

**CENTRES OF CLINICAL EXCELLENCE  
IN HOSPITAL-BASED RESEARCH**

**EVALUATION REPORT**

**APRIL 2001**

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## EXECUTIVE SUMMARY

### **Background**

The Centres of Clinical Excellence in Hospital Based Research (CCE) Program was initiated in 1997. The original aims of the Program were:

- To foster clinical research and training of clinical researchers
- To support innovative clinical research, including clinical research with potential to translate into successful clinical treatments
- To ensure effective translation of biomedical research into clinical practice

One hundred and nine expressions of interest were received, from which 20 were short-listed. Following the submission of full applications and further review, nine awards were made.

Chief Investigator	Title of Centre	Focus of Centre	Location
Prof Barclay	Midwifery Practice and Research Centre	Midwifery Practice	St George Hospital, Sydney
A/Prof Brewster	Darwin Clinical Research Unit in Aboriginal Health	Aboriginal Health	Flinders University NT Clinical School, Royal Darwin Hospital, Darwin
Prof Cousins	Centre for Anaesthesia and Pain Management Research	Pain Management	Royal North Shore Hospital, Sydney
Prof Donnan	Clinical Neuroscience: Epilepsy and Stroke	Epilepsy and Stroke	Austin & Repatriation Medical Centre, Melbourne
Dr Halmagyi	Centre for Neuro-Otology	Balance Disorders	Royal Prince Alfred Hospital, Sydney
Prof Jennings	Cardiovascular Applications in Clinical Research	Cardiovascular Medicine	Alfred and Baker Medical Unit, Melbourne
Prof Marshall	NHMRC Centre for Clinical Excellence in Urological Research	Urology	Repatriation General Hospital, Adelaide
Dr Mountford	Institute of Magnetic Resonance Research	Magnetic Resonance	Royal North Shore Hospital, Sydney
Prof Puddey	Centre for Training in Clinical Cardiovascular Research	Cardiovascular Medicine	Royal Perth Hospital, Perth

Funding was initially for 3 years. However, in December 2000, the Minister for Health and Aged Care approved a six-month funding extension for the nine Centres to enable an evaluation of the Centres and the Program as a whole.

The following Evaluation Committee was appointed to undertake the review

- Professor Don Cameron (Chair) - SRDC member, (Princess Alexandra Hospital, Queensland)
- Mr John Delaney - SRDC member and Chair, Research Agenda Working Group (RAWG)
- Associate Professor Peter Fuller – Chair, NHMRC Training Awards Committee (Monash Medical Centre and Prince Henry’s Institute of Medical Research, Victoria)
- Dr Margaret Davy - (Royal Adelaide Hospital, South Australia)
- Professor Meg Morris - (La Trobe University, Victoria)
- Dr David Roder - (South Australia Health Commission, South Australia)
- Professor Judith Whitworth - (John Curtin School of Medical Research, Australian Capital Territory)

In January 2001, the Centres were asked to complete an evaluation proforma. Site visits were undertaken by the Evaluation Committee in March 2001 to supplement the information presented in the proforma.

## **Evaluation**

Overall, the Program has been highly successful in meeting its objectives, although to varying degrees in the different Centres.

- It is clear that the Program has resulted in enhanced training opportunities in clinical research and has been valuable in demonstrating different approaches to attracting clinicians<sup>1</sup> to undertake clinical research training.
- Clinical research has been enhanced within the Centres, both with respect to the rate of progress of existing research, and to the initiation of new research.
- Translation of research findings into practice has begun but, not surprisingly given the time frame of the Program, is not yet widespread.

Important observations made by the Evaluation Committee regarding the Program include:

- The Program has been important in demonstrating that the Government and the National Health and Medical Research Council (NHMRC) have a commitment to clinical research, the development of competent clinical investigators, and to the translation of clinical research into practice.
- The designation of a Centre as a CCE gave considerable status which was beneficial in the following:
  - Attracting further funds and facilities
  - Enlisting high calibre staff
  - Attracting students.
- The existence of the CCE Program was instrumental in the creation of some Centres. The Program was a catalyst for strengthening interactions within other Centres, giving greater coherence in training and research activities.
- The CCE structure enhanced interdisciplinary research and created an important bridge between investigators and other clinical staff in some Centres.
- Three years is probably too short a time to embed the benefits of the funding and to assess the outcomes, especially for the translation of CCE funded research.
- The relatively flexible nature of the funding allowed certain infrastructure developments rarely possible under Program and project grant funding. This included the development of databases and gene and tissue banks that will underpin future clinical research. The flexibility also allowed groups to capitalise on the opportunistic nature of some clinical research.
- Although not a condition of award, community consultation about the directions of research and significance of outcomes could have been enhanced. This is of particular relevance to Indigenous communities and other disadvantaged groups.
- More interaction with State and Territory Health Departments would aid translation of research into outcomes and incorporation of research findings into policy.

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<sup>1</sup> From medical and non-medical backgrounds

## **Recommendations**

It is recommended that:

1. A new round of Program funding be approved to commence as soon as is practical, based on the model proposed below.
2. In a new Program round, specific funding be allocated for a designated Centre of Clinical Excellence in Aboriginal and Torres Strait Islander Health.
3. Funding of the current Darwin Clinical Unit in Aboriginal Health be maintained until the future funding of the CCE Program is determined.

## **Proposed model for future CCE Program**

### **Aims**

- To foster training of clinical researchers, including those with capacity for independent research and future leadership roles
- To support clinical (human) research with potential to lead to improved health care
- To ensure effective translation of research outcomes into clinical practice as widely as possible

### **Characteristics of Proposed Program**

- Five year Program, with a funding-dependent review after three years
- Funding level to be based on quality and scope of Program, and at an amount that justifies the designation of the group as a 'Centre of Clinical Excellence'
- Further funding of existing Centres of Clinical Excellence be awarded if evidence of additional benefit is demonstrated
- Funding provided in a way that is both flexible and accountable
- Evidence of appropriate community consultation required
- Proposals able to include clinical research in appropriate non-hospital clinical/health care settings
- Expectation that Centres will develop strategies for sustainability during term of grant
- Multidisciplinary collaboration encouraged
- Where appropriate, provide evidence of consultation with public health specialists and health officials, and encourage collaboration of government agencies in translating research outcomes and influencing health policy.

## **BACKGROUND**

The *Centres of Clinical Excellence in Hospital-Based Research* initiative was outlined in the then Opposition's "Health Throughout Life" policy document in 1996. Funding of \$1.5 million per annum was allocated in the Coalition's 1996-1997 Federal Budget to promote innovative clinical research and to address a perceived gap in maintaining and developing clinical research in hospitals and other health care delivery units. The Program proposed that Centres would identify, develop and practise evidence-based medicine, and would strategically link innovative research to clinical treatment.

The Government referred this initiative to the National Health and Medical Research Council (NHMRC), which, ultimately, delegated responsibility for the Program to the Strategic Research Development Committee (SRDC), Chaired by Dr John Best. The SRDC was formed to develop a strategic research capability in areas where the research effort is not commensurate with the magnitude of its importance to health care in Australia. The SRDC assumed responsibility for the CCE Program in July 1997. The Centres of Clinical Excellence Working Group was established, under the Chairmanship of Professor Donald Cameron, to oversee the Program.

### **Establishment of the Centres**

The overall aims of the Centres of Clinical Excellence Program were developed through analysis of the content of the "Health Throughout Life" policy document. They were as follows:

- to foster clinical research and training of clinical researchers
- to support innovative clinical research, including clinical research with potential to translate into successful clinical treatments
- to ensure effective translation of biomedical research into clinical practice.

Applications were particularly encouraged in the then NHMRC 'Special Initiative Areas' (SIAs) of: Aboriginal and Torres Strait Islander health; alcohol and substance abuse; prostate cancer; dementia; injury; nursing and allied health services; and schizophrenia. Applications were also sought from regional and rural research areas.

The NHMRC established an expert committee to make recommendations on the funding of applications under the Government's Centres of Clinical Excellence in Hospital-Based Research Program. The terms of reference and original membership of the Centres of Clinical Excellence (CCE) Working Group are at *Attachment 1*.

The CCE Working Group received 109 expressions of interest and assessed these against the Program's aims, the quality of the proposal, the track record of the investigators, and the potential cohesiveness of the investigatory group. Consideration was also given to whether the proposal had a focus in one or more of the sought after areas (SIAs or regional/rural). The CCE Working Group invited 20 applicants to submit a full application in which they could expand on their proposal using a proforma. Full applications were received in June 1997.

Each full application was sent to three independent peer assessors. Assessors provided numerical scores, and written comments in support of these scores against the criteria for the Program. Applicants were then provided with deidentified assessor comments and given the opportunity to respond. The CCE Working Group then considered the full proposals, together with assessor comments and applicants' responses, for each application.

The CCE Working Group recommended to the SRDC that the available Program funds be used to fund the eight highest ranked applications. The CCE Committee also recommended that the most highly ranked application looking at Aboriginal and Torres Strait Islander health be supported, if other funds could be identified.

The SRDC endorsed the CCE Working Group's recommendation to fund the eight highest ranked proposals, and also agreed with the imperative to support the top Indigenous health application. The SRDC decided to support the Aboriginal and Torres Strait Islander health centre from its own strategic budget.

The SRDC then recommended to the Minister for Health and Aged Care to support the eight highest ranked applications, plus the highest ranked Indigenous health application. The Minister approved these recommendations.

Consequently, nine Centres of Clinical Excellence were funded, each for three years. The nine Centres were as follows:

Chief Investigator	Title of Centre	Focus of Centre	Location
Prof Barclay	Midwifery Practice and Research Centre	Midwifery Practice	St George Hospital, Sydney
A/Prof Brewster	Darwin Clinical Research Unit in Aboriginal Health	Aboriginal Health	Flinders University NT Clinical School, Royal Darwin Hospital, Darwin
Prof Cousins	Centre for Anaesthesia and Pain Management Research	Pain Management	Royal North Shore Hospital, Sydney
Prof Donnan	Clinical Neuroscience: Epilepsy and Stroke	Epilepsy and Stroke	Austin & Repatriation Medical Centre, Melbourne
Dr Halmagyi	Centre for Neuro-Otology	Balance Disorders	Royal Prince Alfred Hospital, Sydney
Prof Jennings	Cardiovascular Applications in Clinical Research	Cardiovascular Medicine	Alfred and Baker Medical Unit, Melbourne
Prof Marshall	NHMRC Centre for Clinical Excellence in Urological Research	Urology	Repatriation General Hospital, Adelaide
Dr Mountford	Institute of Magnetic Resonance Research	Magnetic Resonance	Royal North Shore Hospital, Sydney
Prof Puddey	Centre for Training in Clinical Cardiovascular Research	Cardiovascular Medicine	Royal Perth Hospital, Perth

### **Interim review of the Centres**

In order to monitor the progress of the Centres, the funded Centres were required to participate in an interim review in November 1998. At that stage, eight of the nine Centres had been operational for twelve months. The Darwin Centre also completed an interim review in November 1998, although it had only been operational for approximately six months due to its later commencement date.

In their responses, the majority of the CCE's concentrated on the number and extent of training of clinicians and other health professionals.

The overall findings of the interim review were that the Centres were making excellent progress in relation to clinical training, and in conducting innovative research. In summary, the review found that:

- There was possible scope for the Centres to formalise their research methodology training structure, and to incorporate this training in the host institution's overall environment (for example, to make the training part of the host institution's postgraduate training modules)
- Collaborations between the Centres could be fostered, where appropriate, to promote and encourage synergy and sharing of ideas and methodologies
- There was a need to improve communication between all sectors of Government to ensure that research initiatives were effectively translated into practice
- A future evaluation needed to include questions relating to the distribution and allocation of funding within the Centre and the institution, so that the true level of funding necessary to achieve the aims and objectives of the Programs could be ascertained.

These findings were reported to the Minister in August 2000. As the findings from the Interim Review were based on only 12 months progress, an evaluation of the Centre's achievements at the completion of the Program was recommended.

### **Evaluation of the Centres**

In December 2000, the Minister for Health and Aged Care approved a six-month funding extension for the nine Centres to enable an evaluation of the Centres and of the CCE Program as a whole.

The SRDC established an expert evaluation committee to undertake this task. The evaluation Evaluation Committee comprised the following members:

- Professor Don Cameron (Chair) - SRDC member, (Princess Alexandra Hospital, Queensland)
- Mr John Delaney - SRDC member and Chair, Research Agenda Working Group, (New South Wales)
- Associate Professor Peter Fuller – Chair, NHMRC Training Awards Committee (Monash Medical Centre and Prince Henry's Institute of Medical Research, Victoria)
- Dr Margaret Davy - (Royal Adelaide Hospital, South Australia)
- Professor Meg Morris - (La Trobe University, Victoria)
- Dr David Roder - (South Australia Health Commission, South Australia)
- Professor Judith Whitworth - (John Curtin School of Medical Research, Australian Capital Territory)

In January 2001, the Centres were asked to complete an evaluation proforma (see *Attachment 2*), commenting on the outcomes and activities of the Centre over the three-year term of the grant. In brief, the evaluation proforma requested that the Centres record the achievements against the original Program objectives, the training and research outcomes, the Centre's outreach performance and the strategy for the future of their CCE.

On receipt of the completed proforma, the CCE Evaluation Committee convened a teleconference to discuss the submitted evaluation proformas and identify issues of interest and concern. These

matters were discussed and clarified during site visits of the Centres in early March 2001. The site visits were conducted by the Chair of the CCE Evaluation Committee and two other Committee members (varying each day) and consisted of a three to four hour presentation/ interview/ discussion. *Attachment 3* gives further details of the site visit itinerary.

The Evaluation Committee's findings from the evaluation proforma and the site visits are presented and analysed in the remainder of this report. Recommendations are then made, for consideration by the Minister.

## **OUTCOMES OF THE CENTRES OF CLINICAL EXCELLENCE IN HOSPITAL-BASED RESEARCH PROGRAM**

Overall, it can be said that the Program has been highly successful, with Centres funded under the Program fostering high quality, collaborative research in the management of clinically relevant conditions, with the aim of improving clinical outcomes. Perhaps one of the most unique features of the Program was that the Centres both contributed to Australia's effort in delivering world class research, as well as to enhancing the training of new clinical researchers which, ultimately, will lead to clinical excellence.

### **Overall comments about the outcomes of the Program**

One of the striking aspects of the review of this Program was the fact that the CCE Program had provided the catalyst for bringing individuals together in a successful way. This was either by the creation of a new group - as for the Midwifery Practice and Research Centre and the Darwin Clinical Research Unit in Aboriginal Health groups - or in the strengthening and broadening of existing groups, such as the Centre for Training in Clinical Cardiovascular Research and the Clinical Neuroscience: Epilepsy and Stroke groups.

An important feature of the CCE Program was the beneficial effects provided by the flexibility of funding. This was commented on repeatedly by the recipients and was obvious to the Evaluation Committee. The flexibility in funding permitted developments that underpin important clinical research initiatives and/or facilitate translation into clinical practice. For example, there were developments in relation to clinical databases, tissue and gene banks. Funding for these developments is not usually obtainable through national project grant schemes.

Another significant outcome of the CCE Program was the importance the designation as a Centre of Clinical Excellence bestowed. Centres found this designation extremely useful in their bids to obtain further funding from a variety of sources, and in attracting high quality staff and students to the Centre.

There was variable evidence of translation of research findings into clinical practice. Not unexpectedly, recent research findings were having more effect on practice within the particular unit or hospital than in the wider community. While the Evaluation Committee felt that it was still relatively early to expect widespread uptake or translation of research findings, it believes that more thought needs to be given to involving State and Territory Health Departments in the dissemination of research findings and their incorporation into State and Territory health policy.

The outcomes of the Program are discussed in further detail below.

## **ACHIEVEMENTS AGAINST THE PROGRAM OBJECTIVES**

The original objectives of the Program, as defined in the 'Health Throughout Life' policy document, were to foster clinical research and training, to support innovative clinical research, and to ensure effective translation of research into clinical practice. The success of the Program in meeting these objectives is outlined below.

### **Objective 1: Fostering clinical research and training**

In Australia, as elsewhere, there has been concern about the decline in the amount of clinical research being undertaken, and in the number of clinicians training in research. While the causes may be multi-factorial, it is clear that clinical and administrative duties often make it extremely difficult to be involved in research. By providing some flexibility in funding, the CCE Program has enabled clinicians to both initiate research, and to be actively involved in translating evidence-based research findings into clinical practice. The Program has also given a clear signal that the NHMRC values clinical research and wishes to support it. This has been valuable in influencing young clinicians to commit to formal research training. Further, it has impressed on the hospital administrations that clinical research should be supported.

*"The existence of a grant specifically orientated towards clinical applications and hospital-based research has strengthened the hand of clinical research both in the hospital and associated research institutes"* comment in the submission by the Centre for Cardiovascular Applications to Clinical Research to the CCE Evaluation, 2001.

### **Recruitment of clinicians into research**

In most Centres, CCE funding led to a significant increase in recruitment of clinicians and scientists to training Programs in clinical research. The flexibility of the funding under the Program led to different approaches to the problem, as detailed below.

#### **Provision of stipends**

The most common approach used by the Centres to support training was the provision of stipends in line with those offered by the NHMRC. Frequently, stipends were used to fund the first year of a PhD, with the recipients then being in a competitive position to win regular NHMRC or other competitive stipends in subsequent years. In the Institute of Magnetic Resonance Research, substantially higher stipends were provided to attract clinicians at the completion of their professional training to undertake research training. This was successful in attracting a number of surgeons. In another Centre, however, where standard stipends were offered, surgical trainees or qualified surgeons were not attracted as candidates. In all Centres, arrangements were made for medical graduates to supplement their incomes by undertaking limited clinical work related to their PhD studies. This was important because the significant drop in salary for clinicians moving to a PhD stipend is a disincentive for them to seek formal research training.

#### **Recruitment of a senior staff member**

In one Centre, funds were used to attract back to Australia a senior staff member. Within a short time of his appointment to the Centre, this person had attracted a further six clinicians to undertake doctoral studies through the Centre.

### Work release scheme

In the Midwifery Practice and Research Centre, a work release scheme was developed whereby the CCE provided funds for nurses for between six and 12 months while they undertook a research Program. This provided an important introduction to research, led to an enhancement of the research culture within the clinical environment when the nurses returned to their clinical duties, and led to at least one nurse proceeding to a higher research degree.

### Web-based Program

The Centre for Clinical Excellence in Urological Research, which had been unsuccessful in recruiting surgical trainees into their doctoral Program, developed an innovative Web based Program providing instruction in research design and methodology to pursue the goal of enhanced training in clinical research. The Evaluation Committee thought that this initiative had the potential to develop a more research-aware community, but it is unclear at this stage whether it will lead to clinicians undertaking more extensive research training. On a more positive note, the Centre for Anaesthesia and Pain Management Research had used their funding to support a world-first Web-based Diploma and Masters in Pain Management course through the University of Sydney. This course has attracted a wide-range of students from many disciplines, including nursing, physiotherapy, dentistry, clinical psychology, rheumatology and anaesthesia – both in Australia and internationally (USA, Canada, Europe, Asia). This Centre is playing a leadership role worldwide in developing pain management education for clinicians who are involved in pain management practice.

## **Outcomes of Research Training**

### Training programs

The view of the Evaluation Committee was that, in general, the students recruited into CCE Programs have gained a strong grounding in clinical research methodology. The CCE's had different approaches to how formal the research training provided to students was. In some Centres, research training was very much on an apprenticeship model, while in others it was conducted through formal mechanisms either within the Centre or more widely within the host institution. It appeared that the emphasis of this award flagged to the senior members of the Centre the importance of the training needs of their students. When present during the Evaluation Committee's visits, students commented on the supportive environment for research training in the Centres. They also remarked that their association with the CCE's gave them wide access to a number of disciplines (both scientific and clinical), to which they otherwise would not have been exposed.

### Career paths

It was apparent that the future careers of those who have undergone research training under the Program will vary. All trainees can use the experience to reinforce the importance of evidence-based clinical practice in their future clinical careers. Some of the more successful students will be pursuing research in their own right, with some already being successful in receiving research grants, awards and conference prizes. For example, a PhD graduate of the Midwifery Practice and Research Centre has published six peer-reviewed research articles, three conference presentations and four submissions to government, and presented at six external seminars, has now been retained as a senior staff member at St George Hospital. As a result of her CCE training, a

clinical PhD student in the Centre for Training in Clinical Cardiovascular Research has three scientific publications, made two presentations at a national conference, won five awards and been successful in obtaining \$120,000 in grant funding.

### Independent investigators

One of the objectives of a Program such as this is to contribute to the development of future independent investigators. Some Centres had considered the question of further career development after the period of initial training within the CCE. However, in general, the Evaluation Committee felt that more thought needed to be given to a strategy to produce future independent investigators. This strategy might include the provision of postdoctoral Fellowships in a CCE Program.

### **Objective 2: Supporting innovative clinical research**

The Evaluation Committee viewed that the Program had a positive effect on the research being undertaken in the various Centres. In most cases, there was a clear enhancement of the research projects already in train. Noting that these groups had been selected *inter alia* because of the standard of their existing research programs, to have had these programs enhanced was a positive outcome. In almost all Centres there was evidence of new and innovative projects either arising from the existing research or made possible because of the flexible budget of the CCE. As pointed out elsewhere, the ability to allocate funds to establish databases or to set up tissue and gene banks provides significant benefits for future research. There was evidence that this was already happening (see below).

### **Research productivity**

Regarding the research productivity of the CCE's, it was often difficult to clearly identify the outcomes due to CCE funding compared with outcomes arising from other funding sources. Most groups were very productive, and the number of publications and presentations from people whose stipends were directly attributable to the CCE Program increased over the duration of the Program.

Below are some examples of innovative research projects arising from the CCE Program.

- **Febrile convulsions.** A study within the Clinical Neuroscience: Epilepsy and Stroke CCE has identified gene mutations in patients with juvenile febrile convulsions. This finding allows appropriate counselling and has good potential for the development of novel therapeutic agents.
- **Arterial stiffness and HRT.** In their research on arterial hypertension, the Cardiovascular Applications to Clinical Research CCE identified that females have 'stiffer' arteries with ageing than men, and that hormone replacement therapy (HRT) reduces large arterial 'stiffness' in healthy postmenopausal women. This work was published in 1998.
- **Pre-eclampsia in gestational diabetes.** A study by a student of the Centre for Training in Cardiovascular Research found an increased rate of pre-eclampsia in women with gestational diabetes. He identified clinical indicators that predict risk of pre-eclampsia. Interventions that target such insulin resistance early in pregnancy (such as nutritional and lifestyle

interventions) can have the consequence of decreasing the incidence of pre-eclampsia and its complications in gestational diabetes.

- **Community acquired pneumonia.** In the Darwin Clinical Research Unit in Aboriginal Health, a CCE-funded employee established a sophisticated database to study community-acquired pneumonia. This study demonstrated the existence of a markedly different range of pathogens in the Northern Territory (NT) to those found in southern Australia. Subsequently, appropriate prescribing guidelines were developed for the NT region.

### **Objective 3: Ensuring effective translation of clinical research into practice**

While the majority of the CCE's have initiated the translation of their research into clinical practice, the degree to which this has occurred is variable. The timeframe of the funding for Centres under the Program (three years) is relatively short, and translation of research findings into practice has been mostly at a local level to date. The Centres used a number of translation strategies beyond traditional publication in scientific journals and presentations at scientific meetings. Several groups had developed, or were developing, sophisticated Web-based education programs that would provide a means to influence practice more widely. While some groups were in a position to influence policy change fairly directly, the Evaluation Committee felt that more thought could be given to interaction with State and Territory Health departments to influence policy and to use Health department resources to disseminate information.

Examples of translation of research findings into practice that has occurred as a result of CCE Program funding include:

- **Rehabilitation after heart failure.** A series of studies in the Cardiovascular Applications to Clinical Research Centre demonstrated the efficacy of exercise following heart failure and the physiological mechanisms involved. Rehabilitation programs in Australia are shifting their attention towards the heart failure population due to their high rate of prolonged hospital admissions. Rehabilitation is now part of a comprehensive heart failure disease management program practiced by the Alfred Hospital's Cardiac Transplant Service. Since implementation, there has been nearly a 90% reduction in heart failure readmissions at the Alfred Hospital. The Centre's economic modelling has shown a potential saving by broad implementation of the program of about \$2.8 million/year.
- **Birth centres versus labour wards.** A number of birth centres were established in New South Wales as a result of the Shearman Report (NSW Health Department 1989). The Midwifery Practice and Research Centre conducted a retrospective study to compare obstetric outcomes, primarily caesarean section rates, of low-risk women presenting in spontaneous labour to the birth centre with those attending the hospital's conventional labour ward. The results showed that there was no significant difference in caesarean section rates between the groups (3.5% in the birth centre and 4.3% in the labour ward). The group concluded that the site of booking does not affect clinical outcomes for low risk women in St George Hospital. These results are relevant to contemporary clinical practice as they question the basis upon which birth centres have been popularised, (that is, the medicalisation of birth in conventional labour wards increases intervention rates). This research was published in the *Australian Journal of Advanced Nursing* in 2000.
- **Prevention of diarrhoea in Indigenous children.** One research project undertaken by the Darwin Clinical Research Unit in Aboriginal Health documented the importance of

underlying small bowel mucosal damage and osmotic diarrhoea (lactose intolerance) and their contribution to the high morbidity among Aboriginal pre-school children. Improved hygiene is the key to preventing the underlying tropical-environmental enteropathy of children. A PhD student and Aboriginal Health Worker funded by the Centre have produced a flipchart for use by the ‘Strong Women, Strong Babies, Strong Culture’ Program, the Territory Health Service (THS) Environmental Health Program, and community Health Centres, in order to promote this message.

### **Additional benefits arising from the Program**

Although not implicitly stated in the original objectives of the Program, the CCE funding allowed the Centres to achieve outcomes that they had not anticipated in their original research proposal. These, together with the original objectives, meant that the CCE Program achieved outcomes far in excess of those expected from a standard NHMRC Program Grant. The additional benefits of the Program are outlined below.

### **Enhanced collaborative and multidisciplinary approach**

One outcome of the CCE Program was the ability to foster a collaborative work environment, both within and across disciplines and backgrounds. For example, the recruitment of Dr Reutens to the Clinical Neuroscience: Epilepsy and Stroke Centre has brought expertise in mathematical image analysis, which not only spans the two arms of the Centre, but extends into other areas of research in the Institutes of Neurology. The Program has also enhanced national and international collaboration.

Whereas effective clinical research and its translation into practice may be impeded in a hospital environment where doctors have sole responsibility for research, and may only involve colleagues from other disciplines (nursing, physiotherapy, sports medicine) at the translation stage, a model like that used in the CCE Program, allows contribution to, and initiation of, research from members with a variety of clinical backgrounds. Many of the Centres in the CCE Program are embracing this more inclusive and equitable research team model. In one example, the CCE Program brought together researchers from two distinct disciplines and, despite initial scepticism, the doctors involved acknowledged the added benefit that working together had provided; they become ‘converts’ to this *modus operandi*.

Because this model is believed to be an essential component to effective clinical research, in a future Program, applications advocating a multidisciplinary collaboration (for example, between medical, nursing and allied health workers) could be particularly encouraged.

### **Impact of “Centre of Clinical Excellence” title**

The importance of the designation as a ‘Centre of Clinical Excellence’ was useful in Centres’ bids to attract funding from a variety of sources, to obtain infrastructure support from their hospitals, and to attract high quality staff and students to the Centre. For example, the development of a Biomathematics Unit in the Centre for Training in Clinical Cardiovascular Research has largely come about because of the CCE Program. It allowed the recruitment of required expertise for the Unit from the USA.

## **Flexibility of funding**

The untied nature of the CCE Program funding allowed the Centres to be flexible with how they allocated their research funding.

For example, clinical databases and tissue/gene banks are notoriously difficult to fund, as they are seen by research funding groups as infrastructure support and by hospitals as research tools. Notwithstanding this difficulty, such resources are critically important to the success of multi-centre trials and outcomes studies, and have constituted a barrier to undertaking such multi-centre studies in the past.

Some examples of outcomes achieved as a result of these databases and tissue/gene banks are given below:

- The Centre for Clinical Excellence in Urological Research has developed two clinical databases through the CCE award. One database has been developed as a multi-centre, outcomes database for prostate cancer patients that includes quality of life variables. The other is a bladder cancer outcomes database that has also been specifically designed as a cancer surveillance application. Both databases were identified as important, but had not come into fruition until the CCE grant was awarded.
- An achievement of the Cardiovascular Applications to Clinical Research CCE was the establishment of a Cardiovascular Gene Bank for the collection of DNA samples from patients who have a wide variety of cardiovascular conditions. These patients have clearly defined phenotypes, by virtue of having had cardiac investigations and/or by having participated in research studies at the Centre. It is envisaged that the Gene Bank will provide material that will be used for the identification of new genetic mechanisms for cardiovascular diseases, and can also be applied to the emerging field of pharmacogenetics.
- The Centre for Neuro-Otology Research was able to use its funding to import its existing medical database into a new software environment (Access). This opened up the search capacity of the database so that it can now be searched on questions concerning the demographics, diagnosis, natural history, effects and side effects of treatment. Using these data, the group is developing educational and best practice guidelines for general practitioners and specialists.

To facilitate the development of these important resources in the future, the NHMRC might wish to consider, outside of the CCE Program, making funding available to support the development and maintenance of databases and the establishment of gene and tissue banks.

## **ISSUES IDENTIFIED DURING THE EVALUATION**

During the Evaluation, issues were identified that could be addressed and/or improved upon in a future funding round. These issues, and potential solutions, are mentioned below.

### **Clinical research in Indigenous communities**

The Evaluation Committee noted that Indigenous health clinical research and its translation into health outcomes for Indigenous communities can be difficult, both logistically and politically. However, it remains an area of need. The Evaluation Committee recommended that a future funding round include a designated Centre of Clinical Excellence in Aboriginal and Torres Strait Islander Health, which would actively involve and engage the Indigenous population. The exact nature of this Centre should be determined by the SRDC, in close consultation with the Research Agenda Working Group (RAWG).

The Evaluation Committee acknowledges that, despite initial setbacks, the Darwin Clinical Research Unit in Aboriginal Health is beginning to effectively translate their research findings into improved health outcomes for Indigenous Australians. Ceasing the Centre's funding at this stage would severely undermine the trust that this group has established in the Aboriginal community. The Centre's funding should be extended until the future of the Program has been decided.

### **Program timeframe**

A repeated criticism of the Program was that the funding period was too short, and that publication of research and the translation of research into clinical practice would be more likely to occur in a five year Program. In the proposed new model for a future CCE Program, the CCE Evaluation Committee recommends that funding should be for a period of five years, with a paper-based, funding-linked review after three years, to ensure that their progress towards meeting the aims of their proposed program is on track.

### **Quantum of CCE funding**

The quantity of money awarded to the Centres was between \$120,000 - \$200,000 per annum. Some of the Centres argued that this quantity of funding was equivalent to an NHMRC Project grant, and not appropriate for a 'Centre of Clinical Excellence'. Nevertheless, despite the relatively modest funding, the recognition of the award and the flexibility of funding was appreciated and made a difference.

In recognition of the importance and status of this grant, the Evaluation Committee recommend the base level of funding in a future CCE Program should be set at a level that is appropriate for a 'Centre of Clinical Excellence'. Funding above this level would be commensurate to with magnitude of the proposal.

### **Accountability for CCE funding**

Because of the multiple sources of funding being used by most Centres, the Evaluation Committee found it difficult to attribute outcomes solely to the CCE funding. While supporting flexible use of funds, the terms of award of a future Program might incorporate a requirement that the Centres delineate precisely where they use their CCE funding.

### **Translation of research findings into health policy**

It is recognised that, to translate clinical research findings into clinical practice, the ability to engage and influence local, State/Territory and Federal health policy is important. Several of the Centres have been successful in engaging the appropriate health agencies to ensure that their evidence-based clinical research findings are being widely disseminated. For example, the Exercise in Heart Failure Program of the Cardiovascular Applications to Clinical Research CCE has several workshops planned for the year 2001, to provide further education for medical practitioners, nursing and paramedical staff who provide health care for heart failure patients.

It is important that “translation into clinical practice” also incorporates an element of translation into health policy. The Centres have been particularly successful when they have been able to demonstrate that their proposed clinical practice reduces the cost of patient treatment/care.

Some Centres that attempted to translate their clinical research into community practice experienced difficulty attracting funding for ongoing service delivery from either the hospital or community health sectors. This was the case even if the research (for example, Exercise after Heart Failure) had demonstrated a reduced rate of readmission to hospital.

As noted in the Interim Review, effective translation may require better communication between all levels of government.

### **‘Hospital’-based clinical research**

The first program round was entitled ‘Centres of Clinical Excellence in Hospital-based Research Program’ and was aimed at encouraging research in the hospital environment. The Evaluation Committee recognised that clinical research can, and should, occur in clinical settings outside of hospitals. A future Program may need to be flexible enough to broaden the concept beyond “hospital-based” research.

### **Community consultation**

There were varying degrees of community consultation used by the Centres. Little, if any, community consultation occurred prior to, or at the inception of, the research program. Although this consideration was not explicitly stated in the original objectives of the Program, the Evaluation Committee regarded appropriate community consultation to be an important component of any future Program. This would make clinical research more relevant, and would also ensure effective translation of research findings back into the community.

Because, in the past, Indigenous communities have experienced repeated sampling for research purposes without gaining improved health outcomes for their people, effective, ongoing, communication with this community is particularly important.

### **Scope of research and training**

The Evaluation Committee recognises the value of clinical research being undertaken in environments where there is a researcher interface between basic and clinical research. However, it believes that the thrust of this Program, both with respect to research projects and research training, should concentrate on human studies.

## **THE FUTURE OF THE CENTRES OF CLINICAL EXCELLENCE IN HOSPITAL-BASED RESEARCH PROGRAM**

The funding for the first round of the Centres of Clinical Excellence in Hospital-based Research Program will cease in June 2001. A decision on whether this Program should be continued, and if so, how it can be improved, needs to be made.

### **Strategic considerations for a future CCE Program**

To what extent strategic considerations should influence the CCE Program is unclear. Because clinical research is in need of strategic support level, the support of clinical research and the development of people capable of high quality clinical research may, of itself, be considered strategic. Beyond this, a number of considerations are possible.

### **Refunding existing Centres versus funding of new Centres**

In considering whether existing Centres should be eligible for funding in a further round, the Evaluation Committee recognised that all Centres had obtained considerable benefit from the present round. It also recognised that there are other groups around the country that would benefit from CCE funding, should it be available. Further funding of some of the existing Centres would lead to an enhanced national clinical research capacity. The Evaluation Committee felt that it was undesirable to penalise the Centres that had performed well in the present round, and that still had considerable potential for additional benefit, by excluding them from the possibility of further funding. The Evaluation Committee agreed that existing Centres should be eligible to apply for a new round of Program funding. However, it was reasonable to expect existing groups to demonstrate the additional benefits they would derive from further funding to warrant such funding over that of a new Centre.

### **Quantum of funding**

The initial CCE Program round provided a modest quantum of funding (\$120,000 - \$200,000 per annum) for nine Centres of Clinical Excellence. Some of the Centres commented that the quantum of funding was lower than expected for 'Centre of Clinical Excellence'.

However, the Evaluation Committee also recognised that the awarding of fewer, larger quantum, grants in this initial round would have excluded many of the highly rated Centres. Also, the evaluation of nine Centres enhanced the Evaluation Committee's ability to recognise the key issues that will be important in the success of future Centres of Clinical Excellence, including:

- Strong leadership
- Track record
- Well designed training strategy
- A multidisciplinary approach
- Ability to collaborate beyond the traditional hospital/research environment (including with the community and health policy officers)
- That clinical research involves human, and not animal, studies

The Evaluation Committee recognised that a future round of funding should be high enough to warrant the title of a 'Centre of Clinical Excellence', and therefore distinct from NHMRC Program grant funding.

## **Indigenous health**

It is generally agreed that research to enhance the health of Indigenous Australians has strategic importance.

## **Specific professional groups**

Fostering of clinical research in specific disciplines, such as nursing and allied health, were considered important in the present round. The point was put to the Evaluation Committee that research undertaken by a “professional group” should compete in the open market and that, in any case, most clinical research needs to be multidisciplinary. The Evaluation Committee believed that the adoption of a multidisciplinary approach was the most effective way of obtaining good quality research and translation into clinical practice.

## **Fostering of research in certain diseases versus an open application round**

The basis for deciding which research areas should be supported is difficult. The National Priority Areas could form the basis for selection, or at least could give weighting to applications. However, one of the strengths of the current CCE round was the diversity of Centres that were funded as the result of an open research round. The Evaluation Committee suggests an open research round with awards being made to the highest quality applicants will, most likely, result in the greatest benefit in the long term.

## **Duplication of effort**

Where multiple high quality proposals are received in the same research discipline, a strategic consideration may be made to not fund some, so as to avoid the majority of the Centres conducting research in the same area.

## **Future sustainability of the current Centres of Clinical Excellence**

As intended, most Centres have made plans for ongoing funding and resources beyond the timeframe of the funding provided under this Program. The majority of CCE’s are applying for NHMRC 2002 Project and/or Program Grants. Some of the CCE’s have been successful in attaining funding from their State Governments while others are obtaining additional funding from commercial ventures or charitable sources. Those Centres that have planned strategically and have secured contingency funding argue that the future of their CCE funding should not be penalised as a result of their foresight by being excluded from applying for funds in any future CCE round.

Almost without exception, the Centres identified that the other funding that they were seeking (or had sought) would not allow them to maintain and continue specific development such as their clinical databases and gene/tissue banks. As mentioned above, such items fall between traditional research and infrastructure funding mechanisms.

## **Continuity of funding**

If further rounds are funded, future evaluations should be commissioned and completed before the completion of the funding round, to allow continuity of the Program.

## SUMMARY AND RECOMMENDATIONS

The Evaluation Committee concluded that the overall Program had:

- Enhanced the training of clinical researchers
- Supported innovative research findings
- Begun to translate these research findings into improved clinical care
- Promoted collaboration between trainees and researchers from many different disciplines and training backgrounds
- Provided flexible funding, enabling innovative student recruitment strategies and the support of clinical databases and tissue/gene banks
- Elevated the profile, and excellence, of clinical research.

The Evaluation Committee contends that the Program should continue. Based on the findings of this evaluation, a future Program could be enhanced by incorporating additional elements in a new CCE Program, including:

- An extension to the Program timeframe to five years
- A level of funding based on quality and scope of proposed Program
- A requirement for clearer delineation of the use of CCE funding
- A broadening of the concept of ‘hospital-based’ research
- Where appropriate, translating research findings into health policy
- A requirement for greater levels of community consultation.

As such, it is recommended that:

**Recommendation 1:** A new round of Program funding is approved, to commence as soon as is practical, based on the following model:

### **Proposed model for a future CCE Program**

#### Aims

- To foster training of clinical researchers, including those with capacity for independent research and future leadership roles
- To support clinical (human) research with potential to lead to improved health care
- To ensure effective translation of research outcomes into clinical practice as widely as possible.

#### Characteristics of Program

In addressing the difficulties experienced by the current Centres, the CCE Evaluation Committee recommends that the following characteristics be incorporated into a new CCE Program round:

- Five year Program, with a funding-dependent review after three years
- Funding level to be based on quality and scope of Program, and at an amount that justifies the designation of the group as a ‘Centre of Clinical Excellence’
- Further funding of existing Centres of Clinical Excellence be awarded if evidence of additional benefit is demonstrated
- Funding provided in a way that is both flexible and accountable
- Evidence of appropriate community consultation required

- Proposals able to include clinical research in appropriate non-hospital clinical/health care settings
- Expectation that Centres will develop strategies for sustainability during term of grant
- Multidisciplinary collaboration encouraged
- Where appropriate, provide evidence of consultation with public health specialists and health officials, and encourage collaboration of government agencies in translating research outcomes and influencing health policy.

The CCE Evaluation Committee also acknowledged the importance of funding a designated Centre of Clinical Excellence in Aboriginal Health. The Darwin Clinical Research Unit in Aboriginal Health has an effective research Program that is beginning to translate research findings to improve the health of the local Aboriginal community. There were reservations that ceasing CCE funding in June 2001 would undermine the trust that has been developed between the community and the Darwin Clinical Research Unit in Aboriginal Health researchers. Consequently, the CCE Evaluation Committee recommends that this Centre's funding should be continued until the future competitive funding for a CCE in Aboriginal Health has been initiated.

Because continuation of research in Aboriginal Health is so important, it is recommended that:

**Recommendation 2:** In a new Program round, specific funding be set aside for a designated Centre of Clinical Excellence in Aboriginal and Torres Strait Islander Health.

However, to ensure continuity of the excellent work being undertaken in Darwin currently (for reasons stated above), it is also recommended that:

**Recommendation 3:** Funding of the current Darwin Clinical Unit in Aboriginal Health be maintained until the future funding of the CCE Program has been determined.

## **ATTACHMENT 1 - ORIGINAL MEMBERSHIP OF THE CENTRES OF CLINICAL EXCELLENCE WORKING GROUP**

### **FUNCTIONS**

This committee was convened to make recommendations to SRDC on applications for funding under the Government's Centres of Clinical Excellence in Hospital-based Research Program.

Its functions were to:

- short-list expressions of interest (following consideration of rankings and ratings of each application, and further examination of a reduced group of proposals);
- invite full applications from the short-listed applicants;
- identify appropriate assessors for short-listed applications;
- consider and vote on each application received;
- recommend to the SRDC funding levels for specific projects; and
- develop reporting arrangements, and oversee reporting.

### **COMPOSITION AND MEMBERSHIP**

#### **Initial membership**

Professor W Anderson (Chairperson)

Dr D Cameron

Ms E Percival

Professor L Powell

Professor M Onslow

Professor C Johnson

Professor M Horowitz

#### ***Additional members included at second meeting***

Professor J Touli

Dr A Wilson

Professor J Chalmers

#### **Gender breakdown**

9 males

1 female

## ATTACHMENT 2 - EVALUATION REPORT PROFORMA

### EVALUATION – CENTRES OF CLINICAL EXCELLENCE (CCE) IN HOSPITAL-BASED RESEARCH

*As you know, the Centres of Clinical Excellence in Hospital-based Research Program was established in 1997 for an initial period of three years. The Strategic Research Development Committee (SRDC) of the National Health and Medical Research Council (NHMRC) has responsibility for administering this Program. The Minister for Health and Aged Care, Dr Michael Wooldridge, has recently approved a six-month extension to the funding of this Program to allow for the Program's evaluation. The Minister would like an evaluation report completed by 15 April 2001. An evaluation committee, chaired by SRDC Executive member - Professor Don Cameron, has recently been established to conduct this evaluation.*

*The aim of the evaluation is to assess both the individual centres and the Program as a whole. The Evaluation Committee views this process as a dialogue in which we are seeking input/feedback from the Centres to help us in the overall evaluation and possible future development of the Program.*

*There are two components to the evaluation of the Centres of Clinical Excellence in Hospital-based Research Program – obtaining responses to these questions, and conducting site visits/interviews. Please note the Committee's intended date for visiting your Centre (in the covering letter). We will be writing to you with more detail about the site visits in the near future.*

*To help us conduct this evaluation, could you please address the questions below. You can provide us with all the information you deem relevant in responding to the questions, however, please only include information and outcomes/outputs that are DIRECTLY attributable to the CCE Program and award. Please do not include information on research projects and training schemes that are not directly related to the award.*

*Please return your response by **22 February 2001** to the Project Officer by fax: (02) 6289 9168, email: [gillian.treloar@health.gov.au](mailto:gillian.treloar@health.gov.au), (as an attachment) or by mail:*

*Dr Gillian Treloar  
Research Development Section  
Office of the NHMRC (MDP 70)  
GPO Box 9848  
CANBERRA ACT 2601*

#### SECTION 1: ORIGINAL OBJECTIVES

##### **1. Success against original objectives**

*In your original application, you stipulated specific goals and aims of your Centre and how you were going to attain these. Please outline how far you progressed in achieving these goals.*

##### **2. Changes to original objectives**

*Were any changes made to the original goals and aims? If so, please describe the changes and the reasons made for each change, and discuss any implications that these changes may have had on the stated goals and aims.*

## **SECTION 2: TRAINING AND RESEARCH OUTCOMES**

### **3. Impact of CCE funding**

*In brief, describe how this specific funding/award has made a difference to your Centre with respect to:*

- (a) Training health professional for research*
- (b) Research*
- (c) Health care*
- (d) Commercialisation*
- (e) Translation*

### **4. Trainees**

*Since the award, how has the Centre fostered the training of clinical researchers, hospital clinicians, junior researchers, allied health and nursing professionals, etc? For example,*

- i. How many have started, are current, and have completed their training?*
- ii. What are the skills and competencies attained by these trainees?*
- iii. List the publications, grants, other outcomes etc. that have arisen from this training/research?*
- iv. What have they gone on to do after completion of their training?*

### **5. Main research findings**

*What were the main findings of research conducted under this award, and what conclusions can be drawn from these? What potential (realised or anticipated) is there to translate these findings into innovative clinical treatments?*

### **6. Research outcomes**

*List the research outcomes that have directly arisen from your award,- numbered in chronological progression and sorted into the following research publication sub-categories:*

- a) Refereed journal article [with full author details, and noting whether the journal article appeared in a peer reviewed journal or not],*
- b) Review*
- c) Research book*
- d) Chapter*
- e) Any other relevant publications(eg. Letter/note, unrefereed journal article, other contribution to journal, technical reports, commissioned reports, etc.)*
- f) Patents*
- g) Conference presentations [authors and speaker, title, date and location of presentation],*
- h) Presentations about your Centre's research within other institutions,*
- i) Implementation of a regular seminar series, etc.*

### **7. Translation of research into clinical practice**

*Please describe how your Centre's outputs and outcomes have influenced clinical practice:*

- (a) in your Centre*
- (b) in your hospital/institution,*
- (c) in other centres in your discipline, and*
- (d) in other areas of Australian health care/hospital practice.*

## **8. Other Grants**

*List all research grants (eg NHMRC, NIH, NHF etc.) and institutional funding held by each Investigator during the period of this award.*

## **9. Outcomes database (if applicable)**

*If the development and implementation of an outcomes database was identified as one of the goals/aims of your Centre, please give a brief evaluation of the expansion of the database since the award with respect to:*

- a) quality of data obtained (completeness, accuracy, robustness, replicability, etc),*
- b) the degree to which it can be used to address research and outcome questions,*
- c) the extent to which the data encourages change in clinical best practice,*
- d) other.*

## **10. New research projects arising from CCE funding**

*As a result of the research funded by the award and conducted at the Centre, what new areas for research effort and new projects have been developed or are you pursuing?*

## **SECTION 3: OUTREACH OF CCE**

### **11. Collaboration with other organisations**

*How did funding through this award facilitate the Centre's collaborations with other institutions and organisations? Please describe the nature (including whether they are multidisciplinary) and the importance/value of these linkages.*

### **12. Community consultation (if relevant)**

*Did your Program address specific concerns of rural health groups, ethnic groups in the community, Indigenous people or local community members? Does the Centre seek to involve/engage/consult these groups if relevant?*

## **SECTION 4: FUTURE OF CCE**

### **13. Future sustainability of your CCE**

*What strategies have you put in place to ensure the sustainability of the Centre in the future?*

### **14. Unanticipated benefits arising from of your Centre**

*What additional benefits has the award brought to the Centre that would not have occurred otherwise? Has the funding provided leverage - financial, scientific, institutional, or other? Please describe.*

### **15. Future improvements to CCE Program**

*Please detail any suggestions you have about how the SRDC could have improved this award, or how similar awards could be improved in the future.*

### **16. Administrative and process difficulties**

*Please describe any administrative or process difficulties that hindered the conduct of work in the Centre under this award.*

### **17. Other comments**

*Are there any other comments you wish to make?*

### ATTACHMENT 3 - CCE SITE VISITS – MARCH 2001

Date	Centres Visited	Location	Participating panel members <sup>2</sup>
Friday 2 March	Centre for Neuro-Otology Research Midwifery Practice and Research Centre	Sydney, Central	Prof Judith Whitworth A/Prof Peter Fuller
Monday 5 March	Darwin Clinical Research Unit in Aboriginal Health	Darwin <sup>3</sup>	Dr Margaret Davy Dr David Roder Mr John Delaney Ms Terry Dunbar
Tuesday 6 March	Centre for Training in Clinical Cardiovascular Research	Perth	Dr Margaret Davy Dr David Roder
Wednesday 7 March	Centre for Clinical Excellence in Urological Research	Adelaide	A/Prof Peter Fuller Prof Meg Morris
Thursday 8 March	Centre for Anaesthesia and Pain Management Research Institute of Magnetic Resonance Research	Sydney, Nth Shore	Prof Judith Whitworth Mr John Delaney
Friday 9 March	Cardiovascular Applications to Clinical Research Clinical Neuroscience: Epilepsy and Stroke	Melbourne	Prof Meg Morris Mr John Delaney

<sup>2</sup> All site visits were attended by the Chair of the CCE Evaluation Committee (Professor Cameron) and an SRDC Secretariat support member (Dr Treloar)

<sup>3</sup> In their evaluation of the Darwin CCE, the Committee requested advice on the effectiveness of communication with the local Aboriginal community from an external (Mr Delaney) and local (Ms Dunbar) Aboriginal representative.