

Study methodology

The Kalgoorlie Otitis Media Research Project: rationale, methods, population characteristics and ethical considerations

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Summary

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Otitis media (OM) is one of the most common paediatric illnesses for which medical advice is sought in developed countries. Australian Aboriginal children suffer high rates of OM from early infancy. The resultant hearing loss can affect education and quality of life. As numerous factors contribute to the burden of OM, interventions aimed at reducing the impact of single risk factors are likely to fail. To identify key risk factors and understand how they interact in complex causal pathways, we followed 100 Aboriginal and 180 non-Aboriginal children from birth to age 2 years in a semi-arid zone of Western Australia. We collected demographic, obstetric, socio-economic and environmental data, breast milk once, and nasopharyngeal samples and saliva on seven occasions. Ear health was assessed by clinical examination, tympanometry, transient evoked otoacoustic emissions and audiometry. We considered the conduct of our study in relation to national ethical guidelines for research in Aboriginal and Torres Strait Islander health. After 1 year of community consultation, the study was endorsed by local committees and ethical approval granted. Fieldwork was tailored to minimise disruption to people's lives and we provided regular feedback to the community.

We saw 81% of non-Aboriginal and 65% of Aboriginal children at age 12 months. OM was diagnosed on 55% and 26% of routine clinical examinations in Aboriginal and non-Aboriginal children respectively. Aboriginal mothers were younger and less educated, fewer were employed and they lived in more crowded conditions than non-Aboriginal mothers. Sixty-four per cent of Aboriginal and 40% of non-Aboriginal babies were exposed to environmental tobacco smoke. Early consultation, provision of a service while undertaking research, inclusion of Aboriginal people as active members of a research team and appropriate acknowledgement will assist in ensuring successful completion of the research.

Keywords: *otitis media, Indigenous population, cohort study, ethical guidelines, follow-up bias.*

Introduction and background

Burden of otitis media

In industrialised countries, otitis media (OM) is the most common paediatric illness for which medical advice is sought and antibiotics are prescribed.¹ OM can lead to impaired hearing, which can affect performance at school and social circumstances in adulthood. In industrialised countries, 10–20% of children suffer >3 episodes of OM before age 1 year.² In Aboriginal Australian children not only are the rates of OM and its sequelae much higher than in non-Aboriginal children³ but the disease starts at a much younger age and is frequently asymptomatic until a purulent ear discharge is visible.^{4–6} A recent study in the Northern Territory of Australia showed that 91% of Aboriginal children aged 6–30 months had clinical signs of OM and by age 18 months 40% had had a tympanic membrane perforation.⁷

Risk factors for OM

A wide variety of demographic, social, environmental, immunological and microbiological risk factors for OM have been identified in studies in industrialised countries, although findings have not always been consistent across studies.^{8–15} In Indigenous populations, poverty, crowding, personal hygiene and parental smoking are considered important antecedents to OM.^{16,17} *Streptococcus pneumoniae*, *Moraxella catarrhalis*, *Haemophilus influenzae*, rhinovirus, adenovirus, influenza viruses, respiratory syncytial virus and coronavirus are the pathogens most commonly associated with OM.^{4,6,8,18}

Causal pathways to OM

Figure 1 shows the hypothesised causal network we have developed on which to base our investigations; it illustrates the complexity of causal pathways to OM. Prevention of the more distal factors on causal

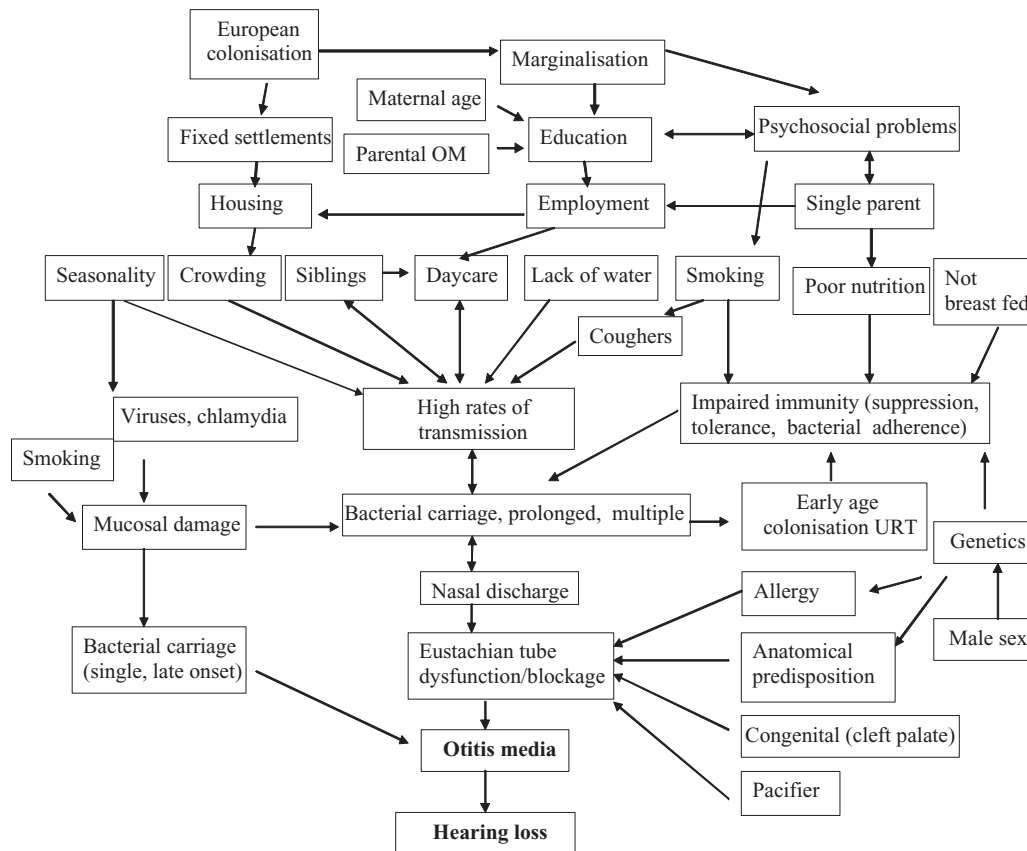


Figure 1. A causal network for otitis media (OM). URT, upper respiratory tract.

pathways to OM may be not only more effective and cheaper, but essential in reducing the overwhelming burden of disease.¹⁹ It is also clear that interventions aimed at reducing the impact of single risk factors in isolation are likely to fail.²⁰ In order to design appropriate interventions to reduce the burden of OM in Aboriginal and non-Aboriginal children, the most important risk factors need to be identified, particularly for children residing in urban arid environments for whom data are limited. We therefore conducted a multidisciplinary longitudinal study in such an environment.

Ethical considerations

Aboriginal peoples have had negative experiences of research which are closely linked to the history of colonisation. Hence, they have been critical of research undertaken in their communities.^{21,22} Researchers tended to collect data for their own rather than Aboriginal peoples' benefit, at times they drew false conclusions – often to the detriment of Aboriginal peoples – and they provided limited feedback to communities. By the 1980s there was increasing concern about the conduct of research on Aboriginal peoples who were also becoming increasingly resistant to conventional research practices.²² Following a series of meetings, a national set of guidelines was developed and endorsed by the National Health and Medical Research Council (NHMRC) in 1991.²³ These guidelines were in place when we developed our study protocol, but were replaced in 2003 by *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*.²⁴

The 1991 guidelines emphasised the need for consultation with communities participating in research, community involvement in research, and consideration of ownership and publication of data.²³ The current guidelines are less prescriptive with a move away from mere compliance with legal requirements to the acknowledgement of cultural differences and consideration of values. The values which form the basis of the new guidelines are: 'spirit and integrity, reciprocity, respect, equality, survival and protection', and 'responsibility'.²⁴

An important issue for us was how best to conduct a demanding study as a true partnership with local communities, ensure optimal data collection related to multiple risk factors, including the collection of biological specimens, and maintain an acceptable level of follow-up.

Aims

This study aimed to: (1) identify important, avoidable risk factors for OM in Aboriginal and non-Aboriginal children in the Kalgoorlie-Boulder area of Western Australia, and (2) to understand how these risk factors arise and interact in the complex causal pathways in order to develop effective intervention strategies.

In this paper we give an overview of methods used in the study and describe the socio-economic, environmental and demographic characteristics of the study population. We specifically address ways in which we sought to engage the Aboriginal and non-Aboriginal communities and describe the planning and progress of our study in relation to NHMRC ethical guidelines.²³

Methods

Study setting

Kalgoorlie-Boulder is located in a semi-arid zone 600 kilometres east of Perth, the capital city of Western Australia. It is the major centre for the Goldfields region and for the mining industry in the area. Approximately 32 500 people live in Kalgoorlie-Boulder and the surrounding areas, 2380 of whom are Aboriginal.²⁵

Engaging the community

In order to undertake this complex study requiring regular follow-up of children from birth to age 2 years, our first priority was to obtain the support of the proposed participating communities and the health service providers. There had been a call from the community for such a study: people were concerned about the potentially negative impact of OM on children's well-being, in particular on their school performance. The coordinator (Elsie Edwards) of Ngunytju Tjitji Pirni Inc (NTP, an Aboriginal Health Service) was chief investigator on our first grant application in 1997 and Aboriginal investigators were part of subsequent funding applications. Formal collaboration with Bega Garnbirringu Aboriginal Health Services Aboriginal Corporation (BEGA) was established in 1999. We learnt that BEGA had limited access to ear, nose and throat (ENT) specialists and, therefore, our study ENT specialist (H.C.) offered his services at no cost until another specialist became available. D.L. also assisted BEGA in

obtaining funding for an Ear Health Worker and we offered parents and children transport to ENT clinics.

People were informed about the study through radio and television interviews, newspaper articles and face-to-face discussions. Aboriginal and non-Aboriginal people provided input into the study design and content of information sheets, consent forms and questionnaires, which were developed in line with routine data collection instruments used by NTP. All research staff pre-tested all forms and piloted specimen collection among themselves. This meant they could explain to future participants what discomfort children might experience.

We held meetings with local medical practitioners to explain the purpose of the study, to ask them to encourage their clients to take part in the study and to seek their approval to access participants' medical records.

After 12 months of developing partnerships with local organisations and health professionals, the study was endorsed by the relevant local Aboriginal organisations, leading to approval from the Western Australia Aboriginal Health Information and Ethics Committee (WAAHIEC) to conduct the study.

The research assistants were Aboriginal Health Workers (AHW) and nurses who were well known to the local community. Nurses and AHWs gained experience in research and played an active role in the local Ear Health Committee which aims to increase awareness about OM and develop programmes to improve ear health. Being enthusiastic about the project themselves, research assistants were able to encourage others to participate in the study.

Recruitment of study participants

Between April 1999 and January 2003, Aboriginal and non-Aboriginal children born in Kalgoorlie Regional Hospital to mothers intending to reside for at least 2 years within 1-h drive of Kalgoorlie were recruited into this prospective cohort study in order to enrol 100 Aboriginal and 180 non-Aboriginal babies. Multiple births, children with severe congenital abnormalities or those whose birthweight was <2000 g were not eligible.

Enrolment and follow-up of study participants

Research assistants visited women postpartum in hospital to provide them with information about the study

with a view to enrolling four babies each week. If mothers were interested, research staff contacted them at home and, if still interested, they arranged a home visit 1–3 weeks post-partum to obtain consent and collect demographic, socio-economic, environmental and obstetric data. Information was only obtained for those fathers living with the enrolled child. Type of employment was classified using the Australian Standard Classification of Occupations.²⁶ The research assistants collected nasopharyngeal samples for microbiological studies and breast milk and saliva for studies of mucosal immunity.

Research staff scheduled follow-up visits when children were aged 6–8 weeks, 4, 6, 12, 18 and 24 months at a convenient time and place for study participants (in the home, project office or a public place). Information on time-dependent variables (e.g. feeding practices, smoking, day-care attendance and use of pacifier) and saliva and nasopharyngeal samples were collected. Research assistants noted any ear discharge but did not routinely perform otoscopy as reliable examination is difficult in very young children. We documented all immunisations given to study participants.

Morbidity data collection

In order to obtain as complete information as possible on any OM episodes, once children reached 2 years of age we collected morbidity data from medical practitioners and Kalgoorlie Regional Hospital, the only hospital in the region. Diagnoses were coded according to the ICD10 classification system.²⁷

Assessment of ear health

At 1–3 and 6–8 weeks of age we screened for sensorineural hearing loss by measuring transient evoked otoacoustic emissions (TEOAE). A failed TEOAE screen may also indicate fluid in the middle ear of young infants^{28,29} and may be useful in identifying children at risk of developing OM in the future.³⁰

Clinical diagnosis of OM by a paediatric ENT specialist was the primary outcome for this study. ENT/audiology clinics were held four times annually, specifically for routine examination of study participants, once before 6 months of age and again at 6–11 and 12–23 months of age. An audiologist assessed hearing at age 12–23 months and from March 2002 onwards also at age 6–11 months.

To obtain additional, possibly less biased, ear health outcomes more frequently on more children, research assistants performed tympanometry from May 2000 onwards during routine follow-ups of children aged 4 months or more.

Analysis

To determine how representative our study population was of the general population in the area, data on the characteristics of births in the general population residing in the Kalgoorlie-Boulder region were obtained from the birth records on the Midwives' database of the Western Australia Data Linkage System.³¹ In this paper, the chi-square test with continuity correction, Fisher's Exact test and Student's *t*-test were used to compare groups of interest.

Ethical approval

Ethical approval to conduct this study was given by WAAHIEC, the Northern Goldfields Health Service and Nursing Education Ethics Committee in Kalgoorlie, Princess Margaret Hospital Ethics Committee and the Confidentiality of Health Information Committee of the Health Department of Western Australia.

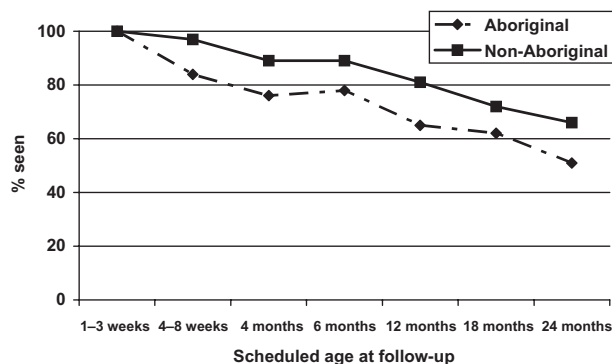


Figure 2. Proportion of Aboriginal and non-Aboriginal children seen at each scheduled routine follow-up visit.

Results

Enrolment of non-Aboriginal babies was completed in September 2002, while the last Aboriginal child was enrolled in January 2003. Approximately two-thirds of Aboriginal children (65%) and 81% of non-Aboriginal children were seen at age 12 months (Fig. 2). Nineteen Aboriginal (19%) and 38 (21%) non-Aboriginal chil-

dren moved away from the area before age 2 years; parents of six (6%) Aboriginal children and one (0.5%) non-Aboriginal child chose to leave the study and one child died. An ENT specialist saw 83% of Aboriginal children at least once and 59% at least twice, while 91% of non-Aboriginal children were seen at least once and 72% twice. OM was diagnosed in 55% of 184 routine examinations in Aboriginal children and 26% of 392 examinations in non-Aboriginal children.

We collected 436 saliva and 509 nasopharyngeal samples from Aboriginal babies and 878 saliva and 1050 nasopharyngeal samples from non-Aboriginal babies. Breast milk was collected from 79 Aboriginal mothers (99% of breast-feeding mothers) and 144 (92%) non-Aboriginal mothers.

Comparison of characteristics of study population with general population of the Kalgoorlie-Boulder Region

The characteristics of the study population and births in the total population of Kalgoorlie-Boulder in 2000 were similar, except that in our study sample there were more teenage Aboriginal mothers, non-Aboriginal study mothers and fathers were older and non-Aboriginal study mothers were less likely to have smoked during pregnancy (Table 1).

Characteristics of mothers

Five non-Aboriginal mothers had Aboriginal children. One-quarter of Aboriginal mothers were teenagers and one-third were single parents (Table 1), but usually lived with their extended family. Almost half the Aboriginal mothers and 16% of non-Aboriginal mothers were brought up in families that did not include both mother and father (Table 2).

While Aboriginal mothers had a lower level of education and were more likely to be unemployed than non-Aboriginal mothers, 41% of Aboriginal mothers had been employed recently (Table 2). Almost half the Aboriginal mothers had received further training after completing high school (Table 2), but only 58% of those for whom we have data (22/38) had completed such courses compared with 86% (113/132) of the non-Aboriginal mothers.

A high proportion of mothers breast fed their babies during the first month of life (Table 2), but by the age of 4 months, fewer than half the babies were being exclusively breast fed. Six-to-eight weeks postpartum, 9% of

Characteristic	Aboriginal ^a			Non-Aboriginal ^a		
	Study <i>n</i> (%)	K-B ^b <i>n</i> (%)	<i>P</i> -value ^c	Study <i>n</i> (%)	K-B <i>n</i> (%)	<i>P</i> -value ^c
Child's gender						
Male	60 (60)	46 (54)	0.5	89 (49)	309 (51)	0.84
Female	40 (40)	39 (46)		91 (51)	301 (49)	
Maternal age (years)						
<20	24 (25)	13 (15)	0.02	7 (4)	32 (5)	0.03
20–24	26 (27)	39 (46)		25 (14)	107 (18)	
25–29	26 (27)	25 (29)		56 (30)	226 (37)	
30+	19 (20)	8 (9)		97 (52)	245 (40)	
Single mother	31 (34)	33 (31)	0.8	5 (3)	33 (5)	0.4
Mothers' place of birth						
Western Australia	88 (94)	99 (92)	0.4	92 (50)	302 (50)	0.96
Elsewhere Australia	5 (5)	9 (8)		58 (32)	189 (31)	
Outside Australia	1 (1)	–		34 (18.5)	118 (20)	
Paternal age (years) ^d						
<25	22 (34)	15 (35)	1.0	22 (12)	72 (13)	0.03
25 to 29	21 (33)	13 (30)		40 (22)	168 (30)	
30+	21 (33)	15 (35)		124 (67)	312 (57)	
Smoking in pregnancy						
Yes	46 (49)	47 (55)	0.53	39 (21)	195 (32)	0.006
No	47 (51)	38 (45)		146 (79)	414 (68)	

^aDiscrepancies in denominators due to missing data.

^bK-B = Kalgoorlie-Boulder all births in 2000.

^c*P*-values refer to differences between general and study population (Aboriginal and non-Aboriginal separately).

^dPaternal information for general population pertains to all fathers for whom information was entered on questionnaires. Some fathers in the general population may not have been residing with child's mother. For the study, paternal information relates to fathers living at same address.

Aboriginal mothers and 4% of non-Aboriginal mothers had introduced solids into their baby's diet, increasing to 67% (48/72) and 56% (93/165), respectively, 4 months postpartum. Non-Aboriginal mothers generally used pacifiers more frequently than Aboriginal mothers (Table 2).

Characteristics of fathers

Demographic data were available for 64 Aboriginal and 186 non-Aboriginal fathers. Sixty Aboriginal and 182 non-Aboriginal fathers were living with the study participant. Forty per cent (19/47) of Aboriginal fathers had received some training after high school, though none had gone to university, compared with 81% (145/180) of non-Aboriginal fathers, 21% of whom had received university education ($\chi^2 = 34.2$, 3 d.f., $P < 0.001$). Aboriginal fathers were less likely to be employed (64%) than non-Aboriginal fathers (98%) ($\chi^2 = 57.0$, 2 d.f.,

$P < 0.001$). If employed, only 11% of Aboriginal fathers had highly skilled jobs (Australian Bureau of Statistics levels 1 and 2) compared with 29% of non-Aboriginal fathers ($\chi^2 = 78.0$, 2 d.f., $P < 0.001$).

Household characteristics

Compared with non-Aboriginal mothers, Aboriginal mothers were more likely to live in rented accommodation, in houses with fewer rooms and with more people than non-Aboriginal families; they were less likely to have heating in their homes and less likely to have more than one type of cooking facility (Table 3).

Characteristics of study children

Fewer Aboriginal study participants attended day care in the first 6 months of life than non-Aboriginal children: of the 59 Aboriginal children seen at each

Table 1. Comparison of sociodemographic characteristics of the study population with those of characteristics of all births in 2000 in the Kalgoorlie-Boulder Region

Table 2. Sociodemographic characteristics of 95 Aboriginal and 185 non-Aboriginal mothers^a

Characteristic	Aboriginal ^b n (%)	Non-Aboriginal ^b n (%)	P-value ^c
Brought up by mother and father	49 (53)	156 (84)	<0.001
Highest level of education			<0.001
Bachelor/postgraduate degree	1 (1)	50 (27)	
Other post-school	42 (45)	87 (47)	
Years 11–12	17 (18)	29 (16)	
≤Year 10	33 (35)	18 (10)	
Any post-school training	43 (46)	137 (74)	<0.001
Employment history			<0.001
Works now/recently	31 (41)	127 (71)	
Worked in past but not recently	26 (35)	48 (27)	
Has never worked	18 (24)	4 (2)	
Current employment type ²⁶			<0.001
ABS skill level 1–2 (higher)	6 (6)	49 (26)	
ABS skill level 3–5 (lower)	25 (27)	78 (42)	
Unemployed	62 (67)	58 (31)	
Pacifier use in children aged:			
1–3 weeks	41 (44)	95 (51)	0.3
6–8 weeks	38 (49)	120 (68)	<0.01
4 months	31 (43)	96 (58)	<0.05
6 months	26 (36)	93 (56)	<0.01
Any breast milk given at age ^d :			
1–3 weeks	80 (84)	157 (85)	1
6–8 weeks	57 (72)	128 (72)	0.9
4 months	45 (62)	103 (65)	0.9
6 months	43 (59)	93 (56)	0.8

^aFive non-Aboriginal mothers had Aboriginal children (i.e. fathers were Aboriginal).

^bDiscrepancies in denominators due to missing data.

^cP-values for comparison between Aboriginal and non-Aboriginal mothers.

^dFollow-up was incomplete after age 1–3 weeks resulting in different denominators in each age group.

ABS, Australian Bureau of Statistics.

follow-up visit to age 6 months, 8.5% had attended day care compared with 21% of 143 non-Aboriginal children ($\chi^2 = 3.73$, $P = 0.05$). However, 63% of Aboriginal study participants were living with older children who attended day care, playgroup or school, compared with 39% of non-Aboriginal children ($\chi^2 = 12.9$, $P < 0.001$).

Exposure to cigarette smoke

Approximately half the Aboriginal mothers and one-fifth of non-Aboriginal mothers smoked during pregnancy (Table 1, $\chi^2 = 22.2$, $P < 0.001$). Sixty-four per cent of Aboriginal babies and 40% of non-Aboriginal babies were exposed to environmental tobacco smoke in the first month of life ($\chi^2 = 13.35$, $P < 0.001$), while 23% of Aboriginal children and 6% of non-Aboriginal children were exposed to tobacco smoke inside the home.

Characteristics of children with incomplete follow-up compared with those followed to age 2 years

A total of 47 (50%) Aboriginal mothers and 64 (35%) non-Aboriginal mothers did not complete 2 years of follow-up. To validate our findings it was important to compare characteristics of children who did not have complete follow-up with those who did. We found no significant differences with regard to education, employment, parity, maternal age, marital status, number of adults or children in the household and maternal smoking (data not shown).

Discussion

To our knowledge, this is the first study to investigate causal pathways to OM by examining microbiological, social, environmental, demographic and immunological factors simultaneously in Aboriginal and non-

Characteristic	Aboriginal ^a n (%) or mean ± SD	Non-Aboriginal ^a n (%) or mean ± SD	P-value ^b
Number of adults in house			
Mean ± SD	2.60 ± 1.04	2.10 ± 0.51	<0.001
Number of other children in house			<0.001
0	18 (19)	93 (50)	
1	24 (26)	45 (24)	
2	19 (20)	34 (18)	
3+	33 (35)	13 (7)	
Lives in:			<0.001
Rented accommodation	69 (73)	45 (24)	
Own house	7 (7)	136 (74)	
Other accommodation	18 (19)	4 (2)	
Number of rooms in house	4.00 ± 1.2	4.96 ± 1.36	<0.001
Number of bedrooms	2.97 ± 0.85	3.36 ± 0.83	<0.001
Number of people/room	1.48 ± 0.59	0.83 ± 0.27	<0.001
Number of children/room	0.76 ± 0.38	0.38 ± 0.20	<0.001
Use only disposable nappies in first month	35 (37)	105 (57)	<0.001
Cooking facilities in household			<0.001
Gas	58 (62)	33 (18)	
Electricity	14 (15)	15 (8)	
Gas + microwave	10 (11)	72 (39)	
Electricity + microwave	6 (6)	29 (16)	
Gas + electricity	4 (4)	6 (4)	
Gas + electricity + microwave	1 (1)	28 (15)	

^aDiscrepancies in denominators due to missing data.

^bP-values for comparison between Aboriginal and non-Aboriginal mothers.
SD, standard deviation.

Aboriginal children living in the same geographical environment. As expected, all indicators point to poorer social and economic status of the Aboriginal participants compared with non-Aboriginal participants, putting Aboriginal babies at particular risk of developing OM (Fig. 1).¹⁷

The study sample was similar to the general population in Kalgoorlie-Boulder except for the higher proportion of teenage Aboriginal mothers (who may have been encouraged to participate by the younger Aboriginal research assistants), the older age of non-Aboriginal study parents and lower proportion of non-Aboriginal study mothers who smoked compared with those in the general population. The apparent difference in smoking rate is likely to reflect the older age of study mothers as older study mothers smoked less than younger ones (manuscript in preparation). Older parents may have been more enthusiastic about taking part in the study than younger parents, some of whom were uncertain how long they would be staying in the area. Social, envi-

ronmental and demographic characteristics of the Aboriginal study population are consistent with those reported for the region in the Western Australian Aboriginal Child Health Survey.³²

Comparison with an urban study of Aboriginal children

It is of interest to compare some of the characteristics of our Aboriginal study population with those of 272 Aboriginal children who were enrolled in a longitudinal study in Perth, the Bibbulung Gnarneep Project.³³ These comparisons emphasise the similarities and differences even between two urban Aboriginal communities, one being a metropolitan area and the other a rural mining town in the same state of Australia. Successful follow-up at age 6 months was somewhat better in Kalgoorlie than in the Perth study (78% compared with 61%) but the same at age 12 months (62–65%). Feeding practices around age 2 months were

Table 3. Characteristics of households of 95 Aboriginal and 185 non-Aboriginal mothers

similar.³⁴ In Perth, 65% of mothers smoked and 80% of the infants were regularly exposed to tobacco smoke, somewhat higher than in the Kalgoorlie study (Table 1).³⁵

In the Perth study, mothers were more likely to have completed post-school training, to be employed and to live in rented accommodation than in Kalgoorlie, but in Kalgoorlie, more households included at least three adults than in Perth.

The research process

How successful were we in conducting this study in line with the ethical guidelines that were available during the planning and recruitment phases of the study and did we meet up to the more recent criteria and values specified in the 2003 guidelines (italicised below)?^{23,24}

We believe that in general we were successful in following these guidelines. We developed good partnerships with local communities and Aboriginal people actively participated in the research from the outset. We closely adhered to guidelines regarding consent, confidentiality and acknowledgement of investigators and participants. But there were several areas which could have been done better; in particular, we should have had wider consultation with members of the communities when planning the study.

The 1991 guidelines indicate that 'research should be potentially useful to the community'.²³ This was clearly the case for our study as members of local communities had expressed their concerns about OM and its consequences. Reduction in the burden of OM would improve *survival* of Aboriginal people as improved hearing could lead to better educational outcomes and quality of life. However, initial *consultation* with members of the community was limited. The senior investigator (D.L.) was new to the community and she had to rely on new friends and colleagues to introduce her to gain the community's support and trust. Dr S Eades, an Aboriginal doctor, provided guidance initially and, subsequently, Aboriginal members of ICHR's Kulunga Research Network were investigators on the project.

While members of the Aboriginal community were *participants* from the start, there should have been more widespread discussion when developing the protocol. As a consequence, the consultation process took place over 1 year following the award of the

first grant. We learnt that it may take longer than anticipated for Aboriginal organisations to consider all aspects of the study, but their input contributed to its success and gave the local community a sense of ownership. For example, the Aboriginal organisations assigned health workers to the project, their members participated in focus group discussions for an adjunct qualitative study, and men and women alike wore the T-shirts we designed as part of a health awareness campaign aimed at reducing smoking and enhancing breast feeding.

We did not consider it necessary to form a separate reference group as has been done for other studies^{21,35-37} as our study was being monitored by the Board of BEGA and members of NTP and we had frequent informal contacts with members of the local Aboriginal community.

In order to develop strong partnerships, *respectful research relationships* and achieve *equality*, we included all stakeholders in the planning process and updated them regularly on progress of the study. We planned follow-up visits so that they would not be too disruptive to people's lives. We sought *reciprocity* and deemed important that there be no research without service. We therefore offered hearing screening to all newborns and pneumococcal conjugate vaccine (PCV, Prevenar™) to non-Aboriginal children, neither of which was generally available at the time (PCV was being given routinely to Aboriginal children). We provided regular ENT follow-up to study participants and their families and arranged prompt surgical intervention if required. PCV is now offered to all Australian children but newborn hearing screening is not available in Kalgoorlie, because there is no resident audiologist. ENT specialist services continue and an exciting hearing screening programme is being developed.

In the spirit of developing true partnerships, AHWs were initially seconded from NTP or BEGA to work part-time on the project. However, they frequently had other commitments and it was only when there were sufficient funds to employ a research assistant (A.S.) to work solely on the research project that recruitment of Aboriginal babies gained momentum and follow-up was more successful. She was asked by members of the community to work on the project to ensure the success of the project and she took on the *cultural and spiritual responsibility* for the project. The Aboriginal staff provided *cultural security* for the Aboriginal aspect of the study, they were the link between non-

Aboriginal investigators and the Aboriginal community and they offered an insight into the broader picture of how children were living with OM.

We made it our *responsibility* to maintain confidentiality and to present results to the local community before submitting manuscripts for publication or presenting results to people outside the local community. We provided feedback to the community in a number of ways. Activities during National Aboriginal and Islander Day Observance Committee week celebrations and newsletters kept study participants and health service providers up-to-date on progress and results emerging from the study. Participating in local social activities also provided an opportunity for people to meet the research team informally. To transfer research into action, community-based awareness projects have already been undertaken³⁸ and more are planned. We must now continue to report results of our study to relevant local committees, so that they can initiate appropriate interventions.

All members of the research team had equal training opportunities and were acknowledged for their contribution to the study. Aboriginal and non-Aboriginal investigators have presented findings at national and international conferences. In 2002 and 2005, investigators contributed to local ear health conferences which were well attended by a wide range of health professionals. Further feedback was provided to medical practitioners and NTP staff in 2006.

In summary, our experiences and comments with regard to conduct of studies in Aboriginal communities concur with reports from other studies^{21,36,37,39} and should be considered by future investigators. It is possible to conduct rigorous research despite constraints.^{21,40} Common themes emerging from our study and the studies cited above include the need for early consultation, time to develop partnerships (which requires adequate funding), consideration of establishing a reference group, Aboriginal participation in the research, the development of trust and ensuring confidentiality, Aboriginal control of results, and appropriate acknowledgement. It takes time to gain people's confidence, but then there is the flow-on effect if people have had a positive experience of research activities. Recently published guidelines for Aboriginal and Torres Strait Islander peoples about health research ethics can also assist Aboriginal people and non-Aboriginal investigators in the appropriate conduct of research in Aboriginal health.⁴¹

Limitations of the study

The main limitation of our study will be the incomplete follow-up of many participants to age 2 years. However, given a peak prevalence of OM well before age 2 years,^{4,8} we will have a principal outcome based on OM for most of the study population. We knew that the Kalgoorlie population was mobile but were not aware of the extent of mobility.

Despite every effort, ENT follow-up at a central clinic was difficult for some children (as the NTP coordinator had forewarned us). Medical practitioners' records and tympanometry during routine follow-up in the field will provide additional outcome measures. Ideally, future studies should include clinical examination of ears at every follow-up visit as has been done elsewhere.⁶ The statistical power of our study to investigate interactions in detail will be low. However, causal pathway analysis uses all available knowledge to construct causal diagrams, then examines the data 'to see if they are consistent with the diagrams' and utilises 'changes in magnitude of... estimates between different models' to determine how interactions between factors may influence risk of disease.¹⁹

Despite the limitations of our study, we have a wealth of information on microbiological, immunological and sociodemographic factors that have not been investigated previously in a single study. Our findings will provide essential information to develop appropriate interventions to limit the serious consequences of OM in Aboriginal and non-Aboriginal children.

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