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Decentralization Does Not Assure Optimal Delivery of PMTCT and HIV-Exposed Infant Services in a Low Prevalence Setting

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Abstract

Background—The consequences of decentralizing prevention of mother-to-child HIV transmission and HIV-exposed infant services to antenatal care (ANC)/labor and delivery (L&D) sites from dedicated HIV care and treatment (C&T) centers remain unknown, particularly in low prevalence settings.

Methods—In a cohort of mother–infant pairs, we compared delivery of routine services at ANC/L&D and C&T facilities in Kinshasa, Democratic Republic of Congo from 2010–2013, using methods accounting for competing risks (eg, death). Women could opt to receive interventions at 90 decentralized ANC/L&D sites, or 2 affiliated C&T centers. Additionally, we assessed decentralization's population-level impacts by comparing proportions of women and infants receiving interventions before (2009–2010) and after (2011–2013) decentralization.

Results—Among newly HIV-diagnosed women (N = 1482), the 14-week cumulative incidence of receiving the package of CD4 testing and zidovudine or antiretroviral therapy was less at ANC/L&D [66%; 95% confidence interval (CI): 63% to 69%] than at C&T (88%; 95% CI: 83% to 92%) sites (subdistribution hazard ratio, 0.62; 95% CI: 0.55 to 0.69). Delivery of cotrimoxazole and DNA polymerase chain reaction testing to HIV-exposed infants (N = 1182) was inferior at ANC/L&D sites (subdistribution hazard ratio, 0.84; 95% CI: 0.76 to 0.92); the 10-month cumulative incidence of the package at ANC/L&D sites was 89% (95% CI: 82% to 93%) versus 97% (95% CI: 93% to 99%) at C&T centers. Receipt of the pregnancy (20% of 1518, to 64% of 1405) and infant (16%–31%) packages improved post decentralization.

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Conclusions—Services were delivered less efficiently at ANC/L&D sites than C&T centers. Although access improved with decentralization, its potential cannot be realized without sufficient and sustained support.

Keywords

prevention of mother to child transmission; vertical transmission; Democratic Republic of Congo; health services accessibility; delivery of health care; prenatal care/utilization; postnatal care/utilization

INTRODUCTION

Access to prevention of mother-to-child HIV transmission (PMTCT) services has improved over time–the proportion of HIV-positive pregnant women who received antiretroviral (ARV) prophylaxis in the 21 African priority countries of the UNAIDS Global Plan[1] increased from 33% in 2009 to 68% in 2013.[2] Despite this progress, this goal to reduce new pediatric HIV infections by 90% and halve AIDS-related maternal deaths by 2015 will not be achieved without improving the quality of service delivery and mitigating loss points throughout the PMTCT care continuum.[3]

After the identification of HIV infection during pregnancy, multiple steps are essential to minimize vertical transmission and assure long-term maternal and infant health.[4,5] In resource-limited settings, barriers to effective HIV prevention and care often arise from deficiencies in the facilities where antenatal care (ANC), labor and delivery (L&D), and postpartum services are provided. For example, these sites regularly lack the CD4 assessment capacity[6–8] needed to appropriately prescribe antiretroviral therapy (ART).[9] As PMTCT programs are pregnancy-focused[10] and frequently in distinct physical locations lacking linkages to HIV care and treatment (C&T),[11–13] there are also postnatal barriers including low uptake of ARV prophylaxis by infants[14,15] and unavailability of diagnostic DNA polymerase chain reaction (PCR) testing.[16]

One strategy to increase coverage levels of maternal and infant interventions is decentralization, a shifting of services to primary care centers.[17] Decentralization to ANC sites has yielded promising results — in South Africa[18] and Rwanda[19], for example, ART initiation by pregnant women was equivalent at decentralized and centralized sites. Decentralization of services in the Democratic Republic of Congo (DRC) has been extremely limited, paralleling the scale-up of other HIV services that has lagged behind in most other countries[7] in the wake of civil wars and decades of political, social, and economic difficulties that impeded the development of vital health care infrastructures.[20,21] Few primary care clinics offer CD4 testing or efficacious ARV regimens for PMTCT[22] recommended by the World Health Organization (WHO). This is reflected in the 35% of Congolese HIV-infected pregnant women who received appropriate ARVs in 2013[23] and the 2% who received a complete package of PMTCT services in 2012.[22]

The DRC, classified by UNAIDS as a focus country for pediatric HIV elimination,[1] accounted for 3% of new HIV infections in children in 2013 despite low prevalence among young women (0.5%).[2] This burden is largely unmet, as evidenced by our network of

ANC/L&D sites in Kinshasa (the largest in this city of 10 million) identifying fewer than 15% of pregnancies among HIV-infected women in 2008.[24] Decentralizing PMTCT and HIV-exposed infant services in the DRC thus has significant potential to alleviate both regional and global burdens of maternal and pediatric HIV, although it is incompletely explored if the delivery of interventions at decentralized sites not historically accustomed to such provision, is on par with that at experienced, specialized sites. Furthermore, the population-level impacts of decentralization in low HIV prevalence areas remain unknown.

To increase program scope and coverage, we decentralized an expanded package of PMTCT and HIV-exposed infant services to 90 high-volume ANC/L&D sites in the resource-deprived, low prevalence setting of Kinshasa. With the goal of informing program scale-up in similar implementation contexts, after rollout of new individual-level registers linking mother–infant pairs, this study had 2 aims. First, we assessed if intervention packages of CD4 testing and zidovudine (AZT) or ART for mothers, and DNA PCR testing and cotrimoxazole prophylaxis for infants were delivered as efficiently at decentralized ANC/L&D sites as at dedicated C&T centers. Secondly, we aimed to quantify the population-level impacts of decentralization by comparing the numbers and proportions of mothers and infants receiving the above intervention packages before and after their availability at ANC/L&D sites.

METHODS

Study Setting, Interventions, and Data Sources

In 2003, the University of North Carolina at Chapel Hill (UNC) initiated its HIV prevention, care, and treatment programs in the DRC (UNC-DRC) by strengthening Kinshasa ANC/L&D sites through the introduction of a minimum package of maternal and infant services, including HIV counseling and testing and PMTCT prophylaxis.[25] This package, instituted in June 2010 in 37 of the city's highest volume facilities, has been described previously.[24–26]

In April 2010, we began rolling out an expanded package to these sites, and 53 others (for a total of 90) were added by September 2012 to cover 32/35 provincial health zones. The prior standard of care was bolstered by training personnel on the 2010 WHO PMTCT guidelines[27] that includes Option A, empathetic counseling skills, co-located delivery care, and the importance of patient retention, paying delivery fees to encourage safe birth, and providing (1) CD4 testing, cotrimoxazole, and AZT for mothers, and (2) cotrimoxazole, extended nevirapine, and DNA PCR testing for infants. Transportation costs to the first visit at either of 2 affiliated (but separately located) HIV C&T centers were provided to promote long-term care uptake; however, once the new interventions were available at ANC/L&D sites, women could opt to remain there for PMTCT and HIV-exposed infant services. At 45 sites, volunteer HIV-infected "mother-mentors" worked as clinic assistants, helping women to navigate care while encouraging C&T uptake. Generally, women with CD4 counts ≤350 could access ART at C&T centers only. Details on the ANC/L&D sites are outlined in Table S1 (see Supplemental Digital Content, http://links.lww.com/QAI/A726).

An essential expanded package component was a new paper register that allowed for mothers and their infants to be linked and longitudinally tracked. Service delivery and patient dispositions were recorded in the registers by the ANC/L&D site providers and UNC-DRC personnel, who made supportive supervisory monitoring visits monthly as part of the expanded package. Data were recorded between a woman's presentation for ANC or L&D, until her infant was confirmed as HIV-infected or ruled out as HIV-uninfected. Details on the populations of mothers and infants tracked in the registers are presented in Table S2 (see Supplemental Digital Content, http://links.lww.com/QAI/A726).

The study sites included the 90 ANC/L&D sites and 2 UNC-DRC C&T centers, Kalembe Lembe Pediatric Hospital and Bomoi Healthcare Center.[28,29] The data sources were the registers at the ANC/L&D sites, which were entered into an Epi Info database, the real-time Epi Info database at the C&T centers,[30] and an aggregate service delivery database from the ANC/L&D sites used to provide program context and quantify decentralization's population-level impacts. The Epi Info databases contained unique patient identifiers to link mother–infant pairs and were linked to each other, as the ANC/L&D database included C&T codes and the C&T database included ANC/L&D codes. This facilitated tracking of individuals between facility types. All database records as of July 2013, when data collection ended, were included in analyses.

Measures and Analyses

In the service delivery aim, we calculated the cumulative incidence of 2 outcomes between 2010 and 2013: (1) receipt of CD4 testing, and AZT or ART (*pregnancy package*), by women newly diagnosed with HIV before L&D, and (2) receipt of DNA PCR testing and cotrimoxazole (*infant package*) by HIV-exposed infants, at 2 facility types: (1) ANC/L&D site, providing *decentralized* services, and (2) C&T center, *specialized* to deliver these services. In the analysis of women, follow-up began at C&T enrollment if the pregnancy was registered at a site before it began offering CD4 testing and AZT; otherwise, follow-up began at ANC presentation. Follow-up ended at the earliest of (1) the outcome, (2) censoring (loss to follow-up, transfer, move, voluntary withdrawal, or end of study), or (3) a competing risk (delivery, miscarriage, or death). In the infant analysis, follow-up began on the date of first visit at ≥1 month of age (when cotrimoxazole is indicated[31]) at a facility offering DNA PCR testing and cotrimoxazole. Additionally, reaching 18 months of age (the end of the early infant diagnosis period, when HIV can be serologically confirmed) was an additional censoring event, and competing risks were limited to death and confirmation of HIV-negative status.

As individuals could opt to receive services at a C&T center, exposure could switch from "decentralized" to "specialized" (but not vice-versa) if this transfer occurred before either component of the intervention package was received; if 1 of the outcome services was received, followup was censored on the transfer date (date of C&T enrollment). To allow for this late entry, we used the counting process configuration as applied by Geskus.[32] Individuals who received the intervention package on their enrollment date and those lost after a single visit[33] were assigned a follow-up time of 1 day. For others censored, if deemed lost to follow-up after a missed visit, follow-up ended on the last visit date. Only newly HIV-

diagnosed women were eligible because the outcome included ARV receipt, and many previously diagnosed women were already on ART; additionally, time in care was likely a confounder and modifier of the associations of interest. Infants were eligible for the infant analysis even if their mothers were not in the analysis of women. DNA PCR testing was defined as specimen collected, not also receipt of result.

Competing risks are events such as death that preclude occurrence of the outcome and can create bias.[34] To account for competing risks in our data, the SAS macro %PSHREG was used to obtain competing risk cumulative incidence functions stratified by facility type (decentralized versus specialized) and to quantify the effects of facility type on delivery of the intervention packages.[35] Crude and adjusted hazard ratios (HRs) and 95% confidence intervals (CIs) were generated using the Fine and Gray subdistribution hazards model,[36] which produces an effect measure due to both the association of the exposure on the event of interest and the possibly differential impact of competing events on exposed and unexposed individuals.[37] We also employed the cause-specific Cox proportional hazards model, which treats competing events as censored, and results in biased effect estimates if its inherent assumption of independence between the outcome and competing events is incorrect.[37]

Causal diagrams were used to identify confounders for adjusted models.[38] In the analysis of women, covariates were age and gestational age at registration along with CD4 count during pregnancy; infant analysis covariates were age at first visit and 3 maternal factors: gestational age, HIV status (undiagnosed or previously diagnosed) at registration, and CD4 count during pregnancy. We employed multiple imputation with fully conditional specification methods[39] to account for missing covariate data; 5 imputed datasets were generated. To relax the linearity assumption in modeling continuous variables, we used Stone and Koo's additive splines constrained to be linear in the tails, with knots at the fifth, 35th, 65th, and 95th percentiles. χ^2 or Cochran-Armitage trend tests were used to compare proportions, with medians compared by the Mann–Whitney test.[40]

In the aim to quantify decentralization's population-level impacts, we calculated the proportions of HIV-infected women who received the pregnancy package pre-decentralization (at affiliated C&T centers only) versus post-decentralization (at either the C&T centers or ANC/L&D sites). Similarly, proportions of their HIV-exposed infants who received the infant package, pre- and post-decentralization, were calculated. All analyses were completed in SAS 9.3 (SAS Institute Inc., Cary, NC).

Ethical Approval

The study was approved by the Kinshasa School of Public Health Ethics Committee and the UNC Institutional Review Board. Consent was obtained at C&T enrollment; activities at the ANC/L&D sites met criteria for waiver of consent.

RESULTS

Aim 1: Service Delivery

Between 2010 and 2013, in our cohort of linked mother–infant pairs, we identified 1482 newly HIV-diagnosed women eligible for the analysis of CD4 testing and ARV regimen

delivery during pregnancy, as well as 1142 HIV-exposed infants eligible for the analysis of DNA PCR testing and cotrimoxazole delivery. Their characteristics and outcomes are described in Table 1. Women at a C&T center did not differ from those at only a ANC/L&D site in terms of age ($P = 0.88$) or gestational age ($P = 0.05$) at registration. The cumulative incidence of receiving the pregnancy package at 14 weeks was less at the ANC/L&D sites (66%; 95% CI: 63% to 69%) than that at the C&T centers (88%; 95% CI: 83% to 92%) (Fig. 1), and both the unadjusted (0.59; 95% CI: 0.51 to 0.69) and adjusted (0.62; 95% CI: 0.55 to 0.69) subdistribution HRs indicate inferior delivery of the package at the ANC/L&D sites compared with the C&T centers (Table 2). No marked changes in delivery of the package over time at either facility type were noted.

Compared with infants at a C&T center, those only at an ANC/L&D site were older at first visit ($P < 0.01$) and more likely had mothers who were previously HIV undiagnosed ($P = 0.01$), of greater gestational age ($P < 0.01$) at registration, healthier as reflected by pregnancy CD4 count ($P < 0.01$), and did not receive AZT or ART ($P < 0.01$). The cumulative incidences of receiving the infant package at 10 months (Fig. 1) at the ANC/L&D sites (89%; 95% CI: 82% to 93%) and the C&T centers (97%; 95% CI: 93% to 99%), as well as the unadjusted (0.85; 95% CI: 0.75 to 0.97) and adjusted (0.84; 95% CI: 0.76 to 0.92) subdistribution HRs (Table 2), suggest that delivery of the package at the ANC/L&D sites was poorer than that at the C&T centers. No marked changes in delivery of the package over time at either facility type were noted. Using age rather than months in care as the timescale, the median age at package receipt at the ANC/L&D sites was 7.3 weeks (interquartile range, 6.6–11.7), similar to that at the C&T sites (7.0 weeks; interquartile range, 6.4–8.9).

Only 14.2% of newly diagnosed cases remaining at the ANC/L&D sites received all 4 components of the pregnancy and infant packages, markedly lower than the 53.5% observed among cases at the C&T centers (Fig. 2). Altogether, just 21.1% of total newly diagnosed cases received all 4 components of the packages, which emphasizes that overall impact was driven more by the ANC/L&D sites where most individuals remained for care.

Aim 2: Population-Level Impacts of Decentralization

During the pre-decentralization period of 2009–2010, considering all HIV-infected pregnant women identified at ANC/L&D sites including those not presenting to C&T (N = 1518), package uptake at affiliated C&T centers was approximately 20% (pregnancy) and 16% (infant). In 2011–2013 when services were decentralized (N = 1405), uptake across facilities increased to about 64% (pregnancy) and 31% (infant). These increases are depicted in Fig. 3. During the period of decentralization, 1260 women and 634 infants received at least 1 intervention at an ANC/L&D site; no temporal changes in pregnancy and infant package uptake were noted. Greater proportions of women ($P < 0.01$) and infants ($P < 0.01$) remained at ANC/L&D sites in later years (Table 1), reflecting the increased dissemination of decentralized services over time.

DISCUSSION

This study, by using a novel system to link and track mother–infant pairs in Kinshasa, DRC, revealed that *decentralized* primary care facilities focused on ANC/L&D delivered PMTCT

and HIV-exposed infant services less efficiently than *specialized* HIV C&T centers. The finding held true for the pregnancy package of CD4 testing and AZT or ART (HR, 0.62; 95% CI: 0.55 to 0.69) as well as the infant package of DNA PCR testing and cotrimoxazole (HR, 0.84; 95% CI: 0.76 to 0.92), and provides unique evidence on integration called "urgently needed" in a recent systematic review.[41] As PMTCT and HIV-exposed infant services are increasingly incorporated into primary care in conjunction with the accelerating global scale-up of WHO Options B/B+,[42] our work provides a caution to program implementers that even with sustained commitment to training, capacity, and monitoring and evaluation (M&E), optimal service delivery may be harder to attain at decentralized sites.

Despite the noted discrepancies between facility types, performance at the ANC/L&D sites was encouraging. At these sites, the cumulative incidences of the pregnancy and infant packages were 66% and 89%, respectively, and substantial proportions of the populations received the interventions on their first day in care. Uptake of interventions by both mothers and infants increased dramatically post-decentralization, resulting in greater absolute numbers of individuals reached, as observed in Nigeria.[43] There were specific areas where the C&T centers appeared to outperform, including CD4 testing (98% of women versus 67%), as observed in Rwanda,[19] and provision of services at visits during later follow-up, consistent with personnel at dedicated sites having a deeper understanding of the need for HIV-related care. These differences inform the selection of strategies to improve service delivery in other contexts, for example point-of-care assays[44,45] (which were unavailable at the ANC/L&D sites) and integrating HIV interventions into routine clinical encounters such as infant immunization visits.[46]

The new register and data systems were instrumental in providing a detailed, individual-level picture of our populations for the first time. Notably, these low-tech tools were successfully implemented in a resource-constrained environment, responding to calls for strengthening of PMTCT systems to improve health,[47–49] targeting areas for improvement, and demonstrating the feasibility of such innovations in similar settings. Despite rigorous M&E and retention efforts, there was frequent loss to follow-up of mothers and infants, particularly at ANC/L&D sites (Table 1; Fig. 2), and between delivery and first infant visit (Fig. 2; see Table S1, Supplemental Digital Content, http://links.lww.com/QAI/A726). Programs decentralizing services must actively combat this phenomenon, which negatively impacts outcomes and their assessment. Accordingly, an inadequate percentage of women ultimately had their infants DNA PCR tested–Fig. 2 shows high attrition, as commonly noted,[50] regardless of facility type. Programs experiencing attrition should employ a multifocal approach with tactics such as peer support,[51] cash transfers,[52] and maternal ART provision,[53] to mitigate loss across the cascade.

Study strengths include examining relevant outcomes (eg, CD4 testing; maternal immunological assessment will occur in an Option B context upon completion of breastfeeding, and in an Option B+ context during ART follow-up), high generalizability because evaluated ANC/L&D sites were locally administered and were not research facilities, and intensive M&E and training that likely resulted in superior data quality and improved service delivery. We believe that stronger magnitudes of effect favoring the C&T centers would have been noted without our strong caliber of technical support to the

ANC/L&D sites, and that decentralized sites lacking such support would underperform relative to the ANC/L&D sites in this study. As the study was in a low HIV prevalence context, it provides valuable information for programs in declining prevalence settings while demonstrating that low prevalence does not imply low unmet need. An additional strength is the competing risks methodology, although in this application, Fine and Gray models yielded effect measures not appreciably different than those from traditional Cox Proportional Hazards models, due to the timing and low frequency of competing events. The presence of competing risks in implementation settings and aim to affect policy[37] informed the chosen methodological approach, which precluded questions of possible bias had competing risks not been taken into account.

Study limitations include (1) inconsistent recording of extended nevirapine initiation, which prevented its inclusion in the infant package, (2) rarely assessing WHO HIV clinical stage, precluding its use as a covariate, and (3) not collecting the data necessary to see if there were sociodemographic differences between women at ANC/L&D and C&T sites. We were not able to evaluate if effects were heterogeneous across ANC/L&D sites due to limited sample size, and we also lacked data on receipt of DNA PCR test result, an important PMTCT indicator. Although it is possible that women who presented at a C&T center or were in contact with a “mother-mentor” were more motivated to follow through with care for themselves and their infants, thus potentially impacting results, we believe that service delivery was primarily provider-driven. Relatedly, we speculated that a woman’s health status (as reflected by her CD4 count) might influence a provider’s likelihood of delivering services, and hence this factor was included in adjusted analyses.

In conclusion, decentralization of PMTCT and HIV-exposed infant services is a structural intervention with great promise to help meet global benchmarks to reduce pediatric HIV, as evidenced by the observed increase in package uptake post-decentralization and the encouraging performance by ANC/L&D sites in delivering key interventions. However, our results also suggest that if the approach is to be maximally effective, efforts to integrate such services into primary care must be accompanied by training and support that are sufficient and sustained, as well as requisite systems for the M&E of impact. This message should be considered in decision-making on resource allocation and program implementation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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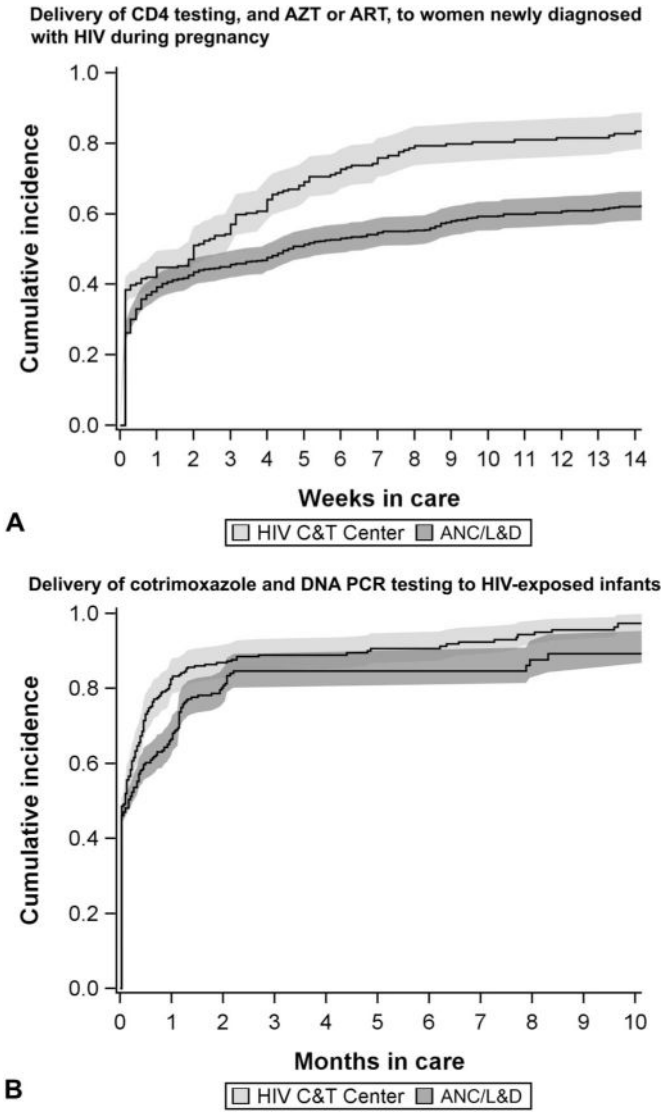

FIGURE 1.

Cumulative incidence of delivery of CD4 testing, and AZT or ART, to women newly diagnosed with HIV during pregnancy (A) and cotrimoxazole and DNA PCR testing to HIV-exposed infants (B), by facility type, Kinshasa, Democratic Republic of Congo, 2010–2013. Bands represent 95% CIs. A, The cumulative incidence function is estimated at the mean values of (1) age at registration, (2) gestational age at registration, and (3) CD4 count during pregnancy. B, The cumulative incidence function is estimated at the mean values of (1) age at first visit at ≥1 month of age, (2) maternal gestational age at registration, and (3) maternal CD4 count during pregnancy (a proxy for HIV disease progression), as well as the reference level for maternal HIV status (undiagnosed, rather than previously diagnosed). If gestational age at registration was not recorded, it was estimated using projected date of delivery and otherwise date of delivery (if available).

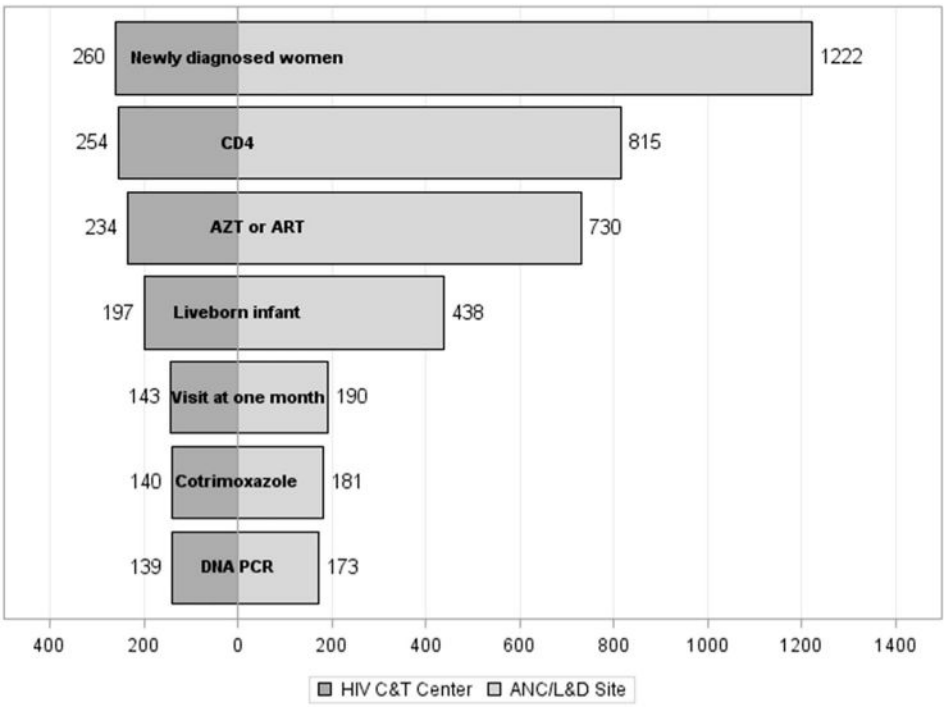

FIGURE 2.

Cascade of PMTCT and HIV-exposed infant services by facility type, Kinshasa, Democratic Republic of Congo, 2010–2013. The percentages represent the counts of infants who have received a DNA PCR test divided by the total number of newly diagnosed women (eg, 173/1222 = 14.2%), not cumulative incidences.

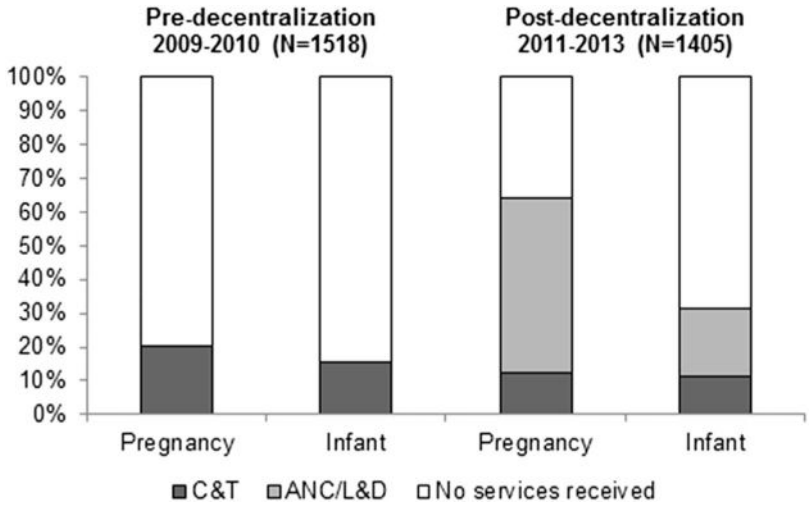

FIGURE 3.

Population-level impacts of decentralization on uptake of pregnancy and infant packages, Kinshasa, Democratic Republic of Congo, 2009–2013. The pregnancy package is CD4 testing and AZT or ART; the infant package is cotrimoxazole and DNA PCR testing.

TABLE 1

Characteristics and Outcomes of HIV-Infected Women and Their HIV-Exposed Infants Included in Cumulative Incidence Analyses, Kinshasa, Democratic Republic of Congo, 2010–2013 *

Women Newly Diagnosed With HIV During Pregnancy (If ANC/L&D Site Person-Time, Pregnancy Registered While Decentralized CD4 Testing and AZT Available)	**At ANC/L&D Site Only (N = 1222)**	**At Affiliated HIV C&T Center for All or Part of Follow-up† N = 260)**	**Total (N = 1482)**
Year of registration, n (%)			
2010	0 (0.0)	77 (29.6)	77 (5.2)
2011	151 (12.4)	176 (67.7)	327 (22.1)
2012	677 (55.4)	6 (2.3)	683 (46.1)
2013	394 (32.2)	1 (0.4)	395 (26.7)
Age at registration, median (IQR),‡ yrs	29 (25–34)	30 (25–34)	29 (25–34)
Gestational age at registration, median (IQR),§ wks	22 (18–28)	22 (17–26)	22 (18–28)
WHO HIV clinical stage at registration, n (%)			
1	403 (33.0)	16 (6.2)	419 (28.3)
2	63 (5.2)	0 (0.0)	63 (4.3)
3	13 (1.1)	0 (0.0)	13 (0.9)
4	3 (0.2)	0 (0.0)	3 (0.2)
Not assessed	740 (60.6)	244 (93.8)	984 (66.4)
Referred to affiliated HIV C&T center, n (%)			
No	988 (80.9)	0 (0.0)	988 (66.7)
Yes	234 (19.1)	260 (100.0)	494 (33.3)
CD4 test during pregnancy, n (%)			
No	407 (33.3)	6 (2.3)	413 (27.9)
Yes	815 (66.7)	254 (97.7)	1069 (72.1)
≤350‖	397 (50.7)	108 (45.6)	505 (49.5)
>350	386 (49.3)	129 (54.4)	515 (50.5)
CD4 count during pregnancy, median (IQR)¶	347 (223–506)	379 (235–577)	353 (227–519)
Antiretroviral regimen during pregnancy, n (%)			
None	188 (15.4)	21 (8.1)	209 (14.1)
AZT	927 (75.9)	142 (54.6)	1069 (72.1)
Triple-drug ART	107 (8.8)	97 (37.3)	204 (13.8)
Outcome,# n (%)			
CD4 testing, and AZT or ART	730 (59.7)	234 (90.0)	964 (65.0)
Delivered **	197 (16.1)	23 (8.8)	220 (14.8)
Lost to follow-up	231 (18.9)	1 (0.4)	232 (15.7)
Miscarriage or died	6 (0.5)	2 (0.8)	8 (0.5)
Transferred, moved, or voluntarily withdrew	43 (3.5)	0 (0.0)	43 (2.9)
Pregnant at study end	15 (1.2)	0 (0.0)	15 (1.0)

HIV-Exposed Infants	**At ANC/L&D Site Only (N = 718)**	**At Affiliated HIV C&T Center for All or Part of Follow-up†† (N = 424)**	**Total (N = 1142)**

Women Newly Diagnosed With HIV During Pregnancy (If ANC/L&D Site Person-Time, Pregnancy Registered While Decentralized CD4 Testing and AZT Available) (If ANC/L&D Site Person-Time, First Visit at ≥ 1 mo of Age While Decentralized Cotrimoxazole and DNA PCR Testing Available)	At ANC/L&D Site Only (N = 1222)	At Affiliated HIV C&T Center for All or Part of Follow-up† N = 260)	Total (N = 1482)
Year of first visit at ≥1 mo of age, n (%)			
2010	0 (0.0)	17 (4.0)	17 (1.5)
2011	234 (32.6)	223 (52.6)	457 (40.0)
2012	320 (44.6)	134 (31.6)	454 (39.8)
2013	164 (22.8)	50 (11.8)	214 (18.7)
Age at first visit at ≥1 mo of age, median (IQR), wks	6.7 (6.4–7.4)	6.6 (6.0–7.3)	6.7 (6.3–7.3)
Maternal HIV status at registration, n (%)			
Previously diagnosed	208 (29.0)	156 (36.8)	364 (31.9)
Undiagnosed	510 (71.0)	268 (63.2)	778 (68.1)
Maternal pregnancy stage at registration,§ n (%)			
≤28 wks	430 (59.9)	330 (77.8)	760 (66.5)
>28 wks, before labor and delivery	143 (19.9)	54 (12.7)	197 (17.3)
Unknown, before labor and delivery	0 (0.0)	1 (0.2)	1 (0.1)
Labor and delivery	145 (20.2)	39 (9.2)	184 (16.1)
Maternal gestational age at registration, median (IQR),§ wks	26 (20–36)	24 (18–28)	24 (20–32)
Maternal WHO HIV clinical stage at registration, n (%)			
1	133 (18.5)	79 (18.6)	212 (18.6)
2	29 (4.0)	26 (6.1)	55 (4.8)
3	5 (0.7)	16 (3.8)	21 (1.8)
4	1 (0.1)	2 (0.5)	3 (0.3)
Not assessed	550 (76.6)	301 (71.0)	851 (74.5)
Maternal CD4 test during pregnancy, n (%)			
No	421 (58.6)	115 (27.1)	536 (46.9)
Yes	297 (41.4)	309 (72.9)	606 (53.1)
≤350//	102 (35.5)	157 (53.2)	259 (44.5)
>350	185 (64.5)	138 (46.8)	323 (55.5)
Maternal CD4 count during pregnancy, median (IQR)¶	421 (284–559)	336 (218–504)	378 (248–545)
Maternal antiretroviral regimen during pregnancy, n (%)			
None	254 (33.4)	49 (11.6)	303 (26.5)
AZT	318 (44.3)	143 (33.7)	461 (40.4)
Triple-drug ART	146 (20.3)	232 (54.7)	378 (33.1)
Extended nevirapine, n (%)			
No	39 (5.4)	26 (6.1)	65 (5.7)
Yes	679 (94.6)	398 (93.9)	1077 (94.3)
Cotrimoxazole, n (%)			
No	109 (15.2)	22 (5.1)	131 (11.4)
Yes	609 (84.8)	409 (94.9)	1018 (88.6)
DNA PCR test, n (%)			

Women Newly Diagnosed With HIV During Pregnancy (If ANC/L&D Site Person-Time, Pregnancy Registered While Decentralized CD4 Testing and AZT Available)	At ANC/L&D Site Only (N = 1222)	At Affiliated HIV C&T Center for All or Part of Follow-up[†] N = 260)	Total (N = 1482)
No	131 (18.2)	22 (5.6)	153 (13.3)
Yes	587 (81.8)	409 (94.4)	996 (86.7)
Positive[‡‡]	20 (3.8)	23 (5.7)	43 (4.6)
Negative	503 (96.2)	379 (94.3)	882 (95.4)
Outcome,[#] n (%)			
Cotrimoxazole and DNA PCR test	562 (78.3)	398 (93.9)	960 (84.1)
Reached 18 mo of age	0 (0.0)	1 (0.2)	1 (0.1)
Lost to follow-up	144 (20.1)	3 (0.7)	147 (12.9)
Died	0 (0.0)	3 (0.7)	3 (0.3)
Transferred, moved, or voluntarily withdrew	9 (1.3)	2 (0.5)	11 (1.0)
Under follow-up at study end	3 (0.4)	17 (4.0)	20 (1.8)

[*] Data from ANC/L&D sites (2 of 90 had zero registered pregnancies) and 2 affiliated HIV C&T centers.

[†] Twelve women contributed person-time at both an ANC/L&D site and an HIV C&T center.

[‡] Among 1336 pregnancies where the woman's date of birth was recorded.

[§] Among pregnancies with actual or projected gestational age. If gestational age at registration was not recorded, it was estimated using projected date of delivery and otherwise date of delivery (if available).

[‖] Denominator: Non-missing CD4 results.

[¶] Among non-missing CD4 results.

[#] Proportions, not cumulative incidences.

[**] Includes 16 women without a recorded delivery date who were projected, at study end, to have delivered.

[††] Eleven infants contributed person-time at both an ANC/L&D site and an HIV C&T center.

[‡‡] Denominator: Non-missing DNA PCR results.

IQR, interquartile range.

TABLE 2

Estimated Effects of Facility Type on the Delivery of Maternal PMTCT and HIV-Exposed Infant Services, Kinshasa, Democratic Republic of Congo, 2010–2013

		Cox Proportional Hazards Model, Unadjusted		Fine and Gray Model, Unadjusted		Fine and Gray Model, Covariate-Adjusted, Multiple Imputation*	
Outcome	**Facility Type**	**Cause-specific HR**	**95% CI**	**Subdistribution HR**	**95% CI**	**Subdistribution HR**	**95% CI**
Receipt of CD4 testing, and AZT or ART, during pregnancy by women newly diagnosed with HIV	ANC/L&D site	0.59	0.51 to 0.69	0.59	0.51 to 0.69	0.62	0.53 to 0.71
	HIV C&T center	1		1		1	
Receipt of cotrimoxazole and DNA PCR testing by HIV-exposed infants	ANC/L&D site	0.85	0.75 to 0.97	0.85	0.75 to 0.97	0.84	0.73 to 0.96
	HIV C&T center	1		1		1	

The estimate for HIV-exposed infants is adjusted for age at first visit at ≥1 month of age, along with 3 maternal factors: HIV status (undiagnosed or previously diagnosed) and gestational age at registration, as well as CD4 count during pregnancy (a proxy for HIV disease progression). If gestational age at registration was not recorded, it was estimated using projected date of delivery and otherwise date of delivery (if available). Missing data were imputed (5 datasets); data were missing on at least 1 adjustment variable for 37% of newly diagnosed women and 49% of HIV-exposed infants.

*The estimate for newly diagnosed women is adjusted for age and gestational age at registration, as well as CD4 count during pregnancy.