EVALUATION OF THE NATIONAL DONOVANOSIS ERADICATION PROJECT 2001 - 2004

Final report prepared for the

Department of Health and Ageing

Australian Research Centre

in Sex, Health and Society

La Trobe University

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Glossary

AHW	Aboriginal Health Worker
AIDS	Acquired Immune Deficiency Syndrome
ANCAHRD	Australian National Council on AIDS, Hepatitis C and Related Diseases
ARCSHS	Australian Research Centre for Sex, Health and Society
ATSIC	Aboriginal and Torres Strait Islander Commission
CDC	Centers for Disease Control
DoHA	Department of Health and Ageing (Commonwealth Government)
DOT	Directly observable treatment
DPO	Donovanosis Project Officer
GP	General Practitioner
GUD	Genital Ulcer Disease
GUMP	Genital Ulcer Multi Plex (PCR) Test
HIV	Human Immunodeficiency Virus
IASHC	Indigenous Australians' Sexual Health Committee
IGCAHRD	Intergovernmental Committee on AIDS, Hepatitis C and Related Diseases
NACCHO	National Aboriginal Community Controlled Health Organisation
NDEAC	National Donovanosis Elimination Advisory Committee
NDET	National Donovanosis Elimination Team
NIASHS	National Indigenous Australians' Sexual Health Strategy
NNDSS	National Notifiable Diseases Surveillance System
NSW	New South Wales
NT	Northern Territory
OATSIH	Office for Aboriginal and Torres Strait Islander Health – Department of Health and Ageing
PCR	Polymerase Chain Reaction
QLD	Queensland
SA	South Australia
STI	Sexually transmissible infection
TEE	Trans-epithelial elimination
WA	Western Australia
WHO	World Health Organisation

Executive Summary

In 1998 31 cases of donovanosis were notified nationally and it was estimated that an additional 300 prevalent cases existed at that time. While donovanosis is not a common infection, it has serious consequences including morbidity and mortality, and is also a risk factor for HIV acquisition. For this reason the National Donovanosis Eradication Project was established by the Australian Government in 2000, with the aim of developing, augmenting and maintaining capacity in primary care centres which would assist in the elimination of this infection within the near future.

A number of features made donovanosis a good candidate for elimination in Australia. It has a long incubation period of up to 1 year, and a relatively low infection rate. It was believed that the available diagnostic test was sufficiently sensitive and specific, and antibiotic treatment was both available and relatively inexpensive. In addition, the practice of 'syndromic management' for genital ulcer disease in areas where donovanosis was endemic meant that even if it was misdiagnosed it would be treated and thus render the elimination of donovanosis possible.

A series of recommendations were made in the report 'Donovanosis: Control or Elimination' written by Penny Miller in 2001[1]. This led to a project implementation plan that was endorsed by the National Donovanosis Eradication Advisory Committee (NDEAC), comprising members of the Indigenous Australians' Sexual Health Committee, individuals with particular expertise in epidemiology and laboratory diagnosis, as well as key state and territory stakeholders. The NDEAC advised the Office of Aboriginal and Torres Straight Islander Health on the implementation and monitoring of the project. Action was required across a number of areas such as surveillance, pathology, and health service practice. Four Project Officers were employed in Western Australia, Queensland and the Northern Territory to assist in this process. In 2004 NDEAC initiated an evaluation of the project. The Australian Research Centre in Sex, Health and Society at La Trobe University was invited to conduct the evaluation.

The purpose of the evaluation was to determine the successes and weaknesses of the project to date, and to determine the need for, and scope of, future funding for the eradication of donovanosis. The evaluation included an epidemiological review and a series of in-depth interviews with a variety of key informants employed in surveillance, pathology, health services and government.

The epidemiological review collected the information on donovanosis available from public records. This included notifications at both the state and national levels, and the collection of standard treatment protocols. Donovanosis information in the Antibiotic Guidelines was compared with the National STI Management Guidelines and other state guidelines to determine consistency of advice on donovanosis diagnosis and treatment.

All Donovanosis Project Officers, who were based in Perth, Alice Springs, Darwin and Cairns, were invited to attend a workshop in Melbourne to discuss key issues in relation to the Program and to allow them the opportunity to gain closure. Project Officers were individually interviewed and were also asked to identify appropriate contacts within their region to comment on the Program. This evaluation utilised the World Health Organisation (WHO) and Centre for Disease Control (CDC) surveillance system guidelines along with the recommendations made in the Miller report. Information gathered during data collection was used to identify key issues and to formulate the recommendations made in this report.

Overall, this project has made an important contribution. While the decline in notifications of donovanosis suggests a measure of success, work remains to be done. A shift in focus from donovanosis to genital ulcer diseases would provide some economies,

and is consistent with the practice of syndromic management, another key strategy in indigenous sexual health. The evaluation found that for such a program to be successful in reducing genital ulcer disease a longer and more realistic timeframe is necessary.

Chapter 1

Donovanosis: The Disease

Donovanosis, also known as granuloma inguinale, is caused by the organism *Klebsiella granulomatis* [2]. It is a treatable genital ulcer disease (GUD) which is considered a tropical disease, despite the fact that it has been found outside the tropics in places such as the Central Australian desert. Several other organisms also cause genital ulcers; donovanosis ulcers may be confused with the ulcers seen with chancroid, syphilis, lymphogranuloma venereum (LGV) and herpes [2].

1.1 Clinical Presentation

Infection begins as firm papule or subcutaneous nodule that ulcerates. There are four types of presentation:

1. The ulcerogranulomatis ulcer is the commonest type of presentation and is beefy red and non-tender, but bleeds to the touch
2. The hypertrophic or verrucous ulcer usually has an irregular edge and is sometimes completely dry
3. A necrotic, foul smelling deep ulcer is accompanied by tissue destruction
4. A dry sclerotic wound with fibrous and scar tissue may be seen [3].

Donovanosis ulcers appear on the genital area in 90% of cases and in 10% of cases the inguinal area is affected [3].

In women donovanosis commonly presents on the labia minora, fourchette and occasionally the upper genital tract and cervix. In men it is more common in uncircumcised than circumcised males and generally presents on the coronal sulcus, sub preputial region and anus. Extragenital sites which have been recorded include lips, gum, cheek, palate, pharynx, neck, larynx, nose, and chest. Dissemination of donovanosis to bone and liver is usually associated with pregnancy and cervical infection [3]. Incubation period estimates include 1-360 days, 14-28 days and 17 days [3]. Experimental lesions were induced in humans 50 days after inoculation [4].

1.2 Transmission

Donovanosis is generally regarded as a sexually transmissible infection (STI) but is also thought to be transmitted in other ways, such as through faecal contamination and autoinoculation [3].

Arguments for STI origin of donovanosis include:

- A history of sexual exposure before appearance of lesions
- Incidence is predominantly in age groups with highest sexual activity
- The presence of lesions on the cervix alone suggests sexual transmission
- Anal lesions in men practicing anal intercourse
- The infection site is usually genital

There is also evidence to suggest that donovanosis is not an STI:

- It occurs in young children and sexually inactive adults
- Rare in sex workers
- Rare in sexual partners of cases
- Primary non-genital lesions are unusual
- There is no well defined incubation period

Low co-infection rates have been found in sexual partners of those with donovanosis in Papua New Guinea and the United States, although in India a study found 26 partners of 50 cases were co-infected. Incidents of sex workers infecting clients have been reported. Cases of children contracting donovanosis have been mostly attributed to their sitting on the laps of infected adults, although transmission can also occur during vaginal delivery[3].

1.3 Laboratory Diagnosis

Laboratory diagnosis of donovanosis can be achieved in several ways:

- **Smear**

A clean microscope slide can be pressed against the rolled edge of the lesion and air dried. Sensitivity is increased with the removal of superadded infection from the ulcer by rolling a cotton swab across the surface of the ulcer. The ulcer should then be stabilized and another swab rolled across the ulcer without causing bleeding. This swab is then rolled over a slide on a flat surface to spread the ulcer material evenly. The slide is air dried and stained by rapid Giemsa method with eosin and thiazine solution or pinacyanole. The sensitivity of this method is around 65-70%.

- **Site specimen**

Tissue from below the ulcer surface is more likely to yield a positive result. The specimen, taken with scalpel or forceps can be crushed between two slides and stained overnight using Giemsa method or Leishman's or Wright's stains. Alternatively a smear from the underside of the tissue can be taken. Prior cleansing of lesion increases sensitivity. The procedure is often painful for the client, and sensitivity is only a little better than that achieved by a smear.

- **Biopsy**

Biopsy can be performed under local anaesthetic and examined by histology. Giemsa or silver stain is used. Histological changes show epithelial proliferation, heavy infiltrate of plasma cells, neutrophils and few lymphocytes. Biopsy is usually required for necrotic and sclerotic variants, and sometimes for hypertrophic lesions.

- **Culture**

Culture has been achieved in Darwin and Durban, South Africa, but requires a transmission electron microscope for identification, and so is not generally available. Culture has only been used as a high powered research laboratory tool and is not likely to be of practical value in clinical work as it is expensive, labour intensive and unreliable.

- **Polymerase chain reaction (PCR)**

PCR is available and was developed in Darwin initially. Preliminary evaluation in NT of the monoplex test showed excellent sensitivity although its inclusion in a multiplex PCR is not yet completely evaluated [3].

1.4 Management & Treatment

People with donovanosis often feel shame and anxiety and may have delayed presenting at health care. This worsens the condition because it is inexorable without treatment – the chronic ulceration continues to extend slowly but surely with tissue destruction an inevitable consequence. The chronic lesions also have a highly offensive smell which often results in social isolation of individuals with this infection.

Some people with donovanosis may have previously sought health care and been misdiagnosed and incorrectly treated. Alternatively, they may have been treated with correct but less effective antibiotic regimens but become non-compliant because of an initial poor or very slow response. These difficulties mean that reassurance about diagnosis and good prognosis are essential.

The most effective treatment is azithromycin 1g weekly for 4-6 weeks, or 500mg (1 tablet) daily for 10 days (ideal for inpatient use). Erythromycin 500mg four times daily for at least three weeks can also be an effective treatment, however it is a complicated regimen and has a high propensity to cause nausea, vomiting and diarrhoea. Ceftriaxone 1g IM or IV only daily (10-14 days) IM/IV can be used for inpatients who are pregnant although azithromycin can also used. Azithromycin is listed as a B1 drug so there is very little theoretical risk (and to date no practical and proven risk) of using it in pregnancy, and it should therefore be the recommended first line treatment [2, 3].

1.5 Donovanosis: Eradication or Elimination?

Eradication programs aim to free the globe of a disease; elimination programs restrict this goal to a region or country. Previously evaluated elimination/eradication programs have frequently focused on vaccine preventable diseases such as smallpox, polio or measles.

In 1995 a team led by Dr Frank Bowden, then employed by the NT, conducted a randomised trial of azithromycin in the 'Top End' to determine its effectiveness in treatment of donovanosis [52]. They found treatment with azithromycin once a week to be very effective.

In 1996, a field trial of azithromycin for treatment of genital donovanosis was conducted in Central Australia by Stephen Skov and Kerry Arabena at the Tristate HIV\STD Program with great success [75]. However, the study identified that health care professionals needed to be educated to use azithromycin and to undertake this as directly observed treatment (DOT), a strategy where regular follow-up is undertaken to ensure that the ulcers are properly healed. This often required the assistance of Aboriginal health workers. Health care professionals needed to be encouraged to commence and continue treatment on clinical suspicion of donovanosis even if the microscopy tests proved negative, which could occur due to poor sensitivity. The success of this trial led to the establishment of a Clinical Nurse Consultant position in NT, filled by Michael Howard during 1997-1999.

New treatment regimes such as once-weekly azithromycin for donovanosis were identified in the National Indigenous Australians' Sexual Health Strategy as a key example of how STI control in primary care could be strengthened and simplified [76]. In 2000, OATSIH commissioned Dr Penny Miller to determine whether a nationally co-ordinated donovanosis control program was desirable given that efforts to control donovanosis were either planned or completed in at least two regional areas (NDEAC Minutes, 8th March 2001). The Miller report, entitled *'Donovanosis: Control or Eradication?'* was considered and endorsed by the Indigenous Australian's Sexual Health Committee in August 2000, and recommended to the Australian National Council on AIDS, Hepatitis C and Related Diseases. Subsequently funding for a period of two years for the Donovanosis Eradication Program was sought and obtained from the Department of Finance and Administration.

The complete eradication of disease was clearly thought possible at this stage. At some point, however, the project was relabelled when it was realised that eradication or 'permanent reduction to zero of worldwide incidence of infection' [73] was not achievable, given the prevalence of donovanosis elsewhere in the world, including Australia's near neighbour, Papua New Guinea. However, whilst the terminology of some documentation associated with the project was changed as is evident from the title of one set of papers: 'National Donovanosis Elimination Action Plan: 2001-2004 by the National Donovanosis Elimination Advisory Committee', this was not consistent – the minutes of both National Donovanosis Eradication Advisory Committee and National Donovanosis Eradication Team continued to use the word 'eradication'.

Chapter 2

The National Donovanosis Elimination Project

2.1 Project Goal

The aim of the National Donovanosis Eradication Program (NDEP) was to introduce by December 2003, the national infrastructure, systems, and clinical awareness required to support the elimination of donovanosis from Australia by 2007.

There were a series of outcomes specified for determining the project's success in the NDEP Action Plan (2001-2004):

- Primary health care centres in donovanosis affected Health Regions (DAHR) are familiar with the content of the National Donovanosis Factsheet
- Primary health care centres in DAHR utilise the national Genital Ulcer Care Plan and Management Guidelines for Genital Ulcer Disease for the management of all cases of Genital Ulcer Disease (GUD)
- Laboratory services are available in all DAHR for the testing of GUD consistent with agreed National Minimum Standards
- Data reporting to agreed national standard is in place from all DAHR
- Research is undertaken where possible to support achievement of the project goal.

This Action Plan also listed as key performance indicators that:

- 95 % of primary health care centres in each DAHR are trained in the content of the National Donovanosis Factsheet
- 95 % of primary health care centres in DAHR utilise the national Genital Ulcer Care Plan and Management Guidelines for Genital Ulcer Disease for the management of cases of Genital Ulcer Disease (GUD)
- Laboratory services in 100% of DAHR offer testing for GUD consistent with agreed National Minimum Standards
- 100% of DAHR provide bi-annual reports to agreed national standard
- 100% of research identified is considered by NDEAC and referred to appropriate agencies for action.

2.2 Governance and Relationship with Other Bodies

The NDEP was endorsed by the Indigenous Australians' Sexual Health Committee (IASHC) and the Australian National Council on AIDS, Hepatitis C and Related Diseases (ANCAHRD). At the time the IASHC was a sub-committee of ANCAHRD which provided advice to the Minister for Health and Ageing, the Department of Health and Ageing and ANCAHRD on issues relating to Indigenous sexual health. The IASHC has since become a sub-committee of the Ministerial Advisory Committee on AIDS, Hepatitis and Sexual Health, and is appointed by the Minister for Health and Ageing. IASHC's membership is drawn from states and territories in addition to the National Aboriginal Community Controlled Health

Organisation (NACCHO), the Standing Committee on Aboriginal and Torres Strait Islander Health (SCATSH), the Aboriginal and Torres Strait Islander Commission (ATSIC) and ANCAHRD.

The project in its entirety was managed by a Secretariat in the central office of OATSIH, comprising Bernard Pearce and Project Officer Bilawara Lee. The program was overseen by the National Donovanosis Eradication Advisory Committee (NDEAC) shown in Table 2.1.

Table 2.1: NDEAC Membership

Name	Position	Responsibilities
Professor Frank Bowden	Chair / Technical Consultant	Medical and Testing technical advice (Support member to Donovanosis Project Officers)
Associate Professor Cindy Shannon	Indigenous Australians' Sexual Health Committee	Chair of IASHC
Ms Joy Savage	Director – (OATSIH)	Representing DoHA (IASHC ex-officio)
Dr Trish Fagan	Senior Medical Officer – OATSIH	Senior Medical Officer OATSIH
Dr David Bradford	President, Australasian College of Sexual Health Physicians (ACSHP)	President, Australasian College of Sexual Health Physicians (IASHC member)
Mr Michael Howard	Technical Consultant	Support member to Donovanosis Project Officers; technical implementation advice
Prof John Kaldor	National Centre in HIV Epidemiology and Clinical Research (NCHECR)	Epidemiology Consultant to assist with development of data records and elimination tracking. (IASHC ex-officio)
Ms Florence Williams	National Community Controlled Health Organisation (NACCHO)	Representing NACCHO. (IASHC ex-officio)
Ms Patricia Nona	Indigenous Australians' Sexual Health Committee (IASHC) Member	Specialist remote service advice. (IASHC representative & member)
Mr Christopher Macaulay	Intergovernmental Committee on AIDS, Hepatitis C and related Diseases (IGCAHRD) Member	Representing NT, WA & Qld Health Departments
Dr Sophie Couzos	National Aboriginal Community Controlled Health Organisation (NACCHO)	Technical adviser, representing Community Controlled Health Organisations in National forums (IASHC observer)
Mr Ron James	Standing Committee on Aboriginal and Torres Strait Islander Health	IASHC Ex-officio
Dr Ivan Bastian	National Public Health Laboratory Network (NPHLN)	Representing the National Public Health Laboratory Network
Mr Bernard Pearce	Assistant Director OATSIH	Representing Department of Health and Ageing
Ms Bilawara Lee	Project Officer, OATSIH	Secretariat to the National Donovanosis Elimination Advisory Committee (NDEAC)

The Terms of Reference for the NDEAC were to:

1. provide advice to OATSIH on the implementation of the NDEP
2. advise OATSIH on the criteria required to progress the national elimination of donovanosis, including data and reporting requirements, and provide a report to OATSIH biannually on progress to date
3. provide regular reports to the Minister for Health on progress to date
4. in recognition of the IASHC's role in auspicing this project, provide regular reports to the IASHC in order to meet the IASHC's requirement to report on progress to the ANCAHRD.

In addition, the National Donovanosis Elimination Team (NDET), a technical advisory group, was formed to assist the state and territory based project officers, and to ensure national consistency in the project's implementation.

Table 2.2: NDET Membership

Name	Position	Responsibilities
Professor Frank Bowden	Technical Consultant	Medical and Testing technical advice (Support for Donovanosis Project Officers)
Mr Michael Howard	Technical Consultant	Project Officer support, technical implementation advice.
Ms Florence Williams	NACCHO	Project Officer support, technical implementation advice.
Professor John Kaldor	NCHECR	Project Officer Support - Epidemiology
Ms Brenda Henry* Ms Noreen Conlon Ms Ann Davis Ms Janelle Wilkey	Project Officer – Based Cairns Project Officer – Statewide – based Perth Project Officer – Based Darwin Project Officer – Based Alice Springs	Assisting local services with the elimination of donovanosis
Mr Bernard Pearce	Assistant Director, OATSIH	Representing Department of Health and Ageing
Ms Bilawara Lee	Project Officer, OATSIH	Secretariat to NDET

* Subsequently replaced firstly by Chris Wilson, and then by Penny Marshall.

2.3 Launch of the NDEP

The NDEP was launched by the Chair of ANCAHRD, Mr Chris Puplick at *2001: A Sex Odyssey*, the annual scientific meeting of the Australasian College of Sexual Health Physicians, in Sydney on 2 May 2001. OATSIH published the situation review document, ***'Donovanosis: control or eradication?*** and distributed copies of the document to members of ANCAHRD and its committees, registrants of the Australian Sexual Health Conference, and OATSIH State Offices.

At this stage NDEAC had met once, on 8 March 2001. A subsequent meeting was held on 16 August 2001, and this was followed by one meeting in 2002 and one in 2003, on 22 July and 27 May respectively. A total of four meetings were thus held.

The technical advisory team (NDET) also met four times, having commenced their meetings on 14th November 2002, with three further meetings in 2003, on 23rd June, 14th August and 22nd October.

2.4 Resources

Funding was provided to resource Donovanosis Project Officers (DPOs) in Queensland, Northern Territory and Western Australia, as these were the states and territories with the highest incidence of donovanosis. Financial Reports were to be provided to OATSIH as per contract and not tabled at NDEAC meetings**.** Information in relation to financing of the NDEP was not provided to the Evaluation Team.

2.5 Treatment and Surveillance Systems

The Action Plan specified that OATSIH, NDEAC and NDET would have responsibility for communicating and encouraging the use of standard treatment protocols nationally, including:

- syndromic management
- short course, directly observed treatment
- inclusion of donovanosis in GUD standard treatment protocols in endemic
- areas
- National Antibiotic Guidelines

In relation to surveillance of donovanosis the Action Plan lists as an objective that 'national surveillance of donovanosis be maintained and strengthened' (see Appendix 4).

2.6 Training

A workshop was held in December 2001 to orient and train the DPOs who had been appointed in Cairns, Darwin, Alice Springs and Perth. At this stage only one DPO, from WA, had been employed. The other DPOs commenced in January 2002. The workshop was delivered by Dr Frank Bowden and Michael Howard, a sexual health nurse who had worked previously as a Donovanosis Project Officer in Central Australia.

2.7 Institutional Structures

The States and Territory nominated where their DPOs would be placed in a setting which was most appropriate for that donovanosis affected area. As will be seen, in WA and the NT this meant that the DPO was placed within a Sexual Health Unit in the Health Department; in Queensland DPOs were placed in a sexual health clinic. Details of any support which the states and Territory were required to deliver for the DPOs at the local level were not provided to the Evaluation Team.

2.8 Reporting

The Action Plan outlined reporting responsibilities. An initial scoping report was to be prepared by each DPO at the completion of the first 3 months of employment ie. April 2002. The purpose of this report was to provide NDEAC with an understanding of a "regional analysis" of donovanosis in each jurisdiction. This information would guide work on 'hot spots' and other areas of need. The report was to include:

- 5 year history of donovanosis data including trends over time;
- distribution by age, race and gender;
- regional distribution.

Biannual Reports were required by NDEAC from the States and Territory in October 2002 (for the period up to June 2002), February 2003 (for the period up to December 2002), August 2003 (for the period up to June 2003), and February 2004. (Final Report) Reports were to cover:

- number of primary health care centres in donovanosis affected health region (DAHR)
- number and percentage of primary health care centres in DAHR trained in the content of the *National Donovanosis Factsheet, Genital Ulcer Care Plan* and *Management Guidelines for Genital Ulcer Disease*
- number and percentage of cases of clinically or laboratory confirmed donovanosis in DAHR which are managed using a *Genital Ulcer Care Plan* and the *Management Guidelines for Genital Ulcer Disease*.
- epidemiological data for 6 month period including:
    - total new cases of donovanosis
    - distribution by age, race and gender
    - commentary on trends
    - total combined PCR tests conducted for Genital Ulcer Disease (once the test is available)

The Action Plan also stated that OATSIH were to provide stakeholders with regular updates on the project's progress. These stakeholders were:

- Commonwealth Minister for Health and Ageing
- ANCAHRD through the IASHC
- IGCAHRD
- DoHA Population Health Division.

2.9 Regional Co-ordination Mechanism

Information on regional co-ordination was not provided to the Evaluation Team.

Chapter 3

Method

3.1 Aim

The specific aim of this evaluation was to determine the successes and weaknesses of the Donovanosis Eradication Project to date, and to determine the need for, and scope of, future funding for the eradication of donovanosis in Australia.

This evaluation will also be seen in a broader perspective. At the first meeting of the NDEAC, it was suggested that a successful donovanosis project might provide information that would be useful in the implementation of a similar project to eradicate syphilis (NDEAC Minutes, 8th March, 2001). The view that the lessons learned from NDEP may be useful elsewhere is supported in the recently released national Sexually Transmissible Infections Strategy 2005-2008, which supports the view that evaluation of the NDEP will be important in the formulation of other STI-specific interventions.

3.2 Method

There are no published guidelines for evaluating elimination or eradication programs. This evaluation utilised the WHO and CDC surveillance system guidelines along with the recommendations made in the Miller report 'Donovanosis: Control or Eradication?'

The evaluation was conducted in four stages.

3.3 Epidemiological Review

This review collected the information on donovanosis available from public records. This included notifications at both the state and national levels, and the collection of standard treatment protocols. Donovanosis information in the Antibiotic Guidelines was compared with the National STI Management Guidelines and other state guidelines to determine consistency of advice on donovanosis diagnosis and treatment.

3.4 Workshop

Donovanosis Project Officers (DPOs), who were based in Perth, Alice Springs, Darwin and Cairns, were invited to attend a one day workshop in Melbourne to review and discuss their experiences. An in-depth individual interview was also conducted at this time. DPOs were asked to identify the appropriate contacts within their region who were involved in the program. This was essential, as not only had all the DPOs ceased employment as DPOs by the time the evaluation was undertaken, but also many of the key players had moved on to jobs in other regions.

3.5 Key Informant Interviews

To address the progress made on the Miller Report recommendations qualitative data was collected from key informants in five areas:

1. DPOs
2. Health Service Practice
3. Laboratories
4. State/Territory Government
5. Commonwealth Government

Most interviews were conducted in person or by telephone by a senior team member from ARCSHS. Owing to the brief timeline and the budget of the project, transcriptions of interviews were not undertaken. Notes were taken during interviews, which were written up immediately afterwards.

3.6 World Health Organization and Communicable Disease Centre Surveillance System Guidelines

The WHO[5] and US CDC [6] have developed guidelines for evaluating public health surveillance systems. In summary these guidelines recommend analysis of the following areas:

- Objectives of the system
- Population under surveillance – risk factors, provision of care, accessibility & coverage
- Events under surveillance – incidence, severity, mortality, communicability, potential for outbreak, socioeconomic impact, public perception, control measures, speed of response, costs of controls, resources, feasibility of surveillance
- Flow diagram of surveillance system
- Detection of events – case definition, forms used, how long does it take, who fills in forms, how was a recent outbreak detected and controlled.
- Reporting procedures – report to who, how is information transferred (mail/phone), timing, collation & management of data.
- Decision-making action taken - timing, who makes decisions, how is it decided
- Feedback - how well is information fed back
- Resources available to the system - staff, equipment
- Sensitivity & specificity, representativeness/non-representativeness, timeliness, simplicity, flexibility, acceptability [5, 6]

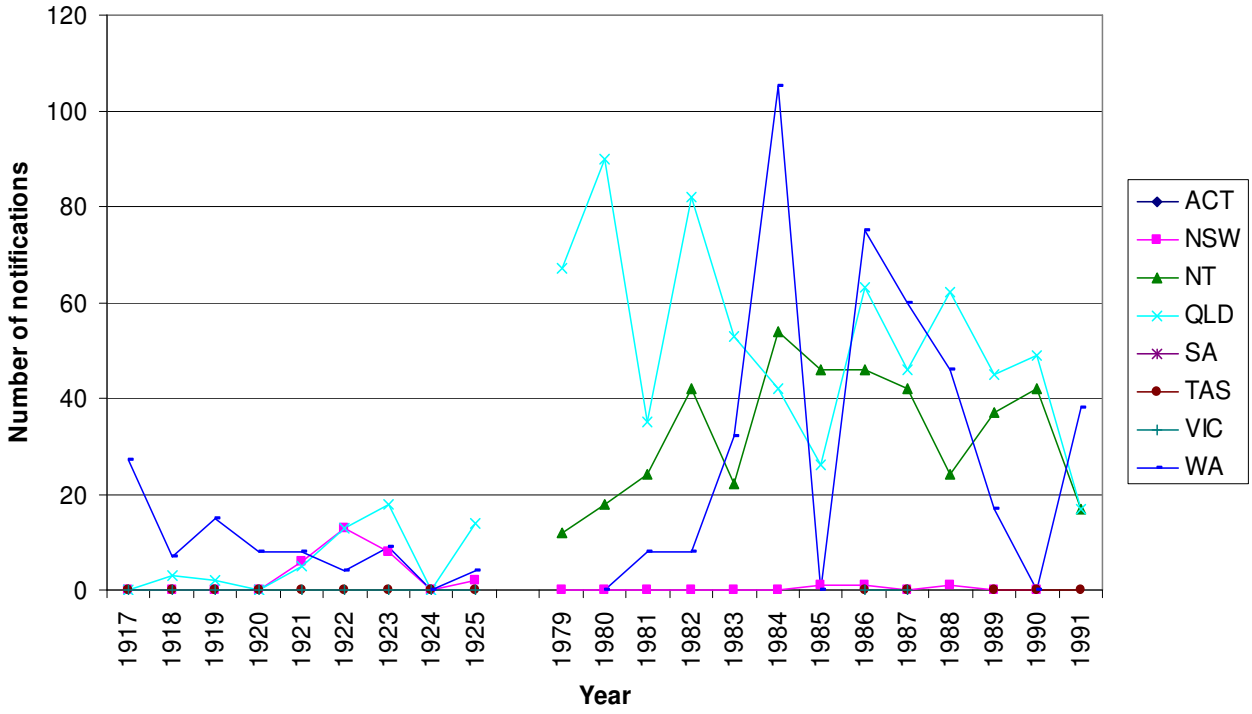
Chapter 4

Epidemiology

4.1 Historical Epidemiology

As is shown in Figure 4.1, notifications of donovanosis in Australia have varied widely over time. Reasons for this are difficult to determine. The increased notifications in the period 1979 to 1991 compared to the early period 1917-1925 are likely to indicate improved detection and diagnosis. This is probably related to the introduction of more general initiatives in Indigenous, remote and sexual health over this period. There was also increasing access to primary health care and specialist services in the late seventies and early eighties.

FIGURE 4.1 ANNUAL DONOVANOSIS NOTIFICATIONS 1917-1991



4.2 Significant Dates

Several initiatives have resulted in improved detection and treatment of donovanosis over the last 12 years. These initiatives are listed below to assist in interpretation of the data shown in the following graphs.

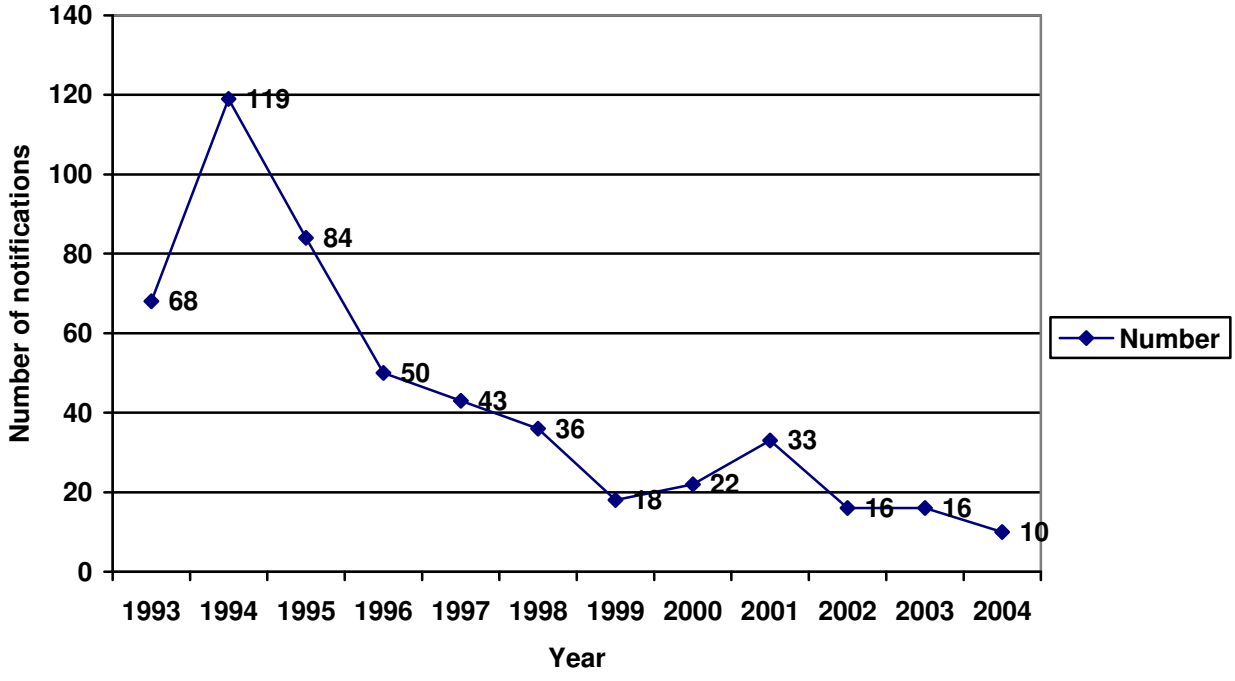
1994	Ceftriaxone trial in NT
1995	1st azithromycin trial in NT

1996	2nd azithromycin trial in NT
1996	Donovanosis education offered to Medical Officers in Alice Springs
1995/6	Trial of PCR monoplex at Menzies
1997/98	Donovanosis Project Officer employed in Alice Springs
2000	Donovanosis Project Officer re-established in Alice Springs
2001	Genital Ulcer Disease (GUD) syndromic management developed.
2001	Donovanosis Project Officers employed in Alice Springs, Perth & Cairns.
Jan 2002	Donovanosis Project Officer employed in Darwin.

4.3 Donovanosis Notifications 1993-2004

In 2005, up until the 27th of May, six cases of donovanosis were notified. [7] In 2004, 10 cases were notified. Overall, donovanosis notifications show a steady decline with peaks in 1994 during the azithromycin trials and in 2001 when the DPOs were employed (Figure 4.2). The number of notifications remained similar during the period 2002-2004. This is likely to indicate improved detection through the program rather than an increase in cases.

FIGURE 4.2 ANNUAL DONOVANOSIS NOTIFICATIONS 1993-2004

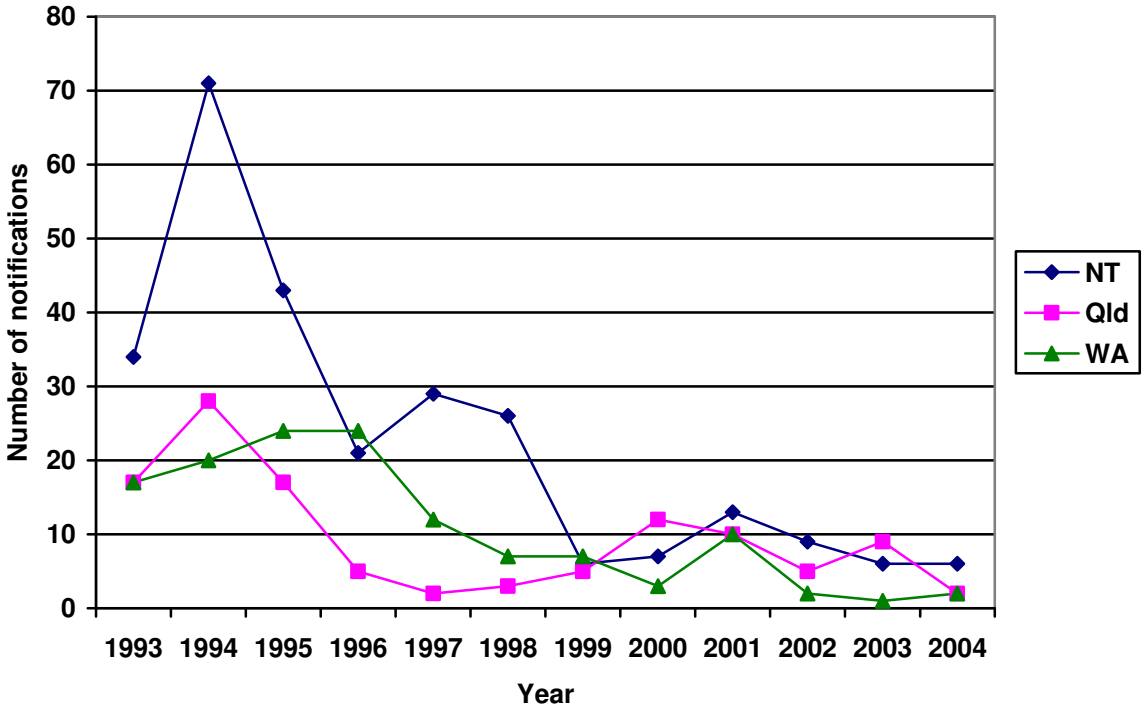


[8-10]

4.31 Donovanosis Notifications by State/Territory 1993-2003

Overall notifications in each State and Territory have declined since the azithromycin trials in 1995-1996 (Figure 4.3). The increase in notifications in the NT in 1997-1998 was during a period when the DPO was first employed. Similarly, the increase in notifications in the States and Territory in 2001 corresponds to the employment of the DPOs. This is likely to indicate enhanced surveillance and improved detection rather than an actual increase in donovanosis cases.

FIGURE 4.3 ANNUAL DONOVANOSIS NOTIFICATIONS 1993-2003
NT, QLD & WA



[8-10]

4.32 Donovanosis Regions in each State and Territory

In Queensland from 2001 to June 2004 donovanosis was identified in two regions: the Far North Region (21 cases) and the North West Region (4 cases). An analysis of past cases of donovanosis from 1997-2001 showed cases occurring in the Northern Region, however no cases were detected in this area in the period from 2001-June 2004.

Figure 4.4

In Western Australia 9 cases were detected in 2001 (2 in Goldfields; 4 in Kimberley; 3 in Pilbara Regions). Four cases were detected in three regions from 2002 to June 2004: in the Kimberly, Goldfields and Pilbara Regions.

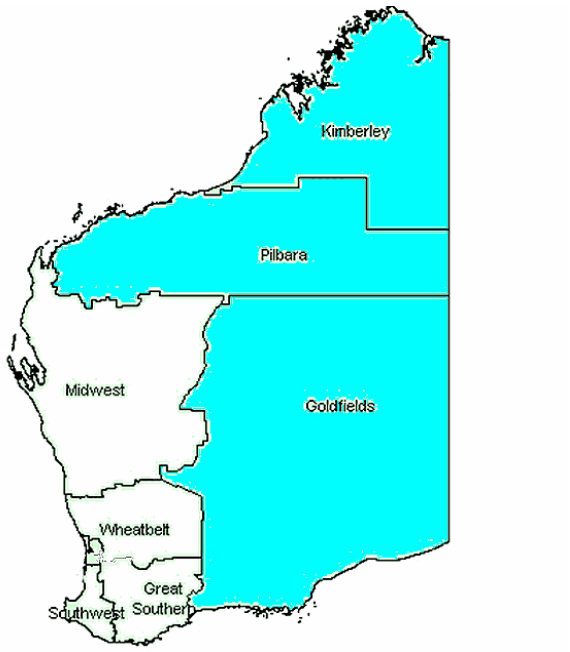


Figure 4.5

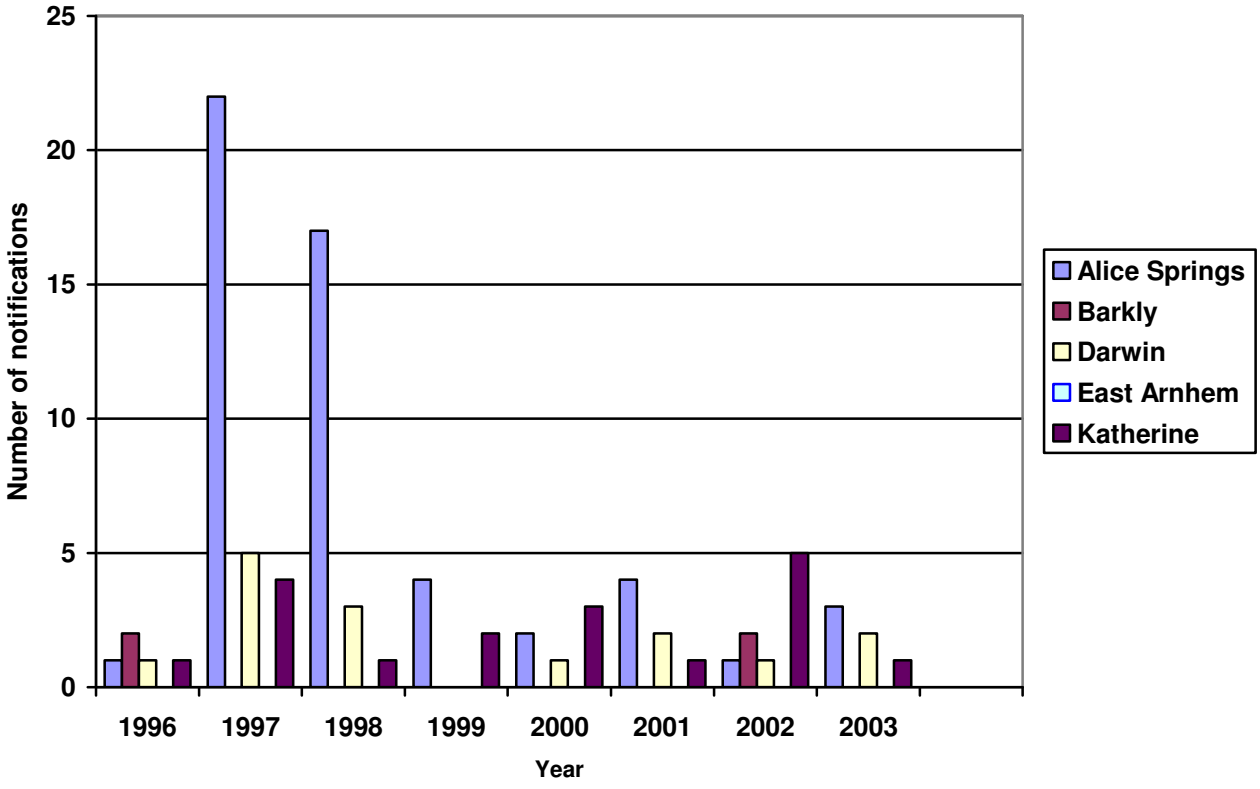
From 2002 to June 2004, the donovanosis program in Alice Springs in the Northern Territory identified 7 cases in two regions: Alice Springs (3 cases) and the Barkly Tablelands (4 cases). In the time period from 2002-June 2003, the Darwin program identified 9 cases in two regions: Darwin (3 cases) and Katherine (6 cases).

Figure 4.6

4.33 Donovanosis Notifications by Northern Territory Region

Information on regional origin of donovanosis cases was available for NT and is shown in Figure 4.7. It demonstrates a large decline since the first DPO was employed in Alice Springs in 1997/8, prior to the establishment of the NDEP.

FIGURE 4.7 NT DONOVANOSIS NOTIFICATIONS 1996-2003

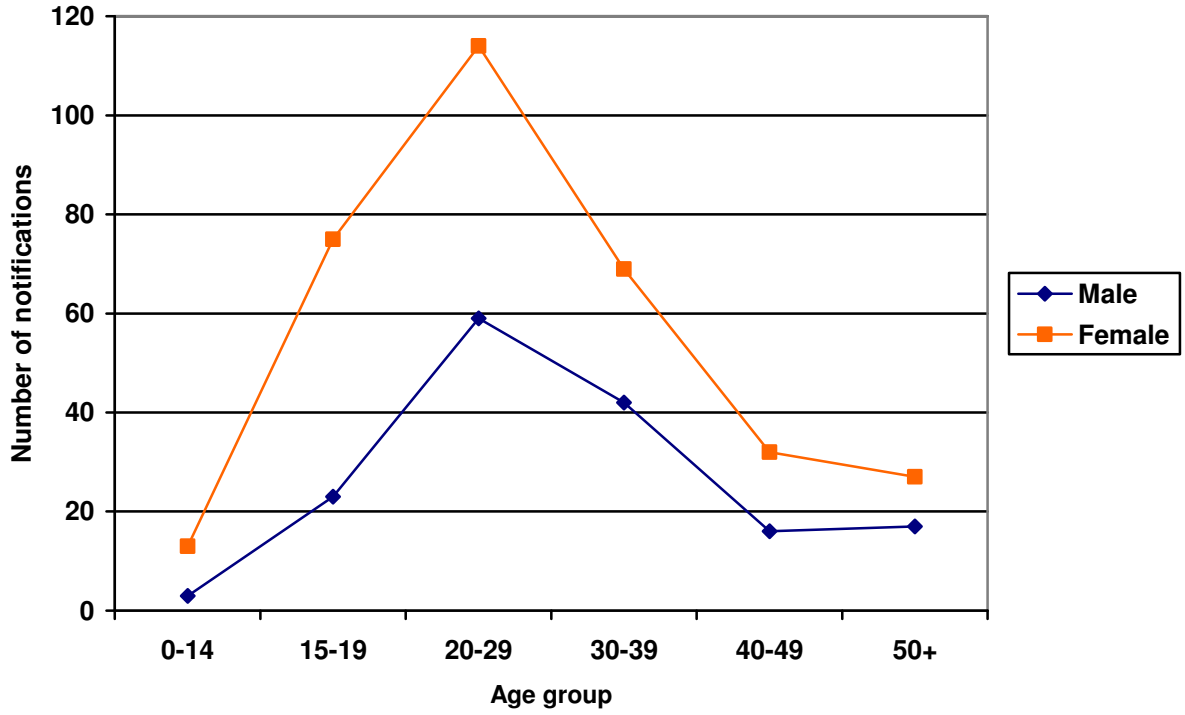


4.34 Donovanosis: Rates in Men and Women

Several Australian reports have indicated higher numbers of women detected with donovanosis. The accumulated donovanosis notifications by gender (1993-2003, shown in Figure 4.8) show that women are more likely to be notified with donovanosis in all age groups, but particularly in the 15-19 year age group (men 23 cases, women 75 cases) and the 20-29 year age group (men 59 cases, women 114 cases). International literature has reported higher incidence in both men and women thought to be related to selective sex bias [11]. There are several possible explanations for this higher reporting:

- Men less likely to access health care
- Women more likely to be diagnosed when attending health care for antenatal care and pregnancy (some present very late, right at delivery!)
- Clinical diagnosis is more accurate for women than men. At one STI clinic clinical diagnosis was 63% accurate in men and 83% accurate in women, with sensitivity of 55% in men and 87% in women when compared to histology [1].
- Donovanosis is more transferable to women. Uncircumcised men are more likely to contract donovanosis which may indicate that donovanosis is more transferable to moist mucus membrane environs such as the vagina.

FIGURE 4.8 CUMULATED DONOVANOSIS NOTIFICATIONS BY AGE & SEX 1993-2003



[8-10]

4.4 Relationship with Other Genital Ulcers

The NDEP promoted syndromic management for all genital ulcers. These included syphilis (both primary and secondary; 'condylomata lata': the flat, moist, warty lesions of secondary syphilis are very easily confused with donovanosis even by extremely experienced clinicians), chancroid *(*rarely seen in Australia) and herpes, which is highly endemic in both urban and rural Australia, including among Indigenous Australians.

Additional information on genital ulcers available from the NT shows that there is still considerable work to be done in education in relation to GUD, as 30% (40/134) of ulcers were managed syndromically in 2002-2004. It can be seen in Figure 4.10 that not all people presenting with a genital ulcer were tested for the same infections.

FIGURE 4.10: GENITAL ULCER DIAGNOSIS NT 2002-2004

Test	Test positive
Positive for syphilis	18% (21/111)
Positive for herpes	51% (38/75)
Positive for Donovanosis	7% (6/83)

[12]

The Northern Territory also reports syphilis rates by region. Figure 4.11 shows that syphilis is an ongoing problem in the NT. The differing numbers of notifications in regions likely indicates detection and diagnosis more successfully achieved in some regions.

FIGURE 4.11 NT ANNUAL SYPHILLIS NOTIFICATIONS BY REGION 1996-2003

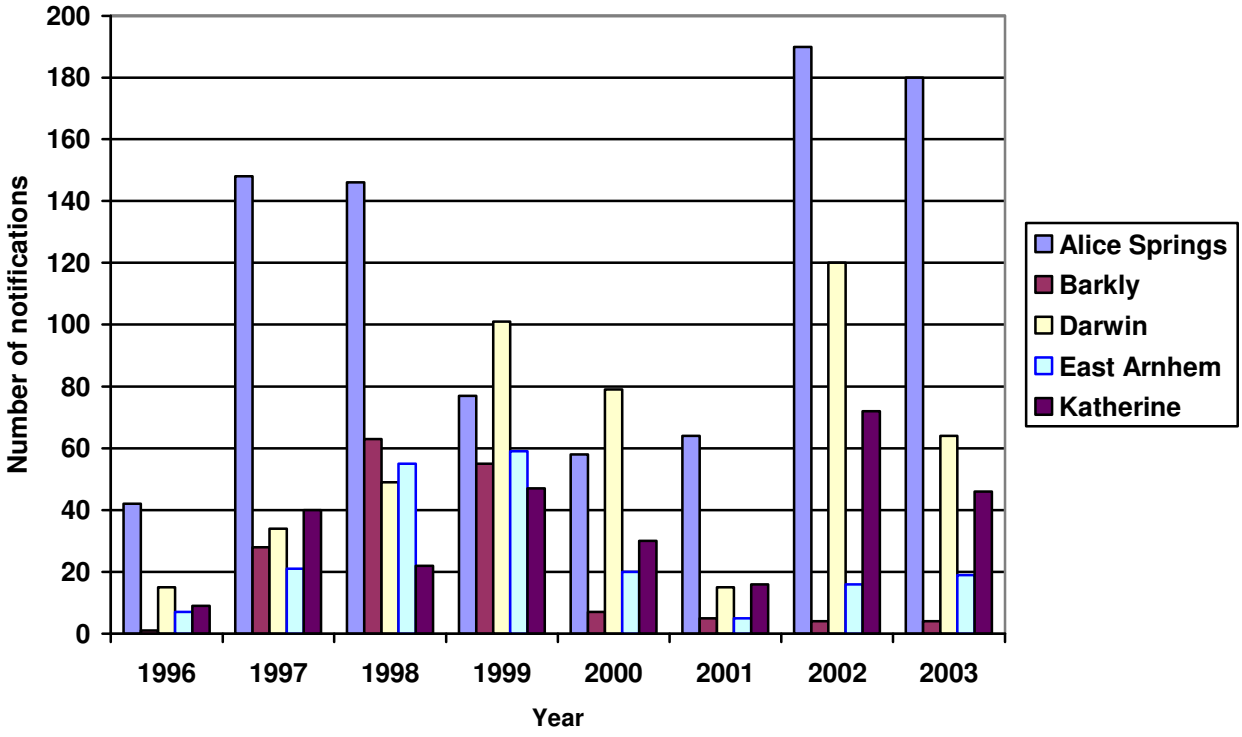
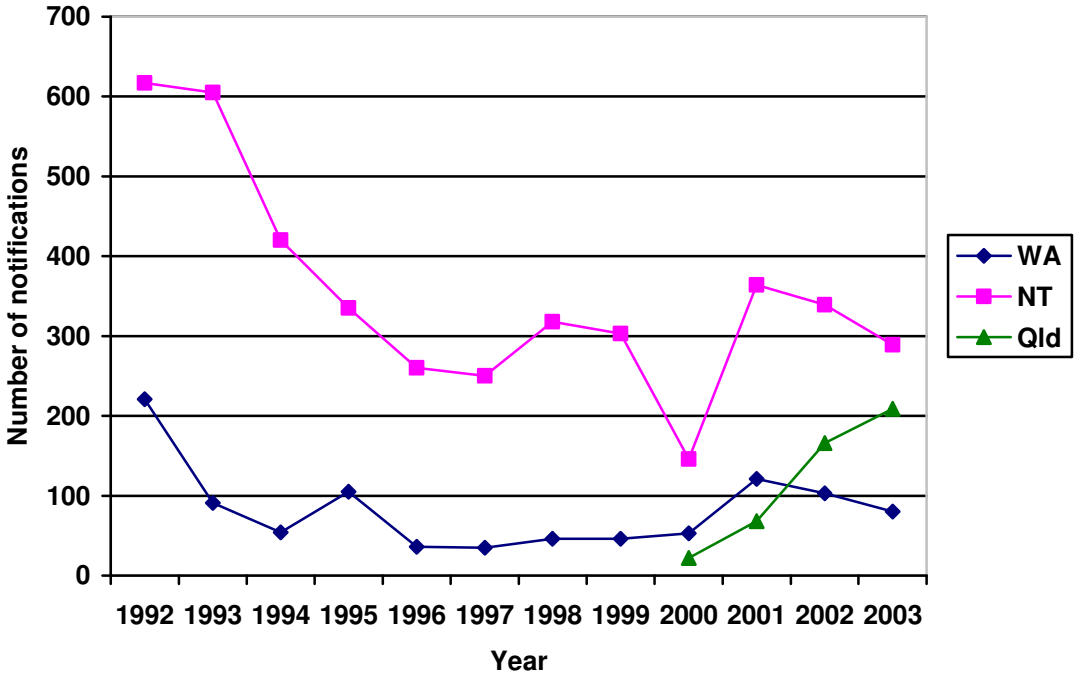


FIGURE 4.12 ANNUAL INDIGENOUS SYPHILLIS NOTIFICATIONS WA, NT & QLD 1992-2003



[8-10]

The recent increase in Indigenous syphilis notifications in QLD (2000 – 2003 and continuing) corresponds to the establishment of the Statewide syphilis surveillance network and data base and so probably reflects improved surveillance. It also parallels the overall increase in syphilis notifications in men (notably men who have sex with men) in NSW, Victoria and Queensland which has occurred from 2001 onwards (Figure 4.12).

4.5 Comparison between Testing Types

In the States and Territory different tests were available at laboratories for donovanosis. The Genital Ulcer Multiplex PCR (donovanosis, herpes, syphilis and chancroid) was available in Queensland, the PCR Uniplex was available in Western Australia (and used for donovanosis, herpes and syphilis) and the monoplex PCR test for donovanosis was initially available in the NT. Subsequently NT sent most swabs to WA for testing.

The following results were extracted from data provided by the DPOs from 2001 to June 2004. Due to the small numbers it is difficult to determine the efficacy of each test. Just under half of diagnoses made were confirmed with clinical diagnosis alone. Information which was unavailable included the number of negative tests, as well as the number which were never clinically confirmed and notified.

GUMP Queensland n=8 tests

GUMP negative	GUMP positive	Negative GUMP & slide positive	Negative GUMP and clinical diagnosis positive
8	0	4	4

PCR Western Australia n=3 tests

PCR negative	PCR positive	Negative PCR & slide positive	Negative PCR & clinical diagnosis positive
1	2	0	1

PCR Northern Territory n=4 tests

PCR negative	PCR positive	Negative PCR & slide positive	Negative PCR & clinical diagnosis positive
0	4	0	0

Slides all cases combined n=42 tests

Slide negative	Slide positive	Negative slide & PCR test positive	Negative slide & clinical diagnosis positive
22	20	4	18

Diagnosis all cases combined n=44

Laboratory test (GUMP, PCR, slide) positive	Clinical diagnosis positive
55% (24)	45% (20)

Chapter 5

Interviews

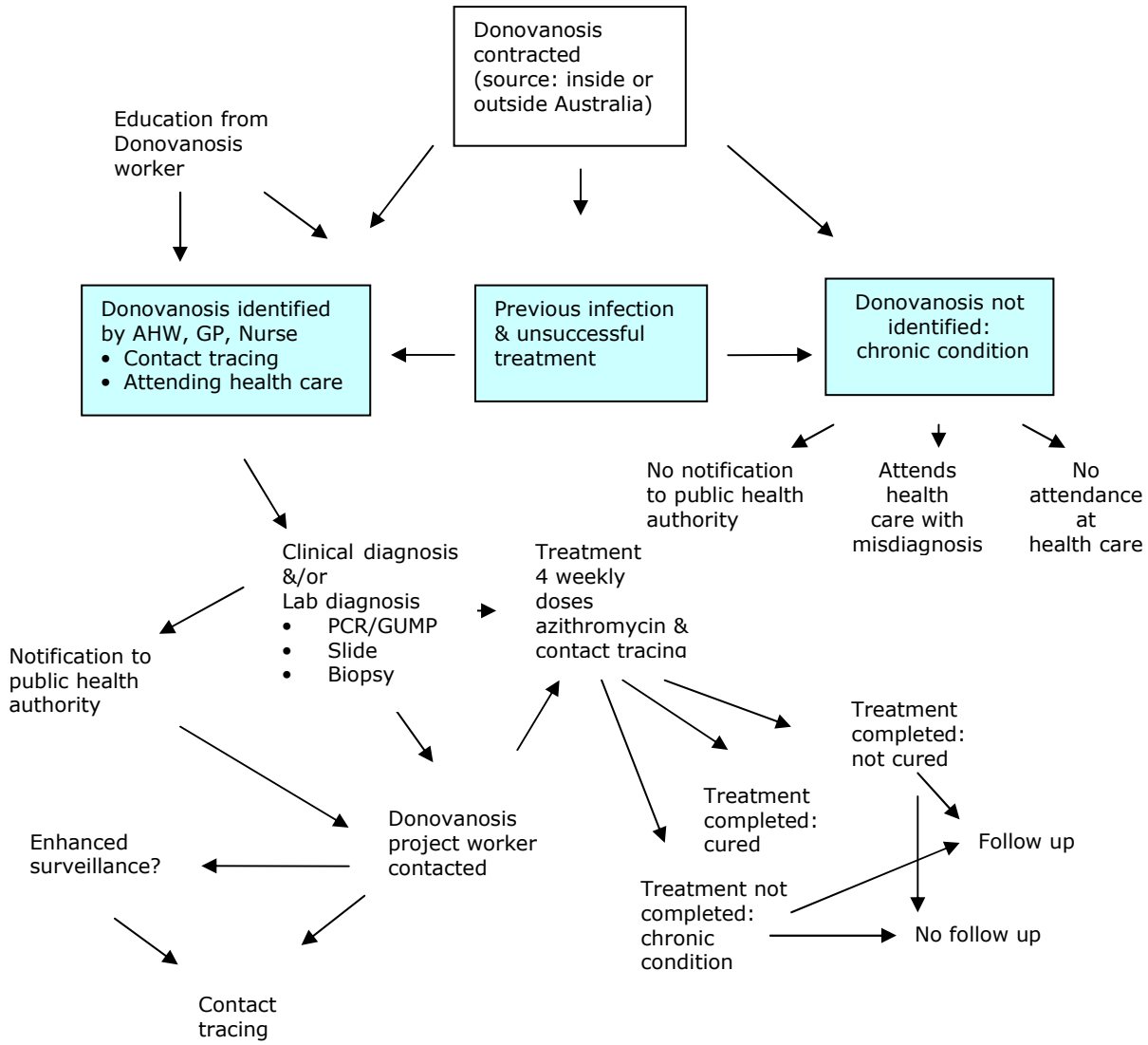
In-depth interviews were conducted with a number of key informants. DPOs were interviewed individually, and with one exception, in person. In addition, four DPOs were brought together for a focused group discussion about a variety of issues including the barriers to, and factors which facilitated, the overall success of the program and the management of the program by the Commonwealth. Most other interviews were conducted by telephone.

5.1 Finding Donovanosis Cases

The flow chart shown in Figure 5.1 indicates the ways in which donovanosis cases were identified and managed during the NDEP. Sources of donovanosis in Australia may originate from within Australia or from other countries where donovanosis occurs, in particular Papua New Guinea with its close proximity to the Torres Strait and Australia. No cases of donovanosis contracted outside Australia were noted, however, by DPOs in interviews. Donovanosis cases followed up by DPOs were new cases or older cases that had been previously unsuccessfully treated. Cases were diagnosed when individuals sought health care either for ulcers, ante-natal care or Pap smears, or when donovanosis was suspected during the course of a health care consultation. It is possible that some cases were never identified or treated and that the individual lived with a chronic disease, or waited until a serious and acute stage has arisen, such as those requiring hospitalisation noted in the case studies (see Appendix 3).

Cases, both clinical and laboratory diagnosed, are notified by health care workers and laboratories to Public Health Units. DPOs were alerted to cases through public health notifications or through direct contacts from health care workers seeking advice and/or assistance. The DPOs worked on improving identification of cases by educating health care staff and the community more generally to be aware of causes of genital ulcers including donovanosis and its treatment. DPOs promoted awareness of syndromic management for genital ulcers, testing and appropriate follow up of cases. This involved negotiating with health care workers, public health units and laboratories.

Figure 5.1 Flow chart



5.2 Role of the Donovanosis Project Officers

Each of the DPOs was appointed by the State/Territory office to whom they subsequently reported, but the overall project was managed by the Commonwealth (Table 5.2). A brief description of the work of each of the DPOs is given here to provide some context for the discussion which follows.

Table 5.2: DPOs' employment

	WA Perth	**NT Darwin**	**NT Alice Springs**	**QLD Cairns**
Date commenced	Oct 2001	Jan 2002	Jan 2002	Jan 2002-Jan 2003, Jan 2003-June 2003; June 2003-Jan 2004
Appointment Level	Project Officer Level 5	Clinical Nurse Consultant Level 3	Clinical Nurse Consultant Level 3	Clinical Nurse Consultant Level 3
Based in	Policy Unit, Dept of Health	Dept of Health and Community Services	Sexual Health Unit	Cairns Sexual Health Service
Has position been maintained in some way?	GUD function now included in new position	No	No, and there is evidence that gains made have been lost.	No, but Syphilis Register nurse monitoring the situation

5.21 Western Australia

Noreen Conlon was the first DPO appointed, and she began work in October 2001, well before the initial Training Workshop was organised by the Commonwealth. Noreen's job description appears in Appendix 1.

Following a scoping study, five regions in WA were noted as having had donovanosis. This resulted in 160 organisations being identified as providing sexual health education, clinical services, pathology or which were dealing with the target population. Noreen visited rural and remote centres, cultural centres, Public Health Units, GPs, and community health centres to provide professional development around GUD and to consult for the development of a WA Donovanosis Elimination Plan. A competition to develop a community educational resource on donovanosis was targeted at health care providers in '*donovanosis affected regions'* and offered a total of $5000 in prize money. The competition not only raised awareness in a fun and creative way about the project, but provided information which health care providers could use to inform themselves and/or their clients. The entry pack contained a Donovanosis Fact Sheet for Health Practitioners, a Donovanosis Fact Sheet for Community Members,

donovanosis statistics and a case study. As a result of this competition, Noreen was able to use local artwork for other stickers and posters. The winning entry of the competition was a song entitled "An ulcer on his pulser".

Travel was a major part of Noreen's work – about 1/3 of her budget was spent on travel to various locations to conduct professional development on GUD. She managed her own budgeting.

Challenges

Noreen identified a major challenge to be that the profile of the NDEP was not strong. The fact that many believed the money would be better used elsewhere had an effect on participation and cooperation. Passive resistance slowly resolved with time and support of the key people in sexual health in WA.

At both the State and Commonwealth level there were significant delays around achieving consensus on practical aspects of the project, such as agreement on the NDEP Action Plan and even on a definition of elimination.

A key to meeting challenges was building trust which required commitment to on-site visits, open communication at all levels (from the Commonwealth through to service providers out bush) and being sensitive to and respectful of the challenges everyone faces when working in the area of sexual health.

Successes

The large geographical area to cover combined with changing staff meant that it was important to establish systems to ensure ongoing GUD professional development. Noreen believes that the systems she established as a DPO have had an impact in STI management more generally.

She also felt that the development of the Aboriginal Sexual Health Resource for WA was a significant outcome of this project. The development of the STI/HIV Flipchart, STI pamphlets and posters resulted in participation of health care providers throughout the state. WA has also committed to maintaining donovanosis enhanced surveillance.

Project Officer Activities
(taken from 6 monthly reports submitted to Commonwealth)

From October 2001 to October 2002

- 68 education sessions were held for 407 participants.
- Review of donovanosis notifications in WA from 1990.
- Audit of services in each donovanosis region targeted for visits; 160 services identified and 83% contacted.
- Education sessions included GUD test, treatment, follow up, specimen collection, resources available for health promotion.
- Followed up cases and provided advice to clinicians.
- Developed the WA Donovanosis Elimination Plan after consultations in endemic regions of WA.

From November 2002-October 2003

- Contact made with 95% of 160 organisations in endemic regions.
- 46 education and training sessions held for 315 participants.
- 37 sessions supporting STI programs.
- Involvement with development of Indigenous sexual health resources, donovanosis information pack, STI postcards, STI/HIV flipchart.
- Followed up cases and provided advice to clinicians.
- Development of a community fact sheet and health provider fact sheet and stickers.

5.22 Queensland

Brenda Henry was one of three DPOs in QLD, and was employed for the first 12 months of the project. She was replaced by Chris Wilson, who held the position for 6 months, and later on Penny Marshall, who was employed for the final 6 months. Both Brenda and Penny were grateful for the support and co-operation of the staff managing the Syphilis Register, for neither of them had access to this database so they were reliant on this assistance.

Challenges

Each of the three DPOs were capable and competent at their work, but it was unfortunate that in the two year position there were so many changes of staff. This was also true of other staff in the unit, so that by the time Penny took up the position, she found that no-one really knew about donovanosis or much about the DEP. Initially Brenda had to get approval for each trip she did by letter and in person with her director. This was subsequently overcome by planning the year in advance and getting approval for the whole plan. Penny also felt subsequently that while Brenda had left a future workplan, by the time she came on board (after Chris's term of 6 months) she would have valued some indication by management that this was still the best way to proceed. Penny found it difficult to report the Action Plan.

In Queensland, DPOs were never given information about the results of attempts to validate the GUMP so that they were never completely confident about the test. This was a particular problem because of the low rate of clinical diagnoses receiving a GUMP positive. The difficulty in accessing information from the laboratories was mentioned by all DPOs.

Successes

All three DPOs delivered an enormous amount of education that was specifically designed to suit the target audience. All of the forms used were focus–tested in the community to ensure community approval before the project began.

Example of Project Officer Activities
(taken from reports submitted to Commonwealth)

2001-2002

- Development of a Genital Ulcer Characteristic (including syphilis, donovanosis, herpes, chancroid & LGV) chart to assist clinicians.
- Member of the GUMP group to assist GUMP testing trial.
- Conducted a literature review on donovanosis.
- Developed education materials in form of power point presentation, practical demonstration of pathology collection, role plays, case histories and management guidelines, graphic displays (men and women).
- Conducted 106 education sessions using developed materials.
- Reviewed past notifications of genital ulcers through liaison with laboratory and Public Health Units. Conducted follow up of old cases that were accessible.
- Focus tested genital ulcer disease materials with primary health care centres
- Developed and implemented a training module on GUD incorporated into TAFE enrolled nurse course, rural health training unit sexual health course and Aboriginal Health Worker Training.
- Provided advice and ensured follow up for Donovanosis cases.

2003-2004

- Review of donovanosis cases 1997-2001
- Education sessions given to Queensland Health Nurses as part of orientation program, Aboriginal Health Worker Training level III & IV, sexual health workshop with sexual health workers, enrolled nurse TAFE course.
- Attended every primary care clinic in Nth Queensland.
- Distribution of GUD flow chart
- Liaised with Syphilis Project Officer to assist identify cases of GUD.
- Followed up cases to ensure appropriate treatment and management
- Provided advice to clinicians

5.23 Northern Territory – Alice Springs

Janelle Wilkey was appointed in Jan 2002. Her position finished in June 2005, having been extended from the original 2 years because she was able to utilise unspent money from the Darwin DPO's position. Janelle received on-the-job training from staff in the unit in which she was based, and felt very much that she was part of a team.

Janelle's work was characterised by the fact that she also managed a central follow-up system for STIs. This is a unique system which was established in Central Australia whereby results from pathology testing are downloaded directly and on a daily basis to a computer based in the Sexual Health Unit. This allowed Janelle to immediately inform health service and remote area staff of any positive diagnosis so that treatment and contact tracing could be initiated as soon as possible. It also allowed her to follow up on any clinically suspicious but pathologically negative cases.

A big part of Janelle's job was to participate in the Men and Women's Health workshops held twice a year which orient new remote area nurses to sexual health issues in their communities. Unfortunately under the new Pathways Program these units are no longer compulsory so Janelle anticipates that sexual health will fall off the agenda for some of these nurses.

Challenges

Initially Janelle felt well-managed locally, but once the management position was lost to Darwin under the Territory restructure of the Health Department she felt local management was less evident. She also expressed concern about the success of both syndromic management and contact tracing in her region.

Successes

Janelle completed enhanced surveillance on a series of 132 ulcer cases and found a previously unrecorded high rate (30%) of herpes diagnoses. As a result of this there was some shift in the way in which she conducted professional training on GUD. The relationship with the laboratories also meant she had access to both positive and negative test results and could therefore be more alert than other DPOs to potential cases.

Example of Project Officer Activities
(taken from reports submitted to Commonwealth)

2002-2003

- Introductory letters and visits to services
- Education sessions to 42 services for 325 participants
- Development and distribution of a resource pack
- Education sessions with remote area nurse orientation, men's and women's health workshop, remote clinics, hospitals, remote area nurse meetings, community educations remote and urban, at risk youth workshop.
- Training included clinical diagnosis and notification, specimen collection, treatment and follow up of GUD.
- Project with Alice Springs Youth Accommodation support services sexual health clinic – included half day workshop and poster competition to be used in resources.
- Maintained and reviewed donovanosis register
- Followed up cases

2004

- Development of safe sex posters for young people
- Development of a GUD flow chart
- Development of a flip chart
- Production of condom wallets aimed at remote area safe sex promotion
- Maintained donovanosis register
- Analysis of two years of data from donovanosis register recording GUD.

5.24 Northern Territory – Darwin

Anne Davis was appointed in January 2002. She was part of the Sexual Health Team, and felt well supported by colleagues. A scoping study was not conducted in the NT as Anne's management believed these issues in relation to donovanosis were well-understood at the territory level. Anne was expected to operate independently, and while this gave her the mobility to manage her role as she saw best, she initially felt that there was no-one at the local level from whom she could get feedback about whether she was on the right track. Despite this, she says she believes the DEP was successful, and she has a great sense of pride from her involvement.

Challenges

Initially Anne had no access to funding so she didn't have the resources available that she needed. It took about 12 months before this was sorted out, and to some extent this limited the way in which she initially developed her work. Her management preferred that she travel by car than fly, and so this limited the contact she was able to have with some places, such as East Arnhem.

Anne felt that she needed to overcome the negative attitudes of some primary health care practitioners, who didn't always follow guidelines because they thought they knew better. She felt that some of the more recent cases she saw were cases she had heard of before, and she believes the doctors treating these cases did not pass these cases to her earlier because of their reluctance to share this information with her as a nurse.

She also had a sense that cases were missed because a lot of people are reluctant to attend health services.

Successes

Anne felt that the education and training she provided had a significant impact on some health professionals. However other health professionals, who saw fewer cases of GUD, were less interested. At times Anne found that it was necessary to follow-up and administer treatment herself, but she was then confident that these cases had been treated appropriately. She spent a lot of time in capacity building and education and felt that she was successful in these endeavours.

Example of Project Officer Activities (taken from reports submitted to Commonwealth)
Jan 2002 – May 2003 ○ Education sessions to urban and remote clinics. Education sessions included early detection, case management and follow up to 21 of 22 Community Controlled Health Organisations and 36 (100%) of Territory Health Department clinics. ○ Collaboration in other Health Department training initiatives eg. Women's Health, Chronic Diseases, Alcohol and Other Drugs. ○ Linking with Family Planning to educate community workers ○ Distribution of sexual health resources to urban and rural health clinics.

5.3 Interviews with Other Key Informants

Interviews were conducted with key informants employed in the areas of health service practice (HS), pathology (P), State/Territory Government (S/T G) and Commonwealth Government (CW). Many of these informants were able to comment from more than one perspective – for example several sexual health practitioners also hold, have held or subsequently took up positions in the State/Territory Health Departments. They are designated as mostly commenting from the first listed viewpoint.

WA

Sandra Thompson (S/T G)

Heath Greville (S/T G)

Michael Leung (P)

David Smith (P)

Donna Mak (HS, S/T G)

NT

Steven Skov (S/T G, HS)

Kath Fethers (HS)

Jan Savage (S/T G, HS)

QLD

David Bradford (HS,S/T G)

Janet Knox (HS,S/T G)

Russell Enbom (P)

Mark Counter (S/T G)

Theo Sloots (P)

Fiona Cannon (HS)

Commonwealth

Bernard Pearce (OATSIH)

Ivan Bastian (P)

John Kaldor (CW)

Frank Bowden (HS/ CW)

Chapter 6

Key Issues

6.1 Testing

The availability of a sensitive and specific laboratory diagnosis for donovanosis is a key aspect in the elimination of donovanosis. Samples used for microscopy may be obtained by smear, site specimen or formal biopsy. The interpretation of these microscopical specimens is, however, very observer-dependent and the sensitivity improves markedly with the experience of the microscopist, which given that donovanosis is a rare condition, is hard to acquire.

History of the Donovanosis PCR

Ten years ago Frank Bowden was concerned at the rising incidence of donovanosis and the possibility that these genital ulcers would increase the potential for HIV spread amongst indigenous Australians. He asked Ivan Bastian, then at the Menzies School, to develop a PCR for donovanosis. After Ivan left Menzies in 1995, development on the test continued to improve its specificity. Unfortunately it was never validated as a diagnostic test because there were not enough donovanosis cases. Attempts to acquire cases from PNG to assist in validation failed as there had been a sudden decrease in donovanosis recently. The use of old stored samples would have contravened ethics regulations, as appropriate consent had not been given.

The Commonwealth was unable to give money for research development but this was possible at the state level, so ultimately the states paid for the finalising of the test development.

David Smith at PathCentre, Perth, picked up on the PCR method and modified and improved the PCR monoplex slightly.

At the same time the Australian multiplex test was a further 'in house' test produced by a developmental laboratory based in Brisbane, at the request of Queensland Health. Earlier Mark Counter had seen a conference presentation by an international speaker in Darwin describing the combining of two tests which led him to believe that a different combination of tests to check for genital ulcer could be useful in Queensland. He approached Theo Sloots at the Sir Albert Sakzewski Virus Research Unit at the Royal Children's Hospital, to develop a multiplex assay for the simultaneous detection of syphilis, chancroid, donovanosis and herpes (Project Proposal, dated Jan 15th, 2001). PhD student Ian Mackay did this work under the direction of Theo Sloots. He took a standard US multiplex PCR test for herpes, chancroid and syphilis, and added into this the donovanosis monoplex PCR. The newly named Genital Ulcer Multiplex PCR (GUMP) test was then sent to QLD Pathology Service (under David Siebert) for use. At this stage only the herpes component had been validated, as there were simply not enough cases to validate the other three components. The difficulty in validating syphilis results was because the GUMP test uses a swab to detect the presence of infection, whereas syphilis traditionally is tested using a search for antibodies in a blood sample. Subsequently it was found that a positive syphilis

serology and a negative GUMP test could be accounted for by a previous positive syphilis result.

The understanding with Queensland Pathology was that as soon as samples were sent to them for diagnosis, they would be forwarded to the developmental laboratory to be included in the validation. Ultimately the GUMP assay was validated for herpes only, because of the low numbers of cases.

An unanticipated outcome of the DEP was that these two independent developments in PCR testing resulted in the formation of an informal laboratory network comprising – David Smith and Gerry Harnett (Perth), Ivan Bastian (Adelaide), Ian Mackay and Theo Sloots (Brisbane) who met in Brisbane once and then spoke by teleconference. There appear to have been two minuted meetings of the Genital Ulcer Multiplex PCR Test Technical Advisory Group, one by teleconference on 30/4/2001, and a final meeting on 3/9/2002.

Part of the NDEP was the validation of the donovanosis PCR. This has proved impossible to achieve, because 50-100 cases are required. At present the sensitivity of the monoplex PCR is estimated by Ivan Bastian to be 80-90%, and specificity is 95-98% - an estimate based on mixed results of some old frozen samples and some newer ones.

In Queensland, some clinicians were of the view that the GUMP test hardly ever detected a positive donovanosis but did detect a lot of syphilis and herpes. This was interpreted by some as suggesting that the US test was working fine but the add-on Australian monoplex donovanosis PCR test lacked sensitivity when mixed with another multiplex test, or that few of the lesions suspected of being donovanosis were in fact donovanosis. However, it subsequently transpired that approximately 5 samples of suspected donovanosis were sent to Brisbane but somehow were never tested for donovanosis. The diagnosing clinicians, not having received a positive diagnosis, therefore assumed these cases were negative, but in fact they had never been tested. This breakdown in communication remains a significant blow to the credibility of the GUMP.

In Queensland, the use of the GUMP test is restricted to Indigenous people from the Northern Zones and only carried out where there is evidence of unclear GUD or suspected donovanosis. Testing is only carried out on genital lesions. Queensland Pathology in Cairns receives the samples first; they stated that it is difficult to get good samples for testing. Impression stains are done in Cairns, and then a dry swab is sent to the Brisbane laboratory for GUMP testing. When the DEP commenced, GUMP was being run as a trial and so swabs were also sent to the developmental laboratory in Brisbane, but now swabs are just sent routinely to Queensland Pathology in Brisbane.

Queensland Pathology Cairns had little interaction with the DPOs; there were clear instructions from Queensland Pathology Brisbane so Queensland Pathology Cairns felt there was no need for interaction with DPOs. Queensland Pathology management has strict guidelines about who accesses results, so they were not in a position to be able to co-operate with the DPOs' wishes to receive information about requested tests. They believed that to get access to these results the DPO would need to formally request this through the Director-General of Health. As no request to do so came from the Director-General, Queensland Pathology Cairns assumed the DPOs found their means of accessing results to be satisfactory.

In Western Australia, Western Diagnostic Pathology provides pathology services to remote communities, and so all specimens of suspected donovanosis are sent there first, before the sample is sent for PCR testing to PathCentre Perth. All bench staff there are able to look for donovanosis. Samples from Central and Western Australia are sent to PathCentre in Perth. For each sample a crushed smear and a biopsy as well as a PCR is carried out. If a donovanosis test is requested, this is done at no cost to the patient. Costs to PathCentre are partly recovered by the Medicare rebate received on herpes or syphilis, but they would be unable to do this if a large number of donovanosis cases came through. There was a proposal to make donovanosis a Medicare item but there were not enough cases to justify the effort involved in making the application. The commonest cause of ulcer currently is herpes.

PathCentre believed the system worked well. Only once did they have a positive slide and a negative PCR, and that was where the slide had not been handled well. Their PCR is 80-85% sensitive and 100% specific. There are recommendations for collection but they cannot verify whether they have been carried out correctly.

6.2 Key Issues in relation to Testing

One of the key points the Queensland DPOs uncovered quickly was the fact that staff on the ground were much too ready to accept a negative microscopy report (and later a negative 'GUMP' report) and to STOP treating for donovanosis, on the basis of the result of an insensitive, and as yet non-validated, test. They would begin well by treating a genital ulcer syndromically for syphilis and donovanosis, and sometimes herpes if the ulcer was painful, by giving the initial dose of azithromycin for donovanosis. But if a negative laboratory result came in no further weekly azithromycin would be given because they saw that the test was negative, so they believed that the patient can't have had donovanosis. If syndromic management is to work towards eliminating donovanosis then it has to be carried through in every case, *even in the face of negative tests*.
In the NDET meeting of 23/6/03, it is recorded that of 36 tests for genital ulcers conducted in Queensland, not one was positive on GUMP. However, it is unclear from the minutes whether these tests were carried out on patients in whom syndromic treatment had commenced and then was subsequently withdrawn on the basis of the negative test.

The belief among practitioners that the diagnostic test was sufficiently sensitive and specific may, in fact, have been one of the major weaknesses of the NDEP. In actual practice the old standard microscopy test proved too insensitive, the new 'in house' monoplex donovanosis PCR test was not widely available and the much vaunted GUMP, although used widely in Queensland, was never properly validated and anecdotally seemed insensitive.

From the first month of the NDEP, it was decided that pathology specimens from WA and Alice Springs would be sent to Perth for viewing by Dr Brett Snowball, and those from Darwin and Queensland to Brisbane to Professor Cook (semi-retired), two experienced histopathologists. The Review team has been unable to determine whether any pathology specimens were, in fact, sent on for viewing by these pathologists.

6.3 Management of the Program

Each DPO worked as part of a team, and her role was overseen by a Manager. However, she was also as independent as her placement structure would allow, and it was intended that she manage her own budget.

The project in its entirety was managed by a Secretariat in the Commonwealth Department's Office of Aboriginal and Torres Strait Islanders, comprising Bernard Pearce and Project Officer Biliwara Lee. The Commonwealth provided documentation to the Evaluation Team which indicates that the program was overseen by the NDEAC which met 4 times:

NDEAC 8 March 2001

NDEAC 16 August 2001

NDEAC 22 July 2002

NDEAC 27 May 2003

There was evidence from a number of key informant interviews that the Committee managing this Program did not keep ahead of the needs of the DPOs. Examples of this include the design of data collection forms; the Annual Reporting requirements; and the draft Action Plan, for which it took 18 months to achieve consensus. The final version of the health practitioners guide was only completed and printed finally in mid-2005, by which time all DPOs had ceased employment in that role. The Commonwealth found that management of the program became far more labour intensive than they had originally foreseen, and given the pressures of other projects, they found it hard to keep abreast of the needs of the NDEP.

The NDET which comprised the DPOs, the secretariat and Dr Frank Bowden, Dr John Kaldor and Mr Michael Howard met by teleconference or in person on 4 occasions:

NDET 14 November 2002

NDET 23 June 2003

NDET 14 August 2003

NDET 22 October 2003

The NDET, as a smaller, perhaps more committed team, appears to have worked well together. While NDET was more focussed on the practicalities of achieving goals, the structure of the lines of authority created problems for DPOs. DPOs highlighted that a challenge for them stemmed from the fact that their work was practice based, and that as the Commonwealth was bureaucracy based, there were inevitably delays in having their questions answered. There appears to have been some issues where jurisdictions had different practices, and where there was no clear guidance given to DPOs. One example of this was whether sexual contacts of clients with donovanosis should be syndromically managed. The NDET minutes of 14/11/02 suggest that in Queensland sexual partners are treated immediately without examination, but the actions taken by the other jurisdictions are not clear. Any guidance given to the DPOs on this issue is not evident in these minutes.

At the end of the project, the DPOs stated that there was no appropriate closure to their work. There was not even a Commonwealth repository where they could store information arising from their efforts.

6.4 Initial Training

A workshop was held in Canberra in December 2001 to orient and train the DPOs. At this stage only one DPO had commenced work; the others did so early in the new year. While it was agreed that this workshop provided the DPOs with a great deal of useful information about donovanosis, it was apparent at this stage that there were not yet clear structures in place to assist the DPOs in their task. It was recognised, for example, that an efficient data collection proforma was needed, but this subsequently took some time to develop, as early versions did not adequately reflect the breadth of work undertaken by the DPOs. An Action Plan was not agreed upon by the states and territories for many more months. No consensus had been reached about how "eradication" of donovanosis should be defined, so that the goals for the Program were not able to be clearly articulated to the DPOs at this stage. The DPOs had anticipated that they would come away with a clear set of guidelines for managing their work, but the reality fell short of this. The DPOs nevertheless felt sufficiently informed to make a start in their new role, and all felt that the most significant benefit of the workshop was the opportunity to network with the other DPOs.

The case definition of donovanosis was not endorsed by the Communicable Disease Network of Australia, sub-committee on STI surveillance, until June 2002. Even more importantly perhaps, the definition of 'elimination', necessary to measure the success of the project, was not established until 2003, towards the end of the project.

6.5 Support for DPOs within own Setting

The job description for the DPO position was written independently by each State/Territory, and thus some variation existed between types of appointment.

DPOs were all able to access the systems of the department or unit within which they were placed and described good working relationships and networking with their work colleagues within this setting. However, not all felt well-supported by their managers. This may reflect the level of experience or knowledge of donovanosis of these managers. It is also apparent that there was little, if any, interaction between the Commonwealth and some of the State/Territory managers in relation to their role as supervisors of the DPOs. At the State/Territory level there appeared to be varying levels of discomfort with what was seen to be an attempt by the Commonwealth to micro-manage a project which had not been set up to operate within the reality of the local situation.

6.6 Interaction with Laboratories

Overall the DPOs appeared to have little direct interaction with the laboratory staff members who were managing the testing. In some situations the lack of interaction appeared, to the outsider, to border on the unco-operative. This may have been the result of a lack of clear direction to the laboratories or to the DPOs at the commencement of the program explaining their roles and responsibilities in relation to each other. The information about testing is an essential part of a program such as this, and yet some DPOs clearly felt a degree of frustration at their inability to develop a collegiate relationship with laboratory staff, although

the various laboratory staff themselves appeared to network well with each other. These difficulties are recorded in the minutes of the NDET (23/6/03).

Traditionally, laboratory staff members expect doctors to order tests and are only medico-legally obliged to provide the referring doctor with the results of tests – in hindsight the NDEAC should have foreseen this problem and set up mechanisms whereby the DPOs could have been enabled to access results and local statistics from local public health/state department health laboratories. In some situations laboratory personnel also played a key role in the management of the program and where this was the case, a relationship which was more beneficial to the program was negotiated.

6.7 Support from the Commonwealth

In many ways the NDEP had an unfortunate beginning. The then Minister for Health, Michael Wooldridge, announced in Parliament that an attempt to eradicate donovanosis would be made. Money was made available reasonably quickly, even before a proper work-up had been completed. This meant that the Commonwealth was always going to find it difficult to keep ahead of the program as it rolled out.

Management of a program such as this from a great geographical distance is never an easy task. In this case it was made more complex by the fact that government department bureaucracy is not set up to respond quickly to immediate challenges. It may have been more efficient if a health service organisation had been contracted to over see the management of this project, which required ongoing supervision across a range of technical areas. The strength of the Commonwealth would perhaps have been in monitoring the progress of the project and acting as a conduit to the Steering Committee.
As time went on it was apparent that managing the project from Canberra became harder and harder, and was hampered by Commonwealth policy eg. Commonwealth employees were not allowed to travel to visit the DPOs; the DPOs needed to come to them.

During the course of the project there were sometimes issues which arose which required an expert opinion, and these proved difficult to resolve because of the management structure. An example is that the DPOs were told that they should educate health care practitioners to wash lesions with saline to get rid of secondary bacteria before taking a smear. However, this view was not supported by a senior sexual health physician in one area, which confused the education messages offered by the DPOs. This should have been addressed immediately it arose.

All of the DPOs believed that the Project was appropriately funded.

6.8 Challenges for the DPOs

All DPOs stated that overcoming the negative attitudes of health practitioners for whom sexual health was not high on the priority list was challenging.
Often this had to be done by sheer doggedness. Initially there appeared to be few spontaneous reports of cases by staff, so DPOs had to take the initiative by ringing and visiting primary care clinics and spending time talking to staff, especially the older Aboriginal/Torres Strait Islander health workers.
All of the DPOs highlighted that the challenges they faced were mostly challenges that arose from Indigenous health provision more generally – such as high

turnover of staff, the low place of genital ulcer disease on the already low position held by sexual health on the agenda, the poor orientation received by many staff of remote areas, professional isolation of staff. DPOs agreed that donovanosis needed to be included in a sexual health framework, and that not all practitioners can manage sexual health well. It was identified that young or inexperienced GPs in Queensland were often unwilling to co-operate in donovanosis testing, and the Queensland DPOs were keen to see nurse practitioners in rural (as opposed to remote) areas be allowed to take pathology tests.

DPOs sometimes struggled to get their message through. Some remote health staff have a paternalistic attitude to others wishing to come in for health promotion; one DPO received a letter from a remote area staff member telling her that the community she worked with was tired of such interference. Sometimes DPOs travelled with sexual health teams visiting communities; this had problems at times, because if the team's rapport with the community was poor, the DPO was treated with suspicion. It was also apparent to the community why the team was there, and so many Indigenous people felt ashamed or lacked confidence to attend. On the other hand, if the DPOs went alone, sometimes the faxes or messages they had sent before their arrival would go unheeded, and when they arrived people were apparently unaware that they were coming. Some DPOs agreed that while Indigenous communities gave their permission for their visit, they sometimes appeared uninterested, and that perhaps this was because the DPOs didn't know the etiquette. Cross-cultural training was given to the Queensland DPOs, but not to NT (Darwin) and WA DPOs. The fact that the DPOs delivered the same education messages to all health care practitioners was an advantage. Even though remote area nurses don't stay for very long, they often travel to other remote areas and so hopefully they will take the knowledge gained on GUD with them.

It is hard to know to what extent the benefits of the DEP have been sustained. In the absence of a DPO, one health care practitioner now gets queries from other health care practitioners who have not looked in the manuals or guidelines for advice on clinical ulcers – she claims they want information immediately while the patient is with them.

Another problem identified by DPOs included lack of standardised reporting on positive and negative cases between different laboratories within the same State/Territory. This is the type of problem that needed to be sorted out by management, as the DPOs lacked the authority to overcome this.

6.9 Key Indicators

To determine progress made on the Outcomes listed in the Action Plan requires more specific parameters than are given in the list of Key Performance Indicators (see Page 11). For example, the first Key Performance Indicator states "95% of primary health care centres in each DAHR are trained in the content of the National Donovanosis Fact Sheet". While from their Reports, the DPOs appear to have achieved this, what it means in practical terms is unclear. Does this refer to all staff of a centre or one staff member? Does 'trained' mean that the centre should have received a visit from the DPO, or that the DPO should have run a donovanosis-specific training session for staff there? Similarly the second Key Performance Indicator states that 95% of primary health care centres should utilise the Genital Ulcer Care Plan and Management Guidelines for Genital Ulcer Disease. This seems somewhat difficult to determine, particularly given the high

turnover of staff in remote areas. The DPOs may have educated staff about the guidelines, but it is difficult to know to what extent genital ulcer assessment subsequently becomes part of their usual practice without a proper research project to ascertain this specifically.

Data collection throughout this Program has been widely variable. Reporting forms were not available at the very beginning; even now they have minimal information; it is difficult to determine the success of the DPOs from what has been routinely provided. Clinical notes from which the details required for enhanced follow-up are derived, were often extremely poor. However, it does appear six-monthly reports were generally provided by DPOs.

The Action Plan stated that OATSIH, NDEAC and NDET will have responsibility for communicating and encouraging the use of standard treatment protocols nationally, including:

- syndromic management
- short course, directly observed treatment
- inclusion of donovanosis in GUD standard treatment protocols in endemic areas
- National Antibiotic Guidelines.

The Department of Health and Ageing has produced an excellent document detailing donovanosis diagnosis and management, and this information has been incorporated into local guidelines. Similar success has not been achieved in relation to the Antibiotic Guidelines or the National Management Guidelines for STI Management. The latest version (Version 12, 2003) of the Antibiotic Guidelines retains the information from Version 11, 2000. It does not mention directly observed treatment, although it does state that treatment for syphilis and gonorrhoea should be commenced if these diseases are unable to be excluded. It states that 'microscopy of scrapings, snip or punch biopsy confirms the diagnosis'. A new version of the Antibiotic Guidelines is planned for 2006.

The National Management Guidelines for STIs was published in 2002, and a new version is similarly planned for 2006. While punch biopsy is suggested to confirm the diagnosis, the fact that PCR may soon be available is highlighted. It also states that 'The National Donovanosis Advisory Committee (NDEAC) recommends directly observed treatment in all cases of suspected or confirmed donovanosis'. Syndromic management in relation to donovanosis is not mentioned in this section.

It is essential that appropriate information about donovanosis be included in the new editions of both of these guidelines.

6.81 Key strategies identified in the Miller Report

Several strategies were identified in the Miller report to assist in the eradication of donovanosis. These included:

1. **Strengthening the capacity of primary health care services to provide early diagnosis and treatment.**
   - Integrate control strategies into primary health care delivery
   - Ensure access to primary health care services
   - Increase community awareness and knowledge
   - Train primary health care workers to recognise, diagnose and treat
   - Train hospital and sexual health care workers to recognise, diagnose and treat

2. **Routine use of laboratory tests**
   - Routine use of lab confirmation of GUD

3. **Encourage use of standard treatment protocols**
   - Syndromic management
   - Short course, directly observed treatment
   - Inclusion of GUD in standard treatment protocols in endemic areas

4. **Active case follow-up**

5. **Enhanced surveillance**
   - Strengthen lab notification of donovanosis in WA and NT

There is no doubt that introduction or improvement in these strategies will improve the likelihood of donovanosis eradication. Some of the elements of these strategies are far broader than the NDEP, for example, the resourcing for primary sexual health care for indigenous people is likely to continue to be inadequate for some years to come. The Miller report also made a number of specific recommendations for donovanosis eradication. Table 6.1 lists the progress made against each recommendation in WA, NT and QLD as well as nationally, and makes a judgement about the extent to which each recommendation has been achieved.

Table 6.1 Progress made by NDEP on the Miller Report recommendations

Recommendation	NT		WA	Qld	Nationally
	Men	Women			
1. Syndromic management of genital ulcer disease should be maintained in areas in which Donovanosis is endemic.	Listed under STIs, Syphilis & Donovanosis 'if man has sores on his genitals or groin' Start treatment before lab results return. Thinks its Donovanosis but the tests negative recommended to talk to the local Sexual Health Unit. No	Listed under STIs, Syphilis and Donovanosis, genital sores. Start treatment before lab results return. No improvement in 4 weeks biopsy [14].	Listed under Donovanosis and genital ulceration 'Treatment is usually commenced on clinical diagnosis after specimens are collected.' 'If lesion has not healed after 6 weeks biopsy' [15].	Listed under STIs, Donovanosis. 'test patients presenting with ulcerated lesions especially those living in rural & remote areas'. If lesion has not healed in 6 weeks biopsy [16].	National Management Guidelines and National Antibiotic Guidelines do not discuss syndromic management.

	improvement in 4 weeks biopsy [13]. *Evidence from DPO that this is not taken up well by HCPs*	*Evidence from DPO that this is not taken up well by HCPs*			
Evaluation	**Achieved**	**Achieved**	**Partially achieved**	**Partially achieved**	**Not achieved**
2. Laboratory confirmation should be routinely offered in all cases of suspected or clinically diagnosed Donovanosis.	Recommended [13] *Not all HCPs are aware of PCR*	Recommended [14] *Not all HCPs are aware of PCR*	Recommended [15]	Recommended [16]	Laboratory confirmationn discussed in both guidelines; however, PCR not available when guidelines written.
Evaluation	**Achieved**	**Achieved**	**Achieved**	**Achieved**	**Achieved**
3. Laboratory confirmation should be used in addition to syndromic management not to replace syndromic management.	If thought to be Donovanosis but tests are negative recommended to talk to the local Sexual Health Unit. [13] *Lab confirmation sought in addition to clinical diagnosis*	Not stated [14] *Lab confirmation sought in addition to clinical diagnosis*	Not stated [15] *Lab confirmation sought in addition to clinical diagnosis*	Not stated [16] *Lab confirmation sought in addition to clinical diagnosis*	National Management Guidelines and National Antibiotic Guidelines do not discuss syndromic management
Evaluation	**Achieved**	**Not achieved**	**Not achieved**	**Not achieved**	**Not achieved**
4. As far as possible, laboratory diagnosis of Donovanosis should be offered using the most valid and acceptable test that is available in a given clinical context, whether PCR or histology.	• Scrape sore and place on glass slide for Donovan bodies [13]	• Contact Donovanos is register [14]	• Impression smear for Donovan bodies • Biopsy in saline for Donovan bodies [15] *As PCR is validated, it is recommended and histo is back-up*	• Impression slide for Donovan bodies • Swab for GUMP (genital ulcer multiplex PCR) [16] *DPOs recommend both*	In National Management Guidelines laboratory confirmation suggested by taking punch biopsy. "A PCR test suitable for a simple swab may be available soon". Antibiotic Guidelines states "microscopy of scrapings, snip or punch biopsy confirms the diagnosis".
Evaluation	**Achieved**	**Achieved**	**Not achieved**	**Partially achieved**	**Not achieved**
5. Ensure laboratories providing histopathology services in areas with endemic Donovanosis	*Some labs put this into the too-hard-basket – many AMS' use private labs.*		*Needs to be better networking with labs*	*Needs to be better networking with labs*	

maintain the capability to perform Donovanosis histology.					
Evaluation	**Unable to be ascertained**		**Achieved**	**Achieved**	
6. Short course, directly observed treatment be adopted in the treatment of all people with Donovanosis.	See recommendation 9				
Evaluation	**Unable to be ascertained**				
7. The use of standard treatment protocols be supported in rural and remote clinics in central and northern Australia.	Promoted to all clinics by project officer.		Promoted to all clinics by project officer.	Promoted to all clinics by project officer.	
Evaluation	**Achieved**		**Achieved**	**Achieved**	
8. In endemic areas donovanosis be included in a Genital Ulcer Disease (GUD) standard treatment protocol rather than a disease specific protocol.	Listed under STIs, Syphilis & Donovanosis 'if man has sores on his genitals or groin' Tests for syphilis, STIs, herpes & HIV are recommended [13]	Listed under STIs, Syphillis and Donovanosis, genital sores, STD testing recommended [14]	Listed under Donovanosis (granuloma inguinale) and genital ulceration. Tests for syphilis, STIs & HIV are recommended [15]	Listed under STIs, Donovanosis. Tests for syphilis, STIs, herpes, syphillis & HIV are recommended [16]	Listed under genital ulcers, 'treat also for syphilis and gonorrhea if unable to exclude'[17]
Evaluation	**Achieved**	**Achieved**	**Partial achievement**	**Partial achievement**	**Achieved**
9. That the National Antibiotic guidelines specifically state that:					
- treatment be directly observed	Check sore each week and give him/her his/her medicine [13]	Women's Business Manual – not stated [14]	'treatment should be directly observed' [15]	'directly observed treatment in all cases of suspected or confirmed donovanosis' [16]	Not stated but rather suggested with statement 'admission to hospital for supervised therapy may be required' [17].
Evaluation	**Achieved**	**Not Achieved**	**Achieved**	**Achieved**	**Not achieved**
- weekly treatment be provided initially for 4 weeks	' give azithromycin 1g by mouth once a week for at least 3 weeks [after 1st dose]or until sore has healed, which ever is longer' [13]	'give azithromycin 1g by mouth once a week for 6 weeks or longer until sore/s healed' [14]	'weekly treatment should be provided initially for 4 weeks' [15]	'azithromycin 1g orally weekly for 4 weeks (category B1 in pregnancy)' [16]	'azithromycin 500mg orally, daily for 7 days or 1g once weekly for 4 doses or until healing occurs' [17]
Evaluation	**Achieved**	**Partial achievement**	**Achieved**	**Achieved**	**Partial achievement**
- the lesion should be examined at 4 weeks after commencement of treatment	'check the sore each week if it isn't better after 4 weeks…' [13]	'look at sores every week [4 weeks]' [14]	're-examination at 4 weeks' [15]	'lesion should be re-examined at 4 weeks after commencement of treatment' [16]	Not stated [17]
Evaluation	**Achieved**	**Achieved**	**Achieved**	**Achieved**	**Not**

					achieved
- if the lesion has healed no further treatment required	'give azithromycin 1g tablet by mouth once per week for at least 3 weeks or until the sore has healed' [13]	'give treatment until sore has healed' [14]	'azithromycin 1g orally, each week for one month or until healing occurs' [15]	're-examination at 4 weeks and if not healed' – treatment continues [16]	Not stated [17]
Evaluation	**Achieved**	**Achieved**	**Achieved**	**Achieved**	**Not achieved**
- if the lesion has not yet healed a further 2 weeks treatment	'give azithromycin 1g tablet by mouth once per week for at least 3 weeks or until the sore has healed' [13]	'give azithromycin 1g by mouth for 6 weeks or longer until sore's have healed' [14]	'if lesion has not yet healed a further two weeks treatment should be given' [15]	're-examination at 4 weeks and if not healed azithromycin 1g weekly for a further 2 weeks' [16]	Not stated [17]
Evaluation	**Not achieved**	**Not achieved**	**Achieved**	**Achieved**	**Not achieved**
- if lesion not healed by week 6 a biopsy should be considered	'if it [ulcer] isn't getting better after 4 weeks, talk with a doctor about a biopsy [13]	'no improvement after 4 weeks of treatment talk to a doctor about the need for a biopsy' [14]	'if the lesion has healed by week six, a biopsy should be considered' [15]	'if no healing at 4 weeks, a biopsy should be taken to exclude neoplasm if one has not already been performed' [16]	Not stated [17]
Evaluation	**Not achieved**	**Not achieved**	**Achieved**	**Not achieved**	**Not achieved**
- follow up at 3 months after lesion healed to ensure no relapse.	'check him 3 months after it is completely healed to make sure it hasn't come back' [13]	Not stated [14]	'follow-up at three months after the lesion is healed' [15]	'patients should be followed until symptoms have resolved' [16]	Not stated more suggested 'follow-up is important as resolution may be slow and recurrence may occur [17].
Evaluation	**Achieved**	**Not achieved**	**Achieved**	**Not achieved**	**Not achieved**
10. Children borne by vaginal delivery to women with active Donovanosis should receive prophylactic azithromycin.		Women's Business Manual not stated [14] *Lots of resistance from HCPs because of low transmissibility of donovanosis*	'pregnancy azithromycin 1g orally, each week for one month or until healing occurs (category B1) or Ceftriaxone 1g IM or IV daily for 14 days (category B1) [15]	'consult a specialist for advice on treating babies born to mothers with Donovanosis at time of delivery' [16] *No babies born in QLD to women with donovanosis*	Not stated [17]
Evaluation	**Not applicable**	**Not achieved**	**Partial achievement**	**Partial achievement**	**Not achieved**
11. That intensive targeted support be provided to strengthen the capacity of primary health care services to provide early diagnosis and effective treatment.	DPO position		DPO position	DPO position	
- This targeted support should	Yes		Yes	Yes	

be provided by three full time workers for two years.				
- The three positions should all be located in central and Northern Australia one in Qld, one in NT and one in WA.	Yes, Darwin & Alice Springs	Yes, Perth	Yes, Cairns	
Evaluation	**Achieved**	**Achieved**	**Achieved**	
The job descriptions for these positions should include:				
- Providing training (regional and onsite) for primary health care workers and hospital staff in diagnosis, treatment and follow up of GUD	Yes	Yes	Yes	
- Provide support and advice to primary health care workers	Yes	Yes	Yes	
- Implement follow up system to increase the numbers of individuals effectively treated	Yes	Yes	Yes	
- Ensure notification of donovanosis.	Yes	Yes	Yes	
Evaluation	**Achieved**	**Achieved**	**Achieved**	
12. In relation to recommendation 11, it is recommended that each region negotiates a written agreement with primary health care services and other key players regarding data collection, storage, access, analysis and dissemination. These agreements should comply with the most current NACCHO data protocol and Commonwealth guidelines.	None	None	One	
Evaluation	**Not achieved**	**Not achieved**	**Not achieved**	
13. That a review of the positions created under recommendations be conducted 18 months after the employment of the workers to assess whether extension	No	No	No	

of the two year term is required.				
Evaluation	**Not achieved**	**Not achieved**	**Not achieved**	
14. In relation to recommendation 11, encourage standardisation of:				
- training protocols,				
- education resources and				
- evaluation mechanisms				
to reduce duplication of effort.	Project officers shared resources	Project officers shared resources	Project officers shared resources	
Evaluation	**Achieved**	**Achieved**	**Achieved**	
15. A short central training program be provided in the clinical diagnosis, laboratory diagnosis, treatment, follow up and control strategies for project officers employed in active case follow-up positions.	Yes	Yes	Yes (3 project officers each provided training for the next one employed)	
Evaluation	**Achieved**	**Achieved**	**Achieved**	
16. National surveillance of donovanosis be maintained and strengthened.				
Evaluation				**Partially Achieved**
17. Laboratory notification of donovanosis be strengthened in Western Australia, the Northern Territory and Queensland to reduce underreporting.	yes	yes	yes	
Evaluation	**Achieved**	**Achieved**	**Achieved**	
18. Support be given for effective and relevant research programs to facilitate control of Donovanosis.	Not aware of any	Not aware of any	Not aware of any	
Evaluatiom	**Unable to be ascertained**	**Unable to be ascertained**	**Unable to be ascertained**	
19. Support be given to primary health care agencies which choose to access the PCR diagnostic test during the research phase.				
Evaluation	**Achieved**	**Achieved**	**Achieved**	

20. Collaboration be encouraged between laboratories regarding the further development of and access in endemic areas to, the in-house PCR method for Donovanosis.	Evidence of informal collaboration	Evidence of informal collaboration	Evidence of informal collaboration	
Evaluation	**Unable to be ascertained**	**Unable to be ascertained**	**Unable to be ascertained**	

6.9 Conclusions

Donovanosis is generally an infection of remote Indigenous people, and is usually only diagnosed in an urban setting if the patient has been visiting a town. There is no evidence to suggest that during the time the DPO has been in operation there has been a noticeable increase in the numbers of Indigenous people presenting to health services with GUD, because the thrust of the DEP was case-*finding*. There is no doubt that sexual health services need to be made more accessible to remote Indigenous Australians and one of the ways to do this may be to provide more choice (eg. in Far North Queensland most health services are state government run primary care clinics, and community-controlled clinics are also needed). Ideally, health service choice should include the option of a private bulk-billing GP practice. Currently most people in remote communities have only one choice of medical service which compounds the difficulties faced by many in attending a service for a sensitive consultation.

It can be seen from Table 6.1 that many of the specific recommendations of the Miller Report have been achieved. It cannot be said that donovanosis has yet been eliminated, although great strides towards this outcome have been made.

While the NDEP made gains in increasing awareness of GUD amongst health care practitioners, there are a number of ongoing systemic problems which work against the success of the DEP. These include the high turnover of staff in remote settings, the difficulty of getting genital ulcer disease included in the orientation program for new staff, the overwhelming volume of general morbidity in Indigenous communities and the subsequent low priority placed on sexual health issues by many communities. In addition, the funding was available for two years only, which was not sufficient time for consolidation of the gains made.

Chapter 7

The Way Forward

The NDEP made a number of significant achievements. It put donovanosis on the map in Australia, it raised awareness of genital ulcer disease and sexual health issues more generally, especially in some regions where donovanosis has been problematic, and it resulted in some important advances in pathology which are needed on a global scale.

It is evident with the benefit of hindsight that the NDEP commenced somewhat prematurely and because of this, some of the goals were optimistic rather than realistic. It could be argued that the NDEP did not have the tools to promote early detection, and this is because there remain major gaps in knowledge about the natural history of donovanosis. Is there an asymptomatic carrier state? How common is this if it does occur? Can an asymptomatic person be detected by screening? Some of these questions should be answerable by a refined and validated PCR test, but this was not readily available across Australia at the time the NDEP commenced.

Rather than early detection, the NDEP focused instead on early case-finding: seeking out established symptomatic cases and offering treatment as early as possible. It might be said that the two major strategies available in 2001 - early case finding and treatment - may have in fact been inadequate to meet the goals of disease elimination.

7.1 Have the Recommendations of the Miller Report been Met?

As shown in Table 6.1, of the 20 recommendations listed in the Miller Report, 8 appear to have been achieved:

2. Laboratory confirmation should be routinely offered in all cases of suspected or clinically diagnosed Donovanosis.
4. As far as possible, laboratory diagnosis of Donovanosis should be offered using the most valid and acceptable test that is available in a given clinical context, whether PCR or histology.
7. The use of standard treatment protocols be supported in rural and remote clinics in central and northern Australia.
11. That intensive targeted support be provided to strengthen the capacity of primary health care services to provide early diagnosis and effective treatment.
    - This targeted support should be provided by three full time workers for two years.
    - The three positions should all be located in central and Northern Australia: one in Qld, one in NT and one in WA.

    The job descriptions for these positions should include:
    - Providing training (regional and onsite) for primary health care workers and hospital staff in diagnosis, treatment and follow up of GUD
    - Providing support and advice to primary health care workers
    - Implement follow up system to increase the numbers of individuals effectively treated
    - Ensuring notification of Donovanosis.

14. In relation to recommendation 11 (appointment of DPOs), encourage standardisation of:
    - training protocols
    - education resources and
    - evaluation mechanisms to reduce duplication of effort.

15. A short central training program be provided in the clinical diagnosis, laboratory diagnosis, treatment, follow up and control strategies for project officers employed in active case follow-up positions.

17. Laboratory notification of Donovanosis be strengthened in Western Australia, the Northern Territory and Queensland to reduce underreporting.

19. Support be given to primary health care agencies which choose to access the PCR diagnostic test during the research phase.

It is difficult to say with certainty the level of success achieved for some of the other recommendations, as they cover issues of a range of different complexities, and some have been achieved in some jurisdictions, but not in others. However, it appears that overall, 11-12 recommendations have been fully achieved in each jurisdiction.

On closer examination some of these recommendations were not achievable within two years. For example:

9. That the National Antibiotic Guidelines specifically state that:
    - treatment be directly observed weekly
    - treatment be provided initially for 4 weeks
    - the lesion should be examined at 4 weeks after commencement of treatment. If the lesion has healed, no further treatment is required). If the lesion has not yet healed, a further 2 weeks treatment is required
    - if lesion not healed by week 6 a biopsy should be considered
    - follow up at 3 months after lesion healed to ensure no relapse

8. In endemic areas Donovanosis be included in a Genital Ulcer Disease (GUD) standard treatment protocol rather than a disease specific protocol.

Such upgrading of management guidelines cannot be altered in all State/Territory and national printed guidelines until they undergo revision and reprinting.

Other recommendations which were only partially achieved are still valid, but will require ongoing effort. For example:

10. Children borne by vaginal delivery to women with active Donovanosis should receive prophylactic azithromycin.

The DPOs reported that this recommendation was met with some resistance by HCPs, and so ongoing education in this area is clearly required.

Two recommendations were definitely not achieved:

13. That a review of the positions created under recommendations be conducted 18 months after the employment of the workers to assess whether extension of the two year term is required.

12. In relation to recommendation 11 (appointment of DPOs), it is recommended that each region negotiates a written agreement with primary health care services and other key players

regarding data collection, storage, access, analysis and dissemination. These agreements should comply with the most current NACCHO data protocol and Commonwealth guidelines.

The extent to which efforts were made to achieve recommendation 12 during the course of the NDEP is unclear.

Similarly, while every effort was made by the DPOs to ensure the remaining recommendations were achieved, it is difficult to judge the extent of their success.

1. Syndromic management of genital ulcer disease should be maintained in areas in which Donovanosis is endemic.
3. Laboratory confirmation should be used in addition to syndromic management and not replace syndromic management.
5. Ensure laboratories providing histopathy services in areas with endemic Donovanosis maintain the capability to perform Donovanosis histology.
6. Short course, directly observed treatment be adopted in the treatment of all people with Donovanosis.
16. National surveillance of Donovanosis be maintained and strengthened.
18. Support be given for effective and relevant research programs to facilitate control of Donovanosis.
20. Collaboration be encouraged between laboratories regarding the further development of and access in endemic areas to, the in-house PCR method for Donovanosis.

7.2 Are the Achievements of the NDEP sustainable?

It is evident that even in the short time since the DPOs completed their employment that donovanosis, and perhaps even genital ulcer disease more generally, has slipped down the priority ladder within health services. It is likely that without continued funding of a genital ulcer program that some of the gains made with donovanosis may be lost, particularly in light of the fact that some of the newer cases seen recently are in the adolescent age-group. This is a serious concern, given that many of the issues which led to the NDEP are still present – the potential for HIV spread within the Indigenous population because of the high rate of genital ulcer disease, and the stigma and shame often associated with sexual health consultations. In addition there is now worrying evidence of high rates of herpes amongst Indigenous communities.

All of the DPOs worked extremely hard to visit the health services within their areas. In one case contact was made with 95% of 160 organisations within the donovanosis affected region. Given the geographical distances involved, it would be challenging for a single worker to sustain this effort over a prolonged period of time.

7.3 What is the Best Way to maintain Sustainability of the Current Rates of Donovanosis?

Key informants were asked to comment on the ways in which donovanosis could best be managed in the future. Most health care practitioners were adamant that continued funding for sexual health positions was essential, but that some changes to the focus of the program were desirable. Suggestions included:

- **Rotation of genital ulcer health promotion material**

In order to continue to keep donovanosis on the agenda of health practitioners it might be useful to promote syphilis for a period of time and then to promote herpes for a similar time period. By this stage, the epidemiological evidence in relation to donovanosis would be clearer, and a decision could then be made about whether to proceed with another round of donovanosis promotion. The advantage of this method is that it should maintain practitioners' interest, and should have a beneficial effect on the rates of syphilis and herpes, which are both very high in Indigenous communities, and much more common than donovanosis.

- **Genital Ulcer Officer**

The DPO role could be subsumed by the role of a Genital Ulcer Project Officer (GUPO) who would manage donovanosis, syphilis and herpes. The Genital Ulcer Project Officer in remote communities could concentrate on ensuring that:

a) primary care staff including AHWs are knowledgeable about GUD

b) that syndromic management in areas where donovanosis has occurred in the past few years must include weekly azithromycin

c) that syndromic management is adhered to for a full 4 weeks and that it is NOT aborted because laboratory tests are negative.

- **Syphilis Officer**

Where there is a Syphilis Register managed by a Nurse, donovanosis could be taken on as an additional duty, as it should not add substantially to the workload. However, care would need to be taken if donovanosis were to be an add-on component of the Syphilis Officer's work, that some focus on it was retained, and that it did not become lost in the overall workload.

- **Congenital Syphilis**

It was suggested by some key informants that eradication of congenital syphilis in Australia is an achievable goal. Both better management of syphilis and regular screening in the sexually active younger population is needed. To attract young pregnant Indigenous women to antenatal care may require more attractive outreach programs.

Interestingly in the United States a syphilis elimination program began in 1999 with the aim of reducing cases to less than 1000 and to make 90% of counties syphilis-free by 2005. The program has led to decreased incidence of congenital syphilis and narrowed the gap between the higher rate of syphilis in African Americans compared to the general American population. The rate of syphilis increased overall (likely due to enhanced surveillance) particularly in men who have sex with men and African Americans. The program involved five strategies: enhanced surveillance, strengthening community involvement and partnership, rapid outbreak response, expanded clinical and lab services and enhanced health promotion [74].

- **Community health promotion in relation to infertility**

The high rate of all STIs was discussed by several key informants. There were suggestions that sexual health promotion at the community level should focus on potential of untreated STIs to cause infertility. This concept should be introduced at school level. In addition, an improved focus on community education would be strengthened by the deployment of a Senior Indigenous Nurse with a skills set equivalent to those of the DPOs.

7.4 Recommendations arising from this Review

The Review Team believes that the NDEP was a somewhat under-prepared and optimistic short-term project which has none-the-less produced some important results. The NDEP has paved the way for further gains in genital ulcer disease prevention and management for Australians, in particular Indigenous Australians.

7.41 Future of NDEAC

The Review recommends that the NDEAC be retained, but with broader objectives. The recently released National STI Strategy will focus attention on chlamydia and gonorrhoea across Australia more generally, which may mean that genital ulcer disease with its generally lower profile could fall by the wayside. NDEAC should therefore be focussed on national management of STIs causing genital ulcer disease in Indigenous communities.

Recommendation 1
Re-formation of NDEAC as the National Genital Ulcer Disease Reduction Committee, to be auspiced by OATSIH.

7.42 Future Funding

The Review recommends that given that the function of NGUDRC would primarily be capacity building within the sector, it is essential that there be a longer and realistic time frame for the achievement of goals. Ideally this should be within a timeframe of 5-6 years. It is essential that consensus be achieved on Action Plans before staff are employed on a project.

Recommendation 2
Continued funding for a Genital Ulcer Disease Reduction Program.

7.43 Testing

The advance made in donovanosis testing was one of the achievements of this NDEP, as it precludes the need for biopsy. Further donovanosis PCR test refinement and validation is necessary. Additional funding is essential to completely validate the multiplex PCR test for GUD for use in remote communities. This will allow research to be undertaken on the actual patterns of aetiology of GUD in remote Australia, which can inform the future composition of recommended regimens for syndromic management of GUD. The NDEP has highlighted the contribution herpes makes to symptomatic GUD in remote central Australia. Given the potential of GUD to fuel increased spread of HIV in remote communities in the future, it is essential that this be taken further. It has been suggested that it would be easier to sort out the gene sequence for the monoplex – a disadvantage of the multiplex is that if there is a strong response to one infection, it can affect the sensitivity of the other tests in the line-up. Australia has been at the forefront of this work. O'Farrell, a donovanosis expert from UK, has recently reviewed the global advances in donovanosis testing for a chapter he is writing, and stated that there has been no new work published on donovanosis testing since Jenny Carter's work in Darwin in 2001 and Ayesha Kharsany's work in Durban in 1999. (O'Farrell, pers comm, 2005).

Also of great benefit to Indigenous communities would be a reliable, sensitive and specific test for diagnosing syphilis from ulcers or mucous membrane lesions early in the infection. Given that work done as part of the NDEP has established

a high rate of herpes in Indigenous people in some areas, a good PCR test, validated for use in remote areas, would also be extremely valuable.

Recommendation 3
Re-convening or formalising of a Technical Advisory Group, to consist of both pathologists and clinicians working in remote areas, to consider the ways in which validation of the donovanosis PCR can best be achieved, particularly in light of the high rates of syphilis and herpes in indigenous populations. Given that the PCR is only 80-85% sensitive that the GUMP remains un-validated and that health care professionals have a heavy reliance on test results, consideration should be given to including in the current laboratory notification forms the words: "A negative test result does not exclude the possibility of donovanosis".

Recommendation 4
Further development on syphilis and herpes tests for use in remote areas should be considered.

7.44 Project Management

There were clearly difficulties faced by the Commonwealth in managing a project which was essentially dealing with primary care practitioners and clinical services more generally. This was inevitable, given the nature and operational practice of bureaucracy. The management of any future funding for similar projects would best be out-sourced to a third party – a national non-government health-related organisation with the experience of managing projects on the ground and with readily accessible expertise to enable clinically based problems to be sorted out quickly. Such an organisation would also require the expertise to oversee test development and validation.

Recommendation 5
Co-ordination of projects incorporating a clinical element which may require immediate feedback for management enquiries should be outsourced to an organisation with an infrastructure capable of dealing with this.

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Appendices

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Appendix 2: Donovanosis Timeline

Date	Occurring	Event
1882	Madras, India	Donovanosis is given a clinical entity by McLeod [18].
1800's	Australia	Donovanosis thought to have been introduced by Macassan traders in 17th or 18th century [19].
1899	Australia	Dr E Goldsmith, the protector of Aborigines in the NT described treatment of two Aboriginal women for donovanosis. Four months of unsuccessful syphilis treatment and two months of successful topical treatment. He described the disease as sexually transmitted and not confined to Aboriginal people [20, 21].
1905	India	Etiological agent of Donovanosis 'Donovan bodies' discovered by Charles Donovan [18].
1913	Portugal	Donovanosis renamed Calymmatobacterium granulomatis [18].
1918	USA	In the southern states of America ethically questionable experiments conducted on a monkey and two African American men who were inoculated with 'Donovan bodies'. One man died of cancer and the other of TB in less than a month with no conclusions drawn [18].
Early 1900's	Queensland & Western Australia, Australia	Policy implemented whereby Indigenous people can be examined by police for STDs such as donovanosis and incarcerated on lock hospitals on islands for isolation [21].
1906	Western Australia, Northern Territory, Australia	Two cases reported in Darwin, and eight cases reported in the Northern Kimberly in Western Australia [20].
1911	Western Australia, Australia	Donovanosis described in the Australasian Medical Gazette as a disease affecting Aboriginal people in WA [22].
1912	Northern Territory, Australia	Several observations of donovanosis reported [20].
1921	Australia	Case report of an Aboriginal girl with oral donovanosis [20].
1922-52	Papua New Guinea	Of a population of 15,000 Marindanim people in the PNG 10,000 cases of donovanosis were identified from 1922-52 [23].
1926/7	USA	In the southern states of America ethically questionable experiments conducted when a Dr McIntosh inoculated a 19 year old African American male with 'Donovan bodies' resulting in headache, swelling and lesions lasting four months. Another African American male 40 years of age became a 'donor' for the infection which was transferred to another 'colored' male who died of liver cancer two weeks later. A 22 year old female with vulval lesion had infectious material removed and injected into the groin of a 19 year old 'colored' girl being treated for myelitis. Lesion developed in five days and seven days later a 'large core' removed. Donovan bodies injected into a 'colored' man's shoulder and monitored without treatment for 87 days. The man had high temperature, inflammation and a large mass was surgically removed. The same man was

		inoculated again with lesions developing and treatment withheld for 35 days [18].
1927	USA	In the southern states of America ethically questionable experiments conducted when Dr Meredith Campbell inoculates animals and two African American men with 'Donovan bodies'. One man had cancer (later died with no donovanosis developing) and the other chancroid (no donovanosis developing). The doctor conducting the experiment later inoculated himself with no donovanosis developing [18].
1928	Australia	'Ulcerative granuloma of the pudenda' described as being conveyed since arrival of white men and from contact with Malay, Papuans and Kanakas [24].
1929	Western Australia, Australia	Thirty two cases reported in Aboriginal people of Western Australia; 12 were males[20].
1931	USA	In the southern states of America ethically questionable experiments conducted when Dr DeMonbruen and Goodpasture withheld treatment to a 27 year old African American man with donovanosis in order to inoculate animals with the disease. After animals developed ulcers they inoculated the groins of six males (one the only European American to be experimented on for donovanosis). Ulcers developed and were cured in 4weeks then re-ruptured later in a more contagious form [18].
1932	Australia	Report on 'diseases of the Australian Aborigines' describes 'ulcerative granuloma of the pudenda' being present at Alligator Rivers, Port Darwin, Bathurst and Melville Island, Wyndham and Derby. Described as mostly affecting women and being of prolonged incubation. Treatment most successful with IV rather than IM antimony tartrate [20].
1932	USA	In the southern states of America ethically questionable experiments conducted when Dr Gage inoculated animals and two African Americans with negative results [18].
1938-1950	USA	A research team from the University of Georgia conducted ethically questionable experiments by transplanting infected tissue into African American people with and without Donovanosis, in some cases withholding treatment. This included in one case streptomycin resistant culture taken from one man and injected into another who developed streptomycin resistant ulcers [18].
1940	USA	In the southern states of America ethically questionable experiments conducted when Dr Sanderson aspirates fluid from two infected patients and injects this into two uninfected patients with 'success' [18].
1947	International	Study of 60 patients found 92% of patients with donovanosis had an incubation period between 3 & 40 days [4].
1969-1974	Durban, South Africa	Donovanosis epidemic reported in Durban [25]
1975	India	Report of oral donovanosis in a female with no other lesions present elsewhere [26].
1975	Vietnam	Thirty-six patients with donovanosis were treated at the 483 USAF Hospital, Cam Ranh Bay, Republic of South Vietnam between October 1970 and September 1971. In 24 cases biopsy revealed Donovan bodies. Lesions generally did not heal during tetracycline therapy. All but 2 of

		the 31 cases treated primarily with ampicillin with complete healing of the local lesions occurring primarily on the penis or in the groin. Of the two remaining patients, one responded to a second course of ampicillin and the other responded to a two week course of lincomycin after dorsal slit had been performed [27].
1976	Papua New Guinea	87 cases of donovanosis seen at the Port Moresby General Hospital [28]
1976	Australia	Case report of an Aboriginal woman with multiple diseases. Donovanosis of unusual severity and extent, closely simulating advanced pelvic malignant disease, was included [29].
1978	India	Study finds Co-trimoxazole two tablets twice daily for 10 patients effective, with donovanosis ulcers healing in 10 days in eight patients and 14 days in two [30].
1979	Queensland, Australia	Thirteen cases diagnosed over twelve months in Townsville. Seven male patients diagnosed four of whom were prison inmates at Townsville. Two patients were married and two were sisters. All female patients were pregnant at time of diagnosis [31].
1980	Queensland, Australia	Case studies of extragenital donovanosis in Nth Queensland. The first case a 41 year old woman with fever, swollen knee joint and osteolytic lesions involving distal bones. The second case was a 49 year old male with multiple faecal fistulae of the lower abdomen and involvement of pelvic organs [32].
1983	Africa	The African Union Against Venereal Diseases and Treponematoses established in 1979. At a 3rd biannual conference in Nairobi (March 1983) Genital Ulcer Disease including Donovanosis was recognized as an important public health problem in Africa and management and recommendations were made including -establishment of microbiological laboratories -efficacy, availability, and compliance in treatment -training of health workers [33]
1986	Western Australia, Australia	Report on 47 consecutive patients with donovanosis over a six year period 1979-1985. Most came from the tropical northern parts of WA and the majority were women with vulval lesions being a common manifestation. Two men had extra-genital lesions [34].
1986	Western Australia, Australia	Case studies of three cases of extragenital Donovanosis. Presenting features include ulceration of the anterior abdominal wall, discharging sinuses of the neck and an abscess of the bone [35].
1988-1997	Durban, South Africa	Epidemic of donovanosis reported [3]
1989	India	Retrospective study of confirmed cases of donovanosis between January 1980- December 1987 at the STD clinic at the Jawaharlal Institute of Postgraduate Medical Education and Research in Pondicherry, India. 6.6% of all STD cases had donovanosis, especially among 20-30 year olds. In 1968-1969 5.4% of STD cases were donovanosis. 25% of married couples were both infected with donovanosis. Most frequent clinical type of donovanosis was fleshy exuberant rather than necrotic or sclerotic types. Syphilis was the most likely associated STD in both sexes [36].
1990	Papua New Guinea	Donovanosis found to be second most common cause of genital ulceration with herpes the first in

		five clinics in PNG [37].
1990	India	Case 0ne: anal stricture in a 25-year old man. The man had a 15 x 6 cm lump from the natal cleft to the scrotum, constriction of the anus so only painful ribbon stools could be passed. The center was ulcerated for 4 cm around the anus. The lesion developed from a pustule into an ulcerative lesion 7 years ago, just after homosexual contact. A tissue smear showed Donovan bodies. The patient was cured with 21 days of oral sulfamethoxazole-trimethoprim, 2 tablets of 400/80 mg twice daily. Case Two: a 25-year old woman with both labia solidly enlarged and edematous. Also ulceration of the groins and perineum. Biopsy showed a few Donovan bodies, but repeated tissue smears were negative. Her ulcer healed completely in 20 days with oral tetracycline, 2.0 g daily, but labia remained swollen [38].
1990	Patiala, India	In 500 patients coming to the Department of Skin and VD, Government Medical College, Patiala, India, from 1983-1988 0.2% diagnosed with donovanosis [39].
1990	Davangere, India	In 450 patients attending the Department of Skin, STD and Leprosy of JJM Medical College, Davangere, India, from May 1984-December 1988 15.3% diagnosed with donovanosis [40].
1990	Allahabad, India	In 1,922 patients of the PG Department of Medicine, MLN Medical College, Allahabad, India, from 1978-1988 3.02% were diagnosed with donovanosis [41].
1990	Punjab State, India	Case report of 15year old boy with anal donovanosis contracted through sexual assault. Treated with 1g streptomycin daily for 27 days with no effect, cured with tetracycline 500 mg QID for 20 days. Infection reported as extremely rare in Nth India [42].
1991	Durban, South Africa	Study of 100 Zulu men and women presenting with genital ulcers at a clinic. Men syphilis 42%, chancroid 22%, donovanosis 11%, herpes 10% & lymphogranuloma venereum 6%, mixed infection in 14, 13 of the 14 syphilis [43]. Women syphilis 40%, herpes 18%, donovanosis 16%, chancroid 14%, lymphogranuloma venereum 7% and scabies 2%, mixed infection in 13, 12 of the 13 syphilis [44].
1993	Northern Territory, Australia	AIDS/STD unit in Darwin surveys District Medical Officers & Remote Area Nurses to estimate number of donovanosis cases seen or treated. 115 cases were estimated of which 36 had been notified [45].
1993	Durban, South Africa	Study of 171 men and women with donovanosis. One of 21 regular sex partners was infected. Serological tests were positive for 40 (23%) for syphilis, and in 4/48 men and 0/15 women were HIV positive. Lesions were ulcero-granulomatous in 162, hypertrophic in eight and necrotic in one. Complete healing was observed in 41(24%) who attended follow up [46].
1994	Northern Territory, Australia	Case report of a patient with donovanosis of the oral cavity presenting some time after apparent successful treatment of a genital infection [47].
1994	Northern Territory, Australia	Study to determine effectiveness and acceptability of IM ceftriaxone sodium in treatment of donovanosis.

		• Cases- 8 women & 4 men • Treatment single dose of 1g ceftriaxone sodium in 2ml of 1% lignocaine • All clients had lesions failing to heal with other antibiotics • Mean duration of infection 3 years • 6 cases had previously had 4-10 courses of antibiotics • Clinical improvement was noted in all lesions 4 healing completely with 7-10g ceftriaxone • Mild recurrences responded to ceftriaxone or short courses of oral antibiotics • Treatment was reported as well tolerated by staff and patients [48].
1995	Northern Territory, Australia	Australian trial of azithromycin for treatment of donovanosis. Once a week dose of 1g of azithromycin for six weeks with follow up assessment at three months. Findings • 31 patients referred into the project • 10 without donovanosis (4 syphilis, 3 syphilis & possible donovanosis & 3 diagnosis unsure) • 21 with donovanosis (20 histological & 1 clinical diagnosis) • 16 patients had all doses & follow up assessment all cured. • 2 patients had nearly a full course but no follow up, 3 patients had one dose and no follow up. • 2 patients received doses of azithromycin & follow up without assistance. All other patients required some form of assistance. Recommendations • Standard treatment protocols include azithromycin as 1st line treatment of possible donovanosis • STD advisory and follow up system be established at Alice Springs Sexual Health Unit to assist practitioners diagnose, manage and follow up patients with donovanosis • Health Services have a policy of seeking assistance from STD & follow up system for all patients with genital ulcerative lesions. At this initial phase patient identity need not be disclosed to register. • If diagnosis of donovanosis with patient's permission their name can be entered into a register for follow up until healing documented [49].
1995	Northern Territory, Australia	Case report 33 year old woman presenting to Alice Springs Hospital with 2 month history of hematuria, right flank pain and UTI. Diagnosed with obstructed right ureter and a stent was inserted. Obstruction presumed to be secondary to a previous stone. She re-presented in 1996 with left iliac fossa mass and right leg pain. Diagnosed with donovanosis mass extending down the iliopsoas muscle. Azithromycin 500mg daily for a week and then 1g weekly for 3 months [50].
1996	Durban, Sth Africa	Study showed that donovanosis was increasing in pregnancy in Durban, South Africa. Concerns that pregnancy promoted dissemination of donovanosis, could not be established as the clinical response to treatment and outcome were similar in both pregnant and non-pregnant women.

		Infection with HIV did not alter clinical presentation and outcome of the disease [51].
1996	Northern Territory, Australia	Study of azithromycin in treatment of genital Donovanosis • Group A, 7 cases given 1g weekly for 4 weeks • Group B, 4 cases given 500mg daily for 7 days After six weeks • Group A in 4 cases lesions had healed • Group B in 1 case lesion had healed • All lesions had improved All eleven cases had lesions healed without further antibiotics and there were no relapses with longest follow up period was seven months [52].
1996	Australia	Azithromycin was approved for use with donovanosis [53]
1996	Northern Territory, Australia	Northern Territory Sexual Health Unit gives donovanosis education to Alice Springs Medical Officers, increasing referrals for Donovanosis from two in previous 12 months (1995) to 11 over a seven month period (Aug 1996- Feb 1997) [45].
1997, February	Northern Territory, Australia	Donovanosis Clinical Nurse Consultant position proposed for the Sexual Health Unit, Territory Health Services [45].
1997-1998, September	Northern Territory, Australia	Donovanosis project officer employed Sexual Health Unit, Territory Health Services (male). • More women than men reported – possibly due to gender of staff at clinics • Followed up 50 people known to be previously diagnosed with donovanosis four were still infected • Register and follow up system to be maintained by the Sexual Health Unit at end of project [54] • Number of cases increased from 8 in 1996 to 41 in 1997 with 39 (95%) healed and two lost to follow up. • Success of program thought to be due to - commitment by PHC organisations - low incidence of Donovanosis - dedicated project officer - new diagnostic test which is more sensitive & less invasive superior treatment regime - education to rural & remote areas [55]
1997	Darwin, Northern Territory, Australia	Case report of a 26 year old Aboriginal woman admitted to Royal Darwin Hospital for colposcopic biopsy for donovanosis. The woman tested positive, was discharged back to her community & lost to follow up. In August 1997 she represented with a right iliac fossa mass extending down the iliopsoas muscle with DVT. She commenced on azithromycin 500mg daily for a week and

		discharged on 1g weekly for four weeks. Her husband had previously been treated several months before her initial presentation. It was unclear whether the woman had any previous treatment on hospital and community records [50].
1997	South India	Between 1993-1997 donovanosis accounts for 14% of genital ulcers referred to a clinic in Pondicherry, Sth India with 15% f these HIV positive [56].
1998	Australia	Case report described of a 54 year old woman from Northern Australia with donovanosis disseminated to bone causing thoracic vertebral osteomyelitis and spinal cord compression. The woman had no genital lesions but had undergone a hysterectomy raising possibility of prior cervical involvement. Despite treatment there was no neurological improvement [57].
1999	United Kingdom	UK National Guidelines on STIs for Donovanosis • Azithromycin recommended in Australian guidelines • CDC recommends Ciprofloxacin as alternative & gentamycin for lesions not responding • Duration of treatment-until healed • CDC recommends minimum 3 weeks of treatment • Prophylactic treatment for babies born to mothers with untreated genital lesions • Sexual partners of case in the 40 days prior to lesions developing and after lesions develop should be assessed and offered treatment • Follow up to symptoms resolve [58].
1999	Mumbai, India	Histopathological analysis of cutaneous lesions in 195 HIV/AIDS patients between 1989 to 1997 at tertiary level public hospital in Mumbai. Of 104 presenting with infectious disease 4 were diagnosed with donovanosis [56].
2000	Darwin, Australia	First polymerase chain reaction assay for Calymmatobacterium granulomatis (donovanosis) trialled with 14 specimens showing good specificity. Required further trials and validation on a larger group of specimens [59].
2000	Durban, South Africa	Study of trans-epithelial elimination (TEE) - where skin eradicates irritants through intact epidermis or epithelium – of vulval granuloma inguinale. 43 cases in the study were examined and TEE was identified as a potential method of spread of infection in all cases [60].
2000	Northern Territory, Australia	Case report of donovanosis causing cervical lymphadenopathy (cervical nodes that drain the tongue, external ear and neck infected by Donovanosis) in a five month old boy [61].
2000, June	Northern Territory, Australia	Donovanosis Project Officer re-established at the Sexual Health Unit, Territory Health Services [55].
2001	Queensland, Australia	Case report of a 39 year old woman in Townsville with a vulval lesion first thought to be a fungating squamous cell carcinoma with investigation diagnosing Donovanosis [62].
2001	Australia	Report produced - Donovanosis control or eradication? A situation review of donovanosis in Aboriginal & Torres Strait Islander populations in Australia. The report recommends an elimination

		program and requirements to implement such a program [1].
2001	Australia	Four Donovanosis project officers appointed based in Alice Springs, Darwin, Perth & Cairns. Officers • work within a broader sexual health, prevention and clinical management model • use education and training to promote usage of standard treatment protocols for early diagnosis, treatment and follow up • immediate syndromic management of GUD is promoted and supported with lab testing • facilitate directly observed treatment • ensures cases are followed up • ensures cases are notified to local and national surveillance • promote prevention strategies to limit spread of all STIs [53].
2001	Australia	Donovanosis Elimination Advisory Committee established to provide advice to the Office of Aboriginal & Torres Strait Islander Health (OATSIH) about the implementation of the National Donovanosis Elimination Project and report on progress to OATSIH, the Federal Minister for Health & Aging and the Indigenous Australians Sexual Health Committee. A National Donovanosis Eradication Team is a technical advisory group that supports the four project officers [53].
2001	Australia	GUD Syndromic management for male or female with an ulcer developed: Primary syphilis chancre, primary or recurrent genital herpes and donovanosis are common causes of GUD. Testing for presentation and treatment initiated without waiting for results. • For herpes like sores (multiple small superficial & painful ulcers) swab from base of lesion to collect moisture, lift crusts if present, burst any blisters with sterile needle and take specimen of moisture • Request Herpes PCR • Using a dry swab, swab base of ulcer • For all other ulcers request genital ulcer PCR (herpes, syphilis, donovanosis PCR) • If clinically suggestive of donovanosis collect scrape and slide. Use wooden spatula collect some cells from edge of ulcer and smear onto a glass slide and let air dry. Request Donovan bodies Label specimen ulcer and site Treatment LA Bicillin 1.8g/4mls IM stat and azithromycin 1g oral stat If herpes clinically suspected Give valaciclovir 500mg twice daily for 5-10 days OR Famciclovir 250mg three times daily for 5 days Review patient in one week with results.

2001	USA	Case study of a 33 year old woman with donovanosis infection since 1982, had taken several courses of antibiotics including ceftriaxone and azithromycin with no complete healing of ulcers. Was given trovofloxin 200mg each night with ulcer size reduced by 75% at end of week one and complete healing after 2 months. No re-occurrence at 20 months [63].
2002	South Africa	Journal article on donovanosis suggests diagnostic tests for different settings • Recommends confirmation of diagnosis prior to commencement of antibiotics • Busy STI clinic with microscope and facility for staining smears, client not likely to return-tissue smear stained by rapid Giemsa method. • Well staffed STI clinic, patient likely to return next day-specimen from site below surface of ulcer, staining slow overnight Giemsa method or Lieshman's or Wright's stain • Lesion biopsy and patient returns for results-patients in this group are often antenatal or gynaecological Giemsa or silver stain. Also required for necrotic and sclerotic variants and sometimes hypertrophic lesions [3].
2002	Karnataka, India	Tissue smear taken from oral ulcers showed Donovan bodies in a 23-year-old male. Treated with oral tetracycline [64].
2002	West Indies	A 23-year-old woman presented with wasting, oedema, ascites, bilateral iliac lymphadenopathy, anaemia and a large ulcer of the cervix uteri. Histopathological examination of colposcopic biopsy of the cervix uteri revealed granuloma inguinale. Dissemination involved cervical ulceration, massive pelvic lymphadenopathy, osteomyelitis of the wrists and septic arthritis of the knees and right elbow. Two months later in outpatient clinic, she had improved but still had post-coital bleeding and a hyperaemic cervix, suggestive of persistent infection. Repeat course of antibiotics was given. After several courses of antibiotics, blood transfusion, surgical debridement and aspiration of affected joints there was improvement [65].
2002	Queensland, Australia	Trial of the Genital Ulcer Multiplex PCR (GUMP).
2003	Northern Territory, Australia	Central Australia Donovanosis Eradication Report • Education – biannual remote area nurse orientation, biannual men's & women's health workshop, remote clinics training, Tenant Creek & Alice Springs hospital in-service, remote area nurse meetings, community education sessions, Sexual health workshop with at risk youth, GUD dinner at Alice Springs. • Resources – STI photo cards with a genital ulcer disease focus, National genital ulcer management flow chart included. • Alukura factsheets – on herpes and Donovanosis for low literacy readers • Alice Springs Youth Accommodation Support Services, sexual health clinic- Donovanosis project officer 2 hours a week on premises to conduct prevention education [66].
2004	Northern Territory, Western Australia,	Donovanosis project officers create and present a 'Winning Clinical Epidemiological Research Poster' on the elimination project at the Australasian Sexual Health Conference Adelaide [67].

	Queensland, Australia	
2004	Australia	National Donovanosis Advisory Committee advises a 2 year donovanosis free time for elimination status, based on the longest incubation period reported for the disease [53].
2004	Australia	In June donovanosis projects ceased.
2004	Rio de Janeiro Brazil	Description of facial ulcers from Donovanosis presenting at Federal University Hospital Rio de Janeiro [68].
2005	Queensland, Australia	Multiplex PCR assay for the detection of genital ulcers developed by…on request of Queensland Health Communicable Disease Unit. Developed for patients presenting for genital ulcer disease caused by herpes simplex virus, Treponema pallidum, Haemophilus ducreyi and Klebsiella granulomatis (donovanosis). The assay was transferred to the QHPS Microbiology laboratory for routine use, as well as laboratories in Sydney and Perth. The publication for the method is described as in preparation [69].

Appendix 3: Case Studies

Available Case Studies of Donovanosis

Year	State	Age	Gender	Diagnosis	Follow up	Description
1990	WA, Perth	young	Female	Warthin-Starry stain positive		Presented for medical attention after haemorrhaging from a large pedunculated lesion from the left labium minus and majus. Confirmed as pseudo-elephantiasis resulting from long-standing Donovanosis of the vulva [70].
1990	WA, Perth	young	Female	Warthin-Starry stain positive		Initial findings consistent with a diagnosis of advanced cervical malignancy, referred to the oncology service. Because of age and Aboriginality a differential diagnosis of Donovanosis was confirmed [70].
1995	NT, Alice Springs	33	Female			Presented to Alice Springs Hospital with 2 month history of hematuria, right flank pain and UTI. Diagnosed with obstructed right ureter and a stent was inserted. Obstruction presumed to be secondary to a previous stone. She re-presented in 1996 with left iliac fossa mass and right leg pain. Diagnosed with Donovanosis mass extending down the iliopsoas muscle. Azithromycin 500mg daily for a week and then 1g weekly for 3 months [50].
1997	NT	26	Female			Admitted to Royal Darwin Hospital for colposcopic biopsy for Donovanosis. The woman tested positive, was discharged back to her community & lost to follow up. In August 1997 she represented with a right iliac fossa mass extending down the iliopsoas muscle with DVT. She commenced on azithromycin 500mg daily for a week and discharged on 1g weekly for four weeks. Her husband had previously been treated several months before her initial presentation. It was unclear whether the woman had any previous treatment on hospital and community records

						[50].
1998	Nth Australia	54	Female			Woman from Northern Australia with Donovanosis disseminated to bone causing thoracic vertebral osteomyelitis and spinal cord compression. The woman had no genital lesions but had undergone a hysterectomy raising possibility of prior cervical involvement. Despite treatment there was no neurological improvement [57].
2000	NT	5 months	Male	Slide negative, PCR positive		Admitted to hospital from a remote community with one month history of cervical lymphadenopathy (effecting cervical nodes that drain the tongue, external ear and neck). Also had anaemia, scabies and viral conjunctivitis. Had been treated for bloody ear discharge with amoxicillin in his community. Treated in hospital with IV ampicillin and flucloxacillin, dexamethasone-framycetin-gramicidin ear drops and topical permethrin cream with improvement. Discharged with oral amoxicillin/clavulanate and given an IM injection of iron. Readmitted two months later left cervical lymphadenopathy and gastroenteritis. On this admission it was noted by chance that his 16-year-old mother had extensive untreated genital Donovanosis, confirmed by histology of a vulval smear. Treatment with oral azithromycin suspension, 10 mg/kg daily for 14 days, with cervical lymphadenopathy resolved. Readmitted 2 months later with a right middle lobe pneumonia and an E. coli urinary tract infection but with no evidence of persisting lymphadenopathy. A small hole persisted in the ear drum[61].
2000	NT	16	Female	Slide positive		Mother of above [61]
2001	WA, Kimberly	21	Female	Biopsy PCR positive.	On 7 days, 15 days & 22 days Azithromycin 1.2g	Lump in December 1999 when pregnant lost baby and discharged from hospital with no treatment. Became pregnant in 2000 ulcer now painful. GP

					given stat and day 3, 5 & 7, 1 gm weekly day 15 & 22. Baby and partner asymptomatic & given Azithromycin.	diagnosed piles, referred to gynaecologist and then surgeon, reduction for piles unsuccessful advised to wait until after pregnancy. Baby delivered ulcer large and painful staff queried what ulcer was with no action. Went to mothers GP in Perth from the Kimberly in 2001 unhappy about previous lack of concern from health staff, referred to dermatologist, biopsy and diagnosis July 2001 [71].
2001	WA	25	Female	PCR & smear positive	Named a contact also tested positive	Attended Sexual Health Clinic with lesion. Also had diabetes.
2001	WA	29	Male	??	Named a contact also tested positive	Follow up from contact, lesion at base of penis for approximately 18 months.
2001	WA	26	Female	PCR positive	No ulcers still treated.	Follow up from contact, initially refused testing. Decided to be tested after it was explanation given that treatment and cure were available.
2001	WA		Male	Biopsy	Treatment not directly observed on patient request.	One lesion on neck (tested negative) and genital lesions (biopsy positive). Also had renal impairment and diabetes.
2001	WA	50	Female	PCR positive	GP Follow up	
2001	WA	29	Female	Clinical diagnosis	Unable to follow up	
2001	WA	21	Female			Non-Indigenous originally from New Zealand living in Australia for some years.
2001	WA	47	Female		Follow up took time socially a movable person.	History of renal impairment, diabetes and alcohol misuse.
2001	Qld, Townsville	39	Female			Vulval lesion first thought to be a fungating squamous cell carcinoma with investigation diagnosing Donovanosis
2002	WA	18	Male	PCR & smear negative Clinical		Lesions not typical 'beefy red'. Herpes and syphilis negative opted to be treated with Azithromycin with successful healing. Community the man came from had a history some years ago of

				diagnosis		Donovanosis cases.
2002	WA	68	Male		Couldn't remember anyone for contact tracing. Follow up took some time socially a movable person.	Presented at Hospital Accident and Emergency requesting a male health worker only. Lesion on thigh treated as fungal. Presented a number of other times at Accident and Emergency with misdiagnosis. Presented as anaemic biopsy taken on one occasion testing positive [72].
2002	NT	29	Female	Smear positive	Review at 5 weeks, 3 & 6 months. Partner declined testing. Baby reviewed with mother.	Genital ulcer 2cm in diameter detected during vaginal delivery. Lesion tested positive for HSV and Donovanosis. Ulcer healed during hospital stay and discharged back to remote community on weekly Azithromycin. MO decided not to prophylactically treat the baby [72].
2002	NT	48	Female	PCR positive	Follow up took some time socially a movable person. Follow and treatment for 4 weeks weekly. Could not be contacted at 3 months, readmitted to hospital at 4 months and reviewed there with no ulceration present.	Presented to Hospital with three painful ulcerations. Two lesions on the perianal and buttock area and a third on posterior thigh. Tests included syphilis, cancroid, Donovanosis and not HSV. Past history of hepatitis C, anaemia, injuries from domestic violence and night sweats. Trichomonas vaginalis and Donovanosis results positive. Treated for malnutrition.
2003	WA	53	Female	PCR & smear positive	Last sexual contact 2 years ago, had been named a contact with a man testing positive for Donovanosis ten years ago.	Living in supported hostel accommodation. Had a past history of alcohol issues. Presented with cut on buttock that ulcerated given Flucloxacillin. Donovanosis talk had been given in the area and hostel carer staff had attended. Consequently sent for sexual health check.
2003	Qld	?35	Female	Clinical diagnosis, smear		Had one ulcer 2-3 years ago detected on routine pap smear and tested positive for Donovanosis. Treatment successful. Represented in 2003 again

				negative		ulcer detected on routine pap smear and successfully treated in her own remote community.
2003	Qld	young	Female	Clinical diagnosis, smear negative	Follow up took some time socially a movable person.	Presented antenatally with genital ulcer.
2003	Qld	??	Male	Clinical diagnosis, smear negative		Lived in town park/camp
2003	Qld	??	Male	Smear positive		Lived in remote area 'out bush'.
2004	WA	33	Male	Smear negative, PCR positive	Follow up took some time socially a movable person.	Presented with genital lesions to a GP at an Aboriginal Medical Service.
2005	WA	37	Female			Lump noticed on vulva during caesarean section. Queried as cancer on biopsy 'odd' cells noted further checked for Donovanosis. Woman had noted a lump one week prior to caesarean section.

Appendix 4

National Donovanosis Elimination Action Plan: 2001-2004*

By the

National Donovanosis Elimination Advisory Committee

Final

** "The National Donovanosis Eradication Project 2001-2004" is the official title of the project. "Elimination" is the more correct epidemiological term.*

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Purpose of this plan

The purpose of this action plan is to provide a framework to commence implementation of the recommendations of the *Donovanosis: control or eradication? A situation review of donovanosis in Aboriginal and Torres Strait Islander populations in Australia.* The Action Plan will be operational from January 2002 to December 2003 and will act to:

- Inform the work of the National Donovanosis Elimination Advisory Committee (NDEAC) and the National Donovanosis Elimination Team (NDET);
- Provide a set of goals, outcomes, and performance indicators for measuring the success of the project
- Inform the sexual health subcommittee of each jurisdictional partnership forum (QLD, NT and WA);
- Inform the development of jurisdictional action plans,
- Guide the work of project officers in each jurisdiction; and
- Form the basis of the final report.

Background

Brief description of the disease

Donovanosis is a relatively uncommon genital ulcer disease (GUD) with low infectivity. It is characterised by large genital ulcers, which become chronic if not treated. The ulceration may be extensive and destructive. Secondary bacterial infection is common – often with anaerobic organisms – and may be associated with a characteristic and offensive smell. The lesions appear to be more severe in pregnant women and extragenital lesions are estimated to occur in approximately 6% of cases. The combination of the mutilating ulcer and the smell often lead to the infected individuals being marginalised from their community.

The epidemiological and biological synergy between Sexually Transmissible Infections (STI) and the sexual transmission of HIV infection is well established. GUD, and donovanosis in particular, are known cofactors for HIV transmission. This has established

STI control as one of the main strategies for the prevention of HIV transmission and increased the importance of eradicating donovanosis.

Definition of donovanosis

Both confirmed and probable cases should be notified.

Laboratory evidence required for confirmed case (either of the following)

1. Demonstration of intracellular Donovan bodies on a stained smear or biopsy specimen taken from a lesion

2. Detection of characteristic bacterial DNA by nucleic acid testing on a specimen taken from a lesion

Evidence for a probable case

Clinically compatible illness involving genital ulceration, in a person from an endemic area or sexual contact with a person from an endemic area, in whom other causes of genital ulceration have been excluded on laboratory or clinical grounds.

Definition endorsed by the Communicable Diseases Network of Australia, subcommittee on STI surveillance– June 2002.

Current burden of disease

Notifications of Donovanosis received by State and Territory health authorities in the period of 1991 to 2001 and year-to-date notifications for 2002 by year – month

YEAR	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
1991	4	4	1	10	7	8	3	9	2	9	12	3	72
1992	1	6	5	10	8	9	8	11	4	0	8	8	78
1993	3	6	2	6	6	3	3	10	8	10	3	7	67
1994	4	12	12	6	14	8	4	8	11	16	17	5	117
1995	5	11	9	5	9	8	2	4	6	8	7	11	85
1996	4	10	3	2	4	3	4	3	4	3	4	6	50
1997	1	0	7	2	3	3	1	6	2	3	8	9	45
1998	2	7	4	1	2	4	4	1	3	2	1	0	31
1999	3	1	0	1	2	1	2	4	0	1	1	1	17
2000	2	2	2	1	1	1	2	0	0	1	1	0	13
2001	4	0	0	2	4	4	9	2	4	3	0	6	38
2002	14	4	1	3	1	29	3	0	1	0	0	0	56

Notifications of Donovanosis received by State and Territory health authorities in the period of 1991 to 2001 and year-to-date notifications for 2002 by year – States and Territories

YEAR	ACT	NSW	NT	Qld	SA	Tas	Vic	WA	Total
1991	0	0	17	17	0	0	0	38	72
1992	0	0	37	17	0	0	0	24	78
1993	0	0	36	14	0	0	0	17	67
1994	0	0	68	30	0	0	0	19	117
1995	0	0	45	18	0	0	0	22	85
1996	0	0	21	5	0	0	0	24	50
1997	0	0	31	2	0	0	0	12	45
1998	0	0	21	3	0	0	0	7	31
1999	0	0	6	3	0	0	0	8	17
2000	0	0	6	6	0	0	0	1	13
2001	0	0	15	10	0	0	0	13	38
2002	0	0	8	46	0	0	0	2	56

- These tables were updated on 25 September 2002 for the reporting period to 10 September 2002.
- Please note that 2001 and 2002 data are provisional and may be revised.
- Donovanosis made notifiable in SA in 2002.
- Web-site: www.health.gov.au/pubhlth/cdi/nndss/year010.htm

Source: *Communicable Diseases Network Australia – National Notifiable Diseases Surveillance System*, personal communication.

Progress towards elimination in Australia

Significant headway has been made in the control of donovanosis in the last decade, with the introduction of azithromycin supporting improved compliance and curing numbers of people who had donovanosis for many years. Donovanosis is in its final phase with a stubborn, but declining incidence in rural and remote Aboriginal communities in northern and central Australia and the Torres Strait. The development of non-invasive screening technology for donovanosis has the potential to significantly assist in eliminating donovanosis. The burden of disease has decreased significantly and the disease is in decline. Elimination however should not be taken for granted. Despite the major gains in the diagnosis and treatment of donovanosis and declining prevalence, significant challenges to elimination persist. It was unlikely that elimination would be achieved by 2003 and there is a very real risk of the disease remaining in small clusters in remote communities across the north of Australia.

The advent of HIV and AIDS has radically altered the significance of persisting endemic donovanosis. Donovanosis is not only an important cofactor for sexual transmission of HIV, it is one we can do something about. Rather than moving on to the next problem, we need to identify declining prevalence as an opportunity to eradicate donovanosis from the indigenous community.

In early 2000, the Commonwealth commissioned Dr Penny Miller to conduct a situation review of donovanosis within Aboriginal and Torres Strait Islander communities and to recommend key strategies to progress toward elimination. ***Donovanosis: control or eradication? A situation review of donovanosis in Aboriginal and Torres Strait Islander populations in Australia,*** was developed with input from people experienced in donovanosis within Indigenous communities around Australia and the Indigenous Australians' Sexual Health Committee (IASHC). The recommendations of this review form the basis of section 3, *The National Donovanosis Elimination Advisory Committee Action Plan 2001-2004: objectives, actions, performance indicators, timelines and responsibilities.*

The National Indigenous Australians' Sexual Health Strategy (NIASHS) recommended that existing primary health care services be strengthened, and in particular, that new treatment regimes are used that simplify the treatment of sexually transmissible infections (STIs). Azithromycin provides a simplified method for treating donovanosis. Through an increased awareness of genital ulcer disease (GUD), it is expected that there will be a number of benefits for the identification and treatment of other sexually transmissible infections, including syphilis, chlamydia and gonorrhoea.

For the purposes of this paper Genital Ulcer Disease is defined as a clinical syndrome featuring ulcer(s) in the genital region. The main causes of ulcers include infections (primary syphilis, herpes simplex and donovanosis) neoplasms inflammation trauma etc. This paper will concentrate on the infectious causes of Genital Ulcer Disease.

The National Donovanosis Elimination Project has been endorsed by the IASHC and the Australian National Council on AIDS, Hepatitis C and Related Diseases (ANCAHRD). The IASHC is a sub-committee of ANCAHRD and is charged to provide advice to the Minister for Health and Ageing, ANCAHRD and the Department of Health and Ageing concerning Indigenous sexual health issues. IASHC membership consists of all members of the state and territory partnership process including:

- National Aboriginal Community Controlled Health Organisation (NACCHO);
- Standing Committee on Aboriginal and Torres Strait Islander Health (SCATSIH);
- Aboriginal and Torres Strait Islander Commission (ATSIC); and
- Intergovernmental Committee on AIDS, Hepatitis C and Related Diseases (IGCAHRD).

Definition of elimination

The following hierarchy of potential public health efforts in dealing with infectious diseases was discussed at the WHO Dahlem Workshop on the Eradication of Infectious Diseases, which was held in March 1997. Differences in these efforts made a distinction between the disease caused by the infection and the infection itself, the level of reduction achieved for either of these, the requirement for continuation of control efforts, and, finally, the geographical area covered by the intervention efforts and their outcomes. Although definitions outlined below were developed for infectious diseases, those for control and elimination apply to non-infectious diseases as well.

- *Control:* The reduction of disease incidence, prevalence, morbidity or mortality to a locally acceptable level as a result of deliberate efforts; continued intervention measures are required to maintain the reduction. Example: diarrhoeal diseases.
- *Elimination of disease:* Reduction to zero of the incidence of a specified disease in a defined geographical area as a result of deliberate efforts; continued intervention measures are required. Example: neonatal tetanus.
- *Elimination of infections:* Reduction to zero of the incidence of infection caused by a specific agent in a defined geographical area as a result of deliberate efforts; continued measures to prevent re-establishment of transmission are required. Example: measles, poliomyelitis.
- *Eradication:* Permanent reduction to zero of the worldwide incidence of infection caused by a specific agent as a result of deliberate efforts; intervention measures are no longer needed. Example: smallpox.
- *Extinction:* The specific infectious agent no longer exists in nature or in the laboratory. Example: none.

Source: *Dowdle, W R (1999) The Principles of Disease Elimination and Eradication, CDC Morbidity and Mortality Weekly Report, 48(SU01);23-7.*

The above description of the hierarchy of definitions clearly shows that Eradication cannot be achieved in its true sense in Australia, if donovanosis remains in other parts of the world, especially in areas close to Australia.

This two-year project aims to put in place across Australia the structures, systems and controls necessary to support the elimination of donovanosis from Australia by 2007. The projects will undergo an evaluation in June 2003 to consider progress toward the aims set out in this plan.

PROJECT SUCCESS MEASUREMENT

Goal

- To introduce by December 2003 the national infrastructure, systems and clinical awareness required to support elimination of donovanosis from Australia by 2007.

Outcomes

- Primary health care centres in donovanosis affected Health Regions (DAHR) are familiar with the content of the *National Donovanosis Factsheet*
- Primary health care centres in DAHR utilise the national *Genital Ulcer Care Plan* and *Management Guidelines for Genital Ulcer Disease* for the management of all cases of Genital Ulcer Disease (GUD).
- Laboratory services are available in all DAHR for the testing of GUD consistent with agreed National Minimum Standards
- Data reporting to agreed national standard is in place from all DAHR
- Research is undertaken where possible to support achievement of the project goal.

Key Performance Indicators

- 95 % of primary health care centres in each DAHR are trained in the content of the National Donovanosis Factsheet
- 95 % of primary health care centres in DAHR utilise the national *Genital Ulcer Care Plan* and *Management Guidelines for Genital Ulcer Disease* for the management of cases of Genital Ulcer Disease (GUD).
- Laboratory services in 100% of DAHR offer testing for GUD consistent with agreed National Minimum Standards
- 100% of DAHR provide bi- annual reports to agreed national standard
- 100% of research identified is considered by NDEAC and referred to appropriate agencies for action.

4. The Donovanosis Elimination Action Plan 2001-2003: objectives, actions, outcomes, timelines and responsibilities.

The Objectives are based on the Miller Review Recommendations into Donovanosis 2000 and are not identified in terms of priority, however many require concurrent actions.

PROJECT OFFICERS				
Objective	**Action**	**Outcome**	**Timeline**	**Responsibility/Status**
A: That intensive targeted support is provided to strengthen the capacity of primary health care services to provide early diagnosis and effective treatment.	Four full-time workers employed for two years should provide this targeted support. The four positions should all be located in central and northern Australia, one in Queensland, two in NT and one in WA.	All Project Officers employed by January 2002. WA employed October 2001.	2001 - 2004	All project officers employed; WA employed 3 months earlier than NT and QLD.
B: That each project officer work with primary health care services and other key players regarding data collection, storage, access, analysis and dissemination.	State/ Territory sexual health committees to assist project officers	Documentation of data protocols in reports provided	Ongoing	Discussions occur during visits and correspondence with services.
C: Encourage standardisation of training protocols, education resources and evaluation mechanisms to reduce duplication of effort.	C.1 Formation of National Donovanosis Elimination Team (NDET) C.2 NDET to develop education and treatment and care resources for National use. C.3 NDET to develop a national media strategy to support this. C.4 Project officers to have regular meetings to discuss	C.1-2 Standardised GUD Fact Sheet, Management Guidelines for GUD, GUD Care Plan, media campaigns etc in use in all jurisdictions. C.3 Documented implementation plan for a targeted media strategy. C.4 Monthly NDET teleconferences and face to	Within six months of all Positions starting / ongoing.	C.1 NDET formed December 2001 C.2 Initial resources agreed May 2002. C.3 Jurisdiction based. C.4 Teleconferences

	project implementation	face meetings prior to NDET meetings.		commenced
D: A short central training program be provided in the clinical diagnosis, laboratory diagnosis, treatment, follow-up and control strategies for project officers employed in active case follow-up positions.	NDET to conduct central training	Completion of course	Within one month of all POs starting	Completed 10 December 2001

Treatment, Care and Support				
Objective	**Action**	**Outcome**	**Timeline**	**Responsibility/Status**
A: Nationally consistent advice on the treatment, care and support for donovanosis	A.1 Resources to be developed by NDET. PO to promote use and inclusion in local treatment and care manuals. A.2 Final Resources to be appended to this plan and published on central website for download and referral. A.3 NDEAC to write to Chief Health Officers for information. A.4 NDEAC liaise with editors of National Antibiotic Guidelines. A.5 NDEAC liaise with the ACSHP for inclusion in the Guidelines for Sexually Transmissible Infections and Genital Infections.	A.1 National Fact Sheet, GUD Flow Chart and GUD Care Plan developed and in use in all jurisdictions. A.2 All resources maintained in single location and are easily accessible. A.3 CHO endorsement. A.4 Inclusion of recommendations in next edition of Antibiotic Guidelines. A.5 Inclusion in ACSHP guidelines	August 2002	A.1 Completed May 2002, to be endorsed by NDEAC July 2002. A.1.2 All jurisdictions utilising resources by January 2003. A.2 November 2002 A.3 Not completed. A.4 Not completed A.5 Not completed

Laboratory				
Objective	**Action**	**Outcome**	**Timeline**	**Responsibility/Status**
A: Laboratory diagnosis of donovanosis should be offered using the most valid and acceptable test that is available in a given clinical and regional context, whether PCR or histology.	NDEAC to work with PHLN, and States and Territories to identify minimum laboratory testing and notification standards. Agreed Standards to be appended to this plan. 2. Commonwealth to develop MOUs/contracts with laboratories in receipt of commonwealth funding to ensure agreed National standards apply. 3. States and territories to monitor public laboratories conducting program related testing to ensure agreed National standards apply.	Laboratories conduct testing in line with agreed national standards.	December 2002	NDEAC/OATSIH Underway.
B: Ensure laboratories providing histopathology services for areas with endemic donovanosis maintain the capability to perform donovanosis histology.				
C: Laboratory notification of donovanosis be strengthened in Western Australia, the Northern Territory and Queensland to reduce under-reporting.				

Data Collection				
Objective	**Action**	**Outcome**	**Timeline**	**Responsibility/Status**
A: National surveillance of donovanosis be maintained and strengthened.	Inclusion of donovanosis in Nationally notified diseases list and support through CDNA Agreed PLHN Donovanosis Definition to be appended to this plan.	Documentation from CDNA All jurisdictions list Donovanosis as notifiable by December 2002	Ongoing	NDEAC. Received CDNA data
B: Develop comprehensive data collection proforma that is acceptable to the three jurisdictions (NT, WA, Qld) and which captures all relevant information for donovanosis	Production and dissemination of State and Territory report format	States and Territories provide reports on agreed Performance Indicators biannually	September 2002	NDEAC/ S&Ts Proforma to be endorsed by NDEAC September 2002
C: Implement a sustainable follow-up system to increase the numbers of individuals diagnosed & effectively treated.	PO to develop communication and implementation strategy on GUD Care Plans to maximise data provided back by clinics on reported cases of donovanosis.	Maximum number of cases of donovanosis correctly documented by primary service provider and followed up by PO.	Ongoing	Project Officers Ongoing

Research				
Objective	**Action**	**Outcome**	**Timeline**	**Responsibility/Status**
A: Support be given for effective and relevant research programs to facilitate control of donovanosis.	NDEAC to write to NHMRC informing them of the NDEAC Communicate with IASHC/ANCAHRD	Documentation of correspondence.	August 2002	NDEAC. Not completed
B: Collaboration be encouraged between laboratories regarding the further development of, and access in endemic areas to, the in-house PCR method for donovanosis.	C.1 NDEAC support joint development of PCR test by participating State laboratory facilities with oversight by NPHLN.	C.1 Test developed and testing commenced.	January 2002	C.1 Test development complete January 2002. Validation commenced.
	C.2 Validation complete and sign off by NDEAC following recommendation by NPHLN.	C.2 Evidence of validation provided to NPHLN and NDEAC	August 2002	C.2 Validation data to be considered by NPHLN August 2002. NPHLN to advice NDEAC by December 2002.
C: Support be given to the introduction of non-invasive screening technology	C.3 Commonwealth to enter into negotiations with states and territories to determine appropriate funding mechanisms for tests.	C.3 Negotiations to begin with each jurisdiction once ethics approval is received by NACCHO affiliate; funding mechanism to be agreed with state and territories	December 2002	Commonwealth to consider methods to assist in expediting funding arrangements to States by December 2002.

Evaluation				
Objective	**Action**	**Outcome**	**Timeline**	**Responsibility/Status**
A: That an external review of the project officer positions created be conducted 18 months after the employment of the workers to assess whether extension of the two year term is required.	NDEAC in conjunction with States and Territories to define terms of review including content and process. Commence review in July 2003	Review completed by August 2003	July/August 2003	Commonwealth OATSIH
B: NDEAC to define progress toward elimination.	B.1 Definition of project communicated to stakeholders. B.2 State and Territory performance reports to ensure data required for monitoring captured and reported as required.	Data captured to allow progress toward elimination.	October 2002	NDEAC To be endorsed by October 2002

4. The role of partners

a) National Donovanosis Elimination Advisory Committee (NDEAC)

The Terms of Reference for the *National Donovanosis Elimination Advisory Committee (NDEAC)* committee are as follows:

5. ***To provide advice to the Department of Health and Aged Care's Office for Aboriginal and Torres Strait Islander Health (OATSIH) on the implementation of*** **The National Donovanosis Elimination Project.**
6. Advise OATSIH on the criteria required to progress the national elimination of donovanosis, including data and reporting requirements, and provide a report to OATSIH biannually on progress to date.
7. Provide regular reports to the Minister for Health on progress to date.
8. In recognition of the Indigenous Australians' Sexual Health Committee's (IASHC) role in auspicing this project, provide regular reports to the IASHC in order to meet the IASHC's requirement to report on progress to the Australian National Council on AIDS, Hepatitis C and Related Diseases (ANCAHRD).

Table 1: National Donovanosis Elimination Advisory Committee (NDEAC) Membership

Name	**Position**	**Responsibilities**
Professor Frank Bowden	Chair / Technical Consultant	Medical and Testing technical advice (Support member to Donovanosis Project Officers)
Associate Professor Cindy Shannon	Indigenous Australians' Sexual Health Committee	Chair of IASHC
Ms Joy Savage	Director – (OATSIH)	Representing DoHA (IASHC ex-officio)
Dr Trish Fagan	Senior Medical Officer – OATSIH	SMO OATSIH
Dr David Bradford	President, Australasian College of Sexual Health Physicians (ACSHP)	President, Australasian College of Sexual Health Physicians (IASHC member)

Mr Michael Howard	Technical Consultant	Project Officers support; technical implementation advice (Support member to Donovanosis Project Officers)
Prof John Kaldor	National Centre in HIV Epidemiology and Clinical Research (NCHECR)	Epidemiology Consultant to assist with development of data records and elimination tracking. (IASHC ex-officio)
Ms Florence Williams	National Community Controlled Health Organisation (NACCHO)	Representing NACCHO. (IASHC ex-officio)
Ms Patricia Nona	Indigenous Australians' Sexual Health Committee (IASHC) Member	Specialist remote service advice. (IASHC representative & member)
Mr Christopher Macaulay	Intergovernmental Committee on AIDS, Hepatitis C and related Diseases (IGCAHRD) Member	Represent NT, WA & Qld Health Departments
Dr Sophie Couzos	National Aboriginal Community Controlled Health Organisation (NACCHO)	Technical adviser, represent Community Controlled Health Organisations in National forums (IASHC observer)
Mr Ron James	Standing Committee on Aboriginal and Torres Strait Islander Health	IASHC Ex-officio
Dr Ivan Bastian	National Public Health Laboratory Network (NPHLN)	Represent the National Public Health Laboratory Network
Mr Bernard Pearce	Assistant Director OATSIH	Representing Department of Health and Ageing
Ms Bilawara Lee	Project Officer, OATSIH	Secretariat to the National Donovanosis Elimination Advisory Committee (NDEAC)

b) National Donovanosis Elimination Team (NDET)

The National Donovanosis Elimination Team (NDET) is a technical advisory team, formed to assist the state and territory based project officers, and to ensure national consistency in the project's implementation.

Table 2: National Donovanosis Elimination Team (NDET) Membership

Name	**Position**	**Responsibilities**
Professor Frank Bowden	Technical Consultant	Medical and Testing technical advice (Support member to Donovanosis Project Officers)
Mr Michael Howard	Technical Consultant	Project Officer support; technical implementation advice.
Ms Florence Williams	NACCHO	Project Officer support, technical Implementation Advice.
Professor John Kaldor	NCHECR	Project Officer Support - Epidemiology
Ms Brenda Henry Ms Noreen Conlon Ms Ann Davis Ms Janelle Wilkey	Project Officer – Based Cairns Project Officer – Statewide – based Perth Project Officer – Based Darwin Project Officer – Based Alice Springs	Assisting local services with the elimination of donovanosis
Mr Bernard Pearce	Assistant Director, OATSIH	Representing Department of Health and Ageing
Ms Bilawara Lee	Project Officer,, OATSIH	Secretariat to NDET

c) State and Territory Project Members

This page is designed for state and territory partners to use when developing their own jurisdiction response to the NDEAC Plan

As a first step, regional donovanosis elimination implementation plans are recommended to be developed by each of the project officers based on the National Project Implementation Plan. States and Territories will have a central role in ensuring the success of the project in their jurisdiction and to assisting the local project officers to meet their obligations with regard to reports and attendance at national training and meetings. OATSIH S &TO will regularly liaise with the organisations sponsoring the positions.

Table 3: State and Territory Partners

Name	Position	Roles / Responsibilities
TBA	Aboriginal Community Controlled Health Services	Partnership member.
TBA	Health Department	Employer of project officer, partnership member.
TBA	OATSIH	Contract manager, partnership member.

Appendix 1: Media Launch

The National Donovanosis Elimination Project was launched by the Chair of ANCAHRD, Mr Chris Puplick at *2001: A Sex Odyssey*, the annual scientific meeting of the Australasian College of Sexual Health Physicians, in Sydney on 2 May 2001. OATSIH have published the situation review document, *"Donovanosis: control or eradication?"* and have distributed copies of the document to members of ANCAHRD and its committees, registrants of the Australian Sexual Health Conference, and OATSIH State Offices.

National Standard Treatment Protocols

OATSIH, NDEAC and NDET will have responsibility for communicating and encouraging the use of standard treatment protocols nationally, including:

- Syndromic management
- Short course, directly observed treatment
- Inclusion of donovanosis in GUD standard treatment protocols in endemic areas
- National Antibiotic Guidelines

Reports to Stakeholders

OATSIH CO are to provide the following stakeholders with regular updates on the project's progress:

- The Commonwealth Minister for Health and Ageing
- ANCAHRD through the IASHC
- IGCAHRD
- DoHA Population Health Division.

Appendix 2: - State and Territory Reporting

1. Initial Scoping Report

An initial scoping report is to be prepared by the project officer at the completion of the first 3 months of employment ie April 2002. The purpose of this report is to provide NDEAC with an understanding of a "regional analysis" of donovanosis in each jurisdiction. This information would guide work on "hot spots" and then to other areas of need. Report to cover:

- 5 year history of Donovanosis data including trends over time;
- Distribution by Age, Race and Gender;
- Regional Distribution.

2. Biannual Report

Reports from States and Territories are required by NDEAC in October 2002 (for the period up to June 2002), February 2003 (for the period up to December 2002), August 2003 (for the period up to June 2003), February 2004*. (Final Report*) Reports to cover the following

- Number of primary health care centres in Donovanosis affected health region (DAHR)
- Number and % of primary health care centres in DAHR trained in the content of the *National Donovanosis Factsheet, Genital Ulcer Care Plan* and *Management Guidelines for Genital Ulcer Disease*
- Number and % of cases of clinically or laboratory confirmed donovanosis in DAHR managed utilising a *Genital Ulcer Care Plan* and the *Management Guidelines for Genital Ulcer Disease*.

- Epidemiological data for 6 month period including:
  - Total new cases of Donovanosis
  - Distribution by Age, race and Gender
  - Commentary on trends
  - Total combined PCR tests conducted for Genital Ulcer Disease (once available)

3. Financial Report:

To be provided to OATSIH as per contract; Not be tabled at NDEAC**.**

Appendix 6: Glossary of key terms and abbreviations

ACSHP	**Australian College of Sexual Health Physicians**
ANCAHRD	**Australian National Council on AIDS, Hepatitis C and Related Diseases**
ATSI	**Aboriginal and Torres Strait Islander Commission**
CARPA	**Central Australian Rural Practitioners Association**
CDC	**Communicable Disease Prevention & Control**
DoHA	**Department of Health and Ageing (Commonwealth Government)**
DOT	**Directly observable treatment**
GUD	**Genital Ulcer Disease**
HIV	**Human Immunodeficiency Virus**
IASHC	**Indigenous Australians' Sexual Health Committee**
IGCAHRD	**Intergovernmental Committee on AIDS, Hepatitis C and Related Diseases**
LCR	**Ligase Chain Reaction**
NAA	**Nucleic Acid Amplification (such as PCR / LCR)**
NACCHO	**National Aboriginal Community Controlled Health Organisation**
NDEAC	**National Donovanosis Elimination Advisory Committee**
NDET	**National Donovanosis Elimination Team**
NIASHS	**National Indigenous Australians' Sexual Health Strategy**
NNDSS	**National Notifiable Diseases Surveillance System**
NSW	**New South Wales**
NT	**Northern Territory**
OATSIH	**Office for Aboriginal and Torres Strait Islander Health – Department of Health and Ageing**
PO	**Project Officers**
PCR	**Polymerase Chain Reaction**
PHD	**Population Health Division – Department of Health and Ageing**
Ref Labs	**Reference Laboratories for donovanosis confirmation**
S & TO	**State and Territory Offices**
SA	**South Australia**

SCATSIH	**Standing Committee on Aboriginal and Torres Strait Islander Health (was HAHU)**
STD	**Sexually transmitted disease**
STI	**Sexually transmissible infection**
WA	**Western Australia**
WHO	**World Health Organisation**