Trends in tuberculosis case notification and treatment outcomes after interventions in 10 zones of Ethiopia

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SUMMARY

SETTING: Amhara and Oromia Regions, Ethiopia.

OBJECTIVE: To determine trends in case notification rates (CNRs) among new tuberculosis (TB) cases and treatment outcomes of sputum smear-positive (SS+) patients based on geographic setting, sex and age categories.

METHODS: We undertook a trend analysis over a 4-year period among new TB cases reported in 10 zones using a trend test, a mean comparison *t*-test and one-way analysis of variance.

RESULTS: The average CNR per 100000 population was 128.9: 126.4 in Amhara and 131.4 in Oromia. The CNR in the project-supported zones declined annually by 6.5%, compared with a 14.5% decline in Tigray, the comparator region. TB notification in the intervention

TUBERCULOSIS CASE NOTIFICATION has stabilised globally, and has shown a declining trend in the African region.¹ At the same time, treatment success rates (TSRs) have improved, reaching a peak of 86% in 2014. This success is attributable to the implementation of the DOTS strategy, a key component of the Stop TB and End TB strategies.^{2,3} Ethiopia has been implementing the DOTS strategy since 1994, and reached 100% national coverage in 2006.4 Before 2011, a persistently low case detection rate (CDR) was the main challenge facing the Ethiopian National TB Programme (NTP). However, when the 2011 national TB prevalence survey yielded a lower estimated TB prevalence than expected, the country's CDR target was revised.⁵ Notified TB cases at the national level declined annually by 7.5% during 2011–2012 and 2013–2014.⁶

Here, we analyse trends in the number of cases notified for all forms of TB and sputum smearpositive (SS+) TB. As 80-90% of TB transmission is attributable to SS+ cases,^{7,8} studying trends in the notification of SS+ TB and all forms of TB cases zones contributed 26.1% of the national TB case notification, compared to 13.3% before project intervention. The overall male-to-female ratio was 1.2, compared to 0.8 among SS+ children, with a female preponderance. Over 4 years, the cure rate increased from 75% to 88.4%, and treatment success from 89% to 93%. Default, transfer out and mortality rates declined significantly.

CONCLUSION: Project-supported zones had lower rates of decline in TB case notification than the comparator region; their contribution to national case finding increased, and treatment outcomes improved significantly. High SS+ rates among girls deserve attention.

KEY WORDS: TB case notification; TB trend analysis; cure rate; new TB cases; Ethiopia

across different levels of SS+ can provide clues regarding the magnitude of TB transmission. We also include age disaggregation not available in most routinely reported data,¹ and examine regional variations.

The objective of the present study was to determine trends in CNR among new TB cases and treatment outcomes of SS+ patients based on geographic setting, sex and age categories over a 4-year period in 10 zones in the Amhara and Oromia Regions of Ethiopia.

MATERIAL AND METHODS

Setting

Ethiopia (population 95 million)⁹ ranks seventh among the 22 high TB burden countries.¹ Amhara and Oromia are the two largest of Ethiopia's 11 regions and home to over 60% of its population. External funding from the Global Fund and the US Agency for International Development (USAID) is the main source of NTP financing in Ethiopia.¹⁰

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Since 2011, comprehensive support to the NTP in the Amhara and Oromia Regions was provided through a project operated by Management Sciences for Health: Help Ethiopia Address Low TB Performance (HEAL-TB; Addis Ababa, Ethiopia). HEAL-TB trained NTP managers and health care providers, assisted in mentoring and supportive supervision, provided microscopes, supported a drug supply management system and increased community awareness about TB. The TB case-finding strategies employed were contact and out-patient TB screening, community referral of presumptive TB cases and TB case finding in congregate settings. We decentralised external laboratory quality assurance (EQA) for Ziehl-Neelsen microscopy and primary TB diagnostic and treatment follow-up testing in Ethiopia.

HEAL-TB was implemented in three phases. In July 2011, 10 zones (the study zones, five from each region) were selected; respectively 11 and 7 zones were added in 2013 and 2014. A zone is the second largest administrative unit (after region) in Ethiopia, with a population ranging between 0.5 and 3.6 million.

Data sources

We used routine quarterly case-finding reports containing data disaggregated by age, sex and TB type from July 2011 to June 2015 and treatment outcome reports for the period from October 2011 to December 2014. Treatment outcomes of patients registered for treatment in the same reporting quarter but enrolled in care 15 months earlier were used. We also used the annual CNR of the Tigray Region for comparison as it is adjacent to the region of study and not supported by HEAL-TB.⁴

Data quality

Lot quality assurance sampling (LQAS) and quarterly data quality assurance systems were used in health facilities and districts in both project-supported and other zones to ensure data quality. Each reporting unit checked the completeness and consistency of data before sending the data to the next level.

Data analysis

We used MS Excel (MicroSoft, Redmond, WA, USA) to compile data and STATA, version 13 (StataCorp, College Station, TX, USA) for analysis. Frequencies, proportions, ratios and 95% confidence intervals (CIs) were calculated to describe case notification and treatment outcome variables.

When computing the CNR, we used yearly TB notification data and total population recorded for each zone.⁹ We stratified the zones into three categories: those with a CNR of more than the 75th percentile were categorised as 'high' CNR, those below the 25th percentile were considered 'low' CNR, and those in between were categorised as 'medium'

CNR. We used a proportion *t*-test to compare two proportions and applied trend tests across the 4 years to test for changes in CNR and treatment outcome trends. We determined differences in average changes among the three CNR categories by applying oneway analysis of variance with multiple comparison tests (Bonferroni). We also used a mean-comparison test (*t*-test) to compute differences between two CNRs. P < 0.05 was considered statistically significant. We used standard World Health Organization and national definitions for case notification and treatment outcomes.^{11,12}

Ethical considerations

The Ethics Review Committees of the Oromia and Amhara Regional Health Bureaux (RHBs) reviewed and approved the study protocol. The data did not capture any personal identifying information.

RESULTS

Case notification rate among new TB cases

A total of 131 071 new TB cases all forms were detected in the 10 zones during the period July 2011–June 2015: 29.3% were SS+, 32.7% were sputum smear-negative (SS–) and 38% were extra-pulmonary TB (EPTB) cases. Of the 66 323 TB cases in Oromia, respectively 34.1%, 33.5% and 32.4% were SS+, SS– and EPTB. In Amhara, of a total of 64 748 new TB cases 24.4% were SS+, 31.8% were SS– and 43.8% were EPTB. Overall, males accounted for 54.2% of TB cases. In the 124 235 age-disaggregated TB cases, 2.5% were children aged <5 years and 12.6% were aged <15 years (Table 1).

The overall CNR per 100 000 population of all forms of TB was 128.9: 126.4 in Amhara and 131.4 in Oromia. The CNR among SS+ cases was 36.5 (Amhara, 30.6; Oromia, 42.4), while the CNR among SS- cases was 42.3 (Amhara, 40; Oromia, 44.5); the CNR for EPTB was 50. The mean difference between the two regions for the CNR of all forms of TB, SS+ and SS- (P > 0.05) was not significant. However, the CNR for EPTB in Amhara (55.8) was higher than that of Oromia (44.2) (P < 0.05).

Over the 4 years, the CNR for all forms of TB declined by 6.5% per year. Amhara showed an annual reduction of 9.2%, compared to 2.8% in Oromia. While the declining trend in Amhara has continued, the CNR for all forms of TB and SS+ in Oromia had increased by respectively 2.1% and 6.4% as of 2013–2014 (Figure 1). A trend test across the ordered CNR of all categories of TB based on the consecutive 4 years showed a declining trend; however, this was not statistically significant (P > 0.05). Data from the comparator region showed a 14.5% per annum decline in CNR.⁴ The contribution of project-supported zones to the overall national CNR

	New TB, all forms n	SS+ TB n (%)	SS— TB n (%)	Extra-pulmonary TB n (%)
	11	11 (76)	11 (78)	11 (78)
Region				
Ămhara	64 748	15822 (24.4)	20 591 (31.8)	28 335 (43.8)
Oromia	66 323	22 623 (34.1)	22 206 (33.5)	21 494 (32.4)
Total	131 071	38 445 (29.3)	42 797 (32.7)	49 829 (38)
Sex				
Male*	58 444	21 007 (35.9)	17 633 (30.2)	19803 (33.9)
Female	49315	17 530 (35.5)	13 889 (28.2)	17 897 (36.3)
Age, years				
<0-4	3 136	340 (10.7)	1 460 (46)	1 336 (42.2)
5–14	12 546	2 306 (18.3)	4 281 (34)	5959 (47.3)
≥15	108 553	32 756 (30.2)	35 998 (33.1)	39799 (36.7)

* Data were disaggregated by age and sex for 94.8% and 82.2% of all forms of TB, respectively.

TB = tuberculosis; SS = sputum smear; += positive; -= negative.

increased from 13.3% before the project began to 26.1% (Figure 2).

Age and sex distribution of all forms of TB and sputum smear-positive tuberculosis

The contribution of children aged <5 years to all forms of TB increased from 648 (2.4%) during the first year to 937 (2.9%) by Year 4. In the same age group, overall SS+ cases increased from 38 (0.5%) to 181 (2%) over the 4 years. In the 0–14 years age category, SS+ case notification increased from 545 (7.5%) to 745 (8.2%) (Figure 3).

The male-to-female ratio over the 4 years was 1.2 in all age groups. In all forms of TB, it was persistently more than 1.2 for the 0–4 years and >15 years age groups. However, the ratio for the 5–14 years age group was 0.9 in all forms of TB and 0.8 in SS+ TB. In the <15 years age group, the male-to-female ratio was 0.8 for SS+ and 0.9 for all forms of TB (Figure 4).

Variations in case notification for sputum smearpositive tuberculosis

Zones with a high CNR for SS+TB had higher CNRs

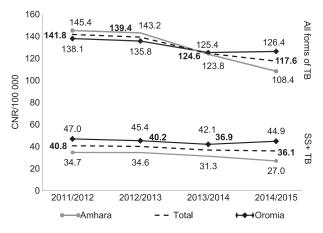


Figure 1 Trend in TB based on regions, July 2011–June 2015. CNR = case notification rate; TB = tuberculosis; SS+ = sputum smear-positive.

of all forms of childhood TB in both regions (P < 0.05). There was a mean variation in CNR for all forms of TB among the three SS+ CNR categories in both the <5 years and the 5–14 years age groups. A higher level of all forms of paediatric TB was noted in the high SS+ CNR category than paediatric case notification in the medium and low SS+ CNR groups (P < 0.01). The mean CNR difference between zones with low and high SS+ CNR was significant (P < 0.00001) (Table 2).

Treatment outcomes for sputum smear-positive tuberculosis

The TSR increased from 89% during the first year to 93% by July–December 2014. The cure rate increased from 75% to 88.4% over the same period. The gap between the TSR and the cure rate narrowed by an average of 8.6% per year. Transfer-out also declined from 4% to 1.1%, deaths from 3.7% to 2.6% and rate of default from 2% to 0.9% (Table 3). These trends were statistically significant (P < 0.05). The overall annual cure rate in Oromia was 86% (95% CI 82.5–91.5) and that of Amhara was 79.5% (95% CI 63.8–93.3). The TSR in Oromia was 93.4% and 89.4% in Amhara; this difference was statistically significant (P < 0.01).

DISCUSSION

The study suggests a steady decline in the CNR of all forms of TB over the 4 study years, although trends varied by region, sex and age. Moreover, the relative contribution of project-supported zones to the overall national TB CNR doubled compared with baseline data. Girls predominated in the proportion of SS+ cases among children, unlike the male predominance in notified TB cases among adults. The study also highlighted that the region and zones with higher CNR for SS+ TB had higher CNRs for all forms of TB among children aged <15 years.

The declining trend in notified TB cases is consistent with previous reports.^{1,4} However, the

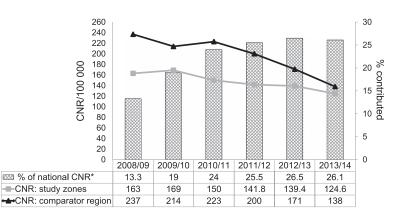


Figure 2 TB case notification in the study zones: contribution to national TB case notifications and comparison with the Tigray Region, July 2008–June 2014. * Per cent contributed to national CNR. CNR = case notification rate; TB = tuberculosis.

decline in CNR in the study zones over 4 years was not statistically significant, and the rate of decline in the project zones was slower than in the comparator region.⁴ The decline in the prevalence of human immunodeficiency virus (HIV) infection and the expansion of antiretroviral treatment in Ethiopia may have contributed to the reduction in HIVassociated TB and thus to the overall decline in CNR.4,13 This study also indicated an increasing contribution by the project-supported zones to the national CNR. While causal attribution is not possible due to the ecological nature of the study, we may infer that the project-supported zones maintained a relatively stable CNR and eventually started to register an increase in the number of notified cases in Oromia.

SS+ TB contributes most TB transmission in the community,^{7,8} and settings with a high SS+ burden would have more childhood TB.^{6,14} Our study confirmed that in settings with high rates of SS+ TB, case notifications among children were higher. There

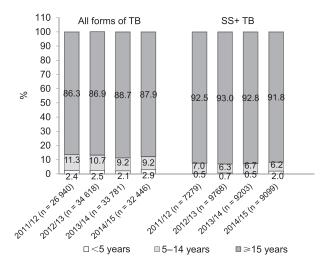


Figure 3 Trend proportions of all forms and SS+TB based on age category, July 2011–June 2015. TB = tuberculosis; SS+= sputum smear-positive.

is a difference in the SS+ CNR (Amhara 30.6% vs. Oromia 42.4%), and the decline in annual CNR varies according to the rates of SS+ TB. In other words, the higher the SS+ CNR, the lower the rate of decline. Possible reasons could be that as regions with lower rates of SS+TB were better performers in early diagnosis and treatment, transmission was curtailed. The two regions had comparable EQA performance,15 and the difference in rates of SS+ TB in the two regions is unlikely to be due to regional differences in laboratory quality. Districts with high rates of SS+ TB could thus be targeted to halt further transmission of TB in the community. The practice of stratifying zones by CNR quartiles could be used for the purpose of prioritising zones for targeted interventions to prevent childhood TB.

The overall male-to-female ratio was consistently >1. This finding is in line with global and national reports, where TB is more common in males than in females.^{1,4} In India,¹⁶ Nigeria^{17,18} and Gambella, Ethiopia,¹⁹ the TB CNR was skewed toward males. Studies show that females tended to have delayed diagnosis and treatment of TB.^{14,20} Some authors have suggested that males, who spend most of their

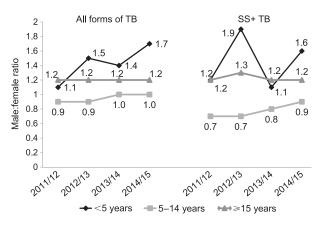


Figure 4 Age-based male-to-female ratios of TB, October 2011–June 2015. TB = tuberculosis; SS_{+} = sputum smear-positive.

	CNR category /100 000 SS+ TB cases						
CNR of all forms of TB by age category years	Low (<28.3) Average (95%Cl)	Medium (28.3–46.4) Average (95%Cl)	High (>46.4) Average (95%Cl)	F-test	<i>P</i> value		
<5							
Overall Oromia Amhara	11.7 (8.9–14.6) 16.3 (5–23) 11.2 (8.2–14.2)	26.6 (13.9–39.3) 37.9 (16.1–59.6) 12.8 (7.4–18.2)	23.7 (15.3–32.0) 19.7 (12.1–27.3) 39.5 (15–79)	1.8 1.32 22	0.18 0.30 0.00*		
5–14							
Overall Oromia Amhara	26.5 (21.5–31.5) 18.5 (12–26) 27.4 (22.2–32.6)	38.8 (33.1–44.4) 37.4 (30–45) 40.4 (30.1–50.7)	63 (49.1–77) 60.4 (42.8–78) 73.4 (6.2–140.7)	19.7 6.3 16.3	0.00* 0.009* 0.0001*		
≥15							
Overall Oromia Amhara	21.6 (18.1–25.0) 17.7 15.0–21.0 22 (18.2–25.8)	34.7 (30.2–39.2) 37.6 (32–43.2) 31.2 (23.4–39)	50 (41–59) 46.8 (36.9–56.8) 62.1 (30.4–93.8)	22.5 4.66 22.2	0.00* 0.02* 0.00*		

Table 2Mean variation in CNR of all forms of TB among children across the low, medium and high case notification rates for SS+TB,July 2010–June 2015

* Statistically significant.

CNR = case notification rate; TB = tuberculosis; SS+ = sputum smear-positive; CI = confidence interval.

time outside or at work, are more likely to be infected.^{21,22} Tuberculous infection rates in females could be lower because they have a more vigorous cell-mediated immune response after infection.²³ More importantly, sociodemographic and cultural factors leading to barriers in accessing health care among females could explain this finding. Fear and stigma associated with TB can have a greater impact among females, leading them to visit traditional healers.²⁴

Females are nevertheless at an increased risk of progression to TB disease during their childbearing years.²³ They are also exposed to TB while caring for the elderly and the young.^{21–24} More female than male TB cases are anticipated in countries with HIV prevalence >1%.^{25,26} Our study also showed that that the CNR and proportion of SS+TB among girls are higher than in boys aged 5–14 years. Understanding the determinants of the sex difference in that age group is important and should be explored further.

In addition to the high TB prevalence in females aged 5–14 years, we found an increasing trend in the proportion of SS+ TB in children. Community data

from Southern Ethiopia showed that a higher proportion of SS+ cases were younger females.²⁷ In a male-dominated, impoverished society, children are rarely taken to the health facilities.^{21,22–24} HIV infection is also prevalent among females in Ethiopia.^{25,26} In rural Ethiopia, as females have to care for the sick, females with TB remain at home, continuing the cycle of transmission of TB to children.¹⁴ Women and children therefore deserve particular attention to combat their vulnerability to TB. Creating awareness about TB using the existing women-led communitybased health extension programme (HEP) in Ethiopia needs to target female girls.

TSR and cure rates have shown significant improvement over the years. Similar findings have also been reported in southern Ethiopia^{28–30} and Oromia.³¹ This might be linked to improved quality of care, strengthened laboratory capacity and the decentralisation of DOTS services. This finding could also reflect adequate treatment regimens, good adherence to treatment and government commitment to comprehensive TB control activities involving health extension workers. The transfer-out rate in this study decreased markedly, from 4.2% to 0.97%

Table 3 Trends in treatment outcomes of new SS+ TB cases over the 4 study years

	Years				Trend test over the 4 study years*	
Treatment outcome	Year 1 (<i>n</i> = 8 552) % (95%Cl)	Year 2 (<i>n</i> = 10417) % (95%Cl)	Year 3 (n = 9805) % (95%Cl)	Year 4 (n = 4726) % (95%Cl)	Z-test	P value
Cure rate Treatment completion Treatment success rate Default Failure Death Transfer out	75.0 (67.6-82.4) 13.9 (8.8-19.0) 88.9 (84.9-93.0) 2.0 (1.1-2.9) 1.3 (0.3-2.3) 3.7 (1.9-5.6) 4.1 (3.1-5.2)	80.3 (74.4-86.2) 10.4 (7.1-13.6) 90.6 (87.5-93.8) 1.3 (0.9-1.7) 1.2 (0.5-1.8) 2.7 (1.8-3.6) 3.6 (1.9-5.2)	87.0 (83.5–90.5) 6.6 (4.3–8.8) 93.5 (91.6–95.5) 1.4 (0.9–1.9) 0.6 (0.2–1.0) 2.6 (1.7–3.5) 1.0 (0.2–1.7)	88.4 (86.2–90.5) 5.1 (3.6–6.6) 92.5 (90.5–94.5) 0.9 (0.6–1.3) 2.3 (1.5–3.2) 2.6 (2.0–3.2) 1.1 (0.5–1.7)	3.8 -3.9 2.14 -2.24 1.73 -1.0 -4.3	0.00 [†] 0.033 0.025 [†] 0.08 0.32 0.00 [†]

* Year 1: October 2011–June 2012; Year 2: July 2012–June 2013; Year 3: July 2013–June 2014; Year 4; July–December 2014.

⁺ Statistically significant. CI = confidence interval (average 2.5%), well below the tolerable level of transfer-out of about 3–4%.¹¹ The low rates of transfer out may indicate improved communication and referral linkages. It also shows the effectiveness of the decentralised approach, where patients are treated close to their homes.

The study has some limitations. Direct causal attribution of interventions to observed trends was not possible. Sex, HIV and age disaggregation was not performed for treatment outcomes, as the information was not captured in routine data sources. However, the large number of notified TB cases included in this analysis and the rigorous analytical methods used are strengths of the study.

In conclusion, the lower decline in CNR in projectsupported zones than in the Tigray Region, which led to the doubling of the contribution of the 10 zones to the national TB CNR and improvements in treatment outcomes, suggests the positive impact of project interventions. However, the higher proportion of SS+ TB among female children suggests the presence of an uninterrupted source of transmission and needs further attention. Moreover, the significant differences in CNR among regions and zones suggest the importance of ensuring that interventions are tailored to the needs of each zone.

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Conflicts of interest: none declared.

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_ R E S U M E

CONTEXTE : Régions d'Amhara et d'Oromia, Ethiopie. OBJECTIF : Déterminer les tendances du taux de notification des cas (CNR) pour les nouveaux cas de tuberculose (TB) et pour les résultats du traitement des patients à frottis de crachats positif (SS+) en fonction du contexte géographique, du sexe et de la tranche d'âge.

MÉTHODES : Nous avons entrepris une analyse de tendance sur une période de 4 ans pour les nouveaux cas de TB déclarés dans 10 zones, grâce à un test de tendance, un test t de comparaison moyenne et une analyse de variance à un facteur.

RÉSULTATS : Le CNR moyen pour 100 000 habitants a été de 128,9 : 126,4 à Amhara et 131,4 à Oromia. Le CNR dans les zones soutenues par le projet a décliné chaque année de 6,5%, comparés au déclin de 14,5% dans le Tigray, la région témoin. La notification de la TB dans les zones d'intervention a contribué 26,1% de la

MARCO DE REFERENCIA: Las regiones de Amhara y Oromia en Etiopía.

MÉTODOS: Se evaluaron las tendencias de la CNR de casos nuevos de TB durante un período de 4 años en 10 zonas, mediante una prueba de tendencias, la prueba de la t de comparación de medias y un análisis de varianza unidireccional.

RESULTADOS: El promedio general de la CNR por 100000 habitantes fue 128,9 en total, 126,4 en Amhara y 131,4 en Oromia. Las CNR en las zonas respaldadas por el proyecto disminuyeron un 6,5% por año, en comparación con una disminución de 14,5% en la región de Tigray de referencia. La contribución de las notification des cas de TB nationale, qui était de 13,3% avant l'intervention du projet. Le ratio homme-femme d'ensemble a été de 1,2 tandis que parmi les enfants SS+ il a été de 0,8, avec une prépondérance des filles. Sur 4 années, le taux de guérison a augmenté de 75% à 88,4% et le taux de succès du traitement de 89% à 93%. Les taux d'abandon, de transfert et de décès ont décliné de façon significative.

CONCLUSION : Les zones soutenues par le projet ont eu des taux de déclin de la notification des cas de TB moindres que ceux des régions témoins, leur contribution à la recherche nationale des cas a augmenté, et les résultats du traitement se sont significativement améliorés. Le taux élevé de TB SS+ parmi les filles requiert toutefois une attention particulière.

RESUMEN

zonas de intervención a la tasa nacional de notificación aumentó de 13,3% antes del proyecto a 26,1%. La proporción global de hombres fue 1,2, pero en los niños SS+ hubo un predominio del sexo femenino de 0,8. Durante los 4 años del estudio la tasa de curación aumentó de 75% a 88,4% y el éxito terapéutico mejoró de 89% a 93%. Las tasas de abandono, transferencia a otro centro y mortalidad disminuyeron de manera significativa.

CONCLUSIÓN: En las zonas respaldadas por el proyecto se observaron tasas más bajas de disminución de la notificación de casos de TB con respecto a la región de referencia. La contribución de la zona del estudio a la notificación nacional aumentó y los desenlaces terapéuticos mejoraron notablemente. Merece una atención especial la alta proporción de casos SS+ en las niñas.

OBJETIVO: Determinar la evolución de las tasas de notificación de casos (CNR) nuevos de tuberculosis (TB) y los desenlaces terapéuticos de los pacientes con baciloscopia positiva (SS+), en función del entorno geográfico, el sexo y las categorías de edad.