Dear researcher,

This package has been put together to provide background information about the National Diabetes Register (NDR), and to describe the process for gaining access to the NDR for research.

If you have any questions about the information contained in this package, please do not hesitate to contact either Daniel Palamara 02 6249 5151 daniel.palamara@aihw.gov.au, or myself.

**Susana Senes**
Unit Head
Cardiovascular, Diabetes and Kidney Unit
Ph: 02 6244 1171
Fax: 02 6244 1044
Email: susana.senes@aihw.gov.au

# National Diabetes Register

# Description

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# What is the National Diabetes Register?

The National Diabetes Register (NDR) is a database, housed at the Australian Institute of Health and Welfare (AIHW), which contains records of people in Australia who commenced using insulin to treat their diabetes after 1 January 1999, and who have provided consent to have their records included on the Register. The data are obtained from Diabetes Australia through the National Diabetes Services Scheme (NDSS), and the Australasian Paediatric Endocrine Group (APEG). The objectives of the Register are to improve current information systems on diabetes and to facilitate the conduct of epidemiological studies. Its use is strictly confined to medical research.

## Background

Diabetes became a National Health Priority Area in 1996. Following this, The National Diabetes Strategy and Implementation Plan was launched in 1998. As part of this Strategy, the Ministerial Advisory Council on Diabetes (MACOD) recommended the establishment of a National Diabetes Register for people with insulin-treated diabetes, and to consider expanding it into a comprehensive National Diabetes Register.

The AIHW submitted a tender application to establish the National (insulin-treated) Diabetes Register in August 1997, and was notified as the successful tenderer in February 1998. In August 1998, the AIHW signed a Schedule under the Memorandum of Understanding with the then Commonwealth Department of Health and Aged Care, to establish and maintain a National Insulin-Treated Diabetes Register (commonly referred to as the 'National Diabetes Register').

## Objectives

There is an increasing demand throughout Australia for epidemiological studies to determine the relationships between environmental, occupational and life-style factors on the one hand and chronic diseases on the other hand. Deficiencies in national information systems enabling the monitoring of incidence and prevalence of diabetes in Australia have long been identified. Mechanisms which enable research about people with diabetes are also incomplete. The NDR seeks to fill some of these deficiencies in current information systems, and to facilitate research on diabetes.

The current objectives of the Register are to:

- collect information about new cases of insulin treated diabetes mellitus (ITDM);
- provide a sampling frame for scientifically valid and ethically approved epidemiological and clinical studies of ITDM and Type 1 diabetes;
- monitor and report on the incidence of ITDM and Type 1 diabetes;
- assess the feasibility and cost of estimating ITDM and Type 1 prevalence;

- provide information to health service providers and planners at Commonwealth, State and local levels; and
- provide assistance in monitoring national diabetes indicators.

## Scope

Registration on the NDR is not determined by the type of diabetes a person has, but by whether or not they use insulin to treat their diabetes. Currently it includes all new cases of ITDM from 1st January 1999 where consent has been provided for inclusion on the Register. In summary, a person is eligible for the register if they:

- started using insulin for the first time since 1st January 1999.

A person is not eligible for the Register if they:

- started using insulin before the 1st January 1999; or
- they do not use insulin to treat their diabetes.

Thus the Register includes people with all types of diabetes (Type 1, Type 2, gestational diabetes, and other forms of diabetes).

## Core data items

The National Diabetes Register contains the following standard set of identifying information for each registrant:

- name
- address
- sex
- date of birth
- country of birth
- Aboriginal and/or Torres Strait Islander origin
- type of diabetes
- date of diagnosis
- postcode at diagnosis
- date of first insulin injection
- in respect of the diagnosing doctor, doctor type and contact information; and
- carer's contact details when supplied and relevant.

The Register does not collect clinical information about the person with diabetes.

## Information to be provided from the NDR

Researchers may approach the AIHW to access the NDR for either:

1. An extract of de-identified data from the NDR; or

2. Named data for record linkage purposes, without contacting the individuals on the NDR (to be done on-site at the AIHW); or

3. Named data with a view to contact individuals on the NDR.

If the research involves contacting individuals on the NDR, once all ethics approvals have been granted, the AIHW will contact subjects, at the researcher's expense. Detailed information will be provided about the study for which they have been selected, and their consent to participate will be requested. The AIHW will only provide information to the researcher about those people who have consented to be included in the research project.

Option 1 will rarely require ethics approval. Options 2 and 3 will almost always require approval from the AIHW ethics committee.

# How does the National Diabetes Register operate?

## Data sources

There are two main data sources for the NDR – the National Diabetes Services Scheme (NDSS) database, administered by Diabetes Australia and the Australasian Paediatric Endocrine Group (APEG) State-based databases. The NDSS database collects information about people with diabetes in all age groups, whereas APEG data focus on people with Type 1 diabetes who are under 15 years of age.

## Management

The AIHW is responsible for the management of the NDR under the guidance of the National Diabetes Data Working Group. The group's terms of reference are to:

- Advise on policy and management issues relating to data held on the Register including the operation of the Register;
- Provide advice on issues relating to the scope and performance of the Register and the utility of obtaining and validating data from all sources.
- Provide advice about the development and monitoring of performance indicators appropriate to the efficient functioning of the Register, and provide guidance in relation to the monitoring and public reporting on performance against these measures;
- Review annually a report on the overall performance of the Register provided by the AIHW, (ie the quality and completeness of data as well as the nature and presentation of the findings);
- Examine wider opportunities relating to the existence of the Register;
- Promote equity of access to Register data for all researchers, and when required provide advice to assist in resolving any problems relating to requests for information.

## Security

The Institute maintains a secure physical and computer environment for the NDR and the data sets that are provided by researchers for matching with the NDR.

## Confidentiality

The AIHW regards security of its data holdings as of primary importance in maintaining its obligations to and the trust of the AIHW's data providers. The AIHW

is required by law (section 29 of the *Australian Institute of Health and Welfare Act 1987*) to ensure the confidentiality of its data holdings. Section 29(1) imposes severe penalties for the divulging or communicating of information concerning a person, except for the purposes of the Act.

### Data provided by State and Territory Registrars

As Commonwealth officers, the release of information by Institute staff is also controlled by the Privacy Act 1988, Public Service Regulations and the Commonwealth Crimes Act.

All restrictions on the use and release of the information provided which are imposed by the State and Territory legislation that controls the operation of the Registries are to be carried through to the operation of the NDR.

### Data provided by National Diabetes Register Users

The confidentiality conditions of the Australian Institute of Health and Welfare Act 1987 will also apply to data provided by National Diabetes Register users.

# How do I gain access to the National Diabetes Register?

The first step in gaining access to the NDR is to contact the NDR project officer, Daniel Palamara on 02 6249 5151 or daniel.palamara@aihw.gov.au, to explain the data request. Based on information provided by the researcher, the NDR team will decide whether or not ethics committee approval is required before proceeding with the request.

If ethics committee approval is not required then the data request will be refined between a member of the NDR team and the data requestor. The data will then be extracted and sent to the data requestor.

If the data request requires ethics committee approval it should be noted that applications to use the NDR will only be considered if the applicant provides assurance of scientific quality—evidenced either by the project having been funded through a competitive peer-reviewed grant process or by review by independent peers acceptable to the AIHW. Before a project can proceed, approval must be sought from the investigator's host ethics committee and the Australian Institute of Health and Welfare Ethics Committee.

## Steps to gain access to the NDR when ethics approval is required

1. The NDR project officer will provide you with a copy of the *AIHW Ethics Committee Guidelines for the Preparation of Submissions for Ethical Clearance.*

2. Complete the application form and forward it to the AIHW with a copy of the project protocol and any other documents, such as evidence of receipt of competitive peer reviewed grants, and approval by local or other Institutional Ethics Committees.

3. The application will be examined initially by AIHW staff to ensure that all the necessary information has been supplied.

4. The AIHW will allocate a National Diabetes Register reference to the request and acknowledge receipt of the application, requesting any missing information. If sufficient information has been supplied, a cost estimate will be provided at this time.

5. If documentary evidence has been provided that the project is being funded through a competitive peer-reviewed grant this will be accepted as proof of the scientific quality of the project. Otherwise the project will be subjected to an independent peer review arranged by the Institute. If the project is not approved by the independent peer review the researcher will be informed and given the reasons for rejection.

6. Successful applications at this point will be submitted for the approval of the Australian Institute of Health and Welfare Ethics Committee. Each Registrar may impose any restrictions considered necessary. Where approval is not given the researcher will be given reasons for rejection.

7. Upon full approval of the application, the applicant will be informed of the approval and of the fee for access with a request for payment.

8. The AIHW will then process the request for NDR information. Once processed, the information will be despatched to the researcher.

## Costs associated with accessing the NDR

The following points provide a guide on how the Institute calculates the cost of a request for NDR information. Please note that this is a guide only and may vary according to the needs and design of the study.

- An Ethics Committee review charge of $250 is levied regardless of success of the application
- Service charges for manipulation and dealing with the data are a minimum charge of $200 (includes up to 30 minutes of time) plus cost recovery at $160 per hour or $1000 per day
- Approx 1-2 hours are allocated to reviewing projects for scientific and ethical acceptability
- Where NDR registrants need to be contacted for permission to participate in the research study, all costs involved in contacting registrants and processing responses, including postage will be charged.