

INTRODUCTION:

Mali has one of the highest rates of infant mortality globally with 62 deaths per 1,000 live births.¹ There were 23 stillbirths per 1,000 live births in Mali.¹ Previous studies have found azithromycin (antibiotic) to be efficacious in reducing infant mortality.²⁻³

The SANTE trial is a randomized controlled trial administering azithromycin or a placebo to pregnant women and infants.⁴ The trial occurred in three districts within Sikasso Region (Figure 1). Those districts were Kignan, Niena, and Koutiala. Kignan and Niena were in Sikasso cercle and Koutiala was in Koutiala cercle (Figure 2). Pregnant women received two doses (first dose during enrollment antenatal care, ANC, visit and a follow-up ANC visit or delivery).⁴ Infants received doses during their first and third pentavalent vaccines (Penta-1 and Penta-3).⁴ Other studies²⁻³ used mass drug administration (MDA) to administer azithromycin while SANTE utilizes routine primary care health facilities.⁴

An assessment of enrollment data and coverage of ANC and infant immunizations in study districts and non-study districts was conducted. Enrollment data was utilized to determine the proportion of pregnant women enrolled in the trial from all those pregnant in the study districts. ANC and infant immunization coverage was examined over time in study districts and non-study districts. It was hypothesized that the presence of SANTE increased ANC and infant immunization coverage.

METHODS:

Assessing Enrollment in SANTE Trial

Trial data and publicly available demographic data was used to obtain the proportion of pregnant women in each study district enrolled in the trial from all those pregnant in the study districts. By assessing this data, intervention coverage across the three study districts can be understood.

Influence of SANTE Trial

Administrative health data provided by the Ministry of Health in Mali was used to compare ANC and infant immunization coverage over time in study districts (Kignan, Niena, and Koutiala) and non-study districts (Sikasso, Yorosso, and Kolondieba). The first and fourth ANC visits (CPN1 and CPN4) were measured for ANC visit coverage. The first and third pentavalent vaccine (Penta-1 and Penta-3) were measured for infant immunization coverage. Study and non-study districts will be compared to see if SANTE increased ANC and infant immunization coverage in study districts.

RESULTS:

Assessing Enrollment in SANTE Trial

Enrollment in SANTE began by December 2020 in Koutiala, May 2021 in Kignan, and July 2021 in Niena. From 2021-2022, there were 110,024 pregnant women⁵ in those 3 districts.

- Of the 83,305 pregnant women⁵ in Koutiala, 33,650 (39.5%) pregnant women enrolled⁶ in the trial (Figure 3)
- In Kignan, there were 12,969 pregnant women⁵ and 6,936 (53.5%) pregnant women enrolled⁶ in the trial (Figure 3)
- Niena had 9,698 (70.5%) pregnant women enroll⁵ from the 13,750 pregnant⁶ in that district (Figure 3)

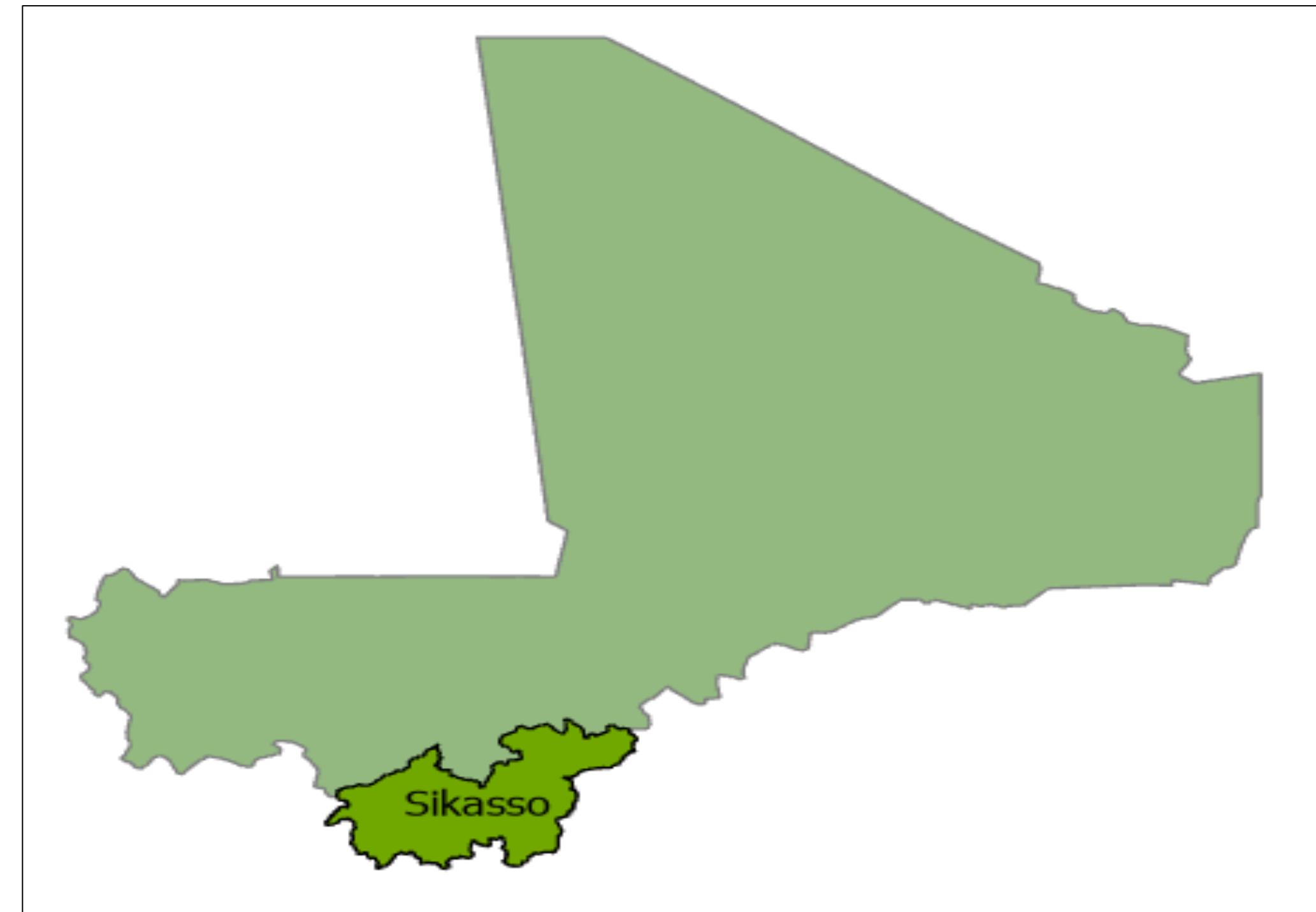


Figure 1. Map of Mali (lighter green) with the region of the trial, Sikasso, outlined.



Figure 2. Map of Sikasso region. Study districts Niena and Kignan located in Sikasso cercle (yellow). Study district Koutiala located in Koutiala cercle (baby blue).

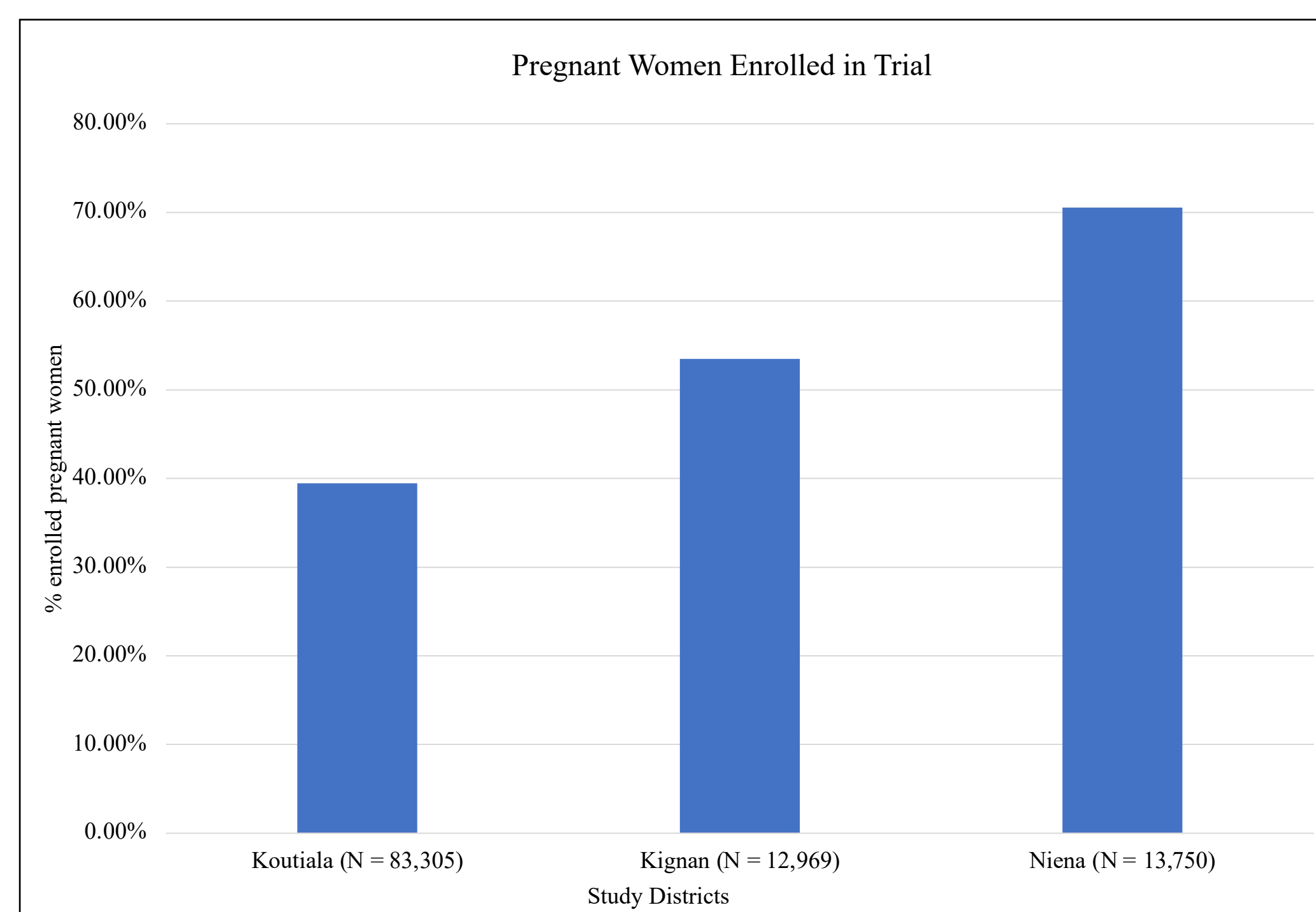


Figure 3. Percent of pregnant women enrolled in trial from all those who are pregnant in study districts. Dates included for Koutiala: December 2020- December 2022.⁴ Dates included for Kignan: May 2021- December 2022.⁴ Dates included for Niena: July 2021 – December 2022.⁴

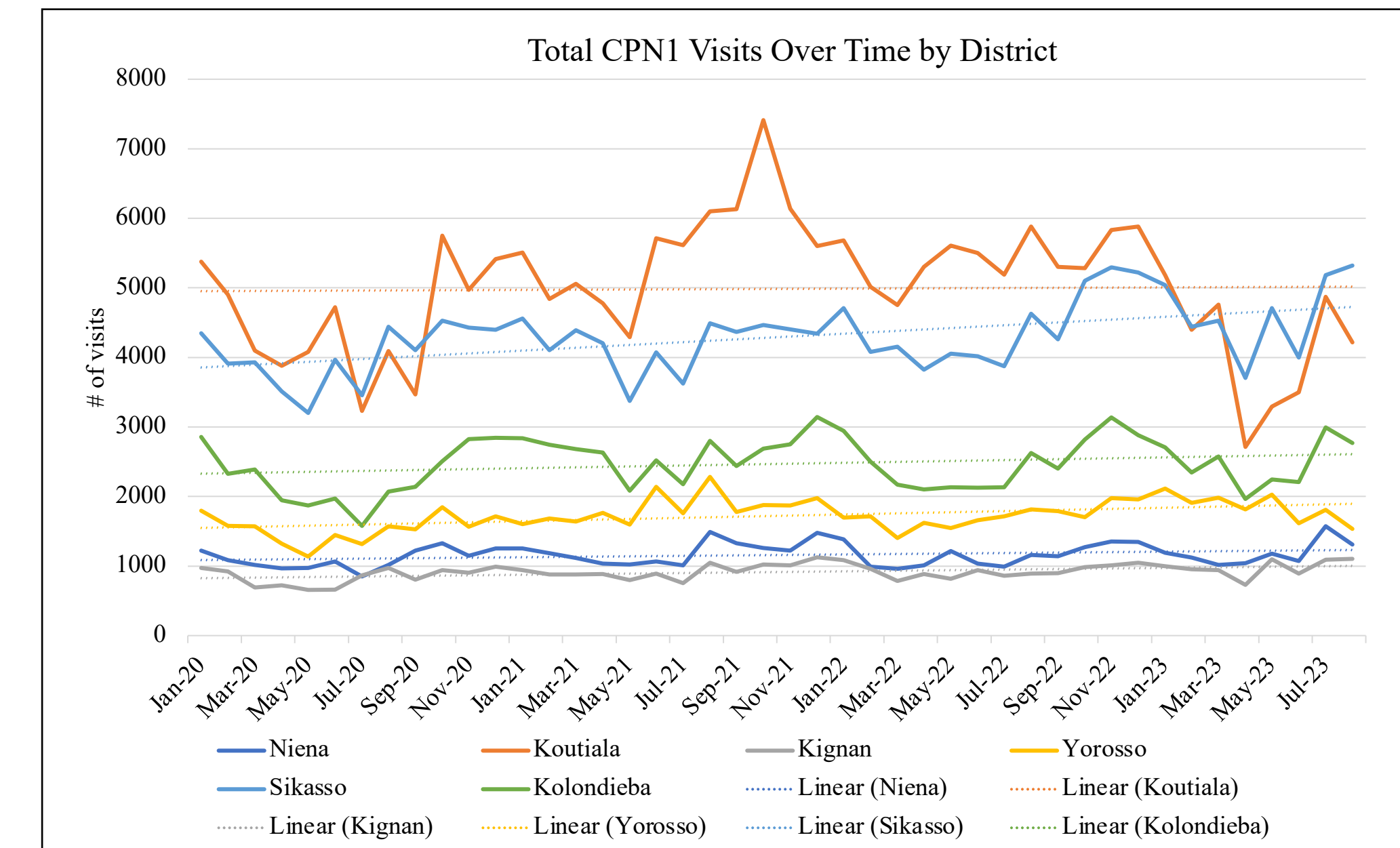


Figure 4. Number of first antenatal visits in SANTE districts and non-SANTE districts.

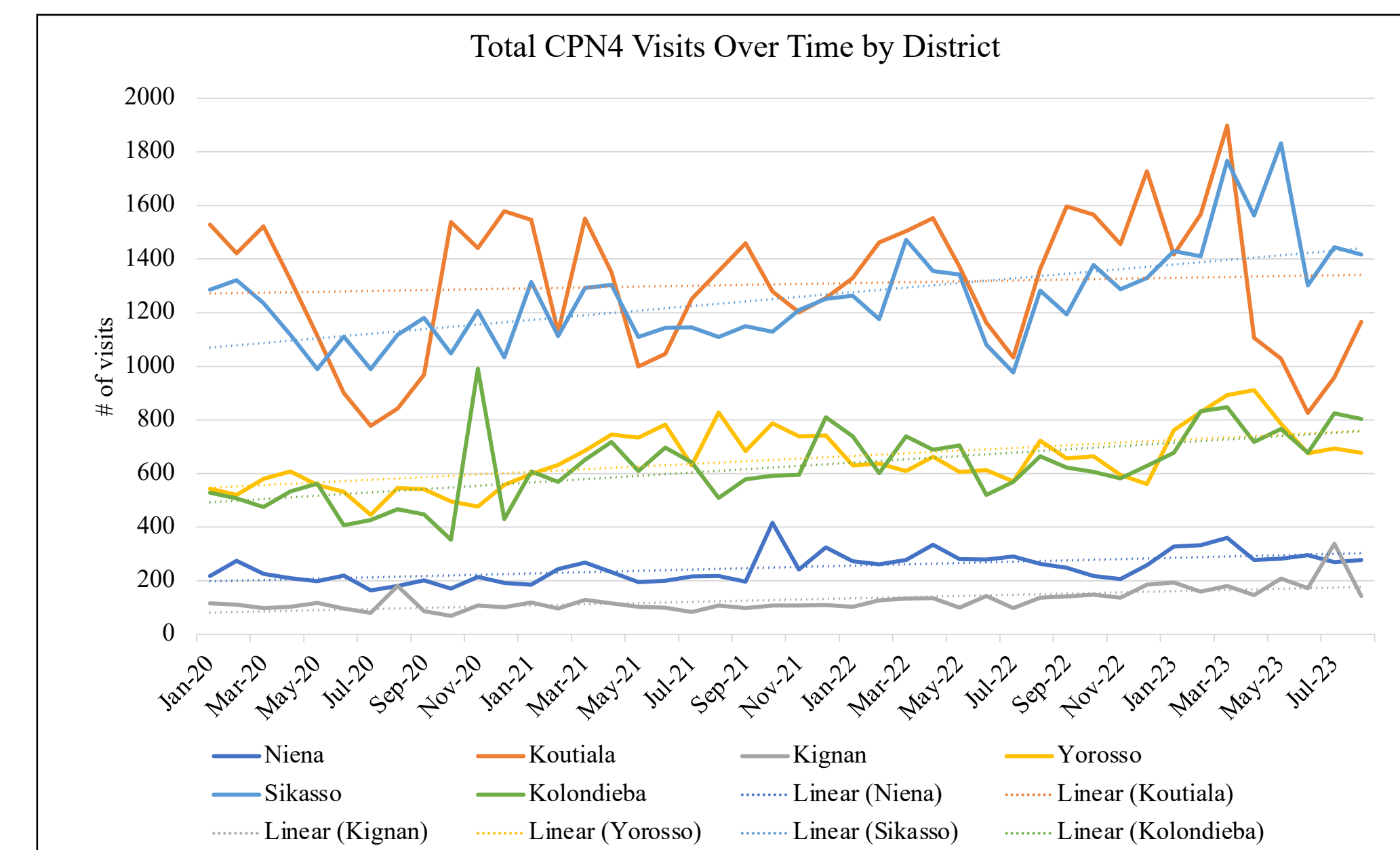


Figure 5. Number of fourth antenatal visits in SANTE districts and non-SANTE districts.

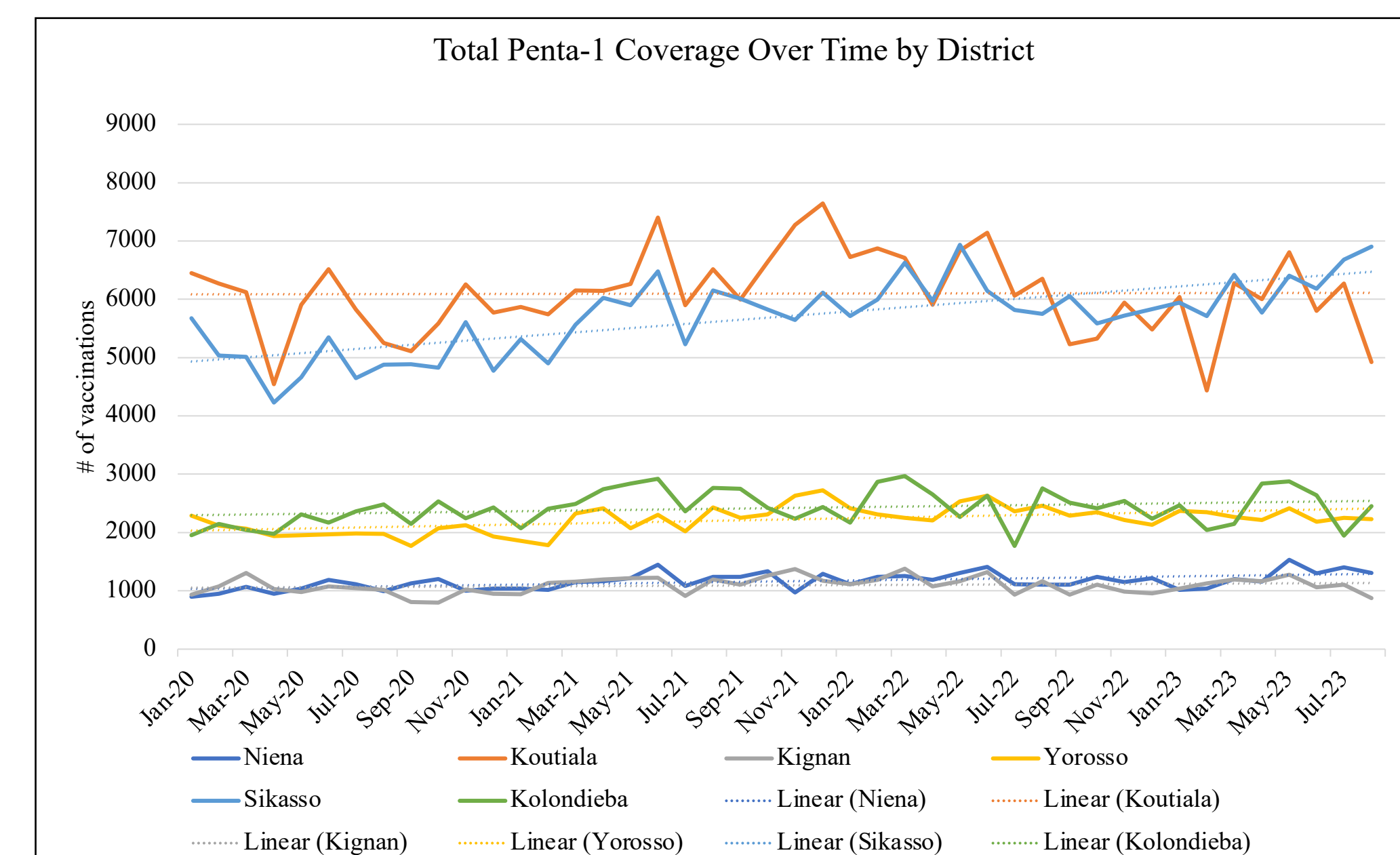


Figure 6. Number of first pentavalent doses in SANTE districts and non-SANTE districts.

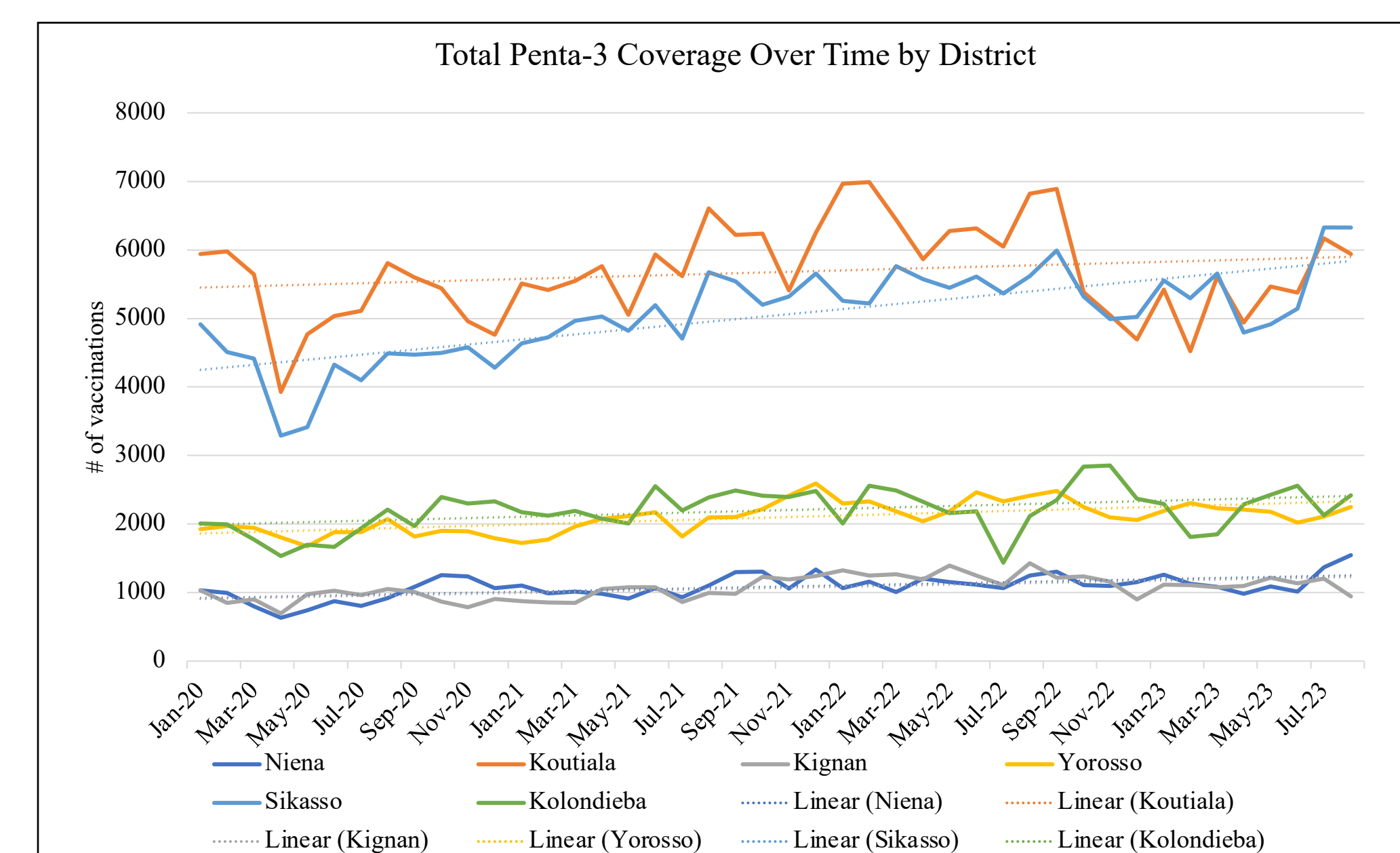


Figure 7. Number of third pentavalent doses in SANTE districts and non-SANTE districts.

RESULTS:

Influence of SANTE Trial

- CPN1 visits⁷ increased in all districts except for Koutiala and Kolondieba (Figure 4)
 - Koutiala and Kolondieba remained constant over time (Figure 4)
- Both study and non-study districts had an increasing trend for CPN4 visits (Figure 5)⁷
- For Penta-1 coverage,⁷ Sikasso was the only district with an increasing trend (Figure 6)
 - Penta-1 coverage remained constant over time in all the other districts
- Penta-3 coverage⁷ in Koutiala, Sikasso, Yorosso, and Kolondieba increased over time (Figure 7)
 - The other two study districts, Niena and Kignan, remained constant over time

DISCUSSION:

Assessing Enrollment in SANTE Trial

- Niena enrolled the most pregnant women (70.5%) (Figure 3)
- Kignan enrolled approximately three-fourths of Niena's enrollment
- Koutiala had the lowest enrollment (39.5%)
- Outreach efforts for the trial in each study district should be analyzed to account for the differences in enrollment across each district

Influence of SANTE Trial

- It was hypothesized that the presence of SANTE would increase ANC and infant vaccination coverage.
- CPN1 visits: both study districts and non-study districts had an increasing trend (Figure 4)
- CPN4 visits: All the study districts and non-study districts increased over time (Figure 5)
- Penta-1 coverage: Sikasso (non-study district) was the only district with an increasing trend (Figure 6)
- Penta-3 coverage: Koutiala (study district) and the non-study districts increased over time (Figure 7)
 - Niena (study district) and Kignan (study district) remained constant over time

The SANTE trial did not create demand for ANC or infant immunization visits as seen in the lack of difference in trends between study districts and non-study districts.

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