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Acceptability of azithromycin for the control of trachoma in Northern Tanzania

Nicola Desmond^a, Anthony W. Solomon^{b,c,d,*}, Patrick A. Massae^d, Ndeeshi Lema^d,
Alessandra Anemona^b, Allen Foster^b, David C. W. Mabey^b

^aMRC Social and Public Health Sciences Unit, 4 Lilybank Gardens, Glasgow G12 8RG

^bClinical Research Unit, London School of Hygiene & Tropical Medicine, Keppel St, London, WC1E 7HT, UK

^cKilimanjaro Christian Medical College, Tumaini University, PO Box 3010, Moshi, Tanzania

^dHuruma Hospital, Rombo District, P.O. Box 948, Moshi, Tanzania

Abstract

Trachoma causes blindness; the prevention strategy includes mass antibiotic treatment. In a community in Northern Tanzania offered mass treatment with azithromycin for the control of trachoma, we used focus group discussions, individual interviews, questionnaires and direct observation to quantify, explore and contextualise reasons for acceptance or refusal. In the village studied, 76% of the population eligible to receive azithromycin were treated. Uptake was significantly higher amongst women (79% treated) than men (72%). Factors affecting acceptability included local prevention norms (such as the belief that injections, rather than oral medicine, should be used for prevention); perceptions of drugs in general and azithromycin in particular; perceptions of the distribution team's expertise; witnessing adverse effects in others; and the timing, quality and quantity of information about azithromycin and its availability. Familiarity with trachoma as a blinding disease was significantly associated with uptake. Individuals who refused treatment seemed to be less altruistic than other respondents. Neither socio-economic status nor use of traditional healers was related to uptake. Pre-distribution community assessment and community education, advance notice of the distribution, standardised distribution guidelines and improved distributor training are recommended to maximise acceptance of azithromycin in future campaigns.

Keywords

azithromycin; trachoma; drug acceptability; Tanzania

1 Introduction

Trachoma is a chronic keratoconjunctivitis caused by the bacterium *Chlamydia trachomatis*. It is endemic in poor rural communities of Africa, Asia, South America and Australia, and is

*Corresponding author. Address: Clinical Research Unit, London School of Hygiene & Tropical Medicine, Keppel St, London WC1E 7HT, UK, Tel: +44 20 7958 8336, Fax: +44 20 7958 8338, anthony.solomon@lshtm.ac.uk.

the leading infectious cause of blindness (Resnikoff et al., 2004). Repeated episodes of infection in childhood, often associated with conjunctival inflammation known as active trachoma, lead to conjunctival scarring, trichiasis, and ultimately blindness in adults (Grayston et al., 1985; Mabey et al., 2003). The World Health Organization (WHO) recommends the “SAFE” strategy for trachoma control, which comprises Surgery to correct advanced disease; Antibiotics to clear *C. trachomatis* infection; and Facial cleanliness and Environmental improvement to reduce transmission.

In the last decade, a single oral dose of the antibiotic azithromycin has been shown to be at least as effective for trachoma control as six weeks twice-daily tetracycline eye ointment (Bailey et al., 1993; Schachter et al., 1999). If the prevalence of active trachoma in 1-9 children is 10% or more, annual mass antibiotic distribution is recommended (Solomon and Burton, 2004). In Tanzania, where an estimated twelve million are at risk of trachoma blindness and one to two million children have active disease (Katenga, 2003), azithromycin has been distributed for trachoma control on an annual basis in selected areas since 1999 (Foster et al., 2003).

The success of mass treatment campaigns probably depends critically on the coverage achieved (Solomon and Burton, 2004; Solomon et al., 2004), which in turn depends on the community’s perceptions of the drug. To date, no published research has considered community perceptions of mass azithromycin distribution. This study examines uptake of and attitudes to azithromycin in a trachoma-endemic community in Northern Tanzania.

2 Population and methods

Rombo is a district on the north-eastern slopes of Mount Kilimanjaro, adjacent to Tanzania’s northern border. Trachoma is endemic. Azithromycin distribution commenced there (in six villages) in 2001; in distribution villages, all non-pregnant residents over the age of twelve months were to be offered a single dose of azithromycin, given as either tablets or paediatric oral suspension. This study was conducted in Kitowo village, Rombo, in April through June 2001, during and immediately after the first round of mass distribution in that community. Kitowo was chosen as a ‘clean’ site for study, having had no previous exposure to research or eye outreach interventions. Chaggas are the overwhelmingly dominant ethnic group. As in other Tanzanian villages, each household is associated with 8-30 others to form a geopolitical unit known as a *balazi*. This name is also used to designate the man or woman who represents the group at village meetings.

After piloting all data collection methods other than treatment observations in Kahe village (another trachoma-endemic Rombo community some distance from Kitowo), an anthropologist (ND) and four local fieldworkers first undertook a house-to-house survey to collect demographic and socio-economic data on all residents. For study purposes, residency in the village was defined as sleeping there for at least two weeks in the month preceding the survey. Demographic data from the survey were later cross-checked against treatment record cards.

Eight semi-structured focus group discussions (FGD) were then held. Each was facilitated by two trained members of the study team. Participants for FGDs were selected by taking stratified random samples from the village population. Criteria for inclusion in groups were based on risk factors for trachoma alluded to in the literature: households with more than three cows (Mmbaga et al., 1992); women in households over 120 minutes from the nearest water source in the dry season and over 60 minutes in the wet season (Dolin et al., 1997; Mburu and Steinkuller, 1983; West et al., 1989); and women in households with children under seven years old (West et al., 1991). A FGD was also undertaken with a randomly selected sample of individuals who did not take azithromycin.

Concurrently, in-depth semi-structured interviews were conducted with a sex-stratified random selection of 33 residents. Topics covered in these interviews included knowledge of trachoma, perceptions of blindness, perceptions of biomedicine and drugs, health seeking behaviour, and perceptions of the azithromycin distribution process. At the end of each interview, the interviewee was asked to identify personal contacts who had not taken azithromycin, who had experienced either complications or particular benefits from the drug, or who suffered from blindness and/or trachoma. This allowed the team to identify 17 additional residents to be interviewed: a snowball sampling technique. Key informant interviews were also undertaken with 3 village government officials and 8 traditional healers resident in the village, to situate findings within the social, historical, medical and political context. Issues explored included those covered in interviews with other residents, plus gender roles within the household and health interventions that had previously taken place in the community. Four members of the azithromycin distribution team were also interviewed. In total, 65 individual interviews were conducted; numbers of 'interviewees' referred to hereunder are subsets of this group of 65 people.

A structured questionnaire was administered (by study personnel, face-to-face) to a sex-stratified random sample of 409 individuals over sixteen years of age.

FGDs and interviews were tape-recorded with the consent of all participants. Recordings were transcribed and translated, then coded and analysed using QSR N5 qualitative analysis software (QSR International, Melbourne, Australia). Quantitative data were analysed using Stata 6 (Stata, College Station, Texas, USA) and EpiInfo 6.04 (World Health Organization, Geneva, Switzerland). To determine whether socioeconomic status predicted uptake of azithromycin, logistic regression analysis was performed (in Stata), modelling the likelihood of being treated as a function of sex, monthly household income, size of landholding, number of cows owned by the household, and number of goats owned by the household; the latter four parameters were included in the model as continuous variables.

The study was approved by the ethics committees of the Kilimanjaro Christian Medical Centre, Moshi, Tanzania and the London School of Hygiene & Tropical Medicine, London, U.K. Cash payments were not made to any informant. Participants in FGDs were offered sodas during the discussion.

3 Results

3.1 Registration

A total of 3824 Kitowo residents were registered in the census. More females (2101, 55% of total) than males (1723, 45%) were registered. The female to male ratio was greatest in the 16–40 years age bracket, probably because a greater number of men of working age leave the village to seek paid employment. Nearly half the population was aged fifteen years or less (data not shown). Six individuals (4 females, 2 males) registered in the census could not be matched to entries on treatment record cards, and 26 individuals (10 females, 16 males) on treatment record cards could not be matched to individuals registered in the census; these individuals have been excluded from our analyses. Of 409 individuals selected to answer questionnaires, tracing questions enabling us to determine the respondent's age and sex were completed by 385 (94.1%)(Table 1).

3.2 Community uptake of azithromycin

Of 3792 registered individuals who had corresponding treatment record card entries, 146 were ineligible for azithromycin: 121 (56 males, 65 females) because they were less than twelve months of age, and 25 because they said they were pregnant. A total of 3646 individuals (96%) were eligible; 2786 (76% of those eligible) took azithromycin (Table 2).

3.3 Factors affecting uptake

Sex and age—Uptake of azithromycin was higher amongst women (79%) than men (72%, $P<0.0001$). In both sexes, uptake was highest amongst 1–10 year olds, and lowest amongst 16–40 year-olds (Table 2).

Prevention norms—Injections were more widely recognised than oral medicines as a method of disease prevention. Six interviewees reported that injections reach more of the body quickly, because they spread through the blood, and are therefore more useful for prevention. Two interviewees stated that the pain of the needle was an indicator of the strength of the vaccination.

Two interviewees who were non-compliers refused to take the drug because they were not ill. *'I am not suffering from eye disease and I don't have any reason to treat them'*. Ten interviewees that took azithromycin offered “prevention” as the reason for their compliance. However no interviewee felt able to expand on this point, suggesting that they did not fully understand either the benefits of, or the rationale for, prevention.

Perceptions of drugs in general, and perceptions of azithromycin—Most medicines can be bought over-the-counter from Rombo shops, village stores, and pharmacies, as well as being obtained on prescription from hospitals and clinics. FGDs and interviews revealed that drugs were widely accepted as a method of health maintenance, rather than being perceived as instruments for treatment or prevention of specific diseases. However, opinions as to whether particular drugs (such as azithromycin) are of use appeared to be based on each individual's belief in his or her ‘type of body’ and ‘type of blood’. Some

drugs were thought to be effective for some people, but ineffective or even harmful for others.

There was a marked lack of knowledge about azithromycin and its therapeutic role. Three non-complier interviewees who had heard that azithromycin was for control of an eye disease questioned the efficacy of an oral drug for this purpose. Five interviewees had had previous experience of trachoma and were accustomed to the use of tetracycline eye ointment. *'They told [us] that the drug is for eyes but people are taking it orally and so they refused as they thought it wouldn't work on the eyes'*.

Knowledge of and beliefs about trachoma—Decisions to accept or refuse azithromycin were influenced by patient beliefs about severity of the trachoma problem in the village and their own susceptibility. People were more likely to comply with treatment if they felt that the illness could have potentially serious consequences for their own health or daily functioning. Simply having heard of trachoma was related to azithromycin uptake: of 409 individuals who completed questionnaires, 312 had heard of the disease, and 241 (77.2%) of them were treated, while 62 (65.3%) of the 95 who had not heard of trachoma took azithromycin; 2 individuals said that they did not know whether they had heard of trachoma (Odds ratio for treatment if had heard of trachoma 1.8, 95% C.I. 1.1-3.1, Fisher's exact $P=0.02$). When asked whether trachoma was a cause of blindness, 356 responded 'yes'; 274 (77.0%) of these were treated. Only 27 (57.4%) of 47 individuals who did not recognize trachoma as a cause of blindness took azithromycin (6 individuals answered 'don't know', or did not answer this question)(Odds ratio for treatment if knew trachoma was a cause of blindness 2.5, 95% C.I. 1.2-4.8, Fisher's exact $P=0.007$).

The swollen eyelids and ocular discharge of children with active disease were not seen as part of a disease process leading, potentially, to trichiasis in old age, but rather as a normal phenomenon. There was also a failure amongst some respondents to appreciate the need to treat adults. *'I have never had [trachoma] and even my children, they have never had it. But when the medicines were brought I insisted on getting medicine for them but not for me, I don't see any reason why I should take it'*.

Knowledge of side effects—During the distribution, reports from those who had experienced either positive or negative side effects spread rapidly. Adverse effects, the risks of which were not explained before the distribution, were often the factor that sealed azithromycin's refusal. *'We had vaccines before but these didn't harm us like [azithromycin]'*, and *'I... wouldn't have taken the medicine because it harmed some people with bleeding and severe diarrhoea'*. Adverse effects of the drug were reported relatively frequently (32% of questionnaire respondents), with diarrhoea, stomach ache and nausea the most common complaints.

Amongst interviewees who took the drug, however, side effects were not always viewed in a negative way. *'...if someone is given medicine, some will say they had diarrhoea, others will say they had dizziness and then it is gone. Others will say they had a headache and it stopped. This means that the medicine has worked'*. *'At the beginning I didn't know if it was ... working, but once I got the side effects I felt that this was a sign it was working well'*.

Timing and community awareness of the distribution—Because the Kitowo distribution took place over a weekend, many village residents were making visits to family in other villages, or relaxing at home. Little advance warning was given: seven interviewees who were treated and five who were not reported that they had first heard of the distribution in the twenty-four hours before the distribution team arrived; this point was also repeatedly raised in FGDs. A community meeting convened by the distribution team several days prior to the start of distribution had been poorly attended due to extended intra-village distances and competing demands of normal daily activities.

Information dissemination—Insufficient information was available to the community before, during and after the distribution. The only information that most received prior to distribution was to come and get free medicine, without clarification of its purpose, or to come and get treatment for eye problems. This probably adversely affected compliance. Interviewees who had refused to take azithromycin said, *‘Medicines are useful but we need enough instructions’* and *‘[I did not take the drug] because I did not get enough instructions’*. Even those who took the drug often did so without understanding why, relying on their trust in ‘professionals’. *‘I was just told to go and get the medicine, we asked [what it was for] but we were told just to take it’*. Only 170 (56%) of 305 treated questionnaire respondents were satisfied with the amount of information that they received. The lack of information encouraged rumours of sinister purposes for the distribution, including stories that the drug induced sterility or cancer.

The provider/recipient relationship—In an effort to enhance azithromycin’s acceptability (West and Taylor, 1988) in Kitowo, two Village Health Workers (VHWs) were recruited to work as members of the distribution team. This had a variable influence on uptake. One interviewee stated *‘if you didn’t come as one from the village we couldn’t understand and couldn’t take the drug’*. Another resident, however, upon recognising one of the VHWs during the distribution, was heard to say *‘why, you are giving me these medicines but you don’t know anything’*. An interviewee commented, *‘the distributors are not trustworthy, because they are not experts in the medicines’*.

In contrast, distribution personnel from outside the village (seconded from the district hospital, health centres and pharmacies) were regarded as ‘doctors’, who had biomedical knowledge and a right to be trusted. Eleven interviewees said that their reason for taking the drug was ‘trust in the doctors’. Comments included *‘You can’t refuse medicines which are given to you by a doctor’* and *‘The doctor is the one who knows where it goes and how it works: I trust the doctors’*.

Perceptions of inappropriate drug handling were found to have a negative impact on treatment acceptability. Three of the interviewees who refused to take the drug reported that they saw the drugs exposed to the elements and felt that this would damage the drugs, making them ineffective or worse. *‘Each team keeps [the medicines] in the sun and dust which is very dangerous and so the drug can change and cause us harm’*.

Criteria used to determine eligibility—During the distribution, there was some uncertainty on the part of distribution teams as to whether individuals who had drunk or

were planning to drink alcohol could be given azithromycin. Treatment was not consistently given or withheld. This caused confusion amongst recipients: a fact noted repeatedly in FGDs and interviews.

Influence of peers and government—The perceived wisdom of local and national government officials was influential for some. Two interviewees said they took the tablets because their balozi had instructed them to: *'I was told by the Balози and so I took them'*. Three others placed their faith in central-level decision-making: *'I am not afraid. I have confidence in the government, they can't bring bad things to the village'*, and *'I don't believe there is any government who would allow its people to receive bad medicines'*.

Altruism or egoism in asymptomatic individuals—Elements of egoism were recognised during interviews with people who refused treatment. This was reflected in their attitudes to the research: azithromycin refusers asked to participate in FGDs were the only informants who asked for payment to compensate for their time and contribution.

3.4 Factors not significant to uptake

Use of traditional healers—Of 409 individuals completing questionnaires, 89 (21.8%) reported visiting traditional healers for at least some medical complaints; 66 (74.2%) of these individuals took azithromycin. Of 320 who did not use traditional healers, 238 (74.4%) took azithromycin.

Socioeconomic status—Complete socioeconomic status data was provided by 360 (88.0%) of 409 questionnaire respondents. Socioeconomic variables are tabulated against azithromycin uptake in Table 3. In the logistic regression model, none of the four socioeconomic variables were significantly associated with likelihood of azithromycin uptake (data not shown).

4 Discussion

Coverage with azithromycin was 76%. At the time of this distribution, the programme's community-level target for antibiotic coverage was 75% or greater (West and Frick, 1999). Azithromycin uptake was higher in women. This may be related to the fact that, in Chagga society, women have primary responsibility for childcare. They are therefore more likely than men to attend azithromycin distribution sessions in the process of taking children, and may accept offered antibiotic themselves while they are there. Higher compliance in women may also be related to patient experience: trachoma, particularly its blinding complications, affects women more frequently than men (Mabey et al., 2003). Though the proportion of women who were treated was significantly higher (in statistical terms) than the proportion of men treated, because the difference in coverage between women and men was numerically small (79% versus 72%); and because the actual coverage thresholds that might mark differential effects on the post-distribution epidemiology and transmission of infection are presently unknown, the programmatic significance of this difference is questionable.

High antibiotic uptake in 1–10-year-olds is encouraging. In a nearby village in Rombo District, children under 10 have been shown to harbour over 90% of the total ocular *C.*

trachomatis load (Solomon et al., 2004). Achieving high coverage in this age group is likely to be very important to the success of antibiotic distribution programmes.

Knowledge of and beliefs about trachoma and its treatment, norms concerning prevention, and perceptions of drugs were all significant factors in determining uptake. If illness is defined as the disruption caused by disease, rather than the disease per se (Eisenberg, 1977) then (because it generally causes minimal life disruption) active trachoma is not an illness but a normal part of childhood in this community. As a result, active disease was recognised, but not prioritised, and treatment, even for symptomatic children, was not universally seen as an imperative. The lack of recognition of orally-administered agents as a means of disease prevention probably stems from experience of smallpox, measles and tetanus vaccination campaigns, and persists despite recent mass-distribution of oral polio vaccine. All of these factors are potentially amenable to influence by education of the community prior to distribution.

The reported frequency of adverse events was higher than is usually associated with the use of azithromycin in trachoma control programmes (Solomon et al., 2001; Whitty et al., 1999); some residents reported that others' post-treatment symptoms made them decide to decline treatment for themselves. It is possible, though, that adverse effects were over-reported to investigators in this study because of expectations that this might lead to further free medical attention. For some recipients, adverse effects were interpreted as evidence that the drugs were working: community education efforts should not shy away from informing people that some recipients will experience side-effects.

Several provider-related factors adversely affected uptake. First, non-local distribution personnel were perceived as 'experts', and worthy of the community's trust, but there was a perception that VHWs involved in distribution lacked sufficient knowledge. Level of trust in the distribution team is an important determinant of compliance. The community's trust in distribution personnel may have been increased had VHWs received more pre-distribution training about azithromycin. Second, recipients received insufficient information about the reasons for and timing of the distribution, and the information that was provided came too late for them to consider it fully before they were actually offered the drug. Third, many residents were unable to attend the distribution because it occurred on the weekend. Fourth, criteria used to determine eligibility were not clear to the distribution team, and were inconsistently applied.

In rural Tanzania, (Western) biomedicine is one component of a medically pluralistic system. For some Kitowo residents, the choice of biomedical services or traditional healers as providers of primary care depends on the nature of the complaint. Contrary to findings in other contexts (Onuhoa, 1981) however, use of traditional healers was not found to be a significant factor in predicting uptake of donated antibiotic.

Bachani (1983) argued that refusal of interventions is associated with particular socio-economic characteristics, the recognition of which would help to identify groups likely to decline participation in community-wide campaigns. Like Conrad (1985), however, we found no relationship between uptake and socio-economic status variables. This may have

been because azithromycin was provided free of charge and distributed to recipients in the village: affordability and access should have been equal for all.

The World Health Organization currently recommend that, once the decision to offer antibiotic treatment has been made, treatment be given on an annual basis for three years before review as to the need to stop or continue (Solomon and Burton, 2004). Issues important to acceptance of the first dose (as studied here) may be different from the issues important to acceptance of subsequent annual doses, when communities will have previous experience of azithromycin. Further studies will be required to address this question.

To help increase azithromycin uptake in future distributions in Rombo, and elsewhere, we recommend that trachoma control programmes:

1. Undertake a rapid assessment in each setting prior to azithromycin distribution, to understand existing knowledge and the socio-cultural context (Heggenhougen and Clements, 1990) and to identify appropriate education messages and channels for their dissemination.
2. Deploy the health education component of the SAFE strategy before and during antibiotic distribution. In particular, the quality and quantity of information provided about azithromycin (and its possible adverse effects) should be improved.
3. Give advance warning of dates and times of distribution.
4. Standardise protocols for distribution, including information about drug handling and contraindications for treatment.
5. Provide more extensive training for all members of the distribution team, especially village health workers. The cost of this additional training will have financial implications for trachoma control programmes.

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Table 1
Demographic details for questionnaire respondents

Age (years)	Males	Females	Both sexes (% of total)
1- 15	0	0	0
16-20	9	13	22 (5.7)
21-40	60	110	170 (44.2)
41-60	52	56	108 (28.1)
61+	45	40	85 (22.1)
Total	166	219	385 ^a

^a 24 individuals completing questionnaires did not complete the tracing questions necessary for us to determine the respondent's age and sex

Table 2**Uptake of antibiotics by age and sex**

Age (years)	Males					Females				
	Eligible	Treated (%)	Refused ^a (%)	Absent ^b (%)		Eligible	Treated (%)	Refused ^a (%)	Absent ^b (%)	
1-5	284	245 (86.3)	34 (12.0)	3 (1.1)		288	254 (88.2)	33 (11.4)	1 (0.4)	
6-10	286	257 (89.9)	25 (8.7)	4 (1.4)		294	265 (90.1)	24 (8.2)	1 (0.3)	
11-15	295	235 (79.7)	57 (19.3)	1 (0.3)		294	255 (86.7)	35 (11.9)	3 (1.0)	
16-20	99	50 (50.5)	44 (44.4)	3 (3.0)		174	121 (69.5)	49 (28.2)	2 (1.1)	
21-40	276	126 (45.7)	129 (46.7)	21 (7.6)		487	340 (69.8)	138 (28.3)	6 (1.2)	
41-60	241	162 (67.2)	74 (30.7)	5 (2.1)		258	197 (76.4)	58 (22.5)	1 (0.4)	
61+	168	106 (63.1)	57 (33.9)	4 (2.4)		202	153 (75.7)	49 (24.3)	0 (0)	
Total	1649	1192 (71.6)	423 (25.4)	43 (2.3)		1997	1594 (79.4)	387 (19.3)	14 (0.7)	

^a includes individuals who refused treatment and those who were refused treatment because they had consumed alcohol (no distinction was made between the two on treatment record cards)

^b includes individuals who had (temporarily) travelled outside the village and those who were at school or work at the time of distribution

Table 3
Uptake of antibiotics by socioeconomic status variables

Variable and category	Number (% of all respondents)	Number treated (% of respondents in that category)	Number refused ^a (% of respondents in that category)
Household's monthly income (Tanzanian Shillings)			
0-4999	2 (0.6)	2 (100.0)	0 (0.0)
5000-9999	315 (87.5)	216 (68.6)	99 (31.4)
10000-19999	27 (7.5)	20 (74.1)	7 (25.9)
20000 or more	16 (4.4)	10 (62.5)	6 (37.5)
Size of household's landholding (acres)			
No land	11 (3.1)	5 (45.4)	6 (54.6)
<0.5	23 (6.4)	16 (69.6)	7 (30.4)
0.5 or more but <2.0	207 (57.5)	142 (68.6)	65 (31.4)
2.0 or more	119 (33.1)	85 (71.4)	34 (28.6)
Number of cows owned by household			
0	193 (53.6)	127 (65.8)	66 (34.2)
1	107 (29.7)	79 (73.8)	28 (26.2)
2	53 (14.7)	36 (67.9)	17 (32.1)
3-5	7 (1.9)	6 (85.7)	1 (14.3)
Number of goats owned by household			
0	40 (11.1)	21 (52.5)	19 (47.5)
1-2	129 (35.8)	91 (70.5)	38 (29.5)
3-5	151 (41.9)	106 (70.2)	45 (29.8)
6-10	40 (11.1)	30 (75.0)	10 (25.0)
All respondents	360 (100.0)	112 (31.1)	248 (68.9)

^a includes individuals who refused treatment and those who were refused treatment because they had consumed alcohol (no distinction was made between the two on treatment record cards). None of the people who were absent at the time of distribution (c.f. Table 2) completed questionnaires.