

Australian National Diabetes Audit

ANDA Data Access and Publication Policy

Version History

| Version | Date | Description | Name | Title |
|---------|------|-------------|------|-------|
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Associated Documents

| Appendices | Description |
|-------------|--|
| Appendix A | A guide for access to ANDA data analysis |
| Appendix B | Research Data Enquiry |
| Appendix C1 | Data extract request form |
| Appendix C2 | Data related documents |
| Appendix D | ANDA Data Access Agreement |

Acronyms and Abbreviations

| | Description |
|-------|--|
| ADS | Australian Diabetes Society |
| AIHW | Australian Institute of Health and Welfare |
| ANDA | Australian National Diabetes Audit |
| AQCA | Australian Quality Clinical Audit |
| AQSMA | Australian Quality Self-Management Audit |
| ICMJE | International Committee of Medical Journal Editors |
| NADC | National Association of Diabetes Centres |

Definitions

| | Description |
|------------------------------------|--|
| ANDA Project Executive | Operational Group |
| ANDA Study Group | ANDA Project Executive, ANDA Scientific Advisory Committee and any participating centres |
| ANDA Scientific Advisory Committee | Multi-organisational and multi-disciplinary |
| Publication Committee | To be formed by the ANDA Scientific Advisory Committee |
| Data Custodian | Monash University |

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1. Purpose and Guiding Principles

The general philosophy of the ANDA Study Group is one of inclusion and collaboration. The ANDA Study Group aims to facilitate access to data from a broad range of investigators and to pursue collaborative research to drive scientific output.

The underlying premise of this policy is that ANDA data must be secure and strictly managed. However the processes to access the data must be efficient and timely to ensure the ANDA resource meets the aims of improving patient-centred care and the lives of people affected by diabetes.

This document describes the processes for accessing multi-centre data from ANDA, managing analysis proposals, and the writing and authorship of publications. The procedural documentation will be publicly available on the ANDA and NADC Websites (**Appendices A, B, C and D**).

2. Background

The Associated Documents outlining the governance of ANDA should be read in conjunction with this policy.

2.1 ANDA Data and Governance Structure

De-identified patient data collected by participating centres are pooled in the ANDA database. These data are added to annually and can be used repeatedly without diminishing their future availability or value.

The Division of Metabolism, Ageing and Genomics, School of Public Health, Monash University hosts and is the custodian of the ANDA dataset. Details relating to the dataset can be found in the ANDA Data Dictionary.

ANDA has links to the National Association of Diabetes Centres (NADC) and the Australian Diabetes Society (ADS). The roles and responsibilities of each of these entities can be found in Section 3: ANDA Data Access Framework.

ANDA data is protected and governed according to the overarching ANDA governance arrangements.

3. ANDA Data Access Framework

The purpose of the activity is to undertake the collection, collation, analysis, audit and reporting of clinical diabetes and patient education and self-care data in diabetes services across all states and territories in Australia.

The broad objectives of the activity are to:

- facilitate and coordinate the national participation for services providing diabetes care across all states and territories;
- collect, validate and collate AQCA (Australian Quality Clinical Audit) and AQSMA (Australian Quality Self-Management Audit) data;
- create individualised reports for each participating site detailing their results, benchmarked against their peers;
- generate comparison reports for the period over which the AQCA and AQSMA projects have been undertaken for sites that have participated in previous AQCA and AQSMA surveys;

- conduct and report feedback provided by a post data collection questionnaire and individual site report assessment questionnaire assessing project process evaluation for both the AQCA and AQSMA surveys; and
- compile a final pooled data report for ANDA-AQCA and ANDA-AQSMA. The project will be achieved through the conduct of a cross-sectional survey by services providing diabetes care across all states and territories.

ANDA Objectives:

1. Consistent application of previous methodology and project structure
2. Level of survey participation
3. Spread of survey participation
4. Quality and completeness of data

ANDA Support Networks:

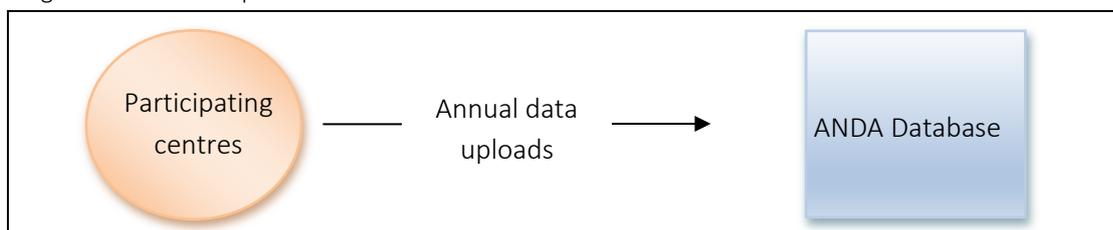
The National Association of Diabetes Centres (NADC) is a national collective of organisations that are involved either directly or indirectly in diabetes services and care. NADC was established to explore mechanisms and implement strategies for improving the standard of care for people with, or at risk of diabetes. NADC member organisations take a leadership role in developing the appropriate networks in their areas in order to achieve this outcome.

The Australian Diabetes Society (ADS) is the peak national medical and scientific body in Australia for diabetes. The ADS is a member-based organisation consisting of health professionals (endocrinologists, diabetes educators, primary care physicians and allied health professionals) as well as clinical and preclinical researchers. The ADS mission is to prevent diabetes and its complications; provide excellence in education for health professionals; promote collaboration, research and education; work with other organisations committed to improved diabetes treatment and care and advocate for health policies around diabetes and its prevention.

3.1 What comprises ANDA?

ANDA is comprised of a central database, which will hold the pooled data of participating centres.

Figure 1. ANDA Components



Direct access to the central database (i.e. users able to log in to ANDA) will be restricted as outlined in section 3.2 ANDA User Groups.

Access to the ANDA dataset will be open to participating centres, including researchers who do not have direct access to the ANDA database.

3.2 ANDA User Groups

There are four distinct groups of ANDA users:

1. The wider research community
2. Department of Health
3. Participating centres
4. ANDA Data Manager whose role includes quality checking the data and providing data extracts for approved research

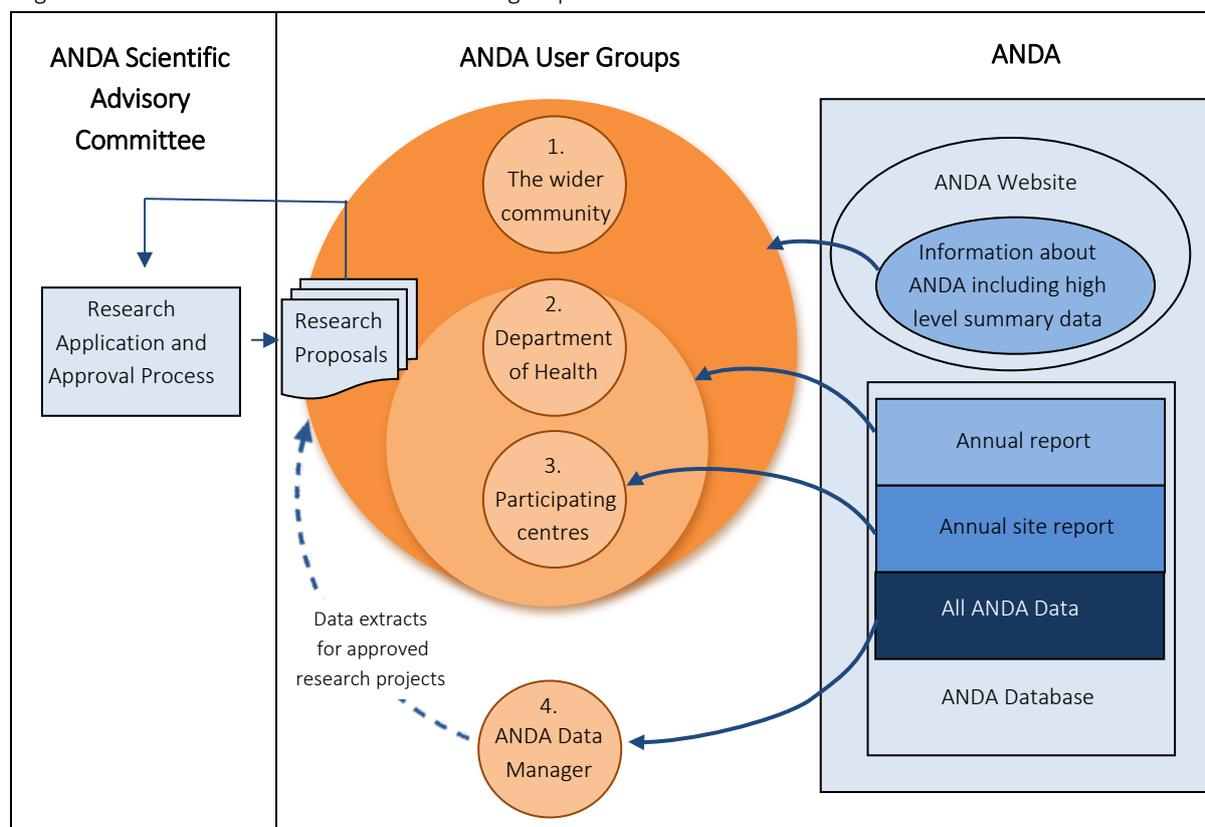
Proposed levels of access to ANDA data for different user groups are:

Figure 2: ANDA Access Levels

| Access Details | USER GROUP | | | |
|--|------------------------------|-------------------------------|--------------------------------|----------------------------|
| | 1. The wider community | 2. Department of Health | 3. Participating centres | 4. ANDA Data Manager |
| ANDA login | | | | Super-user |
| Supply of raw data | | | √ | √ |
| View summary data for all centres combined (Pooled Report) | √ | √ | √ | √ |
| View detailed data for individual centre | | | √ Own centre only | √ All centres |
| Extract multi-centre data for approved study | | | | √ |

Access to ANDA data for the different ANDA user groups and the ANDA Scientific Advisory Committee is shown below:

Figure 3: Data access for different ANDA user groups



Details regarding data access for each user group are described in the sections that follow.

3.3 How will ANDA data be accessed by the wider community?

The wider community will not have direct access to the ANDA database. However they will have access to **a high level summary report of the ANDA participants**. This report will be routinely generated by the ANDA Data Manager. There will be content explaining that the ANDA participants are a subset of people with diabetes, not necessarily representative of the total population nor of the AIHW register.

3.4 How will ANDA data be accessed by the Department of Health?

The Department of Health will receive a high level summary pooled report.

3.5 How will ANDA data be accessed by participating centres?

Users at participating centres will have access to:

- the pooled report
- their site report
- the patient level data that they have contributed.

3.6 How will ANDA data be accessed by the ANDA Data Manager?

The ANDA Data Manager will be able to access the data directly using database tools that are not part of the ANDA system.

The ANDA Data Manager will be able to run a set of annual reports that include data for all centres that contribute to the ANDA pooled report.

The ANDA Data Manager will extract data from the ANDA database for approved studies using methods that will vary depending on the exact requirements.

3.7 How does this access model help meet the overall objectives of ANDA?

1. Monitoring of diabetes outcomes:
Participating centres will have access to a report on the clinical outcomes of the patients under their care and a report on national outcomes. This will be a useful tool for benchmarking.
2. Inform policy development for improved diabetes outcomes:
Studies using ANDA data will provide evidence to support policy development and positive changes in diabetes management practices.
3. Cross-sectional or Time series studies:
The wider research community can see summary information about the data collected and submit requests to use the data.

4. Types of Publications and Reports

4.1 Annual ANDA National Benchmarking Reports

National benchmarking reports will be produced annually and made available to the public through the ANDA, NADC and Department of Health websites. The processes described in this document on publication and authorship do not apply to benchmarking reports. The reports will be authored by the ANDA Study Group with acknowledgement of the individuals and the ANDA Scientific Advisory Committee who have participated in producing/reviewing the reports.

4.2 Scientific Journal Publications and Scientific Abstracts arising from ANDA

It is anticipated that the ANDA Study Group will undertake analyses of multi-centre data to address specific research questions, which will be published in scientific journals and submitted as abstracts to scientific meetings. This is seen as a very effective way of raising awareness and encouraging reuse of the ANDA data. Researchers external to the ANDA Study Group can request access to the ANDA dataset as a collaborative project. Publications arising from access to the ANDA dataset must acknowledge ANDA as a source of data and the Department of Health for funding, as detailed in this document.

4.3 Scientific Journal Publications and Scientific Abstracts arising from data that are in ANDA but where the PI seeks to publish separately from ANDA

The contribution of data to ANDA does not preclude contributing centres from publishing their own centre's data independently from ANDA. However, members of the ANDA Scientific Advisory Committee are expected to disclose competitive publications to those in development by ANDA as they are in a privileged position, overseeing national data.

5. Analysis Proposals

An Analysis Proposal Form will be available on the ANDA and NADC websites.

The ANDA Scientific Advisory Committee will review and prioritise submitted proposals.

Please be aware a small administrative fee may be applicable depending on the time required to extract ANDA data.

6. Review of Analysis Proposals

Proposals will be received by the ANDA Secretariat who, together with the ANDA Data Manager, will document any issues with data quality and completeness to determine if the data are available.

The ANDA Scientific Advisory Committee will review/approve and prioritise proposals.

For each proposal, the Committee will vote to approve, disapprove, or request further information. When considering approvals, the ANDA Scientific Advisory Committee will assess based on the following criteria:

- are data available and adequate to address the objective?
- does the proposal overlap with existing or planned studies?
- are the aims of the proposal consistent with the overall aims of ANDA?
- is the study seeking to use data from all ANDA centres or only some?
- is the analysis feasible with respect to involvement of a skilled statistician and realistic timelines to publication?
- will the outcomes of the analysis be scientifically valid, with respect to generalisability of the sample and issues such as statistical power?
- is the study in the best interest of ANDA patients?
- assess whether the proposal has any ethical implications
- assess any cost implications

Where additional information is requested by the ANDA Scientific Advisory Committee, the ANDA Secretariat will contact the researcher and request any outstanding information.

6.1 Approvals, Data Agreements and Data Extracts

Where an analysis proposal is approved by the ANDA Scientific Advisory Committee, the ANDA Secretariat will work with the ANDA Data Manager to provide access to the data, specific to the analysis described in the proposal, including any reasonable and minor changes and additions that arise during the course of the work.

Successful applicants will be required to sign a data access agreement relating to the use of the data (only for the purposes for which they applied, agree to not attempt to identify individuals, nor to release data to others). This is to be signed by the lead investigator (on behalf of all persons associated with the project, including those who present results and those whose name will appear on publications arising from the project). This agreement includes acknowledgement that the project leader takes responsibility for ensuring:

- ethics and privacy principles are adhered to;
- adequate facilities and resources to enable the project to progress in a reasonable manner;

- the de-identified data are used specifically for the analysis described in the application. If there are to be any substantial changes to the nature of the analysis or the topic to be addressed a new application will need to be submitted.

The approval is for a period of 2 years from date of receipt of data. If at the end of 2 years the project is not completed and/or no publications have been submitted, the researcher can apply to the ANDA Scientific Advisory Committee for an extension of approval, or the data must be destroyed as per NHMRC guidelines. If the project is completed and/or publications have been submitted, the researchers must keep the data in accordance with NHMRC guidelines.

7. ANDA Publication Committees

7.1 Projects by ANDA Study Group

For each manuscript to be written that utilises multi-centre data, a Publication Committee will be formed by the ANDA Scientific Advisory Committee.

A lead author will be designated. When the idea for the manuscript has been proposed by an individual, that individual generally will be given the opportunity to be the lead author. For manuscripts identified by the ANDA Scientific Advisory Committee, a lead author will be chosen from those individuals. The senior author(s) will usually be the supervisor(s) of the lead author.

A data extract will be prepared by the ANDA Data Manager and reviewed by the Publication Committee. After review, a decision will be made as to whether to proceed with a manuscript.

The Publication Committee will determine the journal for submission.

7.2 Proposals from investigators external to ANDA

Investigators external to ANDA are encouraged to apply for access to ANDA data and may choose to invite members of the ANDA Study Group as co-authors, however this is not a requirement of access to or use of ANDA data.

8. Abstracts

All abstracts using multi-centre data must be reviewed by the ANDA Scientific Advisory Committee. To meet abstract submission deadlines abstract authors should submit to ANDA at least two weeks prior to abstract submission deadline when planning a conference abstract.

9. Review and Approval of Manuscripts

9.1 Projects by ANDA Study Group

A final draft of the manuscript will be sent to the ANDA Scientific Advisory Committee for review with a four week deadline (two week deadline for conference abstracts). Generally two members of the Committee will be assigned as primary reviewers.

The comments will be sent to the lead author to consider.

The revised version of the manuscript will be sent to the Publication Committee for approval with a one week deadline.

9.2 Proposals from investigators external to ANDA

The final draft of the manuscript or abstract must be submitted to the ANDA Scientific Advisory Committee for approval prior to publication. Generally two members of the Committee will be assigned as primary reviewers.

10. Publication

10.1 Manuscript and Abstract Approvals

Manuscripts and abstracts that include multi-centre data must:

- include the date of the data extract and list ANDA as the source of data used;
- include 'ANDA Study Group' in the author list;
- include an appendix listing the ANDA Study Group participants (manuscripts);
- include the following acknowledgement:
 "The data on which this paper (book, monograph, abstract, or report) is based was collected as part of the Australian National Diabetes Audit. We thank the participating diabetes centres for their time and generous contribution to the data collection."
 and
 "The Australian Department of Health funds the Australian National Diabetes Audit."
- additionally acknowledge, where applicable:
 other persons who have provided comments, advice, support or other input into the paper, who are not already listed as authors;
- research assistants, technical officers, and 'non-authors' who contribute;
- additional funding bodies.

The author must provide copies of manuscripts or reports to the ANDA Secretariat when the paper/report is finally accepted. A hard or electronic copy of the published paper/abstract should be provided to ANDA Secretariat.

11. Authorship

For all manuscripts, the Publication Committee will be listed as named authors followed by, 'for the ANDA Study Group'. The lead author will be listed first followed generally by other members of the publication committee. The order of the remaining members will be determined by the ANDA Scientific Advisory Committee based on its opinion as to the degree of involvement of each individual.

For abstracts, the same policy will be followed if a writing committee exists and has been involved in preparation of the abstract. If not, the presenter and statistician will be listed followed by 'for the ANDA Study Group'.

11.1 Authorship Criteria (based on ICMJE requirements)

To qualify for authorship, each author must meet at least one criterion in each of the three categories:

1. Category 1

- Conception and design
- Acquisition of data
- Analysis and interpretation of data

2. Category 2

- Drafting of the manuscript
- Critical revision of the manuscript for important intellectual content (this does not include reviewing the manuscript for journal submission approval)

3. Category 3

- Statistical analysis
- Obtaining funding
- Administrative, technical, or material support
- Supervision
- Other (specify)