be classified as having an intra-uterine infection, as determined by two instrument-detected results (i.e. either positive or indeterminate),

of which one was a birth test. As none of these patients had the same facility number on follow-up testing and none could be linked using the current NHLS CDW patient-linking algorithm, the RTHB identifier proved to be the only consistent identifier linking these results (6 of the 9 infants had the same surname registered for their screening and confirmatory tests, but first names differed for all of these patients). Of the 609 infants who tested negative at birth, 3 (0.5%) had an instrument-detected result on the second test (2 positive and 1 indeterminate), which was suggestive of intrapartum or early postnatal infection.

Comparing demographic details of the 635 birth HIV PCR tests with their subsequent registered HIV PCR tests, in only 23 (4%) infants did all four of their primary demographic details (viz. first name, surname, sex and date of birth) match exactly. Whereas first name matched in only 33 (5%) cases, surname proved to be more consistent, with 390 (61%) exact matches, followed by sex in 577 (91%) cases, and date of birth in 579 (91%) cases. Although 116 (18%) infants accessed the same health facility for follow-up testing, among these only 31 (5% of total) had the same facility folder number on repeat testing. Results of patients whose first name and surname differed were analysed further to determine reasons for failed matching: of the 602 infants whose first name did not match exactly, only 1 (0.2%) was recognisably similar for both tests (with one-character difference between the initial and subsequent test results). In comparison, among 245 infants whose surname did not match exactly, 86 (14% of total) were recognisably similar, of whom 59 (68%) had one character difference, 17 (20%) had two character differences, 5 (6%) had three character differences and an additional 5 (6%) had four character differences. Among the 635 birth tests, 468 (74%) were registered for patients who had their first name prefixed by a variation of 'baby of' (i.e. suggesting either the patient had yet to be named or was registered under the mother's details). Even among infant surnames, the prefix (and occasionally suffix) 'B/T' or 'BT' accounted for 37 mismatches, of which 23 had the exact same surname otherwise. Hence, whereas first name could only be matched at most in 36 (6%) of 635 cases, surname could potentially be matched in 499 (79%) cases. Among the 468 infants whose birth test was not registered with their own name, 271 (58%) had exactly the same date of birth and surname or were linked using a facility folder number, and

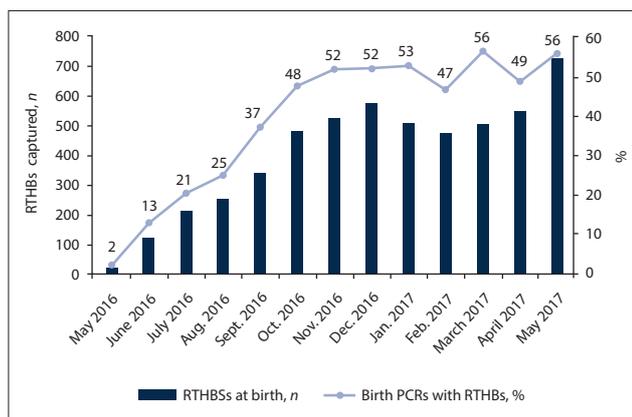


Fig. 2. Number and proportion of Road to Health booklet identifiers captured at HIV PCR birth testing during the pilot project. (PCR = polymerase chain reaction; RTHB = Road to Health booklet.)

an additional 57 (12%) had exactly the same date of birth but the surname, although similar, differed by one or more characters.

Overall, 326 (51% of total) HIV PCR birth tests could be linked to the subsequent HIV PCR test using either the facility folder number or matched with the exact same surname and date of birth. An additional 177 (28% of total) infants could potentially be linked using less stringent demographic criteria, including slight differences of surname and/or date of birth. This leaves at least 133 (21% of total) infants unable to be matched using demographic and/or facility details. The current NHLS CDW patient-linking algorithm was evaluated to determine performance of linking birth tests with subsequent results. A total of 30 true-positive, 44 false-positive, 4 595 true-negative and 605 false-negative patient links were made. Using the RTHB identifier as the gold standard, sensitivity was calculated at 4.7%, specificity at 99.1%, positive predictive value at 40.5%, negative predictive value at 88.4% and overall accuracy at 87.7%. Importantly, name and surname are considered part of the minimum clinical data set in the NHLS, without which clinical specimens are routinely rejected and not tested. During the study period, only 6 (0.1%) specimens registered with the RTHB identifier were rejected on account of no patient name, surname or number provided on the laboratory request form.

Discussion

The proportion of HIV PCR birth tests registered with the RTHB identifier reached >50% after only 6 months in this proof-of-concept pilot project, suggesting RTHBs can successfully be leveraged to provide infants with a unique patient identifier at birth. The project further demonstrated that the RTHB identifiers can readily be incorporated in the laboratory information system and the NHLS CDW environment. This allowed individual patient results to be searched with the RTHB identifier, using the TrakCare Web Results Viewer application, with all results registered with the patient's unique RTHB identifier readily retrieved using a single search. Furthermore, the additional column populating the RTHB identifiers incorporated in the consolidated weekly HIV PCR Results for Action Report, allowed continuous monitoring of uptake and usage of RTHB identifiers among all of the public health facilities in the district. Interestingly, the intra-uterine and intrapartum infection rates among the RTHB identifier cohort are similar to near-contemporaneous birth cohorts described in SA,^[7,8] supporting the potential use of RTHB identifiers for EID surveillance.

Although usage rose rapidly after the first few months of the project, coverage plateaued and did not exceed 56%. This can possibly

be attributed to shortages of printed books with RTHB identifiers, as the printing had been sourced from alternative funding. An additional 10 000 books with identifiers were subsequently printed, thereby preventing a steeper decline in usage. Despite the successes of registering the birth tests with RTHB identifiers, the coverage of the routine 10-week HIV PCR tests proved to be markedly less. Only 12% of infants with a birth RTHB identifier were found to have a subsequent HIV PCR test with a registered RTHB identifier, suggesting primary healthcare clinics need to be better informed and motivated regarding usage of the RTHB identifiers for subsequent tests after birth, especially if the project is to be scaled up.

Where RTHB identifiers were consistently used, they proved to be very effective in linking results and far more reliable than demographic details and facility numbers. Even among infants who were followed up for their subsequent HIV PCR tests at the same facility as the birth test, only a quarter had the same facility number. Overall, three-quarters of birth tests were registered for patients who had their first name prefixed by a variation of 'baby of' (i.e. suggesting either the patient had yet to be named or was registered under the mother's details), 39% of surnames did not match the subsequent HIV PCR test, and both date of birth and sex did not match in 10% of cases. These findings suggest that linking laboratory results of infants using facility numbers and probabilistic matching of demographic details are inherently problematic and unreliable. In patients with RTHB identifiers, only 0.1% of results were rejected on account of missing demographic information, which suggests that the use of RTHB identifiers is unlikely to be associated with healthcare providers omitting demographic information because they now have a unique RTHB identifier. However, we did not conduct specific statistical analyses to test this, which could be considered a limitation of our analysis.

SA's PMTCT programme represents just one screening programme that could benefit greatly from leveraging RTHB identifiers as a system for patient identification. The consistent use of a unique patient identifier from birth that is captured in the laboratory information system promises great advantages for patient care, as well as public health surveillance, planning and response. By linking a patient's barcoded identifier with each registered laboratory test set, whether by scanning the barcode or manually entering the identifier in a searchable field of the laboratory information system, all laboratory results for an individual patient can in effect be retrieved using a single identifier. This could have significant cost-saving benefits, especially for national diagnostic and monitoring programmes that make use of a single laboratory network, as unnecessary repeat testing would be reduced through ready retrieval of previous results. Furthermore, the use of a patient identifier that links clinical records with laboratory results would facilitate cohort monitoring. Hence, records in health information systems could effectively be de-duplicated, thereby enabling surveillance efforts that use routine data for epidemiological purposes and programme planning.^[9] For example, this would make it possible to monitor the HIV infant testing coverage in different age groups and accurately determine overall mother-to-child transmission rates for the first time.

In addition to registering the RTHB identifier as an alternative reference number, it could be used as the patient's folder number, thereby providing a ready alternative to the mother's facility number, and used to link the infant's facility-based file with the home-based immunisation record. The RTHB identifier could also be used to inform the laboratory which HIV PCR requests are for infants (as indicated by the RTHB identifier provided on the laboratory request form) as opposed to unnecessary requests for adults, and thereby

assist with electronic gatekeeping in the NHLS. RTHB identifiers could also be used in the birth registry and in electronic health records, as well as incorporated in the MomConnect programme as a means of establishing a searchable link between mother-infant pairs. Furthermore, identifier stickers provide an opportunity to facilitate linking of other electronic health information systems, including the pharmacy and imaging department, to the laboratory records. As a means of addressing the difficulties in providing all newborn infants with their own primary patient identifier or HPRS number prior to neonatal testing, the RTHB identifiers could be used to bridge the initial period until a final unique patient identifier is issued to the child, thereby ensuring electronic linking of laboratory results and providing the opportunity for longitudinal health monitoring from birth.

An important limitation of using patient-retained records as patient identifiers is the propensity for losing or forgetting these at the time of presenting to a healthcare facility. Indeed, current evidence suggests that few national health systems are able to retain immunisation records at levels of >80% on follow-up, despite distribution levels of >90% with regard to newborns.^[10,11] This can have serious implications for patient care and limit the effectiveness of leveraging the RTHB as a vehicle for patient identification. Additional limitations include the potential costs involved in printing barcoded unique identifier stickers and the infrastructural requirements – in the health facility and clinical laboratory – to capture the unique patient identifiers and regenerate identifier stickers once these are exhausted in the RTHB. However, these concerns can readily be countered on the basis that the use of immunisation booklets as unique identifiers could again place the focus on the importance of home-based vaccination records, thereby improving co-ordination of patient-centred services and recording during immunisation programmes, as well as decreasing unnecessary and expensive re-immunisation and re-testing services.^[12] Furthermore, the use of an additional peel-out identifier card could provide caregivers the opportunity to safe-keep a record of the RTHB identifier in case the immunisation record is lost. As barcoded stickers are inexpensive and technology that is readily available to ensure unique combinations is provided per RTHB, it is anticipated that the cost-savings associated with their use would justify the expense.

Conclusions

In summary, we propose that the patient-retained immunisation record (i.e. the RTHB) represents an unambiguous and stigma-free opportunity to provide a unique identifier to all neonates at birth or first contact with health services. Pre-issued barcoded identifier stickers (with readable numeric/alphanumeric code) will assist with the consistent use of the RTHB identifier and reduce the possibility of transcription error. As the HPRS number (or MPI) is unlikely to be available to all newborn infants at the time of neonatal testing, the RTHB identifier could readily be used, with minimal infrastructural and cost requirements, to bridge patient identification during early infancy until a final unique health identifier (i.e. HPRS number) can be issued. This in turn will support the continuum of

care and surveillance efforts, allowing multiple health visits to be electronically linked, thereby reducing inefficiencies, saving costs and ultimately improving care. Such an initiative has numerous additional advantages, including the ability to match mother-infant pairs. On account of substantial differences in folder numbers and demographic details of infants, patient-linking algorithms are unable to accurately match infant tests in the NHLS CDW, and at best will link only 70 - 80% of patient results, further highlighting the need for a ready alternative for infant patient identification.

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Conflicts of interest. None.

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