

## The “NACCHO Ear Trial” – Aboriginal community controlled clinical research. Community controlled – not just community based

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... to identical glass bottles, so we weren't using the products as they are currently marketed. There was no way you could tell which agent was which. The glass bottles were labelled with the client ID. Each child that was enrolled in the trial was allocated a Client ID Number to maintain anonymity. They were packaged in a packet of four. That was so that each child, so here Client ID 249, had four bottles of the same agent assigned to them, so that if they lost a bottle (e.g. a bottle was dropped or they had re-occurrences of the infection) once randomised to that agent they stuck to that agent. So this Client ID 249 could have been Superfloxin, or it could have been Sofradex. So if they had repeat infections they got the same agent that they started with in the Trial.

These are the assessments the children had. Of course just the base line assessments. We also took the opportunity of looking for very important risk factors for runny ears – factors that are well known in the international literature and we wanted to document them in the Aboriginal situation, that is smoking, living conditions, overcrowding, any effect swimming might have, family size and so on.

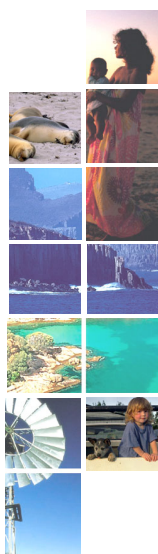
Also the clinical and follow-up aspects of the trial: photographing the tympanic membrane, grading the discharge, taking the swab, checking the bacteria and the antibiotic sensitivity of the agent, grading the perforation size to see if it healed over time and of course testing for hearing before and after.

Our primary outcome was clearance of the ear. A clinical cure was to find us a dry ear and the proportion of children with clinical cure after the initial treatment.

Our secondary outcome was to look at healing of the tympanic membrane and also improved hearing. We also looked at additional outcomes (very important). The bacterial profile of Chronic Suppurative Otitis Media, the validity of the WHO definition were very important. If after two weeks most of these children did not have the bacteria associated with Chronic Suppurative Otitis Media then maybe the six week definition is better, but if after these children actually have all those bugs that are known for a chronic infection than that validates the WHO definition.

Outcomes with twice daily dosages (very important) the development of antibiotic resistance to see if that happened, also to document the degree of hearing loss. Again not many studies actually report the degree of hearing loss of Aboriginal children with runny ears. Some quality of life and socioeconomic indicators, the effect of runny ears on school attendance and also importantly health worker perceptions of the research process.

This is all that I can report today. This is, I can say, the largest Clinical trial in Aboriginal children that we know of conducted in Australia – 147 children were



recruited in that period. 111 children completed the first follow up in 10–14 days – evenly randomised, 55 in the Superfloxin group, 56 in the Sofradex group and the findings are currently going to be reported first to the actual services that took part in the Trial before they are publicly released. That is part of our process.

There is an international conference, an Otitis Media conference, which we have applied to attend in June this year where we will publicly release the findings.

Going on to the process, how we did the Ear Trial, a very important element. How we started. We had a very comprehensive way of starting the Trial in that NACCHO completed a systematic review of the evidence of how to treat runny ears in this product. It is available on the Internet, funded by the Office of Aboriginal and Torres Strait Islander Health. We found that in collating all the information around the world about how to treat runny ears there were some research gaps and those research gaps were presented to the Board. There was a lot of interest by Puggy Hunter in terms of finding answers to some of these questions. There was a national workshop in Darwin in June 1998, attended by Puggy and Steve Larkham who was CEO at the time and other members as well as researchers, which prioritised the research questions, and then the key one about testing Sofradex and Superfloxin was put and confirmed at the NACCHO Annual General Meeting in 1998. Hence the Trial then started.

We set up national partnerships with external research bodies – very important. We established technical consortium. We had an administering institution. The NHMRC can only fund an administering institution so it was important that a relationship was established with James Cook University. But it was very clear from the beginning that NACCHO was the lead agency. The universities were not the lead agencies, it was NACCHO.

We established formal research agreements between NACCHO and the actual sites, even though Aboriginal Community Controlled Health Services are members of NACCHO it was very important to establish clear roles and responsibilities in order to succeed in the Trial, and this process was extended through as I said a number of sites and it enabled research on a national scale, which isn't usually done in Aboriginal health. There are a lot of research studies that are reported relevant to Aboriginal health and conducted in Aboriginal communities but they are often very small-scale, single communities, often over-researched, but very, very rarely do you get national-scale research, something that is really under-valued in Australia.

These are the Trial sites. This is a photograph here of the Derby Aboriginal Health Service where the building where the Ear Study was conducted and each service had a similar allocation of space for the Ear Trial. I would like to acknowledge all those sites so from across Western Australia and Queensland.

We enhanced the capacity of our services. We had a research team comprising thirteen Aboriginal Health Workers who were all trained to undertake the Trial Protocol and also have support persons at each site as well to, if there were any issues that were locally relevant that support person could help but if there were issues that they couldn't immediately deal with we had a Clinical Project Officer, Traven Lea, who dealt with all those problems and he was available every day all of the time.

We supported the research process, we provided equipment, videotoscopy equipment, and salaries for the Health Workers. As I said we provided all the training.

