1. Introduction

Childhood vaccines have been one of the most successful and cost-effective interventions in the history of public health for reducing mortality and morbidity [1, 2]. Maximising the success of vaccination programmes and inducing herd-protection for unvaccinated persons by disrupting transmission [3, 4] requires high population coverage [5].

Vaccine coverage is a key indicator of health system performance, is used as a proxy for the availability and quality of primary healthcare services and is an important predictor of infant mortality rate [6]. It can also help inform when to introduce a new vaccine [7], how close a population is to achieving herd-protection [8, 9], and in modelling lives saved and cost-benefits [10-12].

Coverage levels are universally reported by governments and international organisations, and are particularly important in high mortality regions facing implementation challenges [13, 14]. Data need to be of high quality, geographically-precise, inexpensive and timely, which may be challenging in LMICs where there are resource and infrastructure constraints.

However, estimates have repeatedly been shown to be of low reliability and validity [15-17]. Several methods are used for collecting information on vaccine coverage, including national electronic registers, reporting of health-facility records and population surveys. In countries that lack established national reporting systems or accurate facility records, vaccine coverage data often come from surveys. Subject-held cards can be used to record receipt and date of vaccines but they are not always available or accurate for use in surveys [18-20]. Therefore asking the mother or caregiver questions about the child’s vaccination status is commonly used to supplement card data. Due to the increasing complexity of immunisation schedules [21], recall may become less accurate and the direction of arising biases is unknown.

Therefore understanding if and how caregiver recall should be used is important [18-20, 22, 23]. We assessed the validity, reliability and completeness of caregiver recall of childhood vaccine status to estimate coverage in LMICs. We also developed recommendations to improve the collection, analysis, presentation and interpretation of recall data for investigators and policy makers.

1. Material and methods

In January 2017 we conducted a systematic literature review of methods for estimating childhood vaccination coverage in LMICs, including specific search terms for caregiver recall.

*2.1 Search Strategy*

We searched OvidSP MEDLINE using the following key terms (see supplementary material 1 for full search strategy): “(infant OR child) AND (vaccinat\* OR immunisation) AND (data collection OR survey OR recall OR coverage) AND (evaluat\* OR reliab\* OR valid\*)”. Reference lists of included articles were screened for additional papers.

*2.2 Inclusion and Exclusion Criteria*

We added filters to the search to include observational studies, interventional studies, reviews and articles published in English after 1980 (when many survey techniques and statistics were developed). Arising titles and abstracts were screened and only those that measured childhood vaccine coverage in LMICs were included. All relevant articles were read in full and those that assessed the quality of caregiver recall with regards to validity, reliability or completeness were included in this review.

*2.3 Data Extraction*

The final publications were critiqued with respect to three important components of data quality: validity, reliability and completeness [24]. For data extraction, the definitions from the independent Healthcare Quality Improvement Partnership guidance on data quality were used [25]:

Validity: “Data meaningfully represent exactly what they are intended to represent” [25]. We extracted measures that compared coverage to a gold standard including but not limited to sensitivity, specificity, positive predictive value and negative predictive value.

Reliability: “Data are the same no matter who collects the data or when a person collects the data” [25]. We extracted measures of coverage that were performed on the same population by different investigators, or the same investigators at different times that should reasonably be expected to give the same coverage values.

Completeness: “All the elements of information needed are present in the designated data source and no elements of needed information are missing” [25]. We extracted methods on dealing with missing data where this was explicitly stated, including their evaluations of these methods.

We also extracted author, year, country, vaccine, age of subjects, recall interval, study design and the authors’ recommendations. RM performed data extraction; TC, CK and NBZ advised on data extraction categories and checked the results of the extraction.

We then synthesised recommendations for the collection, analysis, presentation and interpretation of caregiver recall in childhood vaccine surveys. The systematic review was reported according to PRISMA standards.

1. Results

 Our search returned 1268 papers, of which 77 were included in our systematic review of measuring vaccine coverage, and of these 9 met inclusion criteria for this review of caregiver recall (Figure 1). We did not find any reviews on the quality or use of caregiver recall. A summary of the papers is presented in Table 1. As key components of data quality, we present the results relating to validity, reliability and completeness [24, 25].

Figure 1. PRISMA Flow Diagram illustrating selection criteria for systematic review and subsequently for review of caregiver recall

Table 1. Summary of included studies exploring the use of caregiver recall in vaccine coverage estimates.

*3.1 Validity*

Recall data validity was assessed by all nine studies.

George, Victor & Abel compared recall and card data for 1050 children in Tamil Nadu, India [26]. Concordance was 85%, with a weighted Kappa of 0.905 (Table 1). Diphtheria Tetanus Pertussis 3rd dose (DTP3) coverage was 47% by recall and 39% by cards. However, many caregivers recalled at least one vaccination being given when none was recorded on the card, and taking the card as the standard, recall had 12% specificity. If recall indeed overestimates coverage, then truly unvaccinated children may not be targeted for vaccination. Therefore, although it may not be accurate, they assumed that any difference between a higher recall and a lower card estimate was an overestimation on behalf of recall data.

Gareaballah & Loevinsohn’s study in Sudan used four ‘Expanded Programme of Immunization’ (EPI) surveys, in which the recall of 464 illiterate mothers was compared to cards [27]. Compared to the card standard, recall had 87% sensitivity and 79% specificity for all vaccines. Misclassification was bidirectional (6% of mothers over- and 4% under-reporting measles vaccine compared with card).

Langsten & Hill’s study of children aged 12 – 35 months in 12 Egyptian villages involved three rounds of data collection [22]. They compared the recall among those without a vaccination card in round one to the card data when it became available in subsequent rounds (331 children). In examining recall for BCG, DTP3 and measles vaccine, 83 – 98% of caregiver reports were confirmed by cards, showing reasonable validity.

Ndirangu et al. compared both caregiver recall and vaccination cards to clinic records from a cohort of patients as the standard, in the second year of life in KwaZulu-Natal, South Africa. [23]. The cohort were part of a study of maternal HIV (Vertical Transmission Study, VTS) and were attending the study clinic on a one- to three-monthly basis [28]. They matched the clinic records of 821 children aged 12-23 months to their records from Demographic Surveillance System (DSS) surveys, which were performed biannually. At clinic visits vaccine status was recorded per clinic notes, subject-held card and caregiver recall. If a vaccine was due they would administer it and record it in the clinic records and vaccine cards. If subjects had received the vaccine elsewhere, they did not administer the vaccine and made no record. DSS surveys recorded vaccination data for children aged 12-23 months based on card and recall information.

As they could only compare card and recall to those vaccines given in study clinics, they presented sensitivity and not specificity. Sensitivity compared with clinic records was 94 – 98% across antigens for caregiver recall and 94 – 97% for cards (Table 1). They suggested that recall was unlikely to under-estimate coverage from vaccines given in the study, but they were unable to assess over-estimation.

Ramakrishnan et al. surveyed a cohort of 774 children aged 12-23 months in Tamil Nadu every one to two weeks. [19]. They compared caregiver recall and card data from a survey performed at one year against the cohort dat. For overall vaccination status they found that caregiver recall had sensitivity of 41%, positive predictive value of 18%, specificity of 80% and negative predictive value of 93%. Overall the coverage estimate from recall and cards was different from the cohort data (McNemar’s chi2: p < 0.0001) (table 1).

Goldman and Pebley [18] found that the coverage and continuation rates (proportion of those who had the first dose who also had the third dose of a three-dose regimen) was similar for those presenting cards (e.g. DTP1 – 3 continuation rate 70%) and those who claimed they possessed a card but could not present it (e.g. 66.9%); these were higher than the recall data for those who did not possess a card (e.g. 48.5%). This may reflect valid recall, and the absence of a card may be a marker of less frequent contact with the health system and therefore lower vaccine coverage. However, it cannot be determined if the differences are actually due to card-ownership improving recall, and without cards, patients may be more likely in this population to report non-vaccination.

In this study, recall of the vaccination timing differed markedly to card records, with recall alone estimating greater time-compliance than cards alone e.g. for birth dose polio, when interviewed at age four, time-compliance was 41% by recall alone versus 10% by cards alone [18].

*3.2 Reliability*

Only one study addressed intra-reporter reliability of recall over time. Among 45 countries from which Demographic and Health Surveys (DHS) were reviewed, Bangladesh, Indonesia and Tanzania had two overlapping DHS performed [29], therefore overlapping cohorts were surveyed. Vaccine coverage estimates by recall did not differ between the two surveys at the 95% confidence-level (48% and 54%in Bangladesh; 50% and 50% in Indonesia; 43% and 46% in Tanzania). This only looked at three countries so findings may not be generalisable and although DHSs do have large samples, there was no indication that they were powered for this analysis. In addition, DHS studies examine both recall and cards so the coverage estimates do not reflect just recall reliability.

*3.3 Data completeness*

Three studies assessed the completeness of coverage data.

Gareaballah & Loevinsohn [27] reported between 9 and 19% of 464 caregivers were uncertain whether a specific vaccine had been given, depending on the vaccine. For simplicity of analysis, they assumed that the group with uncertain vaccination status were either all vaccinated or unvaccinated and found some change in sensitivity (e.g. 95% versus 87% for measles) and specificity (70% versus 79% for measles). Measles, however, had the least missing data (9%), perhaps due it being more recent and on its own at 9 months, and other vaccines with more missing data were likely to have more varied coverage estimates following these assumptions for missing data.

Vaccine timeliness data from caregiver recall is often missing: Murray et al. noted that DHS, which are frequently used for national vaccine coverage estimates, do not collect date of vaccination from recall [29]. When this was attempted, Goldman and Pebley noted that only 15% of caregivers could provide a date [18].

1. Discussion

This review found a dearth of evidence on reliability and no consensus on how to appropriately deal with missing data, but some agreement on the validity of recall.

Limitations include that measures of validity varied greatly and so were less comparable. In addition, the methods for obtaining, using and validating recall varied. Many studies were low powered and we were unable to assess publications in languages other than English. In addition, five of eight of the selected studies were published prior to 2000, whereas the Global Alliance for Vaccines and Immunization (GAVI) was established in 2000 [30]. This alliance has helped introduce more vaccines into the childhood schedule, which may have made recall harder and worsened recall bias, especially as it may be harder to recall the number of doses amongst multi-dose regimens [31, 32]. As a result, we recommend that further studies on the quality of recall are performed to examine this with the current, fuller, vaccine schedule.

Taking account of this, we discuss issues with caregiver recall and make recommendations for its collection and use, summarised in figure 2.

Figure 2. Flowchart of guidance for investigators on the use of caregiver recall in childhood vaccine coverage surveys depending on the aim, size and resources available.

*4.1 Conducting the Survey*

The interview process for vaccine status based on caregiver recall may be prone to recall bias and social-desirability bias, as respondents try to convey a favourable image of themselves, even if this is not an accurate response [33]. In order to reduce these biases Cutts et al. [21] recommend the following: investigators should display a neutral attitude to vaccination to avoid acquiescence bias; avoid asking too many questions to prevent fatigue and give mothers sufficient time to answer; use standardised questions and visual aids; and have close supervision. However, adequate time and close supervision may imply more resources, which may be difficult in LMIC settings. Adequate time may be context-specific and close supervision could be dependent on the baseline error rate in surveys, which can be assessed separately (see below). There is insufficient information from these studies to determine the effect of recall length on recall bias and the ideal timing of a survey, and further studies are needed to assess this.

An example of thorough supervision in a vaccine survey is given by Gunnala et al. from cluster surveys in Northern Nigeria [34]. There were clear lines of management and accountability to a central coordinator, and for each interview there were two interviewers and one supervisor (although this may be intimidating for respondents). All had two to three days of training and interviewers had been selected based on their performance during training. The final supervisory structure was determined from a pilot phase followed by refresher training. Supervisors were given standardised monitoring forms relating to adherence to survey protocol and data quality. However, this paper did not discuss the effects of this intensive data collection protocol on the quality of recall data or the costs, and so we cannot make a strong recommendation for this.

As noted by Murray et al. [29], most recall surveys do not collect timeliness data, and as noted by Goldman and Pebley [18], timeliness by recall greatly differed from that by cards. It is therefore unclear at this point whether timeliness should be collected in caregiver recall surveys.

Of note, there are standard questionnaires used in vaccine surveys for the DHS and Multiple Indicator Cluster Surveys (MICS) [35] but whether they are appropriate for all settings is beyond the scope of this review.

*4.2 Absence of a Gold Standard*

There is no indisputable gold standard for coverage against which to assess validity of caregiver recall. Most assessments of validity assumed vaccination cards were the gold standard. Although not a primary aim of this review, some studies did assess the validity of cards:

The studies showed a range of validities of cards. For example, against cohort data, sensitivity of card data varied from 94-97% in one study [23] but in another, 70% were incorrect [19]. Issues raised included poor card condition, cards being incomplete, poor card retention [19, 23] and errors in transcribing onto cards [22].

There is also evidence that clinic vaccination records are not highly valid [15, 36, 37] and miss vaccines given at different clinics.

Another standard presented was cohort data from frequent population surveys data. One issue is that cohorts and closely monitored areas may be more sensitised to interventions and records and therefore coverage estimates may not be generalisable to the target population. An example is DSS areas, such as that used by Ndirangu et al. [23], which undergo intense interventions and study. In addition, in this study population, approximately 50% of the mothers attending study clinics were HIV-positive and may have had different healthcare behaviours, resulting in different levels of card retention (two-thirds in this study), maintenance and recall than the general population.

Ramakrishnan et al. [19], using a cohort, reported that their estimate of the validity of recall was likely an over-estimation due to this sensitisation and the relatively short recall period of one year. However, there is no way to be certain which standard is more accurate, therefore it is difficult to determine the magnitude and direction of error in caregiver recall. It may therefore be inappropriate to use the terms ‘validity’, ‘sensitivity’ and ‘specificity’ but rather kappa statistics of inter-rater agreement.

Perhaps cards are a practical standard but more research is needed into the best methods for improving their validity such as training, supervision, audits and incentives [21, 34]. Retention might be improved by having vaccination data recorded on birth certificates as it is an important document that might be retained, however approximately 35% of births worldwide are unregistered with inadequate vital registration systems [38]. In Langsten & Hill’s study, this technique resulted in only 84% being able to present the birth certificate [22]. Prior to a survey, announcements could be made to sensitize populations to the importance of vaccine cards, and during surveys, time (and even re-visits) could be allowed to find them; surveys could also check for obvious documentation errors [21]. If not available, clinic records could be sought. The flaws in each source may be minimised by triangulating data from different sources but there is difficulty in knowing which sources to prioritise. Some of these methods may be too resource-intensive for many settings, and it is not clear how inconsistencies would be resolved.

*4.3 Assessing the Quality of Caregiver Recall and Cards*

Due to varying agreement between caregiver recall and cards in different settings, it may be advisable to assess the quality of caregiver recall and cards in a sample of subjects within each survey.

For recall, this could be done by comparing recall data to card data for a sample of the target population who possess cards, after having made some steps to improve the validity of cards noted above. However, the validity obtained by comparing recall to cards in those who possess cards may be different to those who do not possess a card and so cannot be generalised so easily. The former may prioritise health more highly or have seen or had the card explained to them more recently, and so recall better. An indirect method, recommended by Cutts et al. [21] and used by Goldman & Pebley [18], was to compare coverage in those who reported a card but were unable to present it to those presenting a card, expecting similar estimates if recall is valid. Alternatively, one could compare vaccine coverage to rates of other childhood indicators (e.g. use of oral-rehydration therapy) for those with and without cards, as one would expect similar associations in both groups if recall is reliable [21]. In addition, one may compare recall or cards to clinic data but, as noted above, this too has questionable validity.

Figure 2 shows a few options for assessing the validity of cards. This ranges from simply noting the proportion of records retained, to comparing card data to that collected from a cohort.

We found only one study that assessed the reliability of caregiver recall [29]. Test-retest reliability may be useful but requires resources for at least two surveys.

*4.4 Calculating Coverage*

In view of the quality issues with recall data, it is important to determine whether and how to include caregiver recall in the calculation of vaccine coverage. Goldman & Pebley’s study in Guatemala [18] presented four methods for calculating coverage which consider caregiver recall and the assumptions for each method (Table 2).

Table 2. Methods for calculating coverage including ways to incorporate caregiver recall and the associated biases. Adapted from table 2 from Goldman & Pebley’s study in Guatemala [18], with additional notes about considering the accuracy of cards.

Method 1 (number vaccinated according to cards / number of cardholders) restricts coverage estimate to those who possess a card. Card holders may have a higher rate of vaccination than those missing a card, so this method may overestimate coverage. Method 2 compares the number vaccinated according to card to the total number of children who are vaccine age-eligible. This method may underestimate coverage, since it does not count as vaccinated those children receiving vaccines who possess no card. Method 3 counts as vaccinated those with card documented vaccine receipt and in absence of card counts caregiver reported vaccination divided by the total number of vaccine age-eligible children. Method 4 includes as vaccinated those with card record plus caregiver reported vaccination in absence of cards plus caregiver report of additional vaccines not included in an available card. Methods 3 and 4 do not differ substantially e.g. DTP1: 73.7% versus 74.8%. However, 19% of those with cards reported additional unrecorded vaccines so this may be worth collecting. None of these methods account for any vaccines written on the card that caregivers report were *not* given.

*4.5 Handling and Presenting Data*

Due to the issues with assessing recall and cards, and there not being a ‘gold standard,’ we recommend that where feasible measures of recall or card data quality be reported. This includes: the proportion of recall only responses; the proportion of card retention (and why); and the proportion of vaccine status’s with conflicts between caregiver recall and cards. However, we would not recommend adjusting a primary analysis for these uncertainties because it is unclear how to this can be done accurately. The presentation of these data would allow the reader to take these into account.

There is some literature on dealing with missing data. Gareaballah & Loevhinsohn suggested that for those for whom caregivers age no answer about vaccination status, one should assume they were all unvaccinated to avoid the risk of overestimating vaccine coverage [27]. However, this is likely to bias coverage estimates and could result in excessive resources being deployed to increase coverage, and falsely lower vaccine efficacy estimates.

Certain socio-economic factors (e.g. maternal age [19], maternal secondary education, health service contact [18]) may be associated with the likelihood of being vaccinated, of vaccination being timely [29], presenting cards [18, 29] and of recalling vaccinations more accurately [19, 22]. If there are resources to allow collection during surveys and analysis of socio-economic data that are known to be confounders in that context, one could model for those vaccinations for which mothers are unsure about whether they have been given [21] or when they have been given [29] by imputation or likelihood functions. For example, Murray et al. used a Heckman probit model with sample selection to calculate the total number of timely vaccinations from the combined card and caregiver recall data [29]. In this, they applied the associations of socio-demographic variables with having a card and having timely vaccination to obtain probabilities for timely vaccination amongst those with a card and those without.

It must be stressed that the socio-demographic associations may be context-specific and so associations for that context should be used. For example, Goldman and Pebley looked at the associations between respondent characteristics and presenting a card in Guatemala [18]. In this context, those with a secondary education or higher, those living in urban areas and those with more health service-contact were less likely to present cards, perhaps because they have kept cards elsewhere e.g. in a private clinic. It would be worth reporting these context-specific variables that affect recall for the reader to consider. Gaining context-specific socio-demographic associations will require resources for collection or previous relevant studies and so this process is not appropriate for all surveys.

The DHS and MICS adjust coverage estimates for missing data according to characteristics of the caregiver but not by multiple imputation. This includes adjusting differently for those who present a card and those who do not, and their methods are well documented [35].

A final option for presenting recall data is with a sensitivity analysis. Due to the range of estimates available – from reporting crude estimates to those statistically adjusted –presenting the range of overall coverage estimates is advisable. As is common in DHS, MICS and other surveys, investigators should present coverage estimates based on cards alone, recall data and on card combined with recall data. [35]. This could be followed by presenting decision outcomes based on these two estimates to illustrate the range of effects of different estimates. For example, Caini et al. performed a clustered-lot quality assurance sampling (CLQAS) study to evaluate uptake of meningitis A vaccine in Niger [20]. They presented coverage separately for card history alone (68.8%) and card history with caregiver recall (90.9%). They also noted that, when applied to their CLQAS assessment, the former would have rejected 26 of 31 districts as having inadequate coverage, and the latter only six. If cost data is available, presentation of the range of incremental cost-effectiveness ratio (ICER) is recommended. This would help the reader have a better grasp of the range of possibilities and quality of the estimates.

1. Conclusions

Due to the absence of a definitive standard for vaccination status and coverage in LMICs, alternative methods that rely on clinic data, hand held cards and caregiver recall are still used. While published data show a range of validity of caregiver recall, the validity estimates themselves are subject to error due to biases within the comparator ‘gold standard’. With a lack of information on reliability of recall data and no clearly valid method of dealing with incomplete data, the extent to which caregiver recall of vaccine status can be considered of high data quality or comparable to the ‘true vaccine status’ is unknown and will be context-specific. Excluding caregiver recall would, nevertheless, result in considerable bias in vaccine coverage estimates. We therefore recommend that it be included in vaccine surveys and coverage estimates but encourage that clearer reporting and sensitivity analyses be presented. We call for further studies on the quality of recall so that a more thorough and current assessment of quality can be performed.

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Authors’ Contributions

All authors attest they meet the ICMJE criteria for authorship. RM, CK and TC conceived and designed the study. RM, CK and TC designed the search string and strategy. RM reviewed search results, decided inclusion criteria and decided on the study selection with help from CK and TC. All authors synthesised results. All authors contributed to the writing/reviewing of the paper and approved the final version for submission.

Conflicts of interest

None declared

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