Prevention of Mother-to-Child Transmission of HIV – Assessing the accuracy of routinely-collected data on maternal antiretroviral prophylaxis coverage in Kenya

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ABSTRACT

Objective:

To explore the accuracy of routinely-collected prevention of mother-to-child transmission of HIV (PMTCT) coverage data in Kenya.

Methods:

In case studies at two government hospitals, we reviewed national reporting guidelines, interviewed nurses, and undertook a retrospective analysis of routine hospital data from antenatal care (ANC), maternity and HIV services from January 2009 to June 2010. Each woman attending these services was given a unique study number to enable analysis of her recorded use of PMTCT services across different hospital visits. These data were compared with the hospitals' monthly PMTCT reports to the district.

Results:

Where a woman made more than one visit, PMTCT drug provision could be reported multiple times for the same woman, and women known to be HIV-positive prior to pregnancy were omitted from the denominator of PMTCT coverage calculations. Practices for reporting data on maternal PMTCT prophylaxis provision varied in the two hospitals.

According to study data, using the hospital registers and accounting for multiple visits by the same woman, 642 women were known to have HIV and 412 (64%) were given maternal PMTCT prophylaxis. According to the monthly reports, 430 women were diagnosed with HIV in pregnancy-related services and 538 (125%) were given maternal PMTCT prophylaxis.

Conclusions:

If replicated elsewhere, these reporting practices could lead to over-estimation of national PMTCT coverage. Simple yet accurate routine data collection systems are needed to monitor PMTCT coverage accurately and to highlight where changes need to be made so as to ensure that infants are born HIV-free.

BACKGROUND

Interventions for the prevention of mother-to-child transmission of HIV (PMTCT) have been shown to be efficacious,[1-3] but will only realise their potential if their coverage is maximised.

Kenya reported to UNAIDS that 72% of HIV positive pregnant women received antiretrovirals (ARVs) for PMTCT in 2009.[4] However, in the same report, 27% of children born to HIV-infected mothers were reported to have been HIV-infected,[4] suggesting that effective PMTCT coverage is less complete. One explanation could be inaccurate source data. The source of the data reported to UNAIDS was not specified and no information was provided on the PMTCT regimen used or the age at which the infants' status was determined.

Previous studies, primarily in South Africa, have highlighted deficiencies in PMTCT reporting systems including the multitude of paper-based registers that constitute the basis for health facility reports to the district, data collection instruments not being used as intended, and incomplete reporting.[5-7] The accuracy of routinely-collected PMTCT data has not been assessed elsewhere in Africa, including Kenya. A study of reporting by HIV voluntary counselling and testing centres in Kenya found substantial discrepancies between data at national-level and the source health facilities .[8]

Recognising the difficulties inherent in measuring PMTCT coverage, the aims of this study were to assess the accuracy of health facility reports of PMTCT coverage based on routinely-collected data in two government hospitals in Kenya, and to identify reasons for discrepancies in data and where changes in routine data collection methods might improve the accuracy of PMTCT coverage estimates.

DESIGN AND METHODS

Study setting and sites

We reviewed the PMTCT reporting system in Naivasha District, Rift Valley Province, Kenya. There were two government hospitals in Naivasha District – Naivasha District Hospital and Gilgil Sub-District Hospital. Between them, they provided approximately 35% of HIV testing within antenatal care (ANC) services in the district. Based on hospital reports to the district health office, for the period January – June 2010, HIV prevalence among antenatal women was about 4% in Naivasha and 6% in Gilgil.

These study facilities constituted a convenience sample of clinics selected as they were government hospitals without unusual levels of external involvement in their day-to-day running such as NGO activities or large-scale research projects.

Methods

The national reporting guidelines[9] and reporting instructions in hospital registers were reviewed and 7/14 nurses responsible for reporting on PMTCT at Naivasha and Gilgil Hospitals were interviewed to establish facility-level reporting practices.

A retrospective analysis was carried out of routine hospital registers in ANC, the maternity ward and the HIV clinic in the study hospitals for the period 1st January 2009 – 30th June 2010. Data on socio-demographic characteristics and the reported provision of maternal prophylaxis for PMTCT were extracted from the registers into Epi-Data and transferred into Stata for analysis. Many women appeared several times in these registers reflecting their multiple visits to ANC/maternity/HIV services. A 'matching' algorithm was devised based on ANC/maternity numbers and available demographic information (name, age, location of residence and gestational age) to identify and link data on repeat-attendees. We gave each individual woman a unique study number to enable analysis of her recorded use of services across different hospital visits and clinical departments. These data were compared with the hospital's monthly reports to the district health office.

Ethical approval for this work was provided by the University of Nairobi Kenyatta National Hospital Ethics Review Committee and the London School of Hygiene & Tropical Medicine Ethics Committee. To preserve confidentiality, all files and databases were password-protected and, following matching and the assignment of unique study numbers, all personal identifiers were removed from active files.

RESULTS

Collation of national-level indicator data

The Kenyan PMTCT coverage rates that form the basis for national-level reporting are collated from monthly reports from individual facilities to the district, and thence to the provincial and national levels. Facility-level reporting is paper-based. At the district-level, data are entered into an electronic register, enabling computerised aggregation of indicators from facility-level up to district, provincial and national-levels to generate coverage estimates.

The national-level indicator is defined by the national PMTCT guidelines as the 'ratio of known HIV-infected pregnant women in ANC receiving ARV preventive prophylaxis', which is calculated by dividing 'the total number of HIV-infected pregnant women in ANC receiving maternal ARV prophylaxis' by 'the total number of pregnant women who are diagnosed with HIV in the ANC'.[9] Although at odds with the indicator's description, only HIV diagnoses made during ANC are included in the denominator, thus excluding women known to be living with HIV prior to pregnancy, even though they will also require prophylaxis if they are not receiving highly active antiretroviral therapy (HAART) for their own health.

For women not taking HAART, national PMTCT guidelines for maternal prophylaxis during the study period recommended zidovudine (AZT) from 28 weeks; single dose nevirapine (sdNVP), lamivudine (3TC) and AZT at delivery; and 3TC and AZT for seven days post-partum.[9]

Instructions for facility-level reporting

Nurses at both study facilities reported that the woman's HIV status, irrespective of time of diagnosis, was recorded in the client-held booklet provided to the woman when she first attended ANC, but no record of whether prophylaxis was issued was made in this booklet.

Within the study hospitals, facility-based records in ANC were in the form of paper registers designed and supplied by the Kenyan government, with technical support from USAID, that were filled in by hand. At both hospitals, the nurses reported that every time a woman attended ANC, data related to that visit, including her HIV status and receipt of maternal prophylaxis, was entered on a new line in the register. To avoid double-counting of women diagnosed with HIV in ANC and delivery services, the nurses reported that they had been instructed to enter 'Y' for "Yes" in the 'HIV status' column only if the client was diagnosed with HIV during that visit.

The instructions for filling in the maternal prophylaxis column in the official ANC and maternity registers were ambiguous in the national guidelines and facility registers: 'Indicate if client is given ARV prophylaxis: record 'Y' or 'N''.[9] Nurses' interpretations of these instructions are presented in Table 1. There was no data capture system within the clinic registers for the nurses to report which drugs had been dispensed.

Every month, reports summarising these data were submitted to the district-level health office on a standard form supplied by the Ministry of Medical Services.

Facility-level reporting practices

The methods of reporting on maternal prophylaxis for PMTCT were markedly different in the two study hospitals as outlined in Table 1.

Table 1: Reporting practices on maternal PMTCT prophylaxis by hospital

	Naivasha District Hospital	Gilgil Sub-District Hospital
Reporting in ANC		
Source of maternal prophylaxis	sdNVP dispensed in ANC Referral to HIV clinic for AZT	sdNVP and 1-month AZT supply dispensed in ANC Referral to HIV clinic for subsequent antenatal AZT
Register used in ANC for monthly reporting	A notebook, filled in by hand and kept in the ANC PMTCT room, used to list women to whom maternal prophylaxis has been dispensed	Official Ministry of Health ANC register
When nurses indicated in the register that maternal prophylaxis has been given	Every time a woman is dispensed sdNVP from ANC	Every time an HIV-positive woman attends ANC, whether she has been given maternal prophylaxis at that visit or reports having been given it at a previous visit
How the monthly report was compiled	Counting the women appearing in the notebook kept in the ANC PMTCT room each month	Tallying the 'Ys' in each column of the register for the month, i.e. all visits by all women are captured. In the monthly reports it is impossible to distinguish between one woman who has attended ANC the recommended 4 times and was given maternal prophylaxis once, and 4 women who each attended and were given maternal prophylaxis once.
Reporting in the delivery ward		
Availability of prophylaxis in the delivery ward	Full regimen of sdNVP, AZT and 3TC available	sdNVP and 24-hour supply of AZT and 3TC available in the delivery ward. Referral to HIV clinic for the remaining AZT and 3TC
Register used in delivery ward for monthly reporting	A notebook, filled in by hand and kept in the maternity PMTCT room, was used to list women to whom maternal prophylaxis has been dispensed	Official Ministry of Health maternity register
When to indicate in the register that maternal prophylaxis has been given	If any maternal prophylaxis dispensed while at maternity	If any maternal prophylaxis is taken by the woman while at maternity, irrespective of which drug(s) or where it was prescribed/dispensed
How the monthly report was compiled	Counting the women appearing in the notebook kept in the maternity PMTCT room each month	Tallying the 'Ys' in each column of the register for the month, i.e. all visits by all women are captured so if a woman attended the maternity ward more than once she would be counted more than once..

Despite the variation in the way hospital registers were filled in, nurses reported that this process, although time-consuming, was straightforward. However, they also reported that it was time-consuming and yielded no direct benefit to their own work. Compiling monthly reports to the district was reported to be more complicated as it involved collating data from multiple registers.

Our study was conducted in only two hospitals and therefore provides a limited view of what might be happening nationwide. However, discussions with health workers in another district hospital, four health centres and one dispensary suggest that their reporting practices were similar to those in Gilgil Hospital.

Study data on maternal PMTCT prophylaxis by hospital

After linking any multiple attendances by the same woman, the registers showed that 515 and 127 women of known HIV positive status attended ANC/maternity services during the 18-month study period in Naivasha and Gilgil Hospitals, respectively. Many of these women were recorded as having received maternal prophylaxis multiple times (Table 2).

Table 2: Number of times women were recorded as having received maternal prophylaxis in the ANC and maternity registers

No. of times the woman was reportedly given prophylaxis according to the hospital registers[1]	Data from ANC and maternity registers combined (Jan 2009-June 2010)			
	Naivasha District Hospital		Gilgil Sub-District Hospital	
0	186	36.1%	44	34.6%
1	266	51.7%	63	49.6%
2	56	10.9%	15	11.8%
3	7	1.4%	3	2.4%
4	0	0.0%	2	1.6%
Total	515		127	

Key:

1 Due to lack of specificity in the hospital registers, it was unclear which prophylactic drugs were given to women. This could range from sdNVP to the full regimen in the national guidelines (i.e. NVP, AZT and 3TC). In Naivasha District Hospital, the minimum regimen usually provided was sdNVP; in Gilgil Sub-District Hospital, most women were given sdNVP and AZT.

More than one third of women in each hospital were recorded as not having received any maternal prophylaxis. Limiting this analysis to women who attended ANC, these proportions remained high at 31% and 29% in Naivasha and Gilgil Hospitals, respectively.

None of the nurses interviewed had previously perceived any problems with the accuracy of the data in hospital registers or monthly reports but when the results of this study were presented to them they said they did not believe the high recorded levels of non-provision of prophylaxis and suggested that they might sometimes fail to record the provision of maternal prophylaxis, despite having actually given it to the woman.

Table 3 compares the data extracted directly from the registers with the monthly reports submitted to the district for each of the study hospitals, and with the best estimate of the correct number based on study data.

Table 3: Data on maternal PMTCT prophylaxis by source (Jan 09 – June 10)

	Naivasha District Hospital								
	ANC			Delivery			Combined		
	Registers	Monthly report	Best estimate from study[1]	Registers	Monthly report	Best estimate from study[1]	Registers	Monthly report	Best estimate from study[1]
HIV+ women	196	191	245[2]	265	89	285	461	280	515
PMTCT ARVs dispensed	113	189	121	150	221	208	263	410	329
Coverage[3] (%)	58%	99%	49%	57%	248%	73%	57%	146%	64%
	Gilgil Sub-District Hospital								
	ANC			Delivery			Combined		
	Registers	Monthly report	Best estimate from study[1]	Registers	Monthly report	Best estimate from study[1]	Registers	Monthly report	Best estimate from study[1]
HIV+ women[2]	86	119	95	69	31	32	155	150	127
PMTCT ARVs dispensed	77	99	35	41	29	48	118	128	83
Coverage (%)	90%	83%	37%	59%	94%	150%	76%	85%	65%

[1] This is based on the study's 'matching algorithm' and accounts for multiple visits to MCH services by the same woman.

[2] This includes 45 women who appeared in the PMTCT book but not the ANC register.

[3] Coverage of greater than 100% suggests that only women newly diagnosed wtih HIV in pregnancy-related services were included in the numerator while some women of previously known HIV-positive status who also attended and were given maternal prophylaxis were included in the denominator.

There were discrepancies between the number of HIV-positive women, the courses of maternal PMTCT prophylaxis dispensed, and the coverage in the monthly reports and the registers from which they were compiled. Because recording of HIV-positive women in ANC/maternity registers was limited to newly-diagnosed women, it was impossible to ascertain the total number of HIV-positive pregnant women (including those of previously-known status) who would therefore benefit from either prophylactic ARVs or HAART. This was particularly evident in the reporting by the maternity departments where the number of women given maternal prophylaxis exceeded the number of

women diagnosed with HIV, suggesting coverage of more than 100%. Although some of the women in the maternity ward attended ANC in the same hospital, many women delivered in these hospitals having been diagnosed with HIV during ANC in a different facility; they were therefore not included in the denominator of coverage estimates but they were included in the numerator.

After accounting for multiple visits to MCH services by the same woman in the registers, the best estimate from the study found PMTCT coverage of 64% and 65% in Naivasha and Gilgil Hospitals, respectively, while the monthly reports showed coverage of 146% and 85%, respectively.

Uptake of maternal PMTCT prophylaxis in the HIV clinic

Using the study's matching algorithm, inspection of the HIV clinic registers showed that only 26/245 (11%) and 11/95 (12%) women diagnosed with HIV in ANC in Naivasha and Gilgil Hospitals, respectively, were recorded as having been given AZT monotherapy by the HIV clinic (presumably antenatally, otherwise 3TC should also have been prescribed). In addition, only 6/285 (2%) women discharged from maternity in Gilgil Hospital passed through the HIV clinic, suggesting that incomplete prescription of post-partum prophylaxis was common. Conversely, twelve women (5%) in Naivasha Hospital and six women (6%) in Gilgil Hospital who were recorded in the ANC registers as not having been given any maternal prophylaxis had either received AZT or initiated HAART during that pregnancy according to the HIV clinic records.

DISCUSSION

As has been found elsewhere,[6, 10] it was remarkably difficult to calculate the true coverage of PMTCT services using routine data in the study hospitals. In this study, this was primarily because some women were included in the numerator for these calculations (if they were given maternal PMTCT prophylaxis) but not necessarily in the denominator (if they were of previously-known HIV-

positive status). As a result of the different reporting methods adopted, each study hospital reported different data under the same indicator, which were then collated at district- and national-levels.

Across both hospitals, over one-third of HIV-positive women appear, from direct study of the clinic registers, not to have received any maternal prophylaxis for PMTCT during the 18-month study period, which is of concern. This was not apparent from the hospitals' reported data as both reported very high PMTCT coverage - 146% in Naivasha Hospital and 85% in Gilgil Hospital.

Data from an evaluation of the national PMTCT programme in Kenya in 2010 reported that coverage of maternal ARV prophylaxis was 79% and of infant prophylaxis was 63% while the rate of vertical HIV transmission among infants over 6 weeks of age was reported to be 8%.[12] This was a mixed-methods cross-sectional study, carried out in 325 health facilities nationwide, based on focus group discussions and administration of questionnaires to women bringing their infants to child health services. Its findings are a closer reflection of this study's findings than any of the routinely collected data reviewed. Studies such as these contribute to a better understanding of national-level coverage of services but are expensive to conduct and ways need to be found to ensure routine data accurately reflect PMTCT coverage.

Although as yet unpublished, further data suggest that problems in the reporting of PMTCT coverage may be occurring elsewhere in Kenya. Routinely-collected PMTCT coverage data from three of the largest PMTCT programmes in the country were reported at a recent meeting showing that 2,023 women were expected to need maternal PMTCT prophylaxis, and 4,309 (213%) were given these drugs. (Yonga, I. Pers. comm. 2011.) It is likely that the double-counting of maternal PMTCT prophylaxis provision that we found in our study also occurred in these programmes, leading to over-estimation of coverage. We are not aware of any published studies that directly addressed the

reporting issues we studied but suggest that sufficient data now exist in both this study and the unpublished studies mentioned above to warrant further attention to PMTCT reporting in Kenya.

Similar to findings from a study in South Africa,[6] daily recording of maternal prophylaxis dispensed in ANC in Naivasha Hospital was fairly accurate but the monthly reports did not reflect the daily records. The practice in Gilgil Hospital of recording 'Y' in the maternal prophylaxis column every time a woman received, or was assumed to have received, any prophylaxis and tallying these 'Ys' for the monthly report led to substantial over-estimation of the number of women receiving maternal antiretroviral prophylaxis for PMTCT due to women making repeat visits being counted multiple times.

Data from the HIV clinic revealed that a very low proportion of eligible women accessed AZT there during pregnancy, suggesting that the use of sdNVP monotherapy may have been high, which falls below the standard of care set out in the national PMTCT guidelines at the time of data collection. Conversely, failure to include PMTCT prophylaxis prescribed at the HIV clinic in the ANC and maternity records or in the monthly reports from these departments meant that a small number of women who received PMTCT prophylaxis or HAART were reported as having received no intervention.

Nurses' lack of attention to potential inaccuracies in the PMTCT data at facility-level and in reports to the district reflects their non-use of these data for day-to-day monitoring of clinic performance – a situation previously described as a culture of reporting rather than information-use.[11] Improving nurses' understanding of these data and their relevance to client management is critical to ensuring greater attention to data recording and reporting. Motivation might be improved by introducing reporting feedback loops at facility, district and national levels whereby performance is tracked over time and compared with other departments/facilities.

A combination of factors affects the quality of PMTCT data in Kenya, some relating to the data collection and reporting tools, and others relating to how health workers fulfil their reporting tasks. The reporting tools exclude women who knew their HIV-positive status prior to pregnancy and PMTCT prophylaxis provided at the HIV clinic from the coverage indicator, fail to distinguish between different PMTCT regimens provided, and promote double-counting. That the registers were filled in differently in the two study facilities attests to the insufficient clarity of instruction and supervision with regard to data collection and reporting at facility-level. As a result, district-level reports constitute aggregations of non-standardised data on the coverage of PMTCT services. Irrespective of how the registers were filled in it would have been impossible to accurately determine coverage of PMTCT services using the available tools.

Moving forward, efforts are required to facilitate reporting that captures data on all HIV-positive women attending MCH services, divided into those who are newly-diagnosed and those of previously-known HIV status. This would allow for continued capture of new HIV diagnoses and also provide the denominator for coverage calculations. For the numerator for such calculations, it will be important to address the issues of double-counting inherent in the current system used in Gilgil Hospital. Furthermore, either data on AZT and 3TC prescribed from the HIV clinic should be included in monthly reporting on PMTCT or, for pregnant and post-natal women, these drugs should be availed exclusively within ANC and maternity services.

Following data collection for this study, a new ANC register has been developed by the government that allows for separate recording of new HIV diagnoses and women already known to be HIV-positive, as well as differentiation of the PMTCT regimen provided. When the related reporting forms are revised so that facilities can report this information to district and hence to national levels

this will assist in understanding coverage of PMTCT by drug regimen. However, it will not solve the bigger problem of multiple counting of the same woman.

When introduced, if appropriately designed, a longitudinal ANC register and an electronic health information system throughout Kenya should substantially reduce the multiple counting of women who attend ANC more than once. The longitudinal ANC register will not solve the potential for double-counting among women attending both ANC and maternity but this might be helped by an electronic health information system that networks different departments within and across health facilities.

Such new health information tools need to be extensively pilot tested to ensure that they are sufficiently simple and well-explained to ensure accurate reporting by over-burdened health workers. Health workers will require unambiguous written instructions within the registers and forms themselves on how they should be completed and submitted. Staff mentorship on record-keeping may well be needed, and continued supervision to ensure that all health facilities enter and compile the data correctly will be essential. WHO's forthcoming publication on monitoring and evaluating national PMTCT programmes might help to inform these tools.[13]

CONCLUSION

Weaknesses in the reporting system and staff training/supervision on reporting have led to differences in reporting practices and inaccuracies in data on the provision of maternal PMTCT prophylaxis, primarily resulting in over-estimation of coverage in the two study health facilities. If replicated elsewhere, this could lead to an over-estimation of national PMTCT coverage. Routine data collection systems which are simple yet accurate are needed in order to monitor effective PMTCT coverage and to highlight where changes need to be made so as to ensure that infants are born HIV-free.

KEY MESSAGES

- Weaknesses in the reporting system and staff training/supervision have led to inaccuracies in data on the provision of maternal PMTCT prophylaxis in Kenya.
- Routinely-collected data on maternal PMTCT prophylaxis provision led to substantial over-estimation of coverage in the two study health facilities that may also occur elsewhere.
- Accurate routine data collection systems are needed to monitor PMTCT coverage and highlight where changes are needed to ensure that infants are born HIV-free.

AUTHORS' CONTRIBUTIONS

LF collected the data and drafted the manuscript. SV assisted with data collection. All authors contributed to interpretation of the data and were responsible for critical revisions to the paper. All authors read and approved the final manuscript.

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COMPETING INTERESTS

All authors have completed a conflict of interest statement, which are summarised in the cover letter.

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