# Tracking progress towards universal childhood immunisation and the impact of global initiatives: a systematic analysis of three-dose diphtheria, tetanus, and pertussis immunisation coverage

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## Summary

**Background** Substantial resources have been invested in increasing childhood immunisation coverage through global initiatives such as the Universal Childhood Immunisation (UCI) campaign and the Global Alliance on Vaccines and Immunisations (GAVI). There are longstanding concerns that target-oriented and performance-oriented initiatives such as UCI and GAVI's immunisation services support (ISS) might encourage over-reporting. We estimated the coverage of three doses of diphtheria, tetanus, and pertussis vaccine (DTP3) based on surveys using all available data.

**Methods** We estimated DTP3 coverage by analysing unit record data from surveys and supplemented this with reported coverage from other surveys and administrative data. We used bidirectional distance-dependent regression to estimate trends in survey-based coverage in 193 countries during 1986–2006. We used standard time-series cross-sectional analysis to investigate any association in the difference between countries' official reports and survey-based coverage as the dependent variable and the presence of GAVI ISS as the independent variable, controlling for country and time effects.

**Findings** Crude coverage of DTP3 based on surveys increased from 59% (95% uncertainty interval 51–65) in 1986 to 65% (60–68) in 1990, 70% (65–74) in 2000, and 74% (70–77) in 2006. There were substantial differences between officially reported and survey-based coverage during UCI. GAVI ISS significantly increased the difference between officially reported coverage and survey coverage. Up to 2006, in 51 countries receiving GAVI ISS payments, 7·4 million (5·7 million to 9·2 million) additional children were immunised with DTP3 based on surveys compared with officially reported estimates of 13·9 million. On the basis of the number of additional children immunised from surveys at a rate of US$20 each, GAVI ISS payments are estimated at $150 million (115 million to 184 million) compared with actual disbursements of $290 million.

**Interpretation** Survey-based DTP3 immunisation coverage has improved more gradually and not to the level suggested by countries' official reports or WHO and UNICEF estimates. There is an urgent need for independent and contestable monitoring of health indicators in an era of global initiatives that are target-oriented and disburse funds based on performance.

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## Introduction

In many countries, vaccine-preventable diseases remain major causes of child mortality.[1] Delivery of childhood immunisations is an essential dimension of health systems and is included as an indicator for Millennium Development Goal 4. Overall performance of immunisation programmes has most often been tracked with the coverage of three doses of diphtheria, tetanus, and pertussis vaccine (DTP3).

Over the past 30 years, substantial resources have been invested through global initiatives to scale up immunisation coverage.[2,3] In 1974, WHO launched the Expanded Programme on Immunisation (EPI).[4] After this programme, in 1977, a global goal for universal child immunisation against the six basic antigens (measles, poliomyelitis, diphtheria, pertussis, tetanus, and tuberculosis) was articulated at the World Health Assembly.[4] In 1984, UNICEF in partnership with others launched the Universal Childhood Immunisation (UCI) by 1990 initiative, defined as 80% immunisation coverage.[2] UCI mobilised substantial funds and support for delivery of immunisation services and, in 1990, UNICEF declared that UCI's target had been achieved.[5]

In the 1990s, estimates suggested that improvements in immunisation coverage were stagnating or falling.[2,6,7] In response, the Global Alliance on Vaccines and Immunisations (GAVI), a public–private partnership that aims to increase coverage of basic vaccines and to accelerate the introduction of new vaccines in low-income and middle-income countries, was launched in 1999. Although GAVI provides a range of support, immunisation services support (ISS) is the funding that

aims to increase coverage of basic vaccines such as DTP3. ISS is provided in response to country proposals and represents flexible cash that countries can use to improve immunisation performance.[8]

ISS payments are performance-based, with funds disbursed in proportion to the number of additional children less than 1 year of age targeted or reported to receive DTP3. Payments are divided between two phases: an investment phase (the first 2 years after a country's proposal has been approved) and a reward phase (the third year and onwards after approval).[8] During the investment phase, US$20 is disbursed per additional child targeted by the country to receive DTP3 in the first year following approval of GAVI support. The baseline for determination of the additional number is the number of children receiving DTP3 in the year before the approval of ISS. In the reward phase, GAVI disburses $20 per additional child reported by countries to receive DTP3, compared with the target set during the investment phase or the number of children receiving DTP3 in the previous year if this number is higher.

The number of additional children receiving DTP3 is based on official reports from countries to WHO and UNICEF. These reports are largely but not exclusively based on administrative data from health-service-provider registries. In recognition of the weakness of administrative data systems and the potential for ISS to induce incentives for over-reporting, GAVI requires countries to pass a data quality audit (DQA) of their administrative data system to be eligible for reward payments.[8,9] DQAs are used to assess the accuracy of reports from health centres to districts and nationally on the number of additional children immunised with DTP3 by comparing this number against a re-count of paper records in health centres.[9]

Sample surveys are the other main source of data on immunisation coverage. These include standardised multicountry surveys, such as the demographic and health surveys (DHS), as well as country-specific surveys, such as the EPI 30-cluster by seven household surveys. Using both officially reported data and survey data, WHO and UNICEF jointly publish estimates of national and global DTP3 immunisation coverage.[10–12] WHO and UNICEF estimates aim to reconcile differences between reported and survey data; however, their estimation is not undertaken in a reproducible way and nor do they include an estimation of uncertainty for the measurement of coverage.

There are several lingering concerns about the measurement of coverage. The quality of administrative data on immunisation coverage remains suspect due to problems with measurement,[13] as well as the potential for target-oriented initiatives such as UCI[2,14,15] and performance-based payment systems such as GAVI's ISS[2,7] to encourage health-service providers to over-report coverage. A previous analysis[16] did not detect an effect of GAVI ISS on over-reporting, measured as the difference between officially reported and survey-based coverage; however, new data are now available to assess this effect in a larger number of countries.

In this study we seek to address these concerns by using all available data to systematically assess the survey-based trend in DTP3 crude coverage with uncertainty intervals during 1986–2006; and whether global health initiatives, such as UCI and GAVI ISS, lead to over-reporting of DTP3 immunisation coverage.

## Methods

### Data and definitions

We did a systematic search for data to estimate the coverage of DTP3 immunisation during 1980–2006. Available data fall into five categories: first 225 standardised multicountry surveys for which the microdata (unit-record data) are in the public domain; second, 78 standardised multicountry surveys for which results and sample size are reported but microdata were not available; third, 142 national surveys that measured immunisation coverage reported in the WHO and UNICEF vaccine coverage database[17] for which results and sample size are reported; fourth, 145 national surveys for which results are available but no sample size is reported; and last, administrative data estimates based on health-service-provider registries of DTP3 coverage that countries report yearly to WHO and UNICEF using the joint reporting form on immunisation.[17]

Administrative data estimates based on health-service-provider registries have been reported to WHO and UNICEF since 1999; before this time, only officially reported coverage is available. Officially reported coverage is what countries consider to be the most likely coverage estimate and is largely based on administrative data. For example, between 1999 and 2006, administrative data and officially reported data were equal 76% of the time and within approximately 2 percentage points for 84% of the time. Reasons for these differences are that countries might make adjustments based on, for example, incomplete reporting or officially reported coverage might be based on surveys. For the purposes of survey-based DTP3 coverage prediction we defined administrative data coverage as administrative data when present, otherwise we used the officially reported coverage as an estimate of administrative data—eg, for the period before 1999.

Webappendix 1 lists the surveys for which microdata have been analysed to measure DTP3 coverage. For each survey, we defined crude coverage for DTP3 as the proportion of children whose mothers self-reported that the child had received three immunisations or the child had three documented immunisations (irrespective of the timing) on the immunisation card. We used the responses recorded for children aged 12–23 months to estimate coverage 1 year before the survey, the responses for children aged 24–35 months to measure coverage 2 years before the survey, the responses for children aged 36–47 months to estimate coverage 3 years before

the survey, and the responses for children aged 48–59 months to estimate coverage for 4 years before the survey. We excluded children younger than 12 months who had not completed all immunisations to avoid censored observations. We analysed data by taking into account the multistage sampling design for each survey.

By plotting and examining analysed and reported survey and administrative data estimates by country, we identified 88 extreme outliers by benchmarking estimates against the more standardised multicountry surveys. DHS—an example of these types of surveys—use gold-standard methods for survey design and implementation;[18,19] subsequently they provide reliable measurements for a range of health indicators.[20–22] By contrast, the quality of country-specific immunisation

surveys is sometimes less certain with an absence of documentation or data to assess their design and implementation as well as longstanding criticisms of the 30-cluster EPI survey methods.[23–26] These 88 outliers were excluded from the statistical analysis but included on country plots and are shown as non-solid points.

### Maternal self-report of immunisation status of children

The median proportion of children whose immunisation status was identified by use of immunisation cards across all surveys in which we analysed microdata was 51·5% (IQR 33·3–69·7). For the remaining proportion of children, immunisation coverage estimates rely on the accuracy of maternal self-report. We were not able to directly assess the accuracy of maternal self-report in
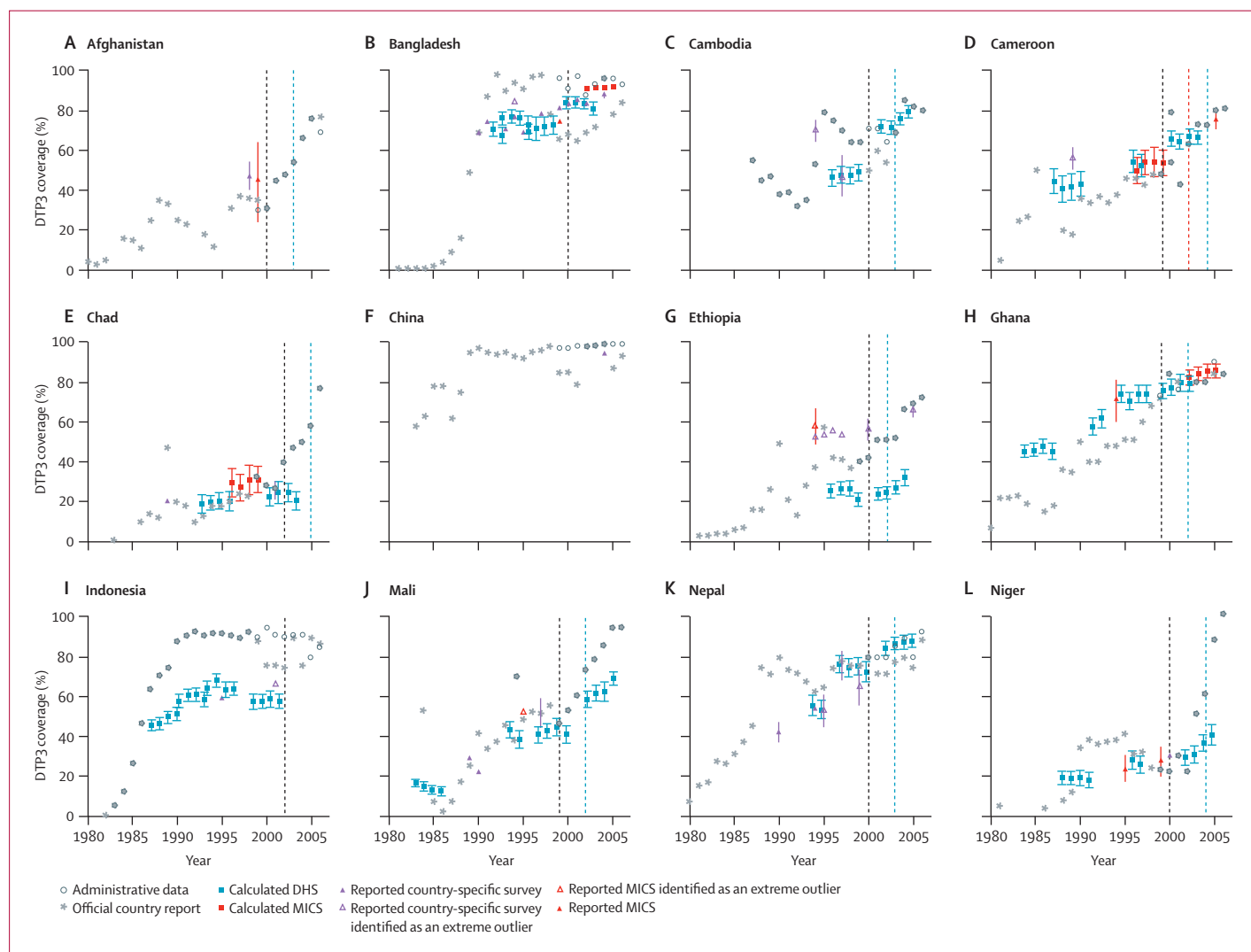


*Figure 1*: Estimates of three doses of diphtheria, tetanus, and pertussis (DTP3) immunisation coverage for different countries

Administrative data are shown as circles; officially reported estimates from countries to WHO are shown as stars; estimates calculated from survey microdata are shown as squares with 95% CIs; reported survey estimates are shown as triangles. Survey data are colour-coded according to the source: demographic and health surveys (DHS) are blue; multiple indicator cluster surveys (MICS) are red; other country-specific surveys are purple. Non-solid points are those surveys identified as extreme outliers. Dotted vertical black lines show the baseline year for recipients of Global Alliance on Vaccines and Immunisations immunisation services support. Dashed vertical blue lines show data quality audits (DQAs) that were passed; red lines indicate DQAs that were failed.
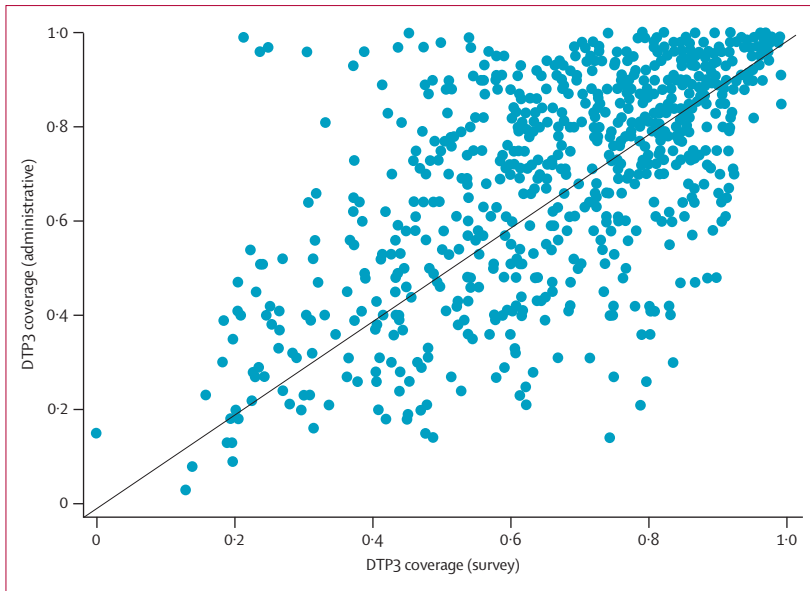
*Figure 2*: Comparison of three doses of diphtheria, tetanus, and pertussis (DTP3) immunsation coverage estimated from administrative data and estimated from surveys

these surveys because this self-report is only elicited for those children that do not have immunisation cards.

Webappendix 2 summarises previous studies[27–34] that examined the validity of maternal self-report against a gold standard based on card-documented immunisation status, linked-provider records, or antibody measurement. Immunisation coverage estimated from maternal self-report was statistically the same as the gold standard in four comparisons; underestimated in five comparisons; and overestimated in seven comparisons. For the four comparisons of DTP3, maternal self-report underestimated coverage in three and overestimated in one.

We assessed the intersurvey reliability of coverage estimates by comparing coverage rates for the same cohort with overlapping data from two consecutive DHS (webappendix 3). In nine of 11 instances the same cohort from a DHS overlapped with the same cohort from another DHS, and coverage rates from the overlap fell within the respective 95% CI. The concordance correlation coefficient[35,36] of estimated coverage across the two measurements was 0·92 (95% CI 0·73–0·98).

Although surveys represent the currently best available source of empirical, independent measures of DTP3 coverage, there is uncertainty as to whether maternal self-report provides an accurate estimate of the level of coverage. This uncertainty, however, is limited to the proportion of children in surveys that do not have immunisation cards. By contrast, evidence suggests that intersurvey reliability is more robust and that we are more certain that surveys provide a robust estimation of the trend or changes in immunisation coverage over time, such as the GAVI performance indicator of the number of additional children immunised with DTP3.

## Estimation of survey-based DTP3 coverage trends

DTP3 immunisation coverage estimates are mostly characterised by continuous time series of administrative data and discontinuous time series of survey-based data. We assessed two approaches to fill in time points with missing survey-based coverage. The first was a specific solution to the problem of missing survey-based DTP3 coverage that we developed, called bidirectional distance-dependent regression (BDDR; webappendix 4 provides detailed information). Briefly, BDDR measures survey coverage for each time point by assessing the association between survey data for a particular country-year, survey data at some time in the past, survey data at some time in the future, and administrative data at the same time. BDDR is estimated with a series of ordinary least-squares (OLS) regressions that are specific to the distance to the survey data in the past and the future, including instances in which there is no survey estimate in the past or future. For countries with only administrative data for the entire period (75 countries), we estimated coverage with a regression model that uses the logit of the final estimated survey-based coverage for each country-year as the dependent variable and the logit of coverage from administrative data, and year fixed effects as the independent variables. Simulation modelling (1000 simulations) was used to simultaneously assess uncertainty due to the survey sampling error, and both parameter and fundamental uncertainty in the BDDR method and regression model of countries with only administrative data used to predict coverage.[37]

The second approach used was multiple imputation, a standard approach to the problem of missing data,[38–40] and was implemented with the Amelia II program[41,42] (100 imputations). We used lags in the logit-transformed dependent variable (up to 5 years in the past), leads in the dependent variable (up to 5 years in the future), logit-transformed administrative data estimates of coverage including the same 5 year lags and leads, country and year fixed effects, and the presence of GAVI ISS as predictor variables for the multiple imputation.

We compared the out-of-sample validity of BDDR and multiple imputation by randomly holding out 20% of the survey estimates, and using the remaining estimates to generate the predictions for that sample. Out-of-sample validity was similar between the two measures and inspection of country plots indicated that the two methods generate very similar estimates. Multiple imputation, however, generates trends that do not have face validity, particularly in cases in which there is just one survey estimate without estimates for adjacent years or when backcasting or forecasting survey-based coverage (webappendix 4 for further details). As a result, we used BDDR in the primary analysis and multiple imputation as a sensitivity analysis.

Because survey data on DTP3 coverage are scarce from 1980 to 1985, we do not estimate trends for this period, although we use the data in both approaches to

estimate trends for 1986–2006. Crude coverage globally and regionally was assessed by weighting each coverage estimate by the total estimated population in need (children younger than 1 year of age) for each country-year from the UN population division.[43] We compared survey-based national and global trends in DTP3 immunisation coverage with countries' official reports and WHO and UNICEF estimates.[43]

### Children immunised with DTP3 in GAVI ISS countries

GAVI uses the number of children immunised with DTP3 instead of DTP3 coverage as the performance indicator for ISS payments. Number immunised was chosen to minimise the effect of problems in measurement of the denominator of coverage (children younger than 1 year of age), which means that GAVI ISS payments will reflect both demographic growth and increases in coverage. The number of children reported to be immunised with DTP3 each year to GAVI by countries receiving ISS payments was kindly provided by the GAVI secretariat (Bchir A, personal communication). We established the number of children immunised from survey-based estimates, and WHO and UNICEF estimates by multiplying coverage by the estimated population in need (children younger than 1 year of age) for each country-year from the UN population division.[43]
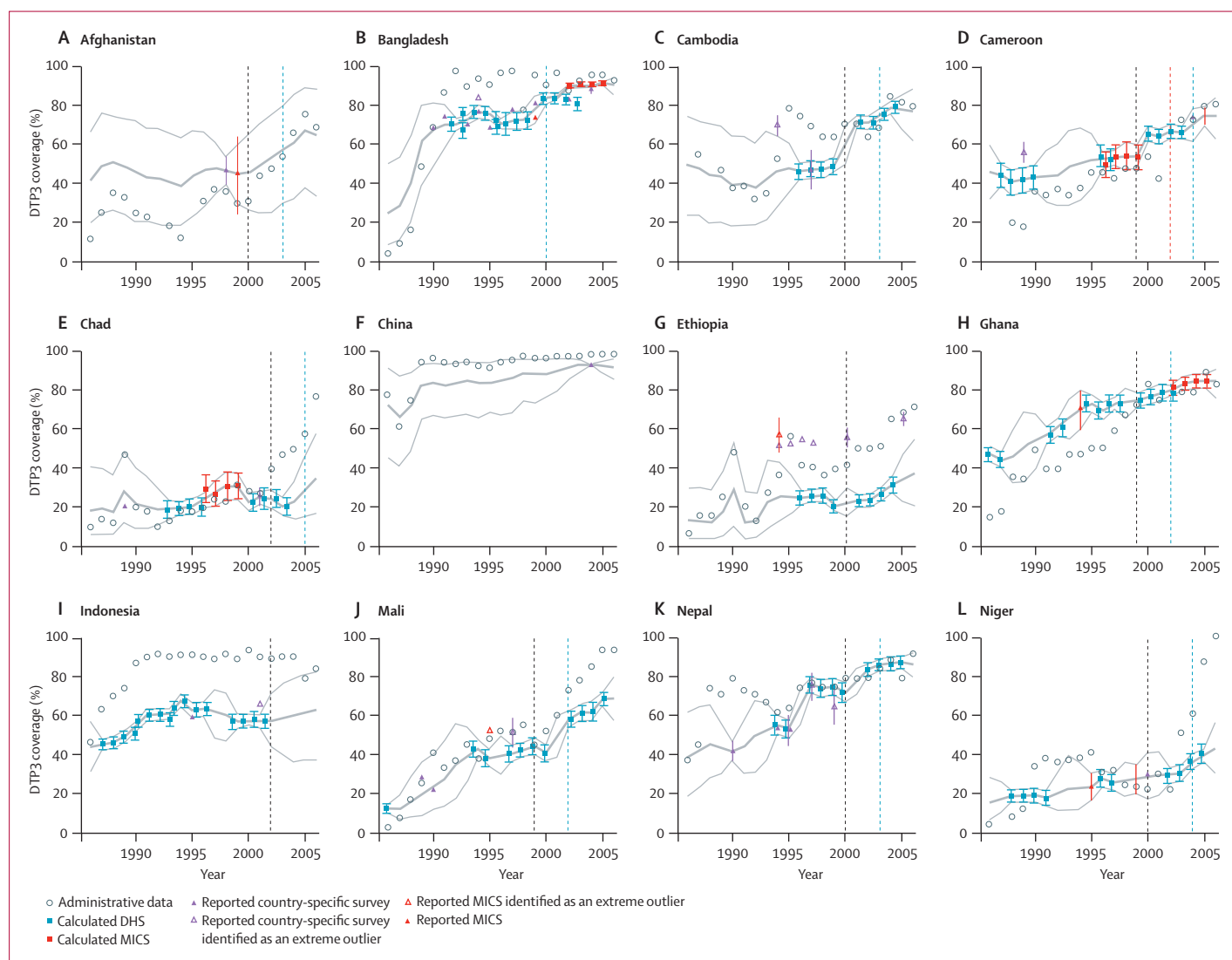


***Figure 3*: Estimated time-trend in survey-based coverage of three doses of diphtheria, tetanus, and pertussis (DTP3) immunisation from bidirectional distance-dependent regression (BDDR) for different countries**
Thick solid grey lines show the predicted survey-based mean from BDDR; thin grey lines indicate 95% uncertainty intervals from BDDR. Administrative data are shown as circles; estimates calculated from survey microdata are shown as squares with 95% CIs; reported survey estimates are shown as triangles. Survey data are colour-coded according to the source: demographic and health surveys (DHS) are blue; multiple indicator cluster surveys (MICS) are red; other country-specific surveys are purple. Non-solid points are those identified as extreme outliers. Dotted vertical black lines show the baseline year for recipients of Global Alliance on Vaccines and Immunisations immunisation services support. Dashed vertical blue lines show data quality audits (DQAs) that were passed; red lines indicate DQAs that were failed.

To investigate the association between the presence of GAVI ISS and reporting of the performance indicator, we used the OLS model with panel-corrected standard errors (PCSE) and the lag of the dependent variable as suggested by Beck and Katz,[44,45] which corrects for heteroskedasticity. The dependent variable was officially reported coverage minus survey-based coverage by country-year, and independent variables were the presence of GAVI ISS by use of a categorical variable denoting the time since the GAVI baseline, a variable denoting the GAVI ISS baseline year, and country and calendar year fixed effects. As noted, this formulation deals with serial autocorrelation, which we identified using the Wooldridge test ($p<0.0001$). By inclusion of the 1 year lag of the dependent variable in the PCSE model, serial autocorrelation was no longer present ($p=0.40$). The Arellano-Bover/Blundell-Bond (ABBB)[46,47] linear generalised method of moments estimators was used to test the sensitivity of our findings

See **Online** for webappendix 5

from the PCSE model. We applied the equilibrium correction suggested by Keele and Kelly[48] to the estimated GAVI ISS coefficients from both models. We used both BDDR and multiple imputation to fill in the missing values of survey coverage.

DQA national verification factors were also kindly provided by the GAVI secretariat (Bchir A, personal communication). National DQA verification factors represent the weighted average (by the number of doses delivered) of district verification factors, which are the ratio of actual doses of DTP3 delivered based on a re-count of paper records in randomly selected health centres in that district over the number of doses of DTP3 reported nationally. We derived corresponding verification factors to the DQA by determining the ratio of survey-based coverage over administrative data coverage.

### Sensitivity analyses

We did two sets of sensitivity analyses. In the first set, we varied the type of survey data used to predict trends in coverage. In our primary statistical analyses we have only included calculated crude coverage from multicountry surveys for which the microdata are available and reported estimates from surveys for which the sample size has been reported. For these surveys, multistage sampling design information is not available, so we have assumed that they have the 90th percentile design effect noted in the multicountry survey programmes. As a sensitivity analysis, we repeated the entire analysis two ways: first, using only data from multicountry surveys for which the microdata are available, and second, including all surveys (ie, including the 145 surveys without a reported sample size). For the second way, we assumed the variance of the estimated coverage to be the same as the variance of the predictions from BDDR. This estimate is conservative as the variance from BDDR is large. In the second set, we varied the approach used to fill in missing survey estimates. In our primary analysis, we used BDDR and as a sensitivity analysis we used multiple imputation. All analyses were done in Stata (version 10.0) and R (version 2.7.1).

### Role of the funding source

The sponsor had no role in the study design, data gathering, data analysis, data interpretation, or writing of this report. The corresponding author had full access to all data in the study and had final responsibility for the decision to submit for publication.

### Results

We provide DTP3 crude coverage estimates from analysed survey, reported survey (with and without sample sizes), and administrative data for 193 countries in webappendix 5. Figure 1 shows twelve examples of DTP3 crude coverage estimates from surveys, administrative data as well as countries' official estimates reported to WHO. These examples are intended to emphasise the
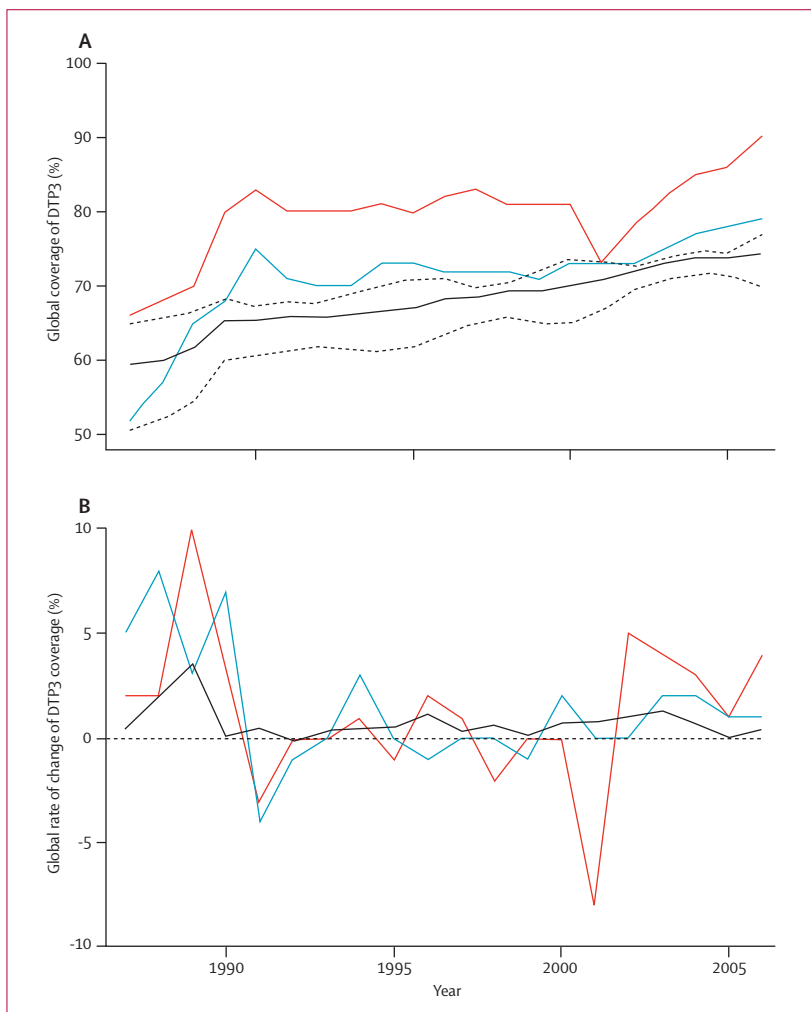


*Figure 4*: Global survey-based coverage of three doses of diphtheria, tetanus, and pertussis (DTP3) immunisation (black) from bidirectional distance-dependent regression (BDDR) with 95% uncertainty intervals, 1986 to 2006 (A), and yearly change in global survey-based coverage of DTP3 (black), 1987 to 2006 (B)
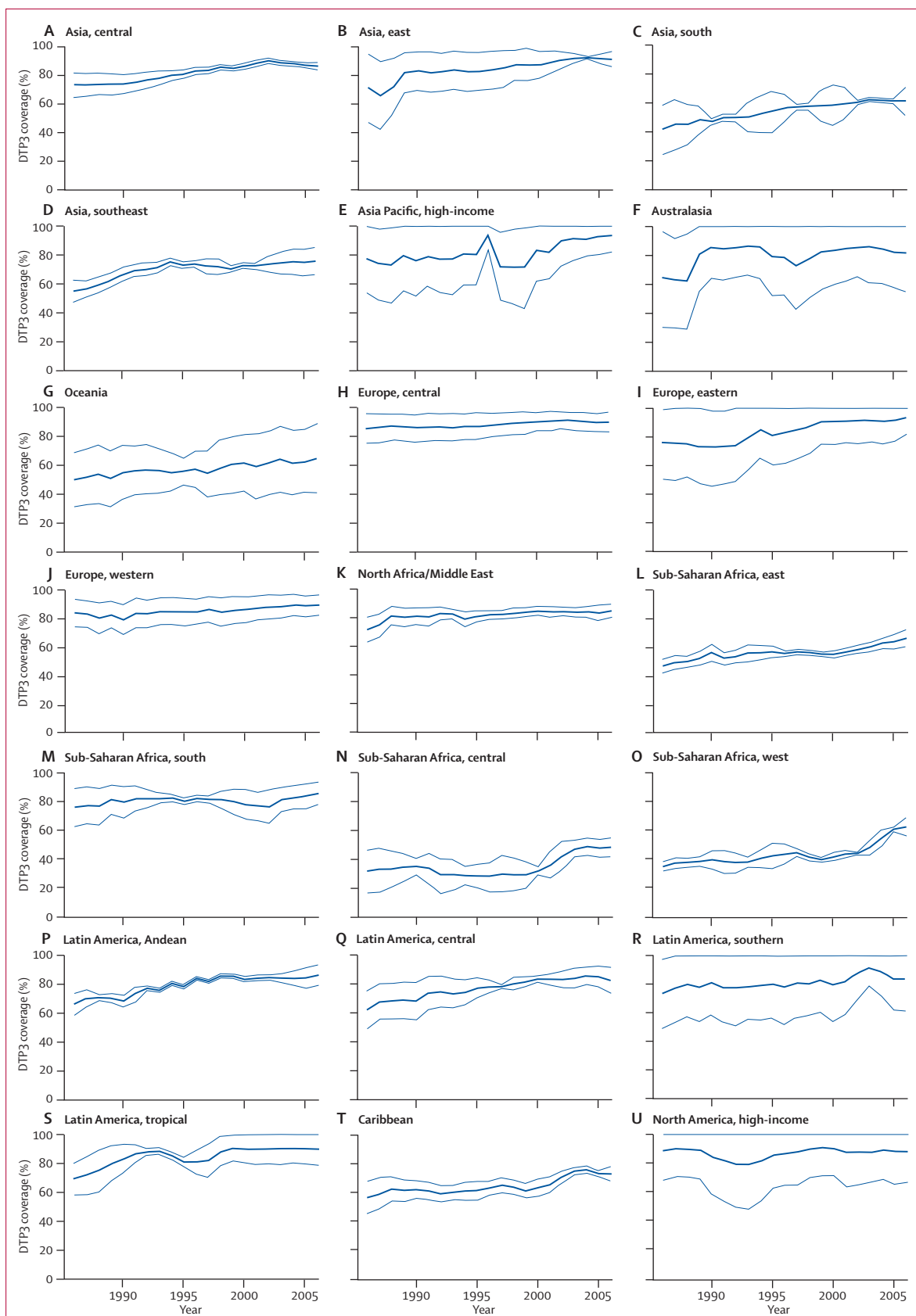Comparisons with officially reported data (red) and WHO and UNICEF estimates (blue) are provided.

*Figure 5:* **Survey-based coverage of three-dose diphtheria, tetanus, and pertussis (DTP3) immunisation from bidirectional distance-dependent regression (BDDR) with 95% uncertainty intervals, 1986 to 2006, by Global Burden of Disease Study 2005 region**

| | BDDR | | Multiple imputation | |
|---|---|---|---|---|
| | PCSE | ABBB | PCSE | ABBB |
| Lag of 1 year | 0·547* (0·025) | 0·598* (0·167) | 0·555* (0·021) | 0·564* (0·131) |
| Base year | 0·013 (0·026) | 0·016 (0·029) | 0·029 (0·027) | 0·019 (0·034) |
| GAVI ISS year 1 | 0·042 (0·027) | 0·049 (0·032) | 0·028 (0·034) | 0·019 (0·037) |
| GAVI ISS year 2 | 0·028 (0·034) | 0·025 (0·032) | 0·029 (0·034) | 0·010 (0·037) |
| GAVI ISS year 3 | 0·057* (0·029) | 0·069* (0·035) | 0·051 (0·031) | 0·032 (0·039) |
| GAVI ISS year 4 | 0·099* (0·030) | 0·102* (0·033) | 0·087* (0·030) | 0·068 (0·040) |
| GAVI ISS year 5 | 0·046 (0·036) | 0·057 (0·036) | 0·024 (0·036) | 0·005 (0·041) |
| GAVI ISS year 6 | 0·146* (0·033) | 0·192* (0·040) | 0·117* (0·038) | 0·128* (0·045) |
| GAVI ISS year 7 | 0·162* (0·039) | 0·238* (0·058) | 0·100* (0·041) | 0·128* (0·065) |
| Intercept | –0·152* (0·035) | 0·059* (0·016) | –0·216* (0·035) | 0·060* (0·019) |
| Number of observations | 3900 | 3900 | 3900 | 3900 |

Data are estimated beta-coefficients (SE) for the independent variables from panel-corrected standard errors (PCSE) and Arellano-Bover/Blundell-Bond (ABBB) models by use of either bidirectional distance-dependent regression (BDDR) or multiple imputation to impute missing survey-based coverage. GAVI=Global Alliance on Vaccines and Immunisations. ISS=immunisation services support. *Coefficients for which $p<0.05$.

*Table 1:* Regression results with the dependent variable as officially reported coverage minus survey-based coverage
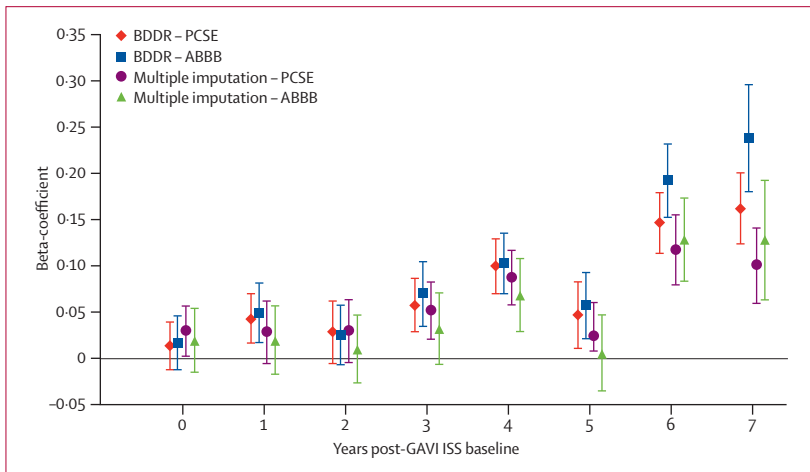


*Figure 6:* **Estimated beta-coefficients (SE) for Global Alliance on Vaccines and Immunisations (GAVI) immunisation services support (ISS) as a function of time since baseline**
Data calculated from regressions with dependent variable as officially reported coverage minus survey-based coverage with panel-corrected standard errors (PCSE) and Arellano-Bover/Blundell-Bond (ABBB) models and either bidirectional distance-dependent regression (BDDR) or multiple imputation to impute missing survey-based coverage.

importance of country by country assessment and to highlight patterns in the data; they are not intended to be representative of the experience seen in all countries. These examples draw attention to the variation in the availability of surveys to estimate coverage across countries. Bangladesh and Indonesia, for example, provide regular and consistent estimates of DTP3 coverage from surveys over time. By contrast, Afghanistan and China have only partial survey data available.

In all countries, officially reported estimates and administrative data exhibit greater variation over time than do survey data, which change more gradually and smoothly. In some countries, officially reported estimates

also suggest a marked peak in DTP3 coverage around 1990 (the year of the declaration of achievement of the UCI goal) that is not always supported by corresponding survey data. Bangladesh, Niger, Chad, and Mali show this pattern in figure 1.

Further, in some countries receiving ISS payments from GAVI, the performance-based payment system seems to be associated with over-reporting of the performance indicator—the number of additional children immunised with DTP3, which manifests itself in two ways. As the additional number of children immunised with DTP3 is benchmarked against the year before the approval of the country proposal for ISS, lowering reported coverage at this baseline year (denoted by the vertical dotted black line in figure 1) will increase the number of additional children immunised. A downwards trend in officially reported coverage at the baseline year is shown by Bangladesh, Indonesia, Niger, and Mali (figure 1). This trend might have also occurred in Afghanistan, although survey data are not available to verify it. A downwards trend in officially reported estimates is also shown in China, at about the time that GAVI was launched in 1999.

The second way that the performance indicator can be over-reported is by overestimation of DTP3 coverage after the baseline year, particularly from the third year after the baseline year when ISS reward payments begin. This pattern of overestimation of DTP3 coverage is seen in Niger, Mali, Chad, and Ethiopia (figure 1) and seems to be increasing with time. Not all GAVI recipients over-report performance; Cambodia, Ghana, and Nepal, for example, do not show either of these two effects. As survey data are not available during the whole GAVI ISS period in countries such as Afghanistan or for part of the GAVI ISS period in countries such as Chad and Indonesia, we are not able to verify the improvements suggested by officially reported estimates and administrative data.

In some countries, improvements in survey coverage seem to be increasing after GAVI ISS; this pattern is seen in Cambodia and Mali and to a lesser extent in Bangladesh, Cameroon, and Niger.

A scatter plot of DTP3 coverage from recorded survey data compared with administrative data indicates that, on average, estimates from administrative data are higher than survey estimates (figure 2). This finding is shown in the national trends over time in survey-based coverage by use of BDDR for 193 countries (webappendix 5). Figure 3 shows the estimated trends for the same twelve example countries by use of BDDR. Figure 4 shows the global crude coverage of DTP3 and the yearly percentage change in crude coverage with BDDR compared with countries' officially reported estimates and WHO and UNICEF estimates. We estimate that survey-based global coverage using BDDR increased from 59% (95% uncertainty interval 51–65) in 1986 to 65% (60–68) in 1990, 70% (65–74) in 2000, and 74% (70–77) in 2006. The improvements that

| | GAVI baseline year | GAVI country years with survey data | Coverage at baseline | | Additional children immunised | | ISS payments (US$) | | | | Survey-estimated total | Cost (US$) per additional child immunised | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Reported | Survey estimated | Reported | Survey estimated | Investment | Reward | Total | Survey estimated | | Reported | Survey estimated |
| **No additional children immunised with DTP3** | | | | | | | | | | | | | |
| Armenia | 1999 | 0·25 | 0·91 | 0·90 | 1487 | –5463 | 9880 | 19860 | 29740 | 0 | 29740 | 20·00 | no add |
| Somalia | 2001 | 0·67 | 0·33 | 0·26 | 7196 | –10596 | 1218100 | 0 | 1218100 | 0 | 1218100 | 169·27 | no add |
| Zimbabwe | 2000 | 0·57 | 0·77 | 0·67 | 28382 | –7917 | 1273080 | 0 | 1273080 | 0 | 1273080 | 44·86 | no add |
| Burma | 2000 | 0·14 | 0·82 | 0·85 | 229898 | –49321 | 1949480 | 2648480 | 4597960 | 0 | 4597960 | 20·00 | no add |
| Subtotal | | 0·41 | 0·71 | 0·67 | 266963 | –73296 | 4450540 | 2668340 | 7118880 | 0 | 7118880 | 63·53 | no add |
| **Children immunised overestimated by more than four times** | | | | | | | | | | | | | |
| Tajikistan | 1999 | 0·25 | 0·96 | 0·82 | 52097 | 6400 | 499960 | 541980 | 1041940 | 127999 | 913941 | 20·00 | 162·80 |
| Pakistan | 1999 | 0·50 | 0·80 | 0·55 | 1779822 | 250666 | 10020000 | 25576440 | 35596440 | 5013318 | 30583122 | 20·00 | 142·01 |
| Togo | 2001 | 0·67 | 0·43 | 0·65 | 107659 | 21644 | 1402540 | 750640 | 2153180 | 432877 | 1720303 | 20·00 | 99·48 |
| Lesotho | 2000 | 0·57 | 0·69 | 0·77 | 9949 | 2032 | 149740 | 49240 | 198980 | 40643 | 158337 | 20·00 | 97·92 |
| Zambia | 2000 | 0·29 | 0·76 | 0·81 | 193156 | 45468 | 655120 | 3208000 | 3863120 | 909359 | 2953761 | 20·00 | 84·96 |
| Liberia | 1999 | 0·63 | 0·23 | 0·44 | 95889 | 22600 | 1222300 | 695480 | 1917780 | 451989 | 1465791 | 20·00 | 84·86 |
| Subtotal | | 0·48 | 0·65 | 0·67 | 2238572 | 348809 | 13949660 | 30821780 | 44771440 | 6976186 | 37795254 | 20·00 | 112·01 |
| **Children immunised overestimated by more than two times** | | | | | | | | | | | | | |
| Niger | 2000 | 0·57 | 0·23 | 0·29 | 452069 | 116427 | 1740240 | 7301140 | 9041380 | 2328533 | 6712847 | 20·00 | 77·66 |
| Côte d'Ivoire | 1999 | 0·75 | 0·69 | 0·72 | 190866 | 52139 | 2050800 | 1766520 | 3817320 | 1042788 | 2774533 | 20·00 | 73·21 |
| Congo (Brazzaville) | 2002 | 0·60 | 0·41 | 0·69 | 55956 | 16149 | 613960 | 505160 | 1119120 | 322983 | 796137 | 20·00 | 69·30 |
| Central African Republic | 2001 | 0·17 | 0·23 | 0·40 | 80550 | 24899 | 445460 | 1165540 | 1611000 | 497979 | 1113021 | 20·00 | 64·70 |
| Guinea | 2000 | 0·57 | 0·57 | 0·46 | 145929 | 50193 | 1286420 | 1632160 | 2918580 | 1003857 | 1914723 | 20·00 | 58·15 |
| Indonesia | 2002 | 0·00 | 0·75 | 0·58 | 771820 | 265664 | 6628420 | 6006000 | 12634420 | 5313270 | 7321150 | 16·37 | 47·56 |
| The Gambia | 2000 | 0·57 | 0·83 | 0·77 | 22886 | 9753 | 129200 | 328520 | 457720 | 195066 | 262654 | 20·00 | 46·93 |
| North Korea | 2001 | 0·00 | 0·62 | 0·29 | 84068 | 35917 | 1188880 | 492480 | 1681360 | 718339 | 963021 | 20·00 | 46·81 |
| Chad | 2002 | 0·40 | 0·40 | 0·25 | 131763 | 56887 | 576600 | 2058660 | 2635260 | 1137745 | 1497516 | 20·00 | 46·32 |
| Democratic Republic of the Congo | 2001 | 0·67 | 0·32 | 0·36 | 1096541 | 510544 | 8120240 | 13810580 | 21930820 | 10210887 | 11719933 | 20·00 | 42·96 |
| Subtotal | | 0·43 | 0·51 | 0·48 | 3032448 | 1138572 | 22780220 | 35066760 | 57846980 | 22771446 | 35075534 | 19·64 | 57·36 |
| **Children immunised overestimated by less than two times** | | | | | | | | | | | | | |
| Afghanistan | 2000 | 0·00 | 0·31 | 0·46 | 519850 | 275810 | 2078040 | 8318960 | 10397000 | 5516196 | 4880804 | 20·00 | 37·70 |
| Burkina Faso | 1999 | 0·50 | 0·34 | 0·52 | 360721 | 197528 | 1748100 | 5466320 | 7214420 | 3950549 | 3263871 | 20·00 | 36·52 |
| Mali | 1999 | 0·75 | 0·47 | 0·45 | 268794 | 151833 | 1715780 | 3660100 | 5375880 | 3036665 | 2339215 | 20·00 | 35·41 |
| Sudan | 2000 | 0·00 | 0·65 | 0·48 | 265951 | 150430 | 3074580 | 2244440 | 5319020 | 3008600 | 2310420 | 20·00 | 35·36 |
| Uganda | 1999 | 0·75 | 0·60 | 0·56 | 461525 | 263321 | 1820340 | 7410160 | 9230500 | 5266410 | 3964090 | 20·00 | 35·05 |
| Tanzania | 1999 | 0·50 | 0·76 | 0·84 | 399413 | 242499 | 2426200 | 5562060 | 7988260 | 4849986 | 3138274 | 20·00 | 32·94 |
| Ethiopia | 2000 | 0·57 | 0·42 | 0·23 | 790921 | 488306 | 3855900 | 11962520 | 15818420 | 9766117 | 6052303 | 20·00 | 32·39 |
| Rwanda | 1999 | 0·63 | 0·85 | 0·86 | 143062 | 88994 | 1814220 | 1047020 | 2861240 | 1779882 | 1081358 | 20·00 | 32·15 |
| Ghana | 1999 | 0·88 | 0·72 | 0·76 | 183803 | 115349 | 1058400 | 2617660 | 3676060 | 2306989 | 1369071 | 20·00 | 31·87 |
| Azerbaijan | 1999 | 0·63 | 0·99 | 0·21 | 37405 | 23649 | 65600 | 682500 | 748100 | 472988 | 275112 | 20·00 | 31·63 |
| Cameroon | 1999 | 0·75 | 0·48 | 0·54 | 298397 | 193506 | 2213300 | 3754640 | 5967940 | 3870124 | 2097816 | 20·00 | 30·84 |
| Nepal | 2000 | 0·71 | 0·80 | 0·73 | 165580 | 108707 | 1409340 | 1902260 | 3311600 | 2174130 | 1137470 | 20·00 | 30·46 |
| Senegal | 2000 | 0·57 | 0·52 | 0·64 | 130257 | 87750 | 494200 | 2110940 | 2605140 | 1755001 | 850139 | 20·00 | 29·69 |
| Georgia | 2000 | 0·00 | 0·98 | 0·79 | 6732 | 4547 | 68020 | 66620 | 134640 | 90943 | 43697 | 20·00 | 29·61 |
| Bangladesh | 2000 | 0·86 | 0·68 | 0·84 | 1094952 | 742024 | 7136520 | 14762520 | 21899040 | 14840483 | 7058557 | 20·00 | 29·51 |

(Continues on next page)

| | GAVI baseline year | GAVI country years with survey data | Coverage at baseline | | Additional children immunised | | ISS payments (US$) | | | | Survey-estimated total | Cost (US$) per additional child immunised | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Reported | Survey estimated | Reported | Survey estimated | Investment | Reward | Total | Survey estimated | | Reported | Survey estimated |
| (Continued from previous page) | | | | | | | | | | | | | |
| Yemen | 2000 | 0·00 | 0·76 | 0·55 | 171 993 | 116 916 | 1 134 080 | 2 305 780 | 3 439 860 | 2 338 316 | 1 101 544 | 20·00 | 29·42 |
| Nigeria | 2000 | 0·57 | 0·38 | 0·26 | 2 366 145 | 1 702 980 | 13 949 300 | 33 373 600 | 47 322 900 | 34 059 598 | 13 263 302 | 20·00 | 27·79 |
| Mozambique | 1999 | 0·50 | 0·81 | 0·63 | 266 276 | 203 625 | 923 160 | 4 402 360 | 5 325 520 | 4 072 491 | 1 253 029 | 20·00 | 26·15 |
| Burundi | 2000 | 0·00 | 0·68 | 0·74 | 132 910 | 103 844 | 649 900 | 2 008 300 | 2 658 200 | 2 076 889 | 581 312 | 20·00 | 25·60 |
| Mauritania | 2001 | 0·17 | 0·61 | 0·73 | 18 535 | 15 627 | 387 740 | 0 | 387 740 | 312 539 | 75 201 | 20·92 | 24·81 |
| Guinea-Bissau | 2001 | 0·17 | 0·47 | 0·44 | 20 272 | 19 071 | 185 180 | 220 260 | 405 440 | 381 414 | 24 027 | 20·00 | 21·26 |
| São Tomé and Principe | 1999 | 0·13 | 0·73 | 0·84 | 680 | 654 | 21 180 | 0 | 21 180 | 13 088 | 8 092 | 31·15 | 32·37 |
| Sierra Leone | 1999 | 0·75 | 0·43 | 0·41 | 98 140 | 95 853 | 359 240 | 1 603 560 | 1 962 800 | 1 917 058 | 45 742 | 20·00 | 20·48 |
| Subtotal | .. | 0·45 | 0·63 | 0·59 | 8 202 314 | 5 392 823 | 48 588 320 | 115 482 580 | 164 070 900 | 107 856 454 | 56 214 446 | 20·52 | 30·39 |
| Children immunised underestimated | | | | | | | | | | | | | |
| Kenya | 1999 | 0·50 | 0·79 | 0·78 | 210 861 | 311 340 | 2 578 200 | 1 639 020 | 4 217 220 | 6 226 807 | –2 009 587 | 20·00 | 13·55 |
| Cambodia | 2000 | 0·57 | 0·50 | 0·61 | 53 543 | 93 336 | 1 337 200 | 0 | 1 337 200 | 1 866 723 | –529 523 | 24·97 | 14·33 |
| Angola | 2002 | 0·00 | 0·47 | 0·34 | 44 674 | 81 865 | 2 987 780 | 0 | 2 987 780 | 1 637 294 | 1 350 486 | 66·88 | 36·50 |
| Eritrea | 2000 | 0·29 | 0·52 | 0·89 | 21 791 | 52 698 | 156 960 | 278 860 | 435 820 | 1 053 960 | –618 140 | 20·00 | 8·27 |
| Djibouti | 2001 | 0·17 | 0·53 | 0·52 | 962 | 2 801 | 112 760 | 0 | 112 760 | 56 024 | 56 736 | 117·21 | 40·25 |
| Laos | 2000 | 0·00 | 0·53 | 0·33 | 4 888 | 16 275 | 1 431 200 | 0 | 1 431 200 | 325 502 | 1 105 698 | 292·80 | 87·94 |
| Comoros | 2000 | 0·00 | 0·70 | 0·61 | 449 | 6 492 | 51 740 | 0 | 51 740 | 129 844 | –78 104 | 115·23 | 7·97 |
| Haiti | 1999 | 0·63 | 0·59 | 0·44 | –378 | 36 321 | 1 256 440 | 0 | 1 256 440 | 726 410 | 530 030 | no add | 34·59 |
| Subtotal | .. | 0·27 | 0·58 | 0·57 | 42 099 | 75 141 | 1 239 035 | 239 735 | 1 478 770 | 1 502 821 | –24 051 | 93·87 | 30·42 |
| Total | .. | 0·42 | 0·60 | 0·58 | 13 877 313 | 7 413 951 | 103 883 880 | 185 957 340 | 289 841 220 | 149 744 946 | 140 096 274 | 20·14 | 39·51 |

Data are baseline coverage from officially reported estimates and estimated from survey data with BDDR, additional children immunised with three-dose pertussis, diphtheria, and tetanus (DTP3) from the GAVI baseline year, ISS payments received, ISS payments implied from changes in survey-estimated coverage, and the cost to GAVI per additional child immunised from officially reported estimates and survey-estimated data. Proportion of years under GAVI ISS funding for which there are survey data are shown. Countries are categorised according to the level of over-reporting of the additional number of children immunised with DTP3. no add=no additional children immunised.

*Table 2:* Additional children immunised and immunisation services support (ISS) payments in countries receiving Global Alliance on Vaccines and Immunisations (GAVI) ISS up to 2006

have been noted, with the exception of the second half of the 1980s, have been gradual and fairly steady at about 1% per year (figure 4B). Due to gaps and lags in the availability of survey data, even globally there is considerable uncertainty in DTP3 crude coverage.

Webappendix 6 provides a country by country comparison of survey-based estimates from BDDR, officially reported estimates, and WHO and UNICEF estimates. Globally, official estimates and WHO and UNICEF estimates show substantially different DTP3 coverage (figure 4A) and greater variation in improvements over time (figure 4B) compared with survey-based estimates. This difference is clearly evident during the period leading up to 1990 when the most intense campaigning to achieve the UCI target took place. In 1990, official reports estimate coverage at 83% and WHO and UNICEF at 75%, compared with the survey-based estimate of 65%. The gap between officially reported estimates as well as WHO and UNICEF estimates and survey-based estimates fell during the

1990s as political pressure waned. Since the launch of GAVI in 1999, however, this gap seems to be increasing. From 1999 to 2006, officially reported estimates show a 9% increase in DTP3 coverage (from 81% to 90%) and WHO and UNICEF estimate an 8% increase (from 71% to 79%). Global coverage over this period based on surveys increased by only 4·9%. In 2006, compared with survey-based estimates, official reports overestimate the number of children immunised with DTP3 by 20·2 million, and WHO and UNICEF overestimate the number of children immunised by 6·1 million.

Although survey-based coverage globally has increased only slowly since 1990, improvements in some regions of the world are more pronounced (figure 5). DTP3 immunisation coverage in the Global Burden of Disease Study 2005[49] regions (webappendix 7 provides a list of countries by region) such as central and western sub-Saharan Africa, where coverage has traditionally been the lowest, seems to be improving, particularly since the early 2000s. Coverage in central Latin America

has increased steadily from around 60% in 1990 to around 80% in 2006, whereas, coverage seems to have stagnated in south Asia at about 60%.

Table 1 summarises the association between over-reporting, calculated as officially reported estimates minus survey-based coverage, and the presence of GAVI ISS as a function of time under ISS. We varied using the PCSE and ABBB models, BDDR, and multiple imputation to fill in missing values. Over-reporting tended to increase with time (figure 6) under the GAVI ISS programme and the estimated beta-coefficients were significant in the sixth and seventh year of participation in GAVI ISS with an approximate 10% increase in official reports minus survey coverage. GAVI ISS also significantly increased over-reporting (officially reported coverage minus survey-based coverage) in the third and fourth years with both PCSE and ABBB when BDDR was used, and in the third year with PCSE when multiple imputation was used.

Overall, we estimate on the basis of surveys that in the 51 countries receiving ISS funding up to 2006 and which have completed the investment phase, 7·4 million (95% uncertainty interval 5·7 million to 9·2 million) additional children were immunised compared with the GAVI baseline year for each country. This number is almost half the 13·9 million additional children immunised with DTP3 reported by countries to GAVI. WHO and UNICEF estimate the additional number of children at 9·5 million. On the basis of official reports of the number of additional children immunised, GAVI disbursed ISS payments of $290 million, combined across the investment and reward phases. On the basis of survey estimates of the number of additional children immunised at a rate of $20 each, we estimate payments to be $150 million; a difference of $140 million (105 million to 175 million). With the survey estimate of the number of additional children immunised and the GAVI ISS disbursement of $290 million, this difference translates into a cost of $39 (31–50) per additional child immunised, compared with the intended rate of $20 per child.

Although this statistical analysis yields clear evidence of an average effect of ISS funding on over-reporting, this effect must be interpreted with caution as there is heterogeneity of the effect across countries. In table 2, for each of the 51 countries receiving ISS funding up to 2006 and that have completed the investment phase, we compare estimates of the number of additional children immunised from official reports with estimates based on survey data using BDDR. We provide details of the payments that should be made if monitoring of increased coverage were based on surveys compared with payments that GAVI disbursed based on officially reported numbers. We also include in this table the ratio of payments disbursed by GAVI over the number of additional children reported by countries to be immunised, compared with the same ratio but sub-stituting in the number of additional children immunised based on survey data using BDDR.
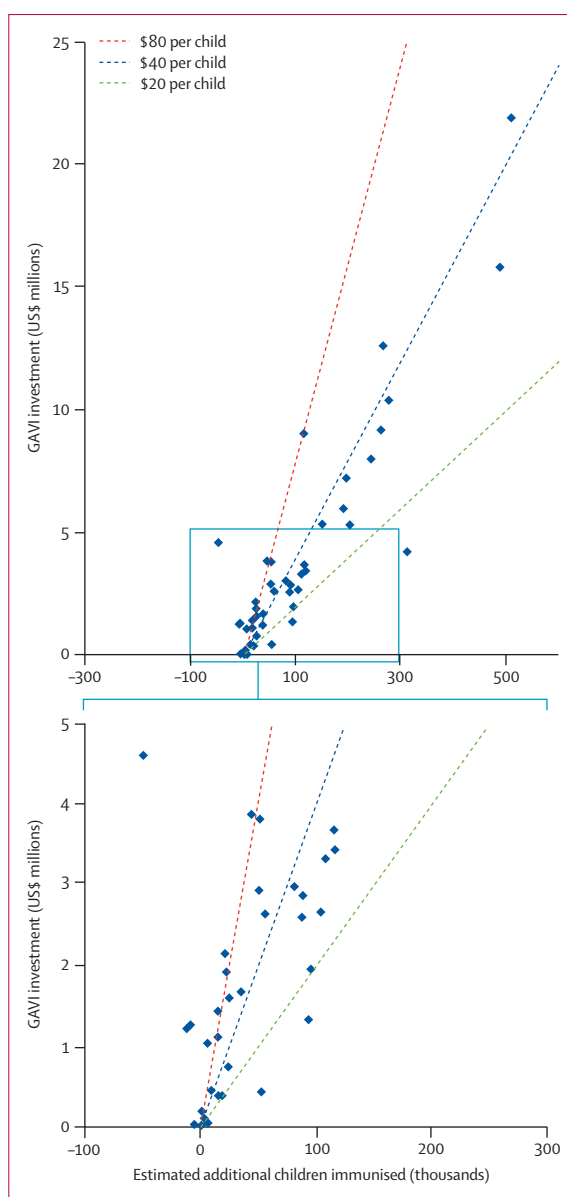


*Figure 7*: Comparison of additional children immunised with three-dose diphtheria, tetanus, and pertussis and Global Alliance on Vaccines and Immunisations (GAVI) immunisation services support (ISS) payments by country

Of 51 countries, in four that reported increases, the additional number of children immunised with DTP3 based on surveys did not increase from baseline; six countries overestimated the additional number of children immunised by more than a factor of four; ten countries overestimated their increase in coverage by more than a factor of two; 23 countries overestimated by a factor of less than two; and eight countries underestimated their increase in the number of children immunised. The overestimation and, in some cases, underestimation of the increase in coverage translates into GAVI payments per extra child immunised with
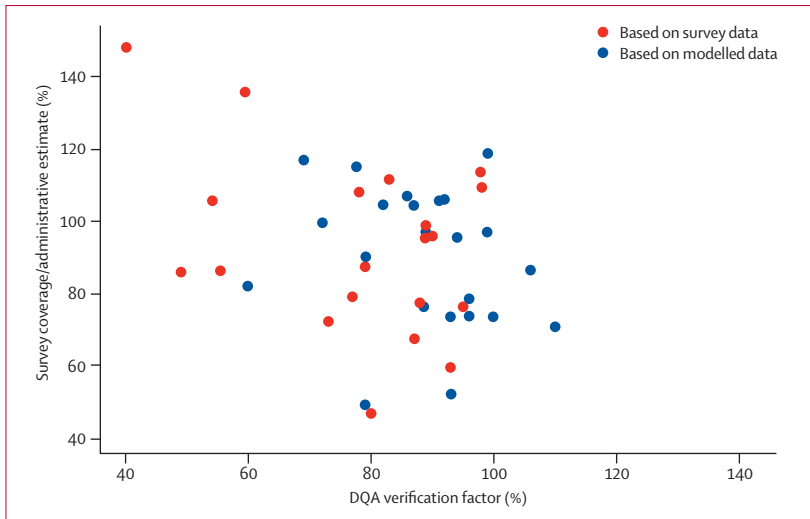
***Figure 8*:** Comparison of national verification factors (ratio of actual doses over reported doses) from the data quality audits (DQAs) with verification factors based on estimated survey coverage using bidirectional distance-dependent regression (ratio of survey-based coverage over administrative-based coverage)
Data include points for which there is a recorded survey estimate in the corresponding year of the DQA (labelled as based on survey data) and those without a recorded survey estimate for that year (labelled as based on modelled data).

DTP3 that vary substantially from the intended $20 per child (table 2; figure 7).

Figure 8 provides a comparison of verification factors (the ratio of actual doses over reported doses) from GAVI-required DQAs compared with the corresponding verification factor derived from our analysis (the ratio of survey coverage over administrative data coverage). Data include points for which there is a recorded survey estimate in the corresponding year of the DQA (labelled as based on survey data) and those without an observed survey estimate for that year (labelled as based on modelled data). One would expect the verification factor from DQAs to be positively correlated with the verification factors calculated from the ratio of survey coverage and administrative data coverage if they are measuring the same thing. The correlation, however, between the survey-based verification factor and the DQA verification is −0·32 (95% CI −0·61 to −0·04); this value indicates that DQAs do not capture the difference between administrative data and survey-based coverage.

See **Online** for webappendix 8

Webappendix 8 shows key results from the sensitivity analyses—variation of the type of survey data included and with multiple imputation instead of BDDR. Briefly, when the analysis was restricted to survey estimates from multicountry surveys such as DHS in which microdata were analysed, global coverage was estimated at 59% (95% uncertainty interval 49 to 65) in 1986, 66% (59 to 68) in 1990, 70% (62 to 73) in 2000, and 73% (69 to 76) in 2006. Overall, the additional number of children immunised with DTP3 decreased to 6·6 million (4·4 million to 8·7 million), the difference between survey-based payments and payments based on official reports increased to $157 million

(119 million to 208 million), and the cost per additional child immunised increased to $44 (34 to 65). Use of all calculated and reported survey estimates, including surveys for which no sample size is available, did not alter the overall conclusions greatly.

By use of multiple imputation instead of BDDR to estimate missing survey values, and calculated and reported survey estimates with sample sizes, global coverage was estimated at 65% (95% uncertainty interval 58 to 70) in 1986, 67% (63 to 68) in 1990, 70% (64 to 75) in 2000, and 75% (69 to 79) in 2006. Overall, the additional number of children immunised with DTP3 in the 51 GAVI ISS recipient countries up to 2006 based on surveys was higher at 8·4 million (6·0 million to 10·7 million), the difference between survey-based payments and payments based on official reports decreased to $123 million (77 million to 170 million), and the cost per additional child immunised decreased to $35 (27 to 48).

## Discussion

Our systematic analysis shows that the crude coverage of DTP3 immunisation based on surveys has not progressed to the level suggested by countries' official reports or the WHO and UNICEF estimates. Furthermore, the way in which improvements in coverage have been achieved is far more gradual than suggested by officially reported estimates, or the WHO and UNICEF estimates. This gradual improvement probably indicates the investments and time needed to build the necessary infrastructure such as human resources that are necessary to deliver immunisation services, particularly to remote populations.[50] Our analysis also shows that in countries receiving GAVI ISS funding, improvements in survey-based coverage are only about half that of officially reported estimates and three-quarters that of WHO and UNICEF estimates.

What factors explain the large discrepancies between officially reported estimates, WHO and UNICEF estimates, and our survey-based estimate? Measurement errors in administrative data on which officially reported data are largely based can occur as a result of incorrect recording in health centres, incomplete recording of immunisations from, for example, exclusion of the private sector, or errors with the way that data are transferred to and collated nationally. During intensive immunisation campaigns designed to immunise all children, such as those during the UCI campaign, administrative data can also incorrectly record new immunisations in children who have previously been immunised. Errors might also arise in the measurement of the denominator due to outdated censuses, incomplete population registries or inaccurate population projections.

The target-oriented UCI campaign and the performance-based ISS payments used by GAVI have also contributed to the differences between officially reported

data and survey-estimated coverage by incentivising over-reporting of the performance indicator. The presence of GAVI ISS was found to increase the difference between officially reported coverage and survey coverage. Although this outcome has not happened in all countries, the presence of GAVI ISS in countries such as Burkina Faso, Democratic Republic of the Congo, Ethiopia, Guinea, Liberia, Mali, and Niger has resulted in a widening gap between officially reported and survey-based coverage. Importantly, over-reporting might not be intentional or attributable to any one person or stage of the data gathering or reporting process. Previous studies have documented instances in which health-centre workers have over-reported coverage in an attempt to meet targets set by supervisors,[14,15] and the gaps between officially reported coverage and survey estimates seen in this analysis might indicate pressure to achieve targets at multiple stages of the reporting system.

Downward adjustments in reported DTP3 immunisation coverage, both at the GAVI baseline year and at around the time that GAVI was launched, can be seen in several countries. A previous study of countries applying for GAVI ISS funding documented adjustments to coverage in the application process in order to be eligible for ISS funding.[7] This practice might also be the case in countries such as India, Indonesia, and China where adjustments during this period resulted in coverage being below the qualifying threshold for ISS of 80% coverage.[51] These adjustments, however, might indicate pressure by international organisations, such as WHO and UNICEF, to determine more accurate estimates of immunisation coverage.

WHO and UNICEF have attempted to correct some of the problems with officially reported estimates; however, substantial differences between WHO and UNICEF estimates and our survey-based estimates remain. There are several reasons for these differences. In the absence of recent survey or other data, WHO and UNICEF assume that officially reported coverage is the best estimate. Survey data are also restricted to children aged 12–23 months at the time of the survey. As we have shown here DQA results are an inadequate measure for assessing the validity of administrative data relative to surveys. However, in some cases, WHO and UNICEF also use DQA results as evidence of the accuracy of administrative data estimates of DTP3 coverage, or to correct such estimates. Unlike WHO and UNICEF, which rely on subjective assessments of data on coverage, the BDDR and multiple imputation approaches used here are empirically-based, replicable assessments of trends in immunisation coverage; they also allow the uncertainty in the estimates to be characterised. Both BDDR and multiple imputation correct for the difference between administrative and survey data seen in other countries. As a result, estimates for countries with only administrative data—ie, most high-income countries, are on the whole lower than administrative data, although the uncertainty

intervals often encompass the administrative data estimates. Although seroprotection is a more strict definition than administrative data-based immunisation coverage, previous serosurveys in high-income countries[52–55] support this pattern by showing lower protection rates than is suggested by administrative data.

These revisions to the trend in DTP3 immunisation coverage over the past 20 years raise a host of important questions. Would the UCI campaign have wound down if it was known at the time that the 80% coverage goal had not been achieved? Would GAVI have been implemented if there was less of a perception that improvements in DTP3 immunisation coverage during the 1990s were stagnating? Although these questions are perhaps of little current relevance for immunisation delivery, they emphasise the need for far more stringent and continuous monitoring of health indicators in an era of global initiatives that are target-oriented and disburse funds on the basis of performance.

In the short term, strengthening the system for tracking DTP3 immunisation coverage is clearly required if GAVI is to meet the commitment that resources entrusted to the organisation are being used for their intended purpose. An incentive to over-report progress, either intentionally or unintentionally, will always exist with performance-based payments; to counteract this problem requires not only independent monitoring, but also a system that is based on rigorous, empirical measurements using the best scientific methods available. The inaccuracy of the DQAs in measurement of the difference between administrative data and survey-based coverage indicates a range of methodological limitations. National verification factors derived from the DQAs are determined as the weighted average of a small random sample of district verification factors.[9] As a result, variability across district verification factors is high and the approach does not examine whether errors are occurring in the aggregation of district reports nationally. The assumption is that vaccine doses recorded in health-centre registries were actually delivered.[9] DQAs are also restricted to cross-sectional measurement and do not continuously assess the performance of administrative data systems.

We believe that the only alternative for GAVI is a monitoring system that benchmarks coverage with periodic surveys, either as a condition or component of GAVI's support. This system means that the coverage of surveys in recipient countries will need to be expanded. Afghanistan, Angola, and North Korea, for example, do not have surveys available to confirm reported increases in DTP3 immunisation coverage under GAVI ISS. Additionally, the frequency of surveys will also need to be increased to every 2 years or at most 3 years because of the need to provide timely measurement to inform the size of reward payments. A number of country-specific and immunisation-specific surveys were identified in our analysis as extreme outliers. This finding emphasises the

importance of using validated and standardised instruments and sampling frames, building in substantial efforts for quality control, and collecting survey data on a range of health topics. More regular multitopic health surveys will not only improve the availability of information to monitor immunisation coverage, but will also address the absence of data to measure other essential health indicators such as child mortality.[20]

Since there are delays between survey implementation and the availability of final results, even with regularly done surveys, increased efforts are needed to strengthen administrative data systems, through initiatives such as the Health Metrics Network, in parallel with the use of empirically-based trend analysis such as those used here, to continuously assess and correct administrative data for the purposes of reporting on performance between surveys.

These changes to the ISS system for monitoring country performance will mean that the payment schedule will also need to be modified. A refund system, for example, could be used to address instances in which the corrected administrative data do not match with the retrospective gold-standard measurements from surveys. A more complicated issue is what should be done about countries that have already received payments for increases in officially reported coverage that are not shown by survey-based estimates? In some of these countries such as Democratic Republic of the Congo, Niger, and Mali, officially reported DTP3 coverage is 80–100%. Survey data for these countries show that immunisation coverage is closer to 40–60%. Another important downstream effect in these countries is that they are now eligible for new vaccine support from GAVI. On the other hand, what should also be done about countries that have been underpaid? Regardless of how GAVI addresses these issues, what is required is to reconstruct a baseline and monitor subsequent performance that is based on the modifications described above.

In this report, we have not addressed whether the increases in DTP3 coverage that have occurred in GAVI ISS recipient countries would have occurred in the absence of GAVI's support. Lu and colleagues[16] showed a significant positive impact of ISS spending on both officially reported and WHO and UNICEF estimates of DTP3 coverage in countries with coverage of 65% or less at baseline. Since both officially reported and WHO and UNICEF estimates of DTP3 coverage overestimate the additional number of children immunised with DTP3 relative to surveys, an unanswered question is whether the impact of GAVI will remain with coverage based on surveys? Globally, survey-based coverage shows that the yearly increase is fairly constant before and after the establishment of GAVI; by contrast both officially reported estimates and WHO and UNICEF estimates show larger yearly increases in the period after the establishment of GAVI. Regionally, however,

larger yearly increases in survey-based DTP3 coverage are seen in central and west Africa after the establishment of GAVI and in countries similar patterns, verified by survey estimates, are seen in Cambodia, Cameroon, Mali, Mauritania, Nigeria, Senegal, and Sierra Leone. A re-analysis of the study by Lu and colleagues[16] with survey-based coverage will be an important next step to understanding the impact of the GAVI ISS programme.

This study has several limitations. Although surveys represent the best available source of empirical, independent measures of DTP3 coverage presently available, our analysis of surveys was restricted to measurement of crude coverage that relies partly on maternal self-report. The available evidence suggests that there is uncertainty about whether maternal self-report in surveys captures the true level of coverage. The time trend in survey-based coverage, however, and subsequently the estimated number of additional children immunised seems to be more robust. There are two ways in which the validity of maternal self-report of immunisation status could be better addressed. The first is to elicit self-reported responses before asking for the immunisation card and irrespective of the presence of one. This response would allow an analysis of the accuracy of maternal self-report amongst children with an immunisation card that is specific to each survey. The second and more robust approach is to validate not just maternal self-report, but also card document responses against measured antibody titres such as tetanus toxoid. This approach would also allow a measure of effective coverage[56] that would capture the individual variation in the effectiveness of immunisation due to the number or timing of doses, or interruptions in the vaccine cold chain. To restrict cost, antibody titres could be measured by use of dried blood spots[57,58] or saliva[59,60] in a random sub-sample alongside card and recall methods. Results from the sub-sample could then be used to correct maternal self-report and card-documented responses in the remainder of the survey sample.

Another limitation is that the unit record data from country-specific surveys are not readily available, which has restricted our ability to estimate immunisation coverage more robustly. This limitation is emphasised by the differences in the results, particularly for GAVI, when analyses were restricted to surveys for which microdata were analysed. Increase in the public accessibility of unit record data from surveys through, for example, a global databank would represent an important step towards allowing more robust monitoring and evaluation.

To foster transparency and encourage public debate, we are making all aspects, including the statistical code used to derive the results in this analysis, available on our website. We also plan to make available regular updates of our assessment of DTP3 immunisation

coverage, as well as to expand measurement of coverage, and when possible, effective coverage for a range of key health interventions, including other vaccines.

Globally, substantial resources are being directed towards increasing the effective coverage of interventions to improve population health. With this increase in aid flows for health comes the responsibility to ensure that these resources are being used cost-effectively and for their intended purpose. Both targets and payments for performance can encourage improvements in health indicators but also lead to over-reporting of performance; monitoring and evaluation systems need to be based on rigorous, empirical measurements that are robust to these effects. Measurement of immunisation coverage must be through more periodic gold-standard surveys that are integrated with improved administrative data if progress towards goals such as universal childhood immunisation is to be better measured and understood.

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