

'We are Not Just Participants—We are in Charge': The NACCHO Ear Trial and the Process for Aboriginal Community-controlled Health Research

Sophie Couzos, Traven Lea, Richard Murray & Margaret Culbong

Objective. *Methodological criteria that characterise ethically sound community-based studies are often described in overviews but are rarely documented in clinical studies. Research investigating the health of Aboriginal Australians is often small-scale, descriptive and largely driven by non-Indigenous people. The 'community-controlled' model of research relating to Aboriginal peoples health is a form of 'participatory' research that shifts the balance of control towards those being researched. This paper describes the methodological issues and principles that underpin community-controlled health research; their practical application; and encourages their adoption in research involving Indigenous populations.*

Design. *Descriptive report of the methods used to conduct the landmark Aboriginal community-controlled multi-centre double-blind randomised controlled clinical ear trial investigating ototopical treatments for chronic suppurative otitis media.*

Results. *The characteristics of the community-controlled research model are illustrated under the headings of: setting the research agenda; research project planning and approval; conduct of research; and analysis, dissemination and application of findings.*

Conclusion. *The 22 methodological elements which defined the community-controlled design of the ear trial may assist community groups, external research bodies and*

Correspondence to: Dr Sophie Couzos, Public Health Officer, National Aboriginal Community Controlled Health Organisation, PO Box 927 Broome, Western Australia 6725, Australia. Tel: +61 (08) 91925258; Mobile: +61 0417178514; Fax: +61 (08) 91925258; Email: scouzos@tpgi.com.au

funding agencies to improve the acceptability, quality and scope of research involving Indigenous peoples. Aboriginal community-controlled organisations are well placed to lead research, which can be interventional and of a high scientific standard without compromising the values and principles of those being researched. With over 120 Aboriginal community-controlled health services (ACCHSs) across Australia, the potential exists for these services to engage in multi-centre research to realise solutions to health problems faced by Indigenous Australians.

Keywords: Review; Participatory; Research; Indigenous; Aboriginal; Community-Based; Community Control; Ethics; Policy; Aboriginal Health Worker; Process; Methodology; CONSORT; Ear; RCT; CSOM; Suppurative; Otitis Media; Fluoroquinolone; Ototoxicity; Ototoxicity; World Health Organisation; Public Health; Chronic Suppurative Otitis Media; Hearing; Ciprofloxacin; Sofradex; Child; Human; Clinical; Trial; Guidelines; Ethnicity

Introduction

The 'community-controlled' model of health research represents a new standard of research involving the Australian Aboriginal population. It is type of 'community-based' or 'participatory' research that shifts the balance of control towards those being researched. Community participation is an ethical and democratic right and makes research more responsive to community needs (National Health and Medical Research Council [NHMRC] & Consumers Health Forum of Australia 2002). However, participation can range from consultation on pre-conceived research plans with individuals or community representatives, through to full community control whereby problems and the research solution are defined and undertaken by the community (Brager & Specht 1973). Many types of participative research have been described (Israel *et al.* 1998) but few studies have documented how community control is applied by Indigenous groups. Community-based research involving the Australian Aboriginal population remains mostly descriptive: there are few controlled clinical trials (Morris 1999) and a focus on identifying solutions to health problems is lacking (Atkinson *et al.* 2002).

The bulk of research examining the differential health status of the Australian Aboriginal population involves Aboriginal people only as subjects. Whilst more Indigenous Australian individuals are now involved as co-researchers, and partnerships between non-Indigenous researchers, Aboriginal communities and organisations exist (Mathews 1998), it remains rare for research to be initiated, driven and implemented by Aboriginal communities or representative agencies.

Aboriginal community control of services and programs is an expression of Indigenous peoples' right to self-determination (United Nations Economic and Social Council 1994). Over the past 30 years, more than 120 Aboriginal community-controlled health services (ACCHSs) have been established across Australia in order to provide culturally appropriate, accessible health services in a setting characterised

by significant healthcare disparities and discriminatory practices on the part of many healthcare providers. These services are initiated, governed and mandated by the Aboriginal population who use the services (the 'community') and provide primary healthcare to a substantial proportion of the Aboriginal population (Murray *et al.* 2003; NACCHO & DoHA 2003). Through employment, engagement, empowerment and social action, ACCHSs have become strategic sites for Aboriginal community development (Murray *et al.* 2003). Service models that are not classified as community-controlled are those where the decision making and management of resources ultimately resides with the government or an externally contracted agency. ACCHSs are members of the National Aboriginal Community Controlled Health Organisation (NACCHO), and nominate delegates to NACCHO from whom a national Board of Directors is elected. NACCHO is the peak non-government body in Aboriginal health in Australia and has a small secretariat located in Canberra, Australia (NACCHO 2003a).

To undertake research, Aboriginal representative organisations or communities have generally required partnerships with research agencies for two main reasons. Firstly, funding bodies in Australia require an appropriate administering institution—usually a university. Secondly, the lack of research infrastructure investment in Aboriginal community-controlled health organisations in Australia means that Aboriginal organisations have to negotiate access to technical expertise from external agencies.

It was within this context that a landmark double-blind, multi-centre, randomised controlled trial (RCT) was developed, managed and conducted by NACCHO in 2001–2002, and known as the 'NACCHO ear trial' (Couzos *et al.* 2003). The main source of funding was the National Health and Medical Research Council (NHMRC). To our knowledge this trial was the largest to ever examine the management of chronic suppurative otitis media (CSOM) in Australia. It was also the first time that multi-centre research had been led by ACCHSs. In 2003, it was judged the best research published in the *Medical Journal of Australia* (Van Der Weyden 2004).

CSOM is a chronic infection of the middle ear characterised by otorrhoea through a perforated tympanic membrane (Couzos *et al.* 2001). It is a major cause of hearing loss among Australian Aboriginal children, with rates of disease exceeding the World Health Organisation's (WHO) definition of a massive public health problem (WHO/CIBA Foundation 1998).

The NACCHO ear trial is used here to illustrate principles that underpin Aboriginal community-controlled health research, to identify methodological issues and so promote their practical application in research involving Indigenous populations. The characteristics that were seen as critical to the success of the trial (Box 1) are based on what is already known about participatory research (Israel *et al.* 1998), the principles of Aboriginal community control (NACCHO 2003a), existing NACCHO endorsed ethical guidelines (National Aboriginal and Islander Health Organisation [NAIHO] 1991; NHMRC 1991; Todd *et al.* 2000) and lessons learned in the conduct of the trial.

Box 1 The Characteristics of Aboriginal Community-Controlled Health Research**Setting the Research Agenda**

- Community-driven research is strategic and based on priority needs.
- The power differentials between community-representative bodies and external research bodies are balanced.
- The research focus is holistic and not just biomedical.
- The generalisability of research findings is considered.
- The capacity of community-controlled services is enhanced.
- Multi-centre research involves national community-based leadership.

Research Project Planning and Approval

- Ethical clearance for Aboriginal health research is given by Aboriginal Human Research Ethics Committees.
- The benefits and risks of the research to the individual and the population are carefully examined.
- There is valid consent from community representative bodies.
- The support that community bodies need for research to proceed is carefully appraised.
- The trial interventions are sustainable.
- The *time* required to plan and implement research is realistic.
- The *cost* required to plan and implement research is realistic.

Conduct of Research

- There is no research without service while the problem of 'no service without research' is avoided.
- Research coordinators have skills in cross-cultural communication and are respectful of community structures.
- There is appropriate and informed client consent.
- Local community-based leadership and communication networks are harnessed.
- The approaches to data collection and management are flexible.

Analysis, Dissemination and Application of Findings

- The ownership of intellectual property is vested in community-representative bodies.
- There is appropriate early community feedback.
- Communities are enabled to document their experiences.
- Research leads to actions promoting policy changes.

Characteristics of a Community-Controlled Research Process

The NACCHO ear trial aimed to compare the effectiveness of ototopical ciprofloxacin (Ciloxan, Alcon Labs, Sydney) with the usual topical CSOM treatment available in Australia at the time. This treatment comprised a combination of framycetin (an aminoglycoside), gramicidin and dexamethasone (Sofradex, Aventis Pharma Pty Ltd, Sydney) (Writing Group for Therapeutic Guidelines Limited 2003). The hypothesis was that the use of ciprofloxacin in children would increase the resolution of otorrhoea by 20% over the use of Sofradex, after nine days of twice-daily treatment. To be included in the study, children were required to be less than 15 years of age with at least two weeks of otorrhoea and tympanic membrane perforation.

The detail of the RCT methodology has been published elsewhere (Couzos *et al.* 2003) in accordance with CONSORT (Consolidated Standards of Reporting Trials) standards (Moher *et al.* 2001). These standards list 22 items to include when reporting a randomised trial but do not require reporting on participatory research principles, nor ethics criteria (Weingarten *et al.* 2004). We outline 22 additional principles (Box 1) that characterised the methodology of the Aboriginal community-

controlled NACCHO RCT under the headings of: setting the research agenda; research project planning and approval; conduct of research; and analysis, dissemination and application of findings.

Setting the Research Agenda

Community-driven research is strategic and based on priority needs

The research questions for the NACCHO ear trial were developed strategically in recognition of the substantial excess burden of disease faced by Aboriginal Australians in an environment of clinical practice uncertainty. Strategic research involves generating questions against explicit priority-setting criteria (Wills & Health and Medical Research Strategic Review Committee 1999) and is particularly important for disadvantaged and marginalised communities because scarce research funds should be directed to areas most likely to improve health inequities. Participatory research principles recognise that the community facing these problems should be driving this strategic process and setting the research agenda. In 1989, Indigenous Australian leaders remarked that:

every approach to inquiry research is based on a set of assumptions. The framework, the cultural, and philosophical value system within which the research is conceived, designed and conducted . . . reflects the values of the dominant culture . . . Aboriginal research, rather than reflecting the fancy of the individual researcher, needs to become problem oriented and . . . the community should be involved in framing the questions so that the research is relevant to their needs. (National Aboriginal Health Strategy [NAHS] 1989)

To this end, NACCHO undertook a systematic review of the literature on the management of otitis media (Couzos *et al.* 2001) which was used to identify gaps in knowledge and to frame research questions in the management of CSOM. These were subsequently prioritised in a national workshop (supported by the Australian Government and the NHMRC) attended by Aboriginal community representatives and researchers (NACCHO 1998).

One of those questions concerned the role of new ototopical antibiotics such as ciprofloxacin (a fluoroquinolone) as treatment for CSOM. Having identified CSOM as a priority, the prospect of a more effective treatment for CSOM appealed to the NACCHO Board of Directors. Given the concern over the use of topical aminoglycosides for CSOM because of their potential for ototoxicity (Couzos *et al.* 2001) a research question was developed, championed by the NACCHO Chair, and approved at the NACCHO Annual General Meeting in 1998 which was attended by over 150 Indigenous Australians.

The above describes a rigorous approach to priority setting, but there are other mechanisms that could have also been used (Kalucy *et al.* 2001; Field & Wakerman 2002).

The power differentials between community representative bodies and external research bodies are balanced

Control over the research process in Australia is predominantly vested in research institutions. ACCHSs generally lack a track record and infrastructure for research, and they tend to be reliant on external institutions to sponsor, validate and legitimise their research ideas. Moreover, when it comes to seek funding, the authority and expertise of community leaders are not recognised by funding bodies in the rating of submissions.

As external research agencies increasingly seek to engage with Aboriginal communities for research, this interdependence provides an incentive for partnerships (Eades & Read 1999; Henderson *et al.* 2002; Holmes *et al.* 2002; Pyett 2002). However, such partnerships are inherently unbalanced without research staff based in the ACCHS sector. As more Aboriginal communities and representative bodies themselves initiate the partnership process, the willingness of traditional research bodies to share or even relinquish control is tested.

NACCHO initiated the research partnerships for the conduct of the ear trial, and this helped ensure that leadership came from the Aboriginal organisation, not the other way around. A formal partnership between NACCHO and James Cook University (JCU) involved the development of a Memorandum of Agreement vesting financial administration of the research project with the university whilst control over the conduct of the trial and research process remained with NACCHO.

A technical consortium was established by NACCHO and comprised experts such as otolaryngologists and organisations including JCU, the Telethon Institute for Child Health Research, Australian Hearing and the Western Australian (WA) Centre for Pathology and Medical Research. The consortium provided assistance in the preparation of the protocol, in the training of Aboriginal Health Workers (AHWs) and data analysis. NACCHO was well positioned to balance the need for 'process' in the conduct of the research with the 'task' of the research—a common source of conflict between partners (Israel *et al.* 1998).

To maximise scientific rigour, blinding and randomisation were agreed to be essential to the design of the ear trial. Blinding was achieved by sterile transfer of ototopicals into identical glass droppers, so that it was not possible for health workers or clients to discern between randomly assigned treatments. Parents and guardians were aware that if their children took part in the trial they would receive either current ototopical treatment (as they would without trial participation) or the new ototopical and that both agents were effective treatments. In this way, blinding and randomisation did not impair a client's authority or capacity to make decisions about their treatment. At the same time, blinding and randomisation met the criteria for good research design that controls for bias and helped counter the criticism that community advocates do not make objective researchers (Pyett 2002).

The research focus is holistic and not just biomedical

ACCHSs view health as more than just the physical well-being of an individual, but also the 'social, emotional and cultural well-being of the whole community' (NACCHO 2003a). In addition to the evaluation of treatments, the ear trial examined risk factors for CSOM (Couzos *et al.* 2003), the impact on school absenteeism (NACCHO 2003b), bacteriological outcomes and quality of life issues. It also raised community awareness of CSOM. While this increased the complexity of the research protocol, this was outweighed by the additional benefits that could then accrue from the study.

The generalisability of research findings is considered

Aboriginal health research was once dominated by anthropological studies that were used to racially vilify Indigenous Australians and justify assimilationist and 'White Australia' policies of the past (Anderson 2002). Policy makers now tend to place emphasis on commissioning research that examines whether treatments or health systems applied to Indigenous Australian populations and healthcare settings achieve the same outcomes as already shown for the general population. The 'transferability' or 'generalisability' of research is the inference that research findings in one population can be applied to others. However, the generalisability of research is usually more about characterising the influence of factors other than 'race'/ethnicity *per se*—such as age, sex, degrees of biomedical risk, diagnostic skill of practitioners, sub-optimal resources, client adherence, culture and socio-economic disparities (Radford *et al.* 1999; Bradby 2003). There is little evidence that *ethnicity* predicts differences in pharmacological responsiveness because it cannot be given a precise biological definition (Nuffield Council on Bioethics 2003). In contrast, a genetic basis for differences in *individual* drug responses has been shown between men and women, such as in their responsiveness to nicotine patches (Yudkin *et al.* 2004). Given the significant heterogeneity of the Aboriginal population within Australia, it is not possible to make any generalisation about an ethnographic basis for differences in drug responses (Couzos & Murray 2003).

The prevalence of CSOM is so high among Aboriginal children, and such a common presentation in ACCHSs, that all subjects in the trial were identified as Aboriginal even though ethnicity was not an inclusion criteria. CSOM is an issue in Indigenous Australians because of social and environmental factors and is not a feature of certain ethnic/racial groups (Couzos *et al.* 2001). As such, the results of the ear trial (being also community-based) reflect the real world and are broadly applicable to other populations.

The capacity of community-controlled services is enhanced

Community-based research aims to explore real-life outcomes (especially of interventions) and in the process, build community resilience and capacity (Israel *et al.* 1998). According to the NHMRC, Aboriginal health-related research 'must develop that community's capacity and infrastructure... through enabling and

supporting community participation and management of the research process ...? (Research Agenda Working Group [RAWG] of the NHMRC 2002).

Enhancing community capacity can be difficult given the dichotomy in traditional research between consumers (patients or organisations representing consumer interests) and research bodies (NHMRC & Consumers Health Forum of Australia 2002). This distinction can be reduced if consumer representative bodies undertake their own research or research partners grant them control over the research process.

For example, the ear trial was conducted by Indigenous Australians within their own representative health services. Eight ACCHSs across Queensland and Western Australia took part in the trial. All 13 researchers administering the research protocol were local AHWs selected and employed by these services with trial funding. Training of AHWs in the trial protocol was conducted at an ACCHS in Perth over one week, although most had previously completed a Federal Government-sponsored hearing health training program. AHWs already had a pivotal role providing treatment for CSOM in ACCHSs and the extension of that role in the ear trial was logical. Empowering this workforce to undertake research provided direct benefits to AHWs and the client population (McMasters 1996; Hecker 1997).

Ensuring ACCHSs can undertake their own research has been a recommendation of the National Aboriginal Health Strategy since 1989 (NAHS 1989). (See also '*The benefits and risks of the research*').

In contrast, traditional research methodology usually relies on institutionally appointed researchers who are external to the community (and who often do not belong to the same ethnic groups) to implement the research protocol. This approach may divert resources away from community-run health services or undermine their role as key service providers (particularly if government-run health services are seen to offer researchers a more familiar, quicker alternative).

Multi-centre research involves national community-based leadership

Undisputed leadership is a necessary requirement to coordinate research on a national scale. In Australia, the Aboriginal community-controlled health sector has vested that leadership role in NACCHO (NACCHO 2003a). The relationship between NACCHO and its member services in the ear trial was an enabling factor for services to work together towards a tangible national goal, for conflict resolution, research protocol refinement, and for the translation of research findings into a national policy context. In contrast, most health-related research involving the Aboriginal population is small-scale and often involves one State/Territory or one community.

Research Project Planning and Approval

Ethical clearance for Aboriginal health research is given by Aboriginal Human Research Ethics Committees

Within Australia, it is not uncommon for research involving Indigenous Australians' health matters to be approved by mainstream human research ethics committees

(HRECs) yet be deemed unacceptable to Aboriginal communities and their representative organisations. Consequently, in many jurisdictions, Aboriginal HRECs have been established with the aim of reviewing the ethical quality of research proposals involving the health of the Aboriginal population. Aboriginal HRECs are distinguished by majority membership from Indigenous Australians and involvement of NACCHO Affiliates (Aboriginal peak bodies at State and Territory level representing the Aboriginal community on health matters) which helps ensure direct accountability to the Aboriginal population (Todd *et al.* 2000). The Western Australia Aboriginal and Health Information Ethics Committee (WAAHIEC 2000) is one such HREC and provided ethical clearance for the ear trial in WA. In Queensland, in the absence of an HREC linked with the Queensland Aboriginal and Islander Health Forum (QAIHF, an affiliate of NACCHO), the Ethics Review Committee (Human Ethics Sub-committee) of JCU approved the Queensland arm of the study. QAIHF was formally invited by NACCHO to appraise the trial from an ethics perspective independent of JCU.

NACCHO is of the view that all health research on Aboriginal peoples should be referred to such Aboriginal HRECs (NACCHO 1997). Where Aboriginal HRECs are still being established, research applications should be referred to the appropriate State or Territory Affiliate of NACCHO (NAIHO 1991). Referral of Aboriginal health-related research to HRECs that are not associated with NACCHO Affiliates tends to disempower representative structures developed by Aboriginal communities and thereby diminishes community control over the research process.

The benefits and risks of the research to the individual and the population are carefully examined

The World Medical Association Declaration of Helsinki states that ‘medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research’ (Dodson & Williamson 1999). The NHMRC requires researchers to specify beneficial outcomes of research involving Aboriginal populations (RAWG of the NHMRC 2002), but what may constitute a benefit or potential harm is often unclear (McAullay *et al.* 2002). Some research such as studies of human genetic variation, may expose whole communities to risk (such as through discrimination)—not just the individual subjects of the research (Bhopal 1998; Dodson & Williamson 1999). Ultimately, it is the community that must decide the balance between protecting its broader interests and concerns for the advancement of knowledge (Sharp & Foster 2002).

The structure of Aboriginal HRECs ensures that they are well placed to ascertain the risk that research may pose to the non-participating Aboriginal population. The ear trial was deemed by an Aboriginal HREC not to pose a risk to those outside the trial. Rather, it was considered to offer benefits, which may extend to the Aboriginal population as a whole.

The benefits to subjects participating in research may be both immediate (if standard treatment or a potentially better alternative is received) and delayed

(if access to future treatment is improved such as through health system reforms) (Bhutta 2002). In the ear trial, the likelihood of benefit for individuals was maximised by not using a placebo treatment arm—based on evidence from meta-analysis of the effectiveness of ototopical antibiotics over placebo (Acuin *et al.* 2003). Since treatment for CSOM is often not sought by families (Couzos *et al.* 2001), had it not been for the awareness raising element of the trial, many children would not have received ototopical antibiotics at all.

The confirmation of likely causal associations in CSOM (such as the degree of overcrowding in housing) added to the weight of evidence for improved provision of services and social infrastructure in Aboriginal communities (Couzos *et al.* 2003). The ear trial also augmented *service* delivery in four ways: workforce support (for ear-related and child health duties); provision of equipment (such as video otoscopy); health worker training; and local partnerships with public health nurses, schools and other community structures. It also paved the way for lasting relationships with other research bodies for future research.

There is valid consent from community representative bodies

The consent of individual research subjects is distinct from seeking the consent of the ‘community’. Resolving issues around who or which body speaks for the ‘community’ is of critical importance and distinguishes research involving specific ethnic populations from mainstream research. Consequently, formal contact with representative health organisations early in the research design process is recommended internationally (World Health Organisation 2003) (Maori Health Committee of the Health Research Council of New Zealand undated). Australian researchers have at times failed to engage with appropriate Aboriginal representative structures (deliberately or unwittingly) and may instead rely on informal community linkages with a few individuals and so generate conflict (NAIHO 1991). It is not uncommon for Aboriginal representative bodies to have their ‘representativeness’ challenged. An extensive national consultation strategy exploring this issue in 2002 reported that ‘... no elected representatives from mainstream politics or from non-Aboriginal health organisations (such as medical organisations) have the support of or speak for all sections of their constituency, [yet] this is never questioned’ (Kimberley Aboriginal Medical Services Council [KAMSC] *et al.* 2002).

For consultation on health matters affecting Aboriginal peoples, representative bodies in Australia have established that the primary point of contact should be the local ACCHS and where no such body exists, the NACCHO Affiliate in that State and NACCHO, particularly for multi-centre research (NAIHO 1991; KAMSC *et al.* 2002).

The ear trial was atypical (if not unique) in that the community-controlled health sector was the instigator of the research. Nevertheless, as all ACCHSs are independent bodies, NACCHO brokered formal research agreements with these services. The agreements set out roles and responsibilities based on core values and research tasks and were locally modified.

The support that community bodies need for research to proceed is carefully appraised

Assessing the feasibility of the protocol in community-based research is critical, as complex protocols and other factors may set community bodies up to fail (Sibthorpe *et al.* 2002). This assessment should identify the nature and extent of support required for them to successfully undertake the research. Community bodies should be informed up-front what the expectations of the research protocol are, what burden this may impose, and what support they will receive to overcome these burdens (McAullay *et al.* 2002).

In the ear trial, whilst the protocol was complex (reflecting the holistic focus), three factors were identified as essential for the research to proceed: the presence of existing infrastructure (such as transport, soundproof rooms, audiometry equipment), incidence and prevalence of CSOM (a minimum number per month of children with CSOM being seen by the service was specified relative to the size of the service population), and the availability of expertise to support the program at community sites (such as a general practitioner and senior AHW). ACCHSs from around the country could nominate to take part in the trial if they fulfilled these criteria. Where minor infrastructure gaps existed, NACCHO provided support to these services (such as equipment for hearing health assessments).

The trial interventions are sustainable

For an intervention to be sustainable it must be able to be continued in the community setting after the departure of the research team. The NHMRC identified 'sustainability' as a core criterion for increasing the value of intervention-type research (RAWG of the NHMRC 2002). If project processes 'fit in well' with clinic processes (Sibthorpe *et al.* 2002), the intervention is more likely to be sustained.

The intervention assessed in the ear trial (ototopical agents administered along with ear washes) was specifically chosen to be relevant to ACCHSs. The workforce and infrastructure on which the intervention depended was no different in the trial to that typically available in these services. With a protocol based on procedures familiar to clinics and AHWs, the ear trial outcomes reflected those in the 'real' world.

CSOM continues (at the time of writing) to be managed in ACCHSs with regular clinical follow-up, ear washes and Sofradex (Writing Group for Therapeutic Guidelines Limited 2003) although policy reforms are in progress (see also 'Research can lead to actions prompting policy changes'). Moreover, the trial inspired some ACCHSs to expand their efforts on ear health, by providing a mobile ear service to outlying Aboriginal communities (personal communication M.C.).

The time required to plan and implement research is realistic

It takes time to establish a process in which several agencies make a formal and sustained commitment to work together to accomplish a national research goal. Without trust, integrity, an understanding of interdependence, and agreement on when involvement by other agencies may be needed, community-based research may not even get off the ground. The level of control sought by ACCHSs may challenge

external research agencies who are generally used to lesser levels of Aboriginal participation (especially if it assigns these external agencies an advisory role only).

Though NACCHO was able to use a pre-existing collaborative framework between its member services and external agencies, the planning phase of the ear trial lasted three years. It took another 15 months to recruit a total of 147 children with CSOM across sites during the clinical phase. While this made the trial the largest of its kind involving Aboriginal children with CSOM in Australia, the longer than anticipated time taken had a direct bearing on costs.

The cost required to plan and implement research is realistic

Undertaking research in cross-cultural settings can be costly (Holmes *et al.* 2002). Researchers and research funding agencies sometimes view efforts to engage appropriately with Aboriginal communities and their representative bodies as too expensive—suggesting that the ‘product’ purchased has little value to them. In addition, funding agencies gauge timelines and research costs against standards established for mainstream clinical research, which usually don’t apply in the community-based context.

For example, the ear trial budget did not allow for a sufficient *number* of AHWs to be employed based on NHMRC projections of the workload. The criterion used by the Chair of NACCHO to proceed or not proceed with the ear trial was a budget sufficient to employ AHWs from within ACCHSs on award rates of pay with back-up relief (for leave, family and cultural obligations). This was a more expensive option than external Indigenous research assistants employed by the university. The ear trial made AHW employment possible with supplementary funding obtained from alternative sources.

Also, the budget did not allow for AHWs to be employed for a sufficient length of *time*. Strict inclusion criteria resulted in slower recruitment of subjects than predicted at some sites. Despite two additional ACCHSs taking part in the study and substantial goodwill from services, AHWs could not be employed for the length of time needed to reach the required sample size and the trial was stopped when funding ceased. In the final analysis, however, the sample size proved to be sufficient to demonstrate a clinically important and statistically significant difference between the two treatment arms (Couzos *et al.* 2003).

Both these funding projections proved to be unrealistic in the community-based setting of the ear trial. The important point is that if funding is based on mainstream standards, it may not be enough for community-controlled research to commence at all.

Conduct of Research

There is no research without service while the problem of ‘no service without research’ is avoided

‘No research without service’ (Miller & Rainow 1997) is an important participatory research principle but is often translated in conventional research practice to mean

'no service without research', particularly when it involves needy populations such as Indigenous Australians. Incentives to participate in research have been offered to powerless communities in the form of medicine, food or services not otherwise available (Bhutta 2002). Clinical researchers may offer routine health service provision to remote Indigenous communities in return for research privileges and this can set up a situation that favours them from both sides of the research equation. For example, the community or representative body may strongly advocate for the continuation of research that has provided them with services out of concern that these may be withdrawn, whilst funding agencies are loath to discontinue funding for research that is so strongly supported by these bodies. Researchers therefore have a responsibility to advocate for sustained interventions through health system reform and community development in preference to more research funding.

The ear trial was designed so that participation neither advantaged nor disadvantaged Aboriginal clients. All participants received ototopicals (the 'service'), but ototopical treatment in accordance with Australian guidelines (Writing Group for Therapeutic Guidelines Limited 2003) would have still been received by clients attending ACCHSs if they decided not to take part in the trial. Written information to this effect was provided in plain language and documented in the client consent forms (NACCHO 2003c). See also '*Benefits and risk of research*'.

Research coordinators have skills in cross-cultural communication and are respectful of community structures

The skills base for community-based researchers includes:

competencies in addition to those required in research design and methods, for example: listening, use of language that is understandable and respectful, group process, team development, negotiation, conflict resolution, [operation] in multi-cultural contexts, ability to be self-reflective and admit mistakes, capacity to operate within different power structures and humility. (NAHS 1989; Israel *et al.* 1998)

The skills base of NACCHO research coordinators included an Indigenous Australian epidemiologist and investigators with a collective 24 years of experience working within the ACCHS sector, appointed by and directly accountable to the nationally elected 22-member Aboriginal Board of Directors.

There is appropriate, informed client consent

Consent forms have often been constructed in ways that have little meaning to research subjects and, if incomprehensible, pose a liability risk for healthcare providers (Paasche-Orlow *et al.* 2003). The consent process used in the ear trial involved plain language advice on: the reasons for the trial; research method; medication type; use and safety profile; explanation of the double-blind design; de-identification of data; period of follow-up; inclusion/exclusion criteria; and the

freedom to withdraw consent (NACCHO 2003c). This advice was delivered by AHWs trained (through role-play) to explain these messages using visual flipcharts and through use of plain language consent forms that were signed by parents or guardians.

Local community-based leadership and communication networks are harnessed

Whilst obstacles to the implementation of a research protocol are commonplace in community-based research, there are ways these can be minimised. In the ear trial, senior members of staff from the participating ACCHSs (such as AHW educators and doctors) took time to learn the trial protocol, support and supervise AHWs and facilitate regular communication with the NACCHO research coordinator. Such staff were not relieved of other duties and their activities were an indication of local commitment to the trial outcomes. Boards and senior of local ACCHS and managers of services were also involved, sanctioning staff commitment and giving their own time to the project. This type of local leadership and engagement was considered a critical success factor.

The colloquial term for CSOM—a ‘runny ear’—was also used to raise community awareness of the ear trial. Posters and pamphlets were designed featuring a ‘running ear’ (Figure 1).

The approaches to data collection and management are flexible

The dynamic context of community-based research means that some flexibility is required in the type of data that will be collected. This means collecting data that is necessary for the objectives of the research, but in such a way that it relates to the context and interests of the community (Israel *et al.* 1998; Humphery 2001). A variety of methodologies for measuring the same outcome may be necessary to account for unforeseen eventualities (e.g. power failure), or for validation. For example, ACCHSs



Figure 1 The ‘Running Ear’ Used to Promote the NACCHO Ear Trial.

sought to determine if otological antibiotics led to healing of tympanic membrane (TM) perforations but in the absence of an optimal method to determine this outcome, several methods were used. Video-otoscopic photographs were one method, and standard otoscopy and a four-scale grid to gauge the size of the perforations as a proportion of the TM surface area was another. Grid measurements were 87.5% concordant with perforation size estimated by at least one of two external otolaryngologists from TM photos (Couzos *et al.* 2003). Whilst the use of video-otoscopy was very popular among Aboriginal children and workers, it proved to be less valuable than the grid method due to occasional technical problems arising with the computer program. (See also '*The interventions are sustainable*').

Analysis, Dissemination and Application of Findings

The ownership of intellectual property is vested in community representative bodies

Many researchers fear that community-controlled research means losing control of the interpretation of research findings (Israel *et al.* 1998). Some suggest that Aboriginal communities may arbitrarily withhold permission for publication of research findings. Aboriginal community representatives see such exceptional action as justified when there is potential for harmful ramifications long after the research issues have been forgotten (see also '*The benefits and risks of the research*').

The issue of intellectual property between researcher and 'community' (Janke 1998) is less vexed if the community representative body is also the research agency. In the ear trial, service agreement contracts specified that intellectual property arising from the trial was vested in both NACCHO and the participating ACCHSs, with NACCHO having a licence to use the joint property for purposes related to improving the health of Indigenous Australians. Research partners may still find it difficult to 'let go' during the data analysis phase when undertaken by community bodies although the power balance then favours a more equal negotiation to resolve differences.

There is appropriate early community feedback

Researchers have a poor track record in reporting research findings back to Aboriginal communities in ways that are satisfactory, and if they do, it is often well after publication of the findings (McAullay *et al.* 2002). The release of research findings to Aboriginal communities prior to formal publication has been advocated as a code of ethics (Eades & Read 1999). Moreover, discussing all results with community bodies allows for joint interpretation of the data (Macaulay *et al.* 1999). The problem is that the early release of findings to research participants and representative bodies may bias against publication in a medical journal. Fortunately, most journals now permit the disclosure of results prior to publication in certain circumstances (International Committee of Medical Journal Editors [ICMJE] 1997).

The findings of the ear trial were reported to health workers, managers of health services and participating communities through ‘information days’ prior to publication. These sessions were used to disseminate a plain language report, receive feedback on the conduct of research and thank all those participating by hosting luncheons and providing specially designed T-shirts.

Communities are enabled to document their experiences

Whilst the primary aim of the trial was to build on the body of knowledge for the management of CSOM, in participatory research ‘new understandings [can] emerge as participants reflect on actions taken’ (Israel *et al.* 1998). Communities seldom have the power to define and document their own experience when participating in research. The ear trial is currently examining these ‘understandings’ from a focus group meeting held with AHWs to record their experiences.

Research can lead to actions promoting policy changes

All forms of research can be used as a lever to influence policy and health system reform, provided it is communicated properly (Milne 1999; Atkinson *et al.* 2002). Research can expand the range of therapeutic tools and improve clinical guidelines but only after the approval of medical and regulatory authorities. Consequently, it can be difficult to assure research subjects and community bodies of the long-term benefits of research as these are often outside the control of researchers.

The ear trial achieved its scientific objective despite a smaller sample size and found that in 111 Aboriginal children with CSOM, ciprofloxacin ear drops were 47% more likely to resolve otorrhoea after a single course of twice-daily treatment, than Sofradex (Couzos *et al.* 2003). The full impact of the ear trial in reforming the standard treatment of CSOM in Australia is yet to be seen although several regions in WA are now using ototopical fluoroquinolones in this way. An application to the Australian Therapeutic Goods Administration has been lodged which paves the way for listing these agents under Pharmaceutical Benefits Scheme which will enable those with CSOM to access subsidised medication. Incorporating research into the policy and advocacy work of community representative bodies means they are better placed to promote policy reform long after traditional research institutions would have moved on to different themes and contexts.

Conclusion

Methodological criteria that characterise ethically sound community-based studies have been described in overviews but are rarely documented in clinical studies because this is usually not required by journal editors (ICMJE 1997). This paper documents the methodological and ethical aspects of a landmark community-based, multi-centre, double-blind, RCT undertaken in Australia by Aboriginal community representative bodies.

We believe that Aboriginal community control from the outset of the ear trial research process prevented potential conflicts around design of the study, ownership of data, funding or other priorities, which have been common problems for community-research body affiliations. The trial confirmed that community-based research can be of a high scientific standard without compromising the values and principles of those being researched. The success of this trial design in terms of community empowerment and social benefit paves the way for more research of this type and demonstrates the untapped potential for ACCHSs to undertake large-scale research projects that examine practical solutions to Aboriginal health problems. Policy makers depend on such quality large-scale interventional research to direct resources into effective, acceptable and much needed programs for disadvantaged populations.

The 22 methodological elements which defined the community-controlled design of the ear trial may assist community groups, external research bodies and funding agencies to improve the quality and scope of research involving Indigenous peoples. Whilst the receptiveness of community groups and their representative bodies is acknowledged as important in the conduct of community-based research, this is often characterised as a 'political' or feasibility issue with the potential to compromise methodological rigour, rather than being considered a core element of research design (Atienza & King 2002). A checklist similar to the CONSORT statement that uses these or similar elements may be useful in ranking funding submissions for the conduct of community-based studies. In order to expand or improve on these elements, we encourage an explicit description of the research process from other community-based RCTs and studies that involve Indigenous populations and ethnic minority groups.

The sense of pride emanating from Aboriginal community-controlled research led the late Dr Puggy Hunter, former Chair of NACCHO and national Human Rights Medal recipient for 2001 (as instigator of this study in 1998) to comment that 'we are not just participants, we are in charge'.

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