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Surveillance and Azithromycin Treatment for Newcomers and Travelers Evaluation (ASANTE) Trial: Design and Baseline Characteristics

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Abstract

Purpose—Immigrants and travelers may be sources of re-emergent infection in trachoma-endemic communities close to trachoma elimination. The primary objective of the A Surveillance and Azithromycin Treatment for Newcomers and Travelers Evaluation (ASANTE) trial was to determine whether a newcomer and traveler surveillance and treatment program in addition to annual mass drug administration (MDA) would reduce *Chlamydia trachomatis* infection when compared to MDA alone.

Methods—ASANTE was a randomized controlled trial in 52 communities in Kongwa, Tanzania. In 26 intervention communities, monitors treated everyone in new households, in-coming children and guardians in existing households, and all persons in households who had travelled between annual MDA events. 26 usual practice communities received MDA only. Surveys of 100 1-9-year-olds from each community were conducted at baseline and every 6 months up to 2 years to assess clinical trachoma and *C trachomatis* infection. Data on demographics and environmental factors were also collected.

Results—Mean prevalences of trachomatous inflammation - follicular (TF) and *C trachomatis* were equivalent between the two arms (5.2% and 3.7% in intervention, and 4.9% and 3.6% in usual practice communities, respectively). Of 318 children with TF, 36.5% tested positive for *C trachomatis*. TF prevalence was higher among households without a bicycle ($P=0.03$) and lower with increasing child's age ($P<0.001$). Infection prevalence was higher among households >30

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minutes from water ($P=0.015$). TF and infection prevalence decreased with increasing years of education ($P=0.004$ and $P=0.002$, respectively).

Conclusion—The ASANTE trial will inform guidance on the surveillance and treatment of persons traveling or newly arriving to communities hypo-endemic for trachoma.

Keywords

trachoma; Chlamydia trachomatis; surveillance; Tanzania; randomized controlled trial; community-based

Introduction

Trachoma due to ocular infection with *Chlamydia trachomatis* is known to be the most prevalent infectious blinding disease and cause of significant visual impairment in the world. The World Health Organization (WHO) estimates that in 2014, 232 million persons lived in trachoma-endemic countries and were at risk of infection.¹ Approximately 40.6 million persons have active trachoma with 68.5% of active disease concentrated in the continent of Africa.² There are 2.2 million blind or visually impaired as a result of repeated infection with *C trachomatis* and the resulting conjunctival inflammation and scarring.^{3,4}

The WHO Alliance for the Global Elimination of Blinding Trachoma by the year 2020 (GET 2020) supports implementation of the SAFE strategy, a multipronged approach of surgery for trachomatous trichiasis, mass treatment with antibiotics to eliminate *C trachomatis* infection, reduction of trachoma transmission through facial cleanliness, and improvements in the environment such as access to sanitation and potable water.¹ In addition to the WHO, other agencies, non-profit organizations, and pharmaceutical companies, both international and regional, form partnerships and support implementation of the SAFE strategy through well-established trachoma control programs.

Mass treatment with antibiotics, specifically azithromycin and tetracycline, has been shown to be effective for eliminating ocular infection with *C trachomatis*.^{4,5} Annual mass drug administration (MDA) for a minimum of 3 years is recommended when the prevalence of trachomatous inflammation - follicular (TF) at the district level in children aged 1-9 years is at least 10%; 5 or more years of MDA are recommended when the prevalence reaches 30%. When the district-level prevalence is below 10%, a single round of MDA or a more targeted approach to assessing prevalence and intervening at the sub-district level is preferred. Children aged 1-9 years are sentinels for monitoring trachoma and infection in their communities because they are the reservoir of infection.

Annual mass treatment has been shown to reduce infection, but infection with *C trachomatis* re-emerges following annual rounds of MDA.⁶ Migration of new families from untreated areas into communities that have been treated, as well as prolonged travel by residents to areas outside treated communities may be sources of re-emergent infection.^{7,8} A survey in Kongwa, Tanzania, showed an association of higher infection prevalence in neighborhoods that had a new family arrive in the previous year compared to neighborhoods that had not.⁷ In a survey of 24 Ethiopian villages receiving biannual MDA, there was a statistically

significant correlation between infection prevalence at 2.5 years and the number of persons traveling in the month prior to the survey.⁸ Although it is possible that some were treated during the annual MDA following travel or in-migration into the community, imported or residual infection reduces the decline in trachoma prevalence within a community and puts elimination goals at risk.

The primary objective of the A Surveillance and Azithromycin Treatment for Newcomers and Travelers Evaluation (ASANTE) trial was to determine the added benefit in reduction of infection with *C trachomatis* in 26 communities randomized to a newcomer and traveler surveillance and treatment program in addition to annual MDA with azithromycin versus 26 communities randomized to annual MDA alone. For trial purposes, MDA was not provided to communities where infection was 1% or less, or TF was less than 5%.

Materials and Methods

Summary

The ASANTE trial was a community randomized controlled trial of 52 communities in the Kongwa District, Tanzania, conducted in collaboration with the Kongwa Trachoma Project (KTP) from 2013 to 2015. Communities were randomized in a 1:1 ratio to annual MDA alone if indicated (usual practice) or annual MDA plus a surveillance and treatment program for newcomers and travelers (intervention). A community census was completed at baseline and was updated yearly at the time of the 12-month and 24-month surveys. Census data were used at the time of each survey visit to select random samples of 100 sentinel children aged 1-9 years at baseline and 6, 12, 18, and 24 months.

The first MDA round was administered immediately after the baseline survey. The 6-month data were used to guide subsequent MDA at 12 months. Survey visits included an ocular examination and clinical photography. Ocular swabs were collected to assess the community burden of active trachoma and ocular *C trachomatis* infection among sentinel children.

All study procedures were conducted according to the guidelines of the Declaration of Helsinki and the protocol and consent forms were approved by the Johns Hopkins University Institutional Review Board and the Tanzania National Institute for Medical Research. The ASANTE trial is registered with [Clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01767506) (NCT01767506).

Eligibility criteria

Communities—All selected communities were located in Kongwa District, Tanzania, and children selected for the ASANTE trial resided in these communities. 48 of the 52 communities selected for the ASANTE trial also participated in the Partnership for the Rapid Elimination of Trachoma (PRET) Study, and were known to have an overall TF prevalence of 8%.⁹ An additional four communities whose TF prevalence was <10% were recruited in December 2012 at the recommendation of the Data Safety and Monitoring Committee (DSMC). Community leaders provided verbal consent for the participation of community residents. After selection of the sentinel children, study personnel secured guardian consent for these children and additional assent from children aged 7 years and older who attended the survey visit. English consent forms were translated into Swahili, and

were also translated into the local languages of Kigogo or Kikaguru by study personnel as appropriate.

Children—Sentinel children selected for participation in survey visits had to meet the following criteria: Be aged 1-9 years; reside in an eligible community at the time of the census; have an identifiable guardian provide consent for participation; have no ocular condition that would preclude trachoma grading or obtaining an ocular specimen; be present in the village during the 2 days of the survey.

Children were excluded from the survey visits if: They were not in the village during the 2 days of the survey, in which case a randomly selected child was identified as a replacement; they were too ill or had an ocular condition that precluded assessment of trachoma; the child and/or guardian refused to have an ocular swab taken at the time of the survey.

Newcomers and travelers—In intervention communities, a newcomer was defined as any family with children younger than 10 years that migrated into the community, either as a new house, or into an existing house. Travelers were families with children younger than 10 years returning to the community after having traveled outside of the community for 8 or more weeks. Travelers were typically highly migratory families that may have maintained homes outside Kongwa in trachoma-endemic districts. We targeted families with children younger than 10 years because that age group is most likely to have infection and trachoma and therefore those families are the most likely to be a source of spreading infection.^{10,11} Study personnel sought verbal consent from newcomer families for participation in updating the census and written consent from newcomer families and traveling families for family-based treatment with azithromycin.

Randomization

The unit of randomization for the ASANTE trial was the community. Among the 48 communities that participated in the PRET Study, randomization was stratified by the prevalence of *C trachomatis* infection at baseline (1% versus >1%) using a constrained randomization approach that allows balancing on the stratification factors. The remaining four communities, each with TF below 10%, were randomized using simple random sampling constrained so that two were assigned to each arm.

Usual practice: Annual mass treatment with azithromycin

A single dose of 20mg/kg up to 1gm of azithromycin, was administered using height-based dosing, and children who could not stand were weighed. Tablets or a pediatric oral suspension (for children unable to swallow tablets) were provided. Children <6 months old were provided topical tetracycline, and parents were told to administer it at least once per day (preferably twice per day) morning and evening, for 6 weeks.

MDA was administered by Community Treatment Assistants (CTAs), with one to two CTAs for each neighborhood. The neighborhoods were geopolitical units within a community that consist of a cluster of households, typically 10 to 20. The CTAs were monitored for performance by the KTP team, and the goal was to achieve at least 80% coverage of children

aged 1-9 years. Coverage was based on observed treatment recorded in treatment books based on the most recent census.

Village leaders were notified when *C trachomatis* infection was 1% or below or TF was <5%, and the community did not qualify for MDA unless infection reemerged after 6 or 18 months.

Treatment coverage was defined as the percentage of children aged 1 to <10 years who were observed to take azithromycin out of all children in that age group. More treatment days were scheduled depending on the percent coverage at the end of 2 days in each neighborhood. For subsequent days, the CTAs went house to house to offer treatment. At the end of mass treatment, each community resident was accounted for as having been treated or not treated. Reasons for nonattendance at mass treatment were noted.

After each community completed mass treatment, treatment verification was conducted by the CTA initially treating the communities. A staff member unaware of the treatment status visited the homes of five randomly-selected households assigned to each CTA. The staff member interviewed the head of the household to report the treatment status of each member of the household. Discrepancies were resolved through discussions with the treatment team.

Cessation of MDA

At baseline, eight communities assigned to usual practice and nine communities assigned to the intervention achieved a pre-specified target prevalence of *C trachomatis* infection of 1% or below. The 17 communities were “graduated” from MDA and did not receive MDA at baseline. Surveys of the random sample of sentinel children continued as scheduled in the ASANTE trial to monitor for re-emergence of infection, pre-specified as infection increasing to 6% or more at the interim survey, and MDA reinstated as appropriate.

For intervention arm communities that stopped MDA, azithromycin was used solely for the newcomer and traveler treatment program.

Intervention: Annual MDA plus a newcomer and traveler surveillance program

The intervention communities received annual MDA as described for usual practice communities. In addition, active weekly surveillance by local residents hired as community monitors (CMs) within their neighborhoods was conducted to identify and treat newly arrived and traveling families. CMs were nominated during village meetings and received 2 days of training and certification as per the ASANTE protocol.

CMs visited each of their assigned households weekly to identify newcomer families and resident families that had traveled outside the community for at least 8 weeks, and offered azithromycin treatment within 1 week to all members (adults and children) in the families that had come/returned from outside Kongwa, or from communities that had not received MDA in the previous year. The village community health worker (CHW) maintained a supply of azithromycin sufficient to treat eligible families and accounted for all azithromycin used for this purpose. The CHW observed treatment provided, just as was done during MDA. Each CM was monitored monthly by a site visit by the CM supervisor,

who visited the new households identified in the previous month and the traveling households, resolved any issues, and completed a random check of existing households with no new events to confirm data. All surveillance events had to be confirmed by the CM supervisor.

Censuses

At baseline and 12 and 24 months, a complete census was conducted, prior to the survey. Information on the occupants of each household, including the names, ages, and sex of all persons residing in a household were collected. Demographic information and exposure to environmental factors that may influence the prevalence of trachoma, including education completed by the head of household, distance to the closest source of water, observations on clean face status of children aged 5 years and younger, presence of latrines, and location and use of the household's cooking fire were collected via questionnaire. These data were a reference for surveys and for recording the administration of MDA in a community.

During surveillance, census data for all newcomers were collected in the same fashion as captured at a baseline census.

Surveys

The purpose of the surveys was to collect clinical information from the sentinel children who represented the community burden of trachoma and *C trachomatis* infection at baseline and each follow-up visit. A total of 100 sentinel children aged 1-9 years as of the most recent census were randomly selected in each community and invited to a central site for examination. The trachoma grader, using a 2.5X loupe and torch, examined both tarsal conjunctiva of each eye for signs of trachoma, TF and trachomatous inflammation-intense using the WHO simplified grading scheme.¹² An image of the upper conjunctiva of the right eye of a random sample (5%) of all children surveyed was taken using a handheld Nikon D-40 camera with a Macro Nikkor autofocus lens (Nikon, [AU: city, state and country?]). The images were used for quality control purposes, to monitor potential drift over time.

A dry ocular swab was taken of the right eye following strict adherence to field protocol to avoid contamination. It was stored under refrigeration for up to 30 days, and then sent to the Johns Hopkins International Chlamydia Laboratory for determination of laboratory evidence of infection by a nucleic acid amplification test. A 5% sample of children also had dry "air swabs" taken to check for field contamination.⁹ The procedures were the same during follow-up visits at 6, 12, 18, and 24 months from baseline. A new cross-sectional random sample of children was selected at each study visit, using the latest census survey as the sampling frame.

Laboratory assessment of *C trachomatis* infection by nucleic acid amplification test

The Johns Hopkins International Chlamydia Laboratory used the APTIMA Combo 2 (AC2) commercial test for the detection of *C trachomatis* (Hologic Inc, San Diego, CA, USA) to assess the prevalence of infection among sentinel children. In communities with active trachoma prevalence under 15%, 4-5 consecutive samples were pooled into one test transport tube before running the assay.¹³ If prevalence was 15% or higher, samples were not

pooled. APTIMA Assay Software using the *C trachomatis*/*Neisseria gonorrhoeae* protocol provided the test results based on the total relative light units in each sample. For pools that yielded a negative result, all specimens in that pool were considered to be negative for *C trachomatis*. For each pool that yielded a positive test, the original individual samples within that pool were tested to determine which samples were positive for *C trachomatis*. Equivocal pools were retested and deconstructed for individual sample analyses; individual equivocal specimens were retested in duplicate and considered negative if both tests yielded a negative result. Positive and negative control samples were included in all runs.

Masking

It was not possible to mask the communities to the assignments received. However, survey team members were masked to study assignment and did not participate in any surveillance visits. The primary outcome was *C trachomatis* infection, and all laboratory personnel received only numbered vials with no link to community or to study assignment. The Data Safety and Monitoring Committee was not masked to treatment assignment.

Power and sample size calculations

Power calculations for the ASANTE trial were based on the primary outcome, proportion of communities with prevalence of *C trachomatis* 1% at 24 months after baseline. We used a 2-sided Fisher's exact test and a significance level of $\alpha=0.05$ to estimate the power with the assumption that the average initial prevalence of infection was 3% with the expectation of a decrease in the infection rate by half (1.5%) after 1 year. We assumed a 50% re-emergence rate in control communities after MDA was stopped with none in the intervention arm, and that MDA would result in halving infection rate at each round. We estimated a power of 83% to detect a ratio of 2-fold comparing the proportion of intervention communities who achieved the infection outcome compared to control communities who achieved the outcome, with a sample size of 26 communities per study arm.

Outcomes

The primary outcome was the proportion of communities in the intervention arm compared to the usual practice (control) arm with a prevalence of *C trachomatis* infection 1% at 24 months.

The secondary outcomes for the ASANTE trial were as follows: The proportion of communities with a prevalence of TF <5% at 24 months in communities randomized to the newcomer and traveler program with MDA (intervention) compared to communities receiving MDA only (usual practice); the trajectory of decline in infection with *C trachomatis* and clinical trachoma in the usual practice communities; an assessment of the factors associated with re-emergence of infection and clinical disease in the communities in which MDA had ceased.

Results

The demographic characteristics of the communities randomized to each study arm were comparable (Table 1). Of the 48 communities with previous data from the PRET study, 26%

of households were new at baseline in the usual practice arm (2,291/8,708 total households at baseline),⁹ 29% of households (2,780/9,569) were new in the intervention arm.

TF and *C trachomatis* infection prevalence at baseline were equivalent in both study arms; TF prevalence was 5.2% (95% confidence interval, CI, 3.2-6.6%) in the intervention communities and 4.9% (95% CI 3.2-6.5%) in the usual practice (control) communities; *C trachomatis* prevalence was 3.7% (95% CI 2.5-5.0%) in the intervention communities and 3.6% (95% CI 2.4-4.9%) in the usual practice communities (Table 2). The average prevalence of infection was 3.6-3.7% in both arms, showing *C trachomatis* infection was present even with trachoma rates as low as 5%. The average percent of children younger than 10 years who received MDA was 87% and did not differ for the usual practice and intervention arms (Table 3).

Table 4 presents the relationship between clinical trachoma and infection with *C trachomatis* among sentinel children in these low risk communities. Of the 318 children with active trachoma based on clinical examination (6.0% of 5,308), 36.5% of these children also tested positive for *C trachomatis* infection. There were 75 children (1.5%) with both TF and trachomatous inflammation - intense, and of these, 64.0% tested positive for *C trachomatis*.

Table 5 shows the prevalence of TF and *C trachomatis* infection stratified by demographic and household characteristics at baseline. The prevalence of TF was significantly higher among households that did not own a bicycle (5.9%) compared to households with bicycles (4.4%). The prevalence of TF decreased with increasing age of the child ($P<0.001$, test for trend) although the prevalence was similar for ages 1, 3, and 4 years (6.6–6.8%), while the prevalence among children aged 2 years was higher (7.8%). The prevalences of both TF and *C trachomatis* infection decreased with increasing years of education of the head of the household ($P=0.004$ and 0.002 , respectively). The prevalence of infection with *C trachomatis* was significantly higher among households more than 30 minutes from a water source (4.7%) compared to households located within 30 minutes of a water source (2.7%). The prevalence of TF was also higher for households that were more distant from a water source, but the difference was not statistically significant ($P=0.08$). There were no differences in the prevalence of clinical disease or infection for households with or without latrines and mud roofs. There were also no differences in prevalence by sex.

Discussion

The baseline characteristics of the communities randomized to the usual care and intervention arms were well balanced in the ASANTE trial, suggesting that randomization was successful and that known and unknown confounding factors were on average also balanced among the study groups. These communities were at the lower end of the clinical disease spectrum with an average clinical infection prevalence of 5%, yet still exhibited a demonstrable level of infection, at 3-4% infection with *C trachomatis*.

Environmental factors were overall not related to the prevalence of infection with the exception of distance to a water source for *C trachomatis* infection, although the directionality of the association was similar to that observed in other studies^{6, 14}. Household

factors that could be markers for socioeconomic status also showed an association with TF and a directionality similar to that observed in other studies, but was only significant for bicycle ownership^{6, 14}. Education of the head of household was the only demographic factor significantly associated with TF prevalence. There was, however, a trend of decreasing prevalence of TF with increasing age of the child, but this trend was not seen with the prevalence of infection with *C trachomatis*. It is noteworthy that even at this low level of infection and disease, that there was still an association with water sources and other markers of lower socioeconomic status that is usually seen in more highly trachoma endemic communities.

In the Kongwa district, where an impact assessment revealed that the prevalence of TF in 1-9-year-olds was 8%, MDA is limited to the participating ASANTE communities and an additional sub-district with a prevalence of clinical trachoma that exceeded 10%. The district has ongoing general development activities, such as a World Bank water project, but no trachoma-specific hygiene activities.

The ASANTE trial provided a unique opportunity to frequently monitor the trajectory of decline in prevalence with MDA alone when compared to MDA with a newcomers and travelers surveillance and treatment program. Since ASANTE communities were graduated from MDA when *C trachomatis* infection was 1% or TF was <5%, the ASANTE trial also provided an opportunity to monitor re-emergence of infection in communities that had ceased MDA and to monitor re-emergence of infection when a newcomer and traveler surveillance program is conducted in the absence of MDA.

With the GET 2020 goal to eliminate trachoma worldwide by the year 2020, endemic countries will see sharp reductions in the prevalence of trachoma as uptake of trachoma control programs increase. Novel interventions targeting sources of re-emergent infection are critical for trachoma elimination, and are particularly essential when the prevalence of infection is very low. The results of the ASANTE trial will inform guidance for nationwide trachoma control programs on surveillance and treatment of persons traveling or newly arriving to communities in areas endemic for trachoma.

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Table 1

Baseline characteristics of communities by study arm, A Surveillance and Azithromycin Treatment for Newcomers and Travelers Evaluation (ASANTE) trial, Kongwa, Tanzania

Characteristic	MDA plus travelers and newcomers program (intervention)	MDA alone (usual practice)
Communities, n	26	26
Population per community, median n (IQR)	1,664 (1,297-1,997)	1,437 (1,246-1,887)
Households, median n (IQR)	352 (288-477)	328 (269-431)
Education of head of household, median years (IQR)	3.5 (2.9-4.4)	4.0 (3.0-4.5)
Households >30 minutes from a water source, median % (IQR)	51.4 (32.6-78.1)	52.5 (37.0-70.9)
Households with latrines, median % (IQR)	80.4 (71.2-85.5)	82.0 (73.8-88.9)
Households owning a bicycle, median % (IQR)	44.8 (34.0-51.6)	44.9 (37.1-51.6)

IQR, interquartile range; MDA, mass drug administration

Table 2

Baseline prevalence of trachomatous inflammation - follicular and *Chlamydia trachomatis* infection in children <10 years by study arm, A Surveillance and Azithromycin Treatment for Newcomers and Travelers Evaluation (ASANTE) trial, Kongwa, Tanzania

	MDA plus travelers and newcomers program (intervention)	MDA alone (usual practice)
Trachomatous inflammation-follicular, mean % (95% CI)	5.2 (3.7–6.6)	4.9 (3.2–6.5)
<i>Chlamydia trachomatis</i> infection, mean % (95% CI)	3.7 (2.5–5.0)	3.6 (2.4–4.9)

CI, confidence interval; MDA, mass drug administration

Table 3

Baseline mass drug administration (MDA) treatment coverage by study arm, A Surveillance and Azithromycin Treatment for Newcomers and Travelers Evaluation (ASANTE) trial, Kongwa, Tanzania

	MDA plus travelers and newcomers program (intervention)	MDA alone (usual practice)
Overall, mean % (SE)	79.5 (2.3)	77.2 (2.6)
Children <10 years, mean % (SE)	86.9 (1.5)	86.8 (1.5)

SE, standard error

Table 4

Relationship between infection with *Chlamydia trachomatis* and clinical trachoma at baseline, A Surveillance and Azithromycin Treatment for Newcomers and Travelers Evaluation (ASANTE) trial, Kongwa, Tanzania

Trachoma status	n	Positive for <i>C trachomatis</i> infection, %
No trachoma	4,990	1.7
Active clinical Trachoma	318	36.5
Trachomatous inflammation - follicular only (TF)	195	25.6
Trachomatous inflammation - intense only (TI)	48	37.5
TF and TI	75	64.0

Table 5

Trachomatous inflammation - follicular (TF) and *Chlamydia trachomatis* infection by demographic and household characteristics at baseline, A Surveillance and Azithromycin Treatment for Newcomers and Travelers Evaluation (ASANTE) trial, Kongwa, Tanzania

Characteristic	n	TF		C. trachomatis Infection	
		%	P-value *	%	P-value *
Household					
Distance to water source					
30 minutes	2,427	4.1	0.08	2.7	0.015
>30 minutes	2,856	6.0		4.7	
Household has latrine					
No	1,098	6.3	0.44	4.8	0.18
Yes	4,183	4.8		3.5	
Household owns a bicycle					
No	2,526	5.9	0.03	4.0	0.22
Yes	2,757	4.4		3.6	
House has mud roof					
No	4,677	4.9	0.29	3.5	0.14
Yes	607	6.6		5.6	
Education of head of household					
No formal education	2,013	6.4	0.004&	5.1	0.002&
1-7 years	3,151	4.4		3.0	
7 years	122	3.2		0.8	
Child					
Age in years			<0.001		0.19
1	638	6.6		4.2	
2	619	7.8		4.2	
3	690	6.7		4.1	
4	643	6.8		4.4	
5	604	5.8		4.0	
6	555	2.7		2.5	
7	564	2.3		2.7	
8	529	2.8		3.2	
9	463	2.8		4.3	
Sex					
Male	2,638	5.4	0.39	3.5	0.26
Female	2,667	4.8		4.0	

* Adjusted for clustering at the community level

& Test for trend