Australian National Diabetes Audit

Longitudinal Register Protocol

ANDA - L

Protocol Version 6 dated 04 March 2020

ads Australian Diabetes Society

MONASH University

nadc National Association of Diabetes Centres

Table of Contents:

Acknowledgement 3

Synopsis 4

1. Background 5

1.1 Diabetes care in Australia 5

2. ANDA-L Quality Clinical Audit 6

2.1 Ethics 6

2.2 Governance 6

2.3 Co-ordinating Centre and Central Data Management 7

3. Aims 8

4. Methodology 8

4.1 Coordination 8

4.2 Patient Population 8

4.3 Study Design 9

4.3.1 ANDA_L Operating Procedures 9

4.3.2 Survey Period 12

4.3.3 Consent 12

4.3.4 Withdrawal of Consent 13

4.3.5 Aboriginal/Torres Strait Islander consumer acceptance 13

4.4 The Dataset 13

4.5 Data Capture/Database 14

4.6 Data Security 14

4.7 Data Verification and Validation 15

4.8 Data Analysis and Reporting 15

5. Statistical Methods 15

5.1 Sample size 15

5.2 Two time point analyses 15

5.3 Three time point analyses 16

6. Funding 16

7. Data Linkage 16

8. Contact Details 16

9. Milestones 17

10. References 19

11. Appendices 20

Appendix 1: Development of Quality Clinical Indicators 20

Appendix 2: Data collection form baseline 22

Appendix 3: Data collection form followup 23

Appendix 4: Data dictionary 24

Appendix 5: Participant information statement 26

Acknowledgement

The Australian Government Department of Health has funded the conduct of the Australian National Diabetes Audit (ANDA) from 2013-2021

ANDA/ANDA-L Project Executive Members

Coordinating PI/Project Lead	Prof Sophia Zoungas
Clinical Lead	Dr Georgia Soldatos
Senior Biostatistician	A/Prof Arul Earnest
Project Manager/Secretariat	Ms Dimitra Giannopoulos
Data Management Officer	Ms Trieu-Anh Truong
Data Analyst	Dr Farhad Salimi
Representative for stakeholder engagements/ communications	Ms Natalie Wischer
Technical Advisor	Prof Susannah Ahern
Clinical Research Fellow	Dr Naomi Szwarcbard

ANDA/ANDA-L Scientific Advisory Committee Members

Coordinating PI/Project Lead	Prof Sophia Zoungas
Clinical Representatives	Prof Barbora deCourten, Prof Jeff Flack, Prof Jenny Gunton, Clinical Prof Jencia Wong
Representatives for stakeholder engagements/ communications	A/Prof Sofianos Andrikopoulos, Ms Natalie Wischer
Representative from the Primary Health Community sector	Dr Konrad Kangru
Consumer representative	TBA
Representatives from the Australian Government Department of Health	Ms Sally Rayner Dr Supriya Budala
Data related/science expert	A/Prof Wendy Davis, Prof Jane Speight
Chair	As appointed

Synopsis

The Australian National Diabetes Audit (ANDA) is a well-established, important biennial, quality activity facilitated by the National Association of Diabetes Centres (NADC), in services providing care for people with diabetes across Australia in all States and Territories. Participating diabetes centres, including primary, secondary and tertiary care receive an individualised report of their patient data to compare with other diabetes centres.

In addition to the primary output audit report received by participating centres, the pooled national report is an important source of cross-sectional data on the clinical status and outcomes of individuals attending services providing diabetes care across the country.

There are two ANDA audits that alternate each year:

- ANDA-AQCA (Australian Quality Clinical Audit). This audit focuses on clinical indicators known to impact on the care of the person with diabetes.

- ANDA-AQSMA (Australian Quality Self-Management Audit). This audit is more focused on self-management and diabetes distress and collects data related to diabetes education, self-care practices and quality of life.

The Australian National Diabetes Audit Longitudinal Register (ANDA – L) is a substudy of ANDA with its main focus to prospectively follow up the same cohort of patients over a 2 - 4 year period during the ANDA-AQCA data collection. This allows participating centres to observe changes in clinical indicators for people with diabetes at both a group and individual level and offers a rich source of understanding of treatments, and clinical outcomes for people with diabetes. ANDA-L will provide longitudinal descriptive reporting to treating centres for quality management.

1. Background

1.1 Diabetes Care in Australia

The National Association of Diabetes Centres (NADC) established in 1994 is a national collective of diabetes centres brought together by a common desire to see improvement in the standard of diabetes care in Australia. With a focus on proactive maintenance of good health and prevention of complications, the NADC aims to integrate care across the acute hospital system and community based services. In particular, key strategies identified were the development of standards of care and quality review initiatives, information provision, and training and support for health professionals.

Supported by the Australian Diabetes Society (ADS), the NADC promotes the ANDA/ANDA-L initiative as part of monitoring and improving quality of care.

Overview of NADC member centres

The NADC promotes mechanisms for improving the standard of care for people attending different services providing diabetes care.

Are there differences between the diabetes centres that participate in ANDA?

There are 6 membership levels of NADC:

1. Centres of Excellence
   Recognised diabetes centres that have demonstrated excellence in education, research, service delivery, practice/policy development and education. These centres must be tertiary level facilities.

2. Tertiary Diabetes Centres
   NADC centres that have the full range of diabetes service providers including endocrinologists, diabetes nurse educators, dietitians and podiatrists on staff (full time) and who have demonstrated a high standard of care through service delivery and organisational capacity and have been accredited by the NADC.

3. Secondary Care Diabetes Services
   These services have a range of full and/or part-time diabetes staff but often do not have an endocrinologist as part of their usual team. They may be working toward accreditation as a Tertiary Care Diabetes Service.

4. Primary Care Diabetes Services
   These centres have part-time staff and work closely with the local general practitioners to provide care for people with diabetes.

5. Pharmacy Diabetes Services
   These centres have staff that have received training and/or have expertise in diabetes and work closely with the local general practitioners and allied health staff to provide additional care and services for people with diabetes.

   NADC Pharmacy Diabetes Service membership is offered to groups of professional healthcare workers who have an active involvement in diabetes care provided in the pharmacy context, and are committed to the goals and objectives of the NADC and to monitoring the outcomes of their service, but do not have the full complement of services or resources of a larger diabetes service.

6. Network Members

The NADC Network membership is offered to Primary Health Networks (PHNs) and Primary Care Partnerships (PCPs) around Australia. PHNs and PCPs work directly with general practitioners, other primary health care providers, secondary care providers and hospitals, to facilitate improved outcomes for patients. PHNs and PCPs are committed to providing efficient and effective primary health care, with objectives that align closely with those of the NADC.

2. ANDA-L Quality Clinical Audit

ANDA-L is a population based observational follow-up of diabetes patients undergoing treatment and management for diabetes. De-identified/coded data will be obtained from patient medical records and the patients themselves on key clinical outcomes as part of routine clinical care. This activity is multi-centred with diabetes centres/sites participating nationally.

This activity provides current data which enables comparisons to data collected prospectively. It provides a framework by which quality improvement initiatives will be developed both within diabetes centres and nationally. It has the potential to improve understanding of current practice in the treatment of diabetes and reasons for variation in outcomes, to improve understanding and increase awareness about diabetes and its management, to improve quality of patient care through comparisons of diabetes centres in Australia and to facilitate research.

2.1 Ethics

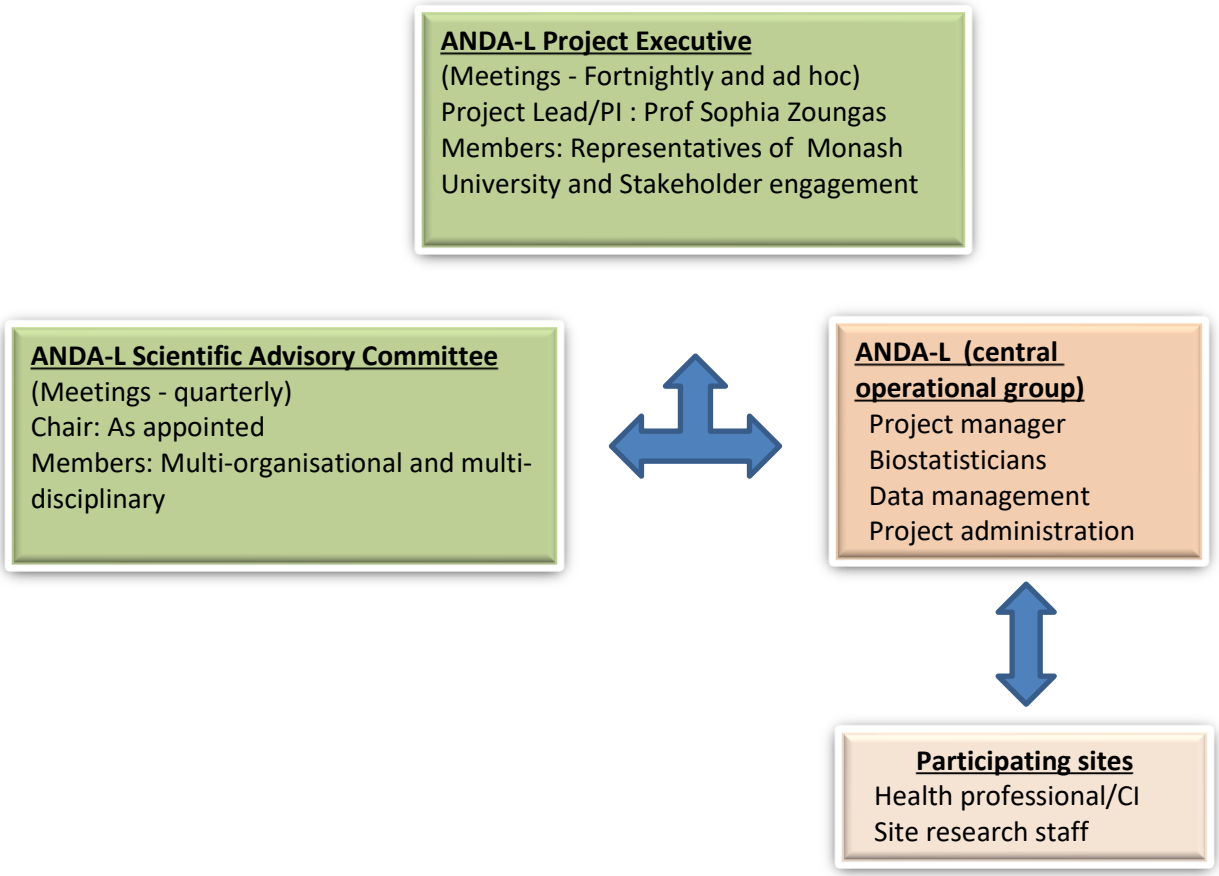
ANDA has received Human Research Ethics Low Risk approval from the Monash Health Human Research Ethics Committee. The participating centre/site is required to seek advice regarding local ethics requirements.

ANDA-L has received Human Research Ethics approval from the Monash Health Human Research Ethics Committee and registered with the Monash University Human Research Ethics Committee. Each participating centre/site is required local ethics and governance approval prior to commencing this activity.

2.2 Governance

A Scientific Advisory Committee has been established to provide strategic guidance to ensure the objectives, outcomes and deliverables of ANDA-L, as specified by the Department of Health, are achieved. This committee consists of representatives of key stakeholder organisations working to agreed Terms of Reference. The underlying responsibility of the Scientific Advisory Committee is to assist ANDA-L to maintain high visibility, appropriate engagement and relevance for diabetes service delivery.

Fig 1: ANDA-L Governance Structure

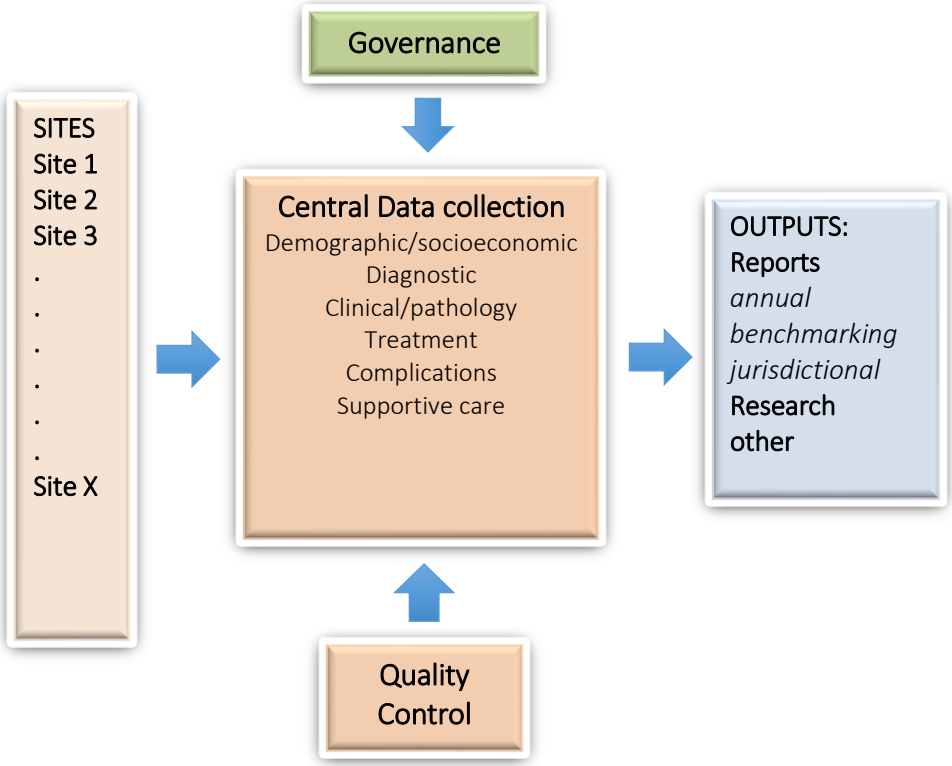


2.3 Co-ordinating Centre and Central Data Management

The ANDA-L Co-ordinating Centre is Monash University. Monash University ANDA-L staff working out of the School of Public Health and Preventive Medicine will project manage this activity under the direction of the Scientific Advisory Committee.
ANDA-L activities include:

- Overall management of the activity
- Management of ANDA-L budget
- Ethical oversight and management on behalf of participating sites,
- Training of participating sites/or inhouse data collectors
- Data management and data querying
- Maintaining a secure environment for data collected
- Data analysis
- Reporting
- Data access request management

Fig 2: ANDA/ANDA-L – Data management overview



3. Aims

ANDA-L aims to (over a 2 to 4 year period):

- Measure and report on longitudinal trends in the characteristics, type of care and major clinical outcomes (including survival) of a cohort of patients with diabetes attending diabetes services nationwide, with all data aggregated at a national level .
- Evaluate longitudinal associations between patient characteristics, quality of care and major clinical outcomes (including survival).

4. Methodology

4.1 Coordination

ANDA-L coordination and conduct is overseen by the ANDA Secretariat and central operational group based in the Division of Metabolism, Ageing and Genomics, School of Public Health and Preventive Medicine, Monash University . The major project milestones are summarized in section 8.
All contact and correspondence with participating diabetes centres will only occur through the ANDA Secretariat to ensure identity of sites remain double-blinded.

4.2 Patient Population

Inclusion criteria:
All patients who meet the following criteria are invited to participate:

- Attend a participating diabetes centre
- Aged 18 years or over
- Not pregnant at the intial baseline routine clinical visit

- Have the capacity to make the decision to opt out or be included in this activity (not cognitively impaired).

Exclusion criteria:

Patients are excluded from this activity based on the following criteria:

- Aged less than 18 years of age
- Pregnant at the time of the intial baseline routine clinical visit
- Cognitively impaired and unable to to comprehend and make the decision to opt out or be included in this activity.

4.3 Study Design

ANDA-L involves potential sites/diabetes centres (participating in ANDA-AQCA) identifying a cohort of patients to be followed up longitudinally over a 4 year period. Clinical indicator data is collected through completing an ANDA-AQCA data form for the same patients at baseline, 2 years and 4 years commencing in 2019 (2021 and 2023 respectively) (Fig 3). The baseline data collection timeframe is restricted to the months of May through June. This data will also be used for the purposes of the cross sectional data analysis and reporting specific to ANDA (Fig 4). The same data collection timeframe applies for the 2 year and 4 year follow up time points.

4.3.1 ANDA-L operating procedures

ANDA-L consists of the following tiered/ordered processes:

1. ANDA Secretariat operating procedures

1.1 Initial call for expressions of interest distributed to diabetes centres in 2019.

1.2 Formal invitations to diabetes centres (sites) expressing their interest to participate and logging site acceptances.

1.3 Allocation and confirmation of unique site codes to participating sites in a double-blinded/coded manner, where only the ANDA Secretariat can access the identified copy. Sites that have participated in past surveys will use their previously allocated unique site code. Sites that have not participated in past surveys are allocated a new unique site code.

1.4 Distribution of Participant Information Statement (PIS)(Appendix 5), data collection forms (Appendix 2,3) and instructional study documents.

2. Participating site operating procedures – Baseline

2.1 Participating sites inform patients of ANDA – L during their routine clinic consultation through discussions with their health professionals. Patients are given the PIS to read, have an opportunity to ask any questions and consider whether they would like their data included in ANDA-L and linked to government databases (National Death Index (NDI), Pharmaceutical Benefit Scheme (PBS) and/or Medicare Benefit Schedule (MBS)). The PIS explains the voluntary nature of participation. Participating site staff involved in the patients clinical care will collect routine clinical data. This will take place during the patient's routine clinic consultation. Should the patient not wish to have their data included in ANDA-L and have their data linked, they are free to opt out. This will not affect their ongoing care.

2.2 The participating site assigns a unique patient idenitification number and baseline data collection can commence. Baseline data is set to be collected over a 4 to 8 week period during the month(s) of May and/or June.

2.3 Once participating sites have completed data collection for all patients, they submit their data collection (paper-based/web-based/electronic data extraction) to the ANDA Secretariat for processing, collation and validation through Data Management.

2.4 Any queries from Data Management will be relayed back to the participating site through the ANDA Secretariat for clarification.

2.5 Participating sites are required to keep on site a log of patients with their assigned patient idenitification number for reference when collecting data for follow-up at the 2 and 4 year time points.

3. Participating site operating procedures – Follow-up (2 year and 4 year data collection time points)

3.1 Participating sites follow-up the same cohort of patients at the scheduled 2 and 4 year time points from baseline during the months(s) of May and/or June.

3.2 Female adult patients that become pregnant during the course of this activity will have their pregnancy event recorded by the pariticipating site during their follow-up. This cohort of patients will have their data censored and will not be included in the analysis and reporting, however will have their data collected for monitoring purposes at the follow-up time points.

3.3 Should patient visits not fall within this time frame, a grace period of +/-3 months is permitted to collect data. This will allow for maximum numbers of the same cohort of patients attending their diabetes centre to be captured.

3.4 In the event the patient does not attend the site for follow up during this period, a staff member from the participating diabetes centre will contact the patient via phone to collect clinical information and outcomes within this grace period. Patient medical records will may also be reviewed and any data collected dated within 3 months before to 3 months after the scheduled 2 year and 4 year time points will be accepted.

3.5 Full data collection is to be submitted to the ANDA Secretariat for processing, cleaning, collation and validation.

3.6 Any queries from Data Management will be relayed back to the participating site through the ANDA Secretariat for clarification.

4. Data Management operating procedures (Further information in subsections 4.4, 4.5, 4.7)

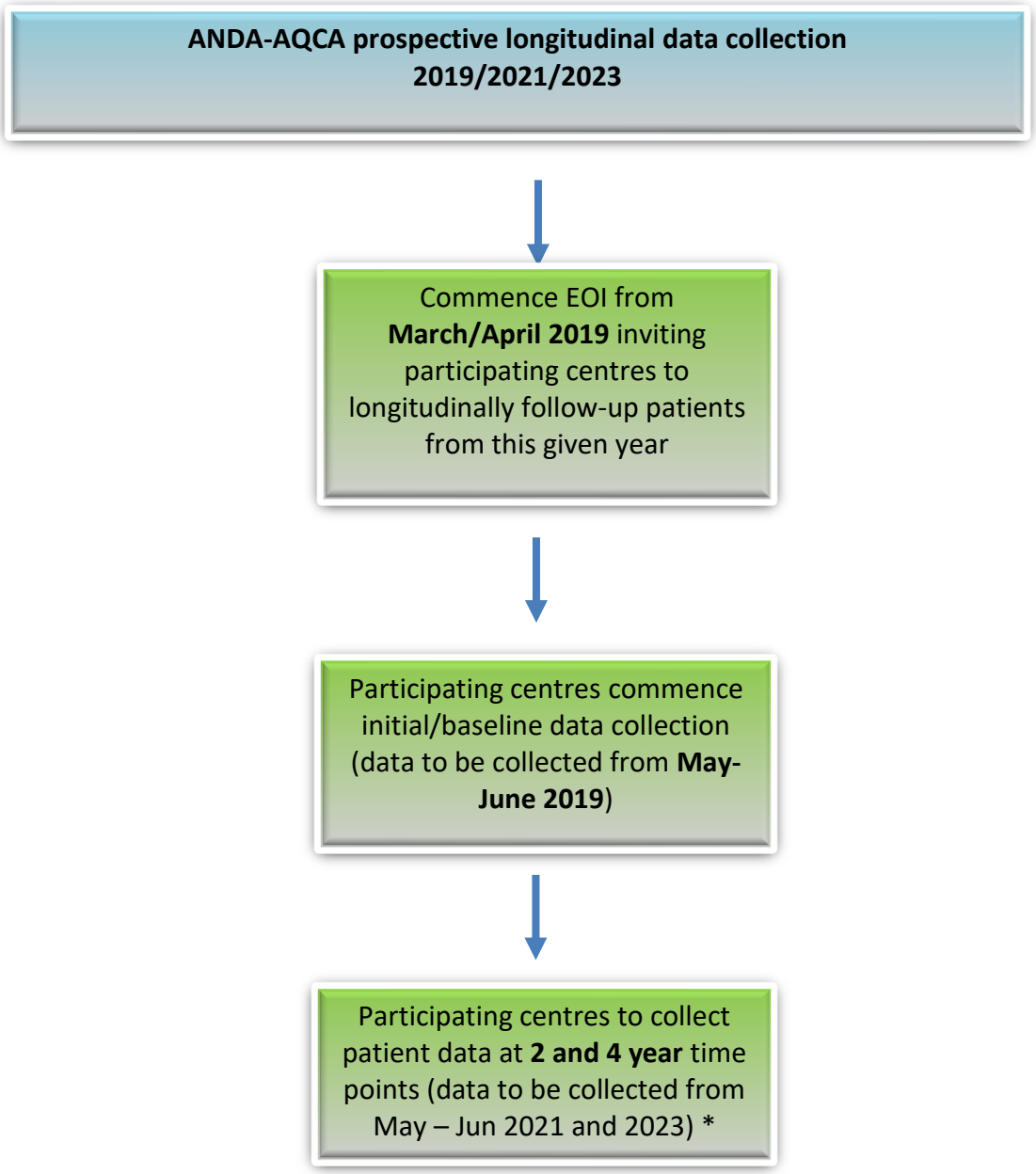
4.1 Participating sites are required to send their completed data collections to the ANDA Secretariat. There are 3 formats that participating sites could to collect clinical data. Participating sites that opt for completing paper based data collection forms are required to be send them via registered post or hand delivered, to the ANDA Secretariat at Monash University Level 3, 553 St Kilda Road, Melbourne VIC 3004. The ANDA Secretariat will check and collate the original forms and forward them to the data management centre for processing. Participating sites with computerised databases can opt to extract ANDA-L data and provide it directly to the ANDA Secretariat through a secure web based data transfer process. Participating sites may opt to enter data directly into a secure (pass word protected) web-based interface.

4.2 Data management will be responsible for data entry, cleaning, collation and validation (including missing data query resolution) at each time point of this study.

4.3 Data analysis and reporting.

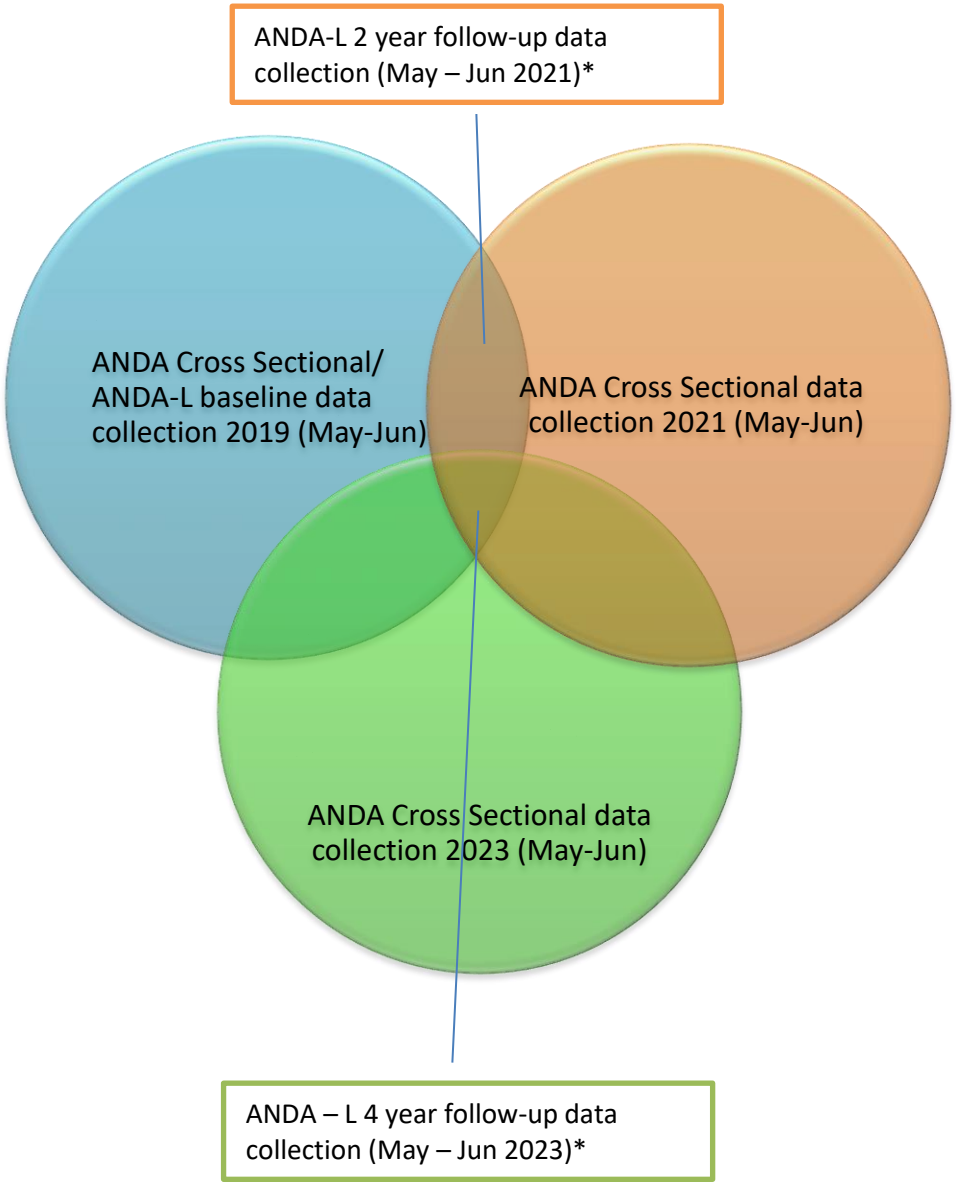
Participating sites may enter data directly into a secure web-based interface, REDCap (Research Electronic Data Capture)[22], stored on a secure Monash University server. Assigned staff members will be allocated a unique username to access the database. After data entry completion, sites will be able to download and print a pdf version and file at their local site.

Fig 3. Longitudinal Prospective Data Collection Overview



** +/-3 month extension permitted*

Fig 4. Cross sectional overlap with longitudinal Prospective Data Collection



**+/-3 month extension permitted*

4.3.2 Survey period

Centres will conduct the initial baseline data collection over 4 consecutive weeks (May or June) in the baseline data collection. *(For centres not able to collect data on more than 30 participants at baseline, the survey can be extended for another four weeks (May and June))*.

Centres conducting follow-up data collection at the 2 year and 4 year time points will do so over the same time period (*For centres not able to collect data on all the cohort during this time period, it can be extended +/-3 months. If in the event that patients do not attend the clinic for data collection, follow-up can be completed via phone and access to medical records).*

4.3.3 Consent

The opt-out process has been used successfully in over 75% of clinical quality registries in Australia . The

rationale for this approach is based on minimising selection bias by achieving near 100% coverage of a population. By limiting the possibility of 'cherry picking' participants or omitting specific groups of patients otherwise not able to be captured by standard consenting processes, clinical validity increases, enabling meaningful analysis and comparison of variation in health outcomes across sites and other geographical spaces. Opt-out consent enables the full spectrum of public health information to be reported and analysed, increasing capacity to influence and inform clinical guidelines, policy development and funding decisions.

ANDA-L will be employing an opt out process. Participating site health professionals (clinicians and nurses directly involved in the care of the patient) will discuss this activity directly with the patient and provide them with a patient information statement (PIS). A 2 week opt out window time frame will be provided to allow patients to opt out of ANDA-L before consent is assumed. Data will be collected by each participating site on the day of the patient receiving the PIS but will not be in the ANDA-L dataset until the 2 week opt out time window has passed. Should the patient opt out of this activity, the data will not be included. This information is part of the patient's medical record and no additional information is required. Patient details will be included unless they have notified ANDA-L Central Management via the Freecall 1800 telephone number listed on the PIS.

At the subsequent follow-up time points of data collection, participating site health professionals are required to confirm with patients that have been included in this activity of their involvement in the follow up data collection process and option to withdraw at any time should they not want their data included.

It is at the discretion of the participating health professional involved in the care of the patient to assess whether the patient has the capacity to make the decision to opt out or be included in this activity. Should the patient be cognitively impaired to a degree of not being able to understand and go through the decision making process, the patient will be excluded from this activity.

4.3.4 Withdrawal of Consent

In the event that a patient wishes to withdraw from ANDA-L, the data already collected will be removed from the ANDA-L database. No additional data from the time of withdrawal will be collected. A patient wishing to withdraw at anytime during this activity will be advised to contact ANDA-L Central Management via a freecall telephone number. ANDA-L Central Management will notify participating sites which patients have opted and that are not required to have any further data collection at the follow-up time points. Participating sites are advised to keep a log of these patients so that data collection is not performed at the follow-up time points.

4.3.5 Aboriginal/Torres Strait Islander consumer advisor acceptance

ANDA-L will be implemented in the most effective and culturally respectful way possible. Within this activity patients attending participating sites have the right to have their values, beliefs and cultural circumstances respected.

The Guidelines for Ethical Research in Australian Indigenous Studies pertaining to Aboriginal/Torres Strait Islander patients in this activity is adhered to. Consultation has been sought through a consumer advisor of the Aboriginal/Torres Strait Islander community and accepted. (AIATSIS Guidelines for Ethical Research in Australian Indigenous Studies 2012).

Information about ANDA-L and patient involvement has been presented to and communicated between this representative and ANDA-L central management.

4.4 The Dataset

A minimum dataset consisting of key clinical outcome variables is collected as part of clinical care.

Currently, the dataset remains a one page scannable form with required written data kept to a minimum, most fields being yes/no or other choice options (Appendix 2, 3). The data definitions provide defintions for each data field, including all valid field types (Appendix 4). The information collected from each participating site is categorised below:

- Diabetes type, management and lifestyle issues
- Blood pressure
- Height, weight and smoking status
- Diabetes-related eye information
- Diabetes-related foot information
- Health professional attendances
- Complications/Events/Comorbidities
- Lipids
- Medications
- Kidney function
- Blood glucose control

4.5 Data Capture/Database

Participating sites can capture ANDA-L data through 3 processes:

1. *Scannable paper-based form*

An application of Teleform© version 10.9 software is used to design, read, scan and verify the data collection form. The Teleform© Verifier module allows an on screen version of the scanned image to be viewed, and corrections made where necessary. Once such corrections are made and accepted, data from these forms are transferred to a password protected database with restricted access.

2. *Web-based data collection form*

Participating sites may enter data directly into a secure web-based interface, REDCap (Research Electronic Data Capture)[22], stored on a secure Monash University server. Assigned staff members will be allocated a unique username to access the database. After data entry completion, sites will be able to download and print a pdf version and file at their local site.

3. *Electronic Data Extraction*

Participating sites have the option to extract ANDA-L data directly from their in-house databases. This may be through applications installed by third-party providers or through an upload of regular hospital/clinic data extracts. Data will be transferred via a secure file transfer protocol (SFTP).

4.6 Data Security

Data will be collected via the ANDA online data entry system, hosted by Monash University, the data custodian. All activity will be in accordance with Monash University's Information Technology Services Secrity Framework policy. Security of the data is ensured in the following ways:

1. The web application is hosted on the web server located in the Monash Clayton campus (Red Zone) server room. Access to this server room is available only to the Systems IT Administrators.
2. To ensure the data are not compromised in transit, all communication between participating site's browser and server occurs through a Secure Sockets Layer (SSL) certificate, where all data is encrypted by a private key on the server before it is sent on a wire to the client where it is decrypted by a public key.
3. All user accounts will be password-protected and limited to authorised personnel who have been granted access. The authentication process for user access to the registry will involve formal registration including identity checks and verification from an existing authorised user (e.g. ANDA Administrator, Principal Investigator or Data Manager). When ANDA is notified that a staff member has left the project, their access to the system will be removed. ANDA will conduct a review of user access every 6 months to ensure the user list remains up to date. All

systems access will be attached to an individual user account and all access to the server logged.

4. Disaster recovery processes are built into the Monash's security framework policies, and are in place to minimise the effects of major incidents on business activities. For example, in the case of fire or loss of data, the database server is mirrored each day to a backup facility at the Monash Noble Park campus. Backups on the system are stored in a secure location with limited access and numbered seals are used on the storage container to detect any unauthorised access. Access to the storage media by staff is logged.
5. Individual hospital sites will manage and secure any paper-based data records in accordance with the Health Records Act (2001). Sites will archive and destroy any paper records according to site-specific general record retention schedule(s). This will be the responsibility of the Site Coordinator who oversee each site's operations.

Any staff with access to data will be trained by ANDA Project Managers (or delegates) according to Good Clinical Practice guidelines, state and federal privacy legislation and the NHMRC's National Statement on Conduct in Human Research. Only the ANDA Project Manager and Monash staff working directly with the Project Manager will have access to raw ANDA cohort data.

4.7 Data Verification and Validation

Every effort will be made to ensure data completeness and correctness, with specific validation reports generated for each site.

These validation reports will contain lists of missing or potentially invalid data, as well as possible duplicate individual entries and will be forwarded to the sites by the ANDA Secretariat. Sites will then have 4 weeks to respond to these validation reports.

Once returned to the ANDA Secretariat, they will be forwarded to the data management centre where any additional or corrected data items will be entered/corrected respectively prior to final data analysis.

Where duplicates are identified, these will be reviewed and the first entered record retained, supplemented by any additional data in the second record that was missing in the original. The second entered record will then be deleted.

4.8 Data analysis/reporting

In analysing the data, specified data assumptions, decisions and data manipulations will be observed. Data analysis and reporting will include:
For categorical data, frequencies and percentages will be reported. For continuous variables, the mean (standard deviation) or the median (interquartile range) will be reported depending on the distribution of the data. The amount of missing data will be quantified. Within-site and between site comparisons will be performed, after adequately assessing the amount of data available, any differential missingness for data by site and distributional assumptions using appropriate regression models.

Reports will be provided to sites to allow comparison within sites and against other participating sites.

5. Statistical Methods

5.1 Sample size

It is estimated that approximately 1000 patients would be required in total to detect a meaningful difference in any single clinical indicator (eg.HbA1c). Assuming 20% attrition at least 1200 patients would be required. If there are 50 consenting sites totaling 4000 patients, to ensure an even spread of recruits across sites, 30% from each site ideally should be recruited.

5.2 Two time-point analyses

Paired t-tests will be used to detect significant changes in key continuous outcomes. Mc-Nemar tests will be used

for binary outcomes. Linear regression models and a conditional logistic regression models will be used to assess change after accounting for key confounders.

5.3 Three time-point analyses

Generalized estimating equation models will assess the effectiveness of standard of care. These modelsare flexible in handling both continuous and categorical endpoints and allowing for the adjustment of confounders.

6. Funding

The Australian Government Department of Health has funded the conduct of ANDA/ANDA-L from 2017-2021. Further funding may be sought during the life of this activity.

7. Data Linkage

In developing a richer dataset, ANDA-L anticipates linking patient information that is collected from the participating diabetes centres to the following Government databases:

(1) National Death Index (NDI)
(2) Pharmaceutical Benefits Scheme (PBS)
(3) Medicare Benefits Schedule (MBS)

This would provide valuable evidence based information for policy and research into the health and well-being of people with diabetes. It provides a better understanding of this population and allows ANDA-L to follow-up its outcomes into the future.

Data linkage involves assigning an identifying number to each patient that has their data collected in ANDA-L and storing a set of links to all records for that patient. There are strict privacy and preserving policies, protocols and procedures to ensure the security and confidentiality of the patients that the records relate to.

The data linkage process involves three main stakeholders:
(1) Data Custodians who are responsible for the data collection and dissemination of the data managing administrative research datasets. They are also responsible for collecting and storing personal and health information. As data custodians, under the School of Public Health and Preventive Medicine (SPHPM), Monash University, the ANDA-L Central Data Management team will manage the ANDA-L dataset, collect and store personal and health patient information. They will work within the organisations responsible for linking the datasets together creating linkage ID's to allow for data to be linked together from the external government data sources.

(2) Researchers who use deidentifiable linked data for the purposes of analysis and research/report preparations. As researchers the ANDA-L Biostatistics Unit within SPHPM would only have access to ANDA-L deidentified linked data.

(3) Data Linkage Organisations who link the datasets from different organisations together and create linkage identification numbers. There are 2 national accredited integrating Authorities that can perform data linkage for ANDA-L data collections: (i) Australian Bureau of Statistics (ABS), (ii) Australian Institute of Health and Welfare (AIHW).

8. Contact details:

ANDA-L Central Operations Group - Management
Email: anda@nadc.net.au
Address: Monash University

Level 3, 553 St Kilda Road,
Melbourne VIC 3004

Secretariat

For all activity related enquiries regarding day to day operational activities, including access to data, please contact the ANDA/ANDA-L Secretariat on anda@nadc.net.au

Monash Health Human Research Ethics Committee

Any complaints or queries about any aspect of this activity, the way it is being conducted or any questions about your rights as a participating site, please contact the Monash Health Human Research Ethics Committee Manager on 03 9594 4611

9. Milestones

ANDA-L: ANDA-AQCA Project Timeline: Establishment of infrastructure and development of project components

ANDA-AQCA: Conduct & Report												
	2019											
	Jan	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
Revise ANDA-AQCA 2017 dataset												
Initial call for expressions of interest												
Formal invitations and site acceptances												
Allocation of site codes												
Distribution of PICFs, Data Collection forms and resources												
ANDA-AQCA Data Collection (baseline)												
Data received from ANDA-AQCA sites												
Data entry and validation												
Data queries generated for sites												
Integration of returned data queries												
Final Data Analysis												
Final Data Reports to sites												→ Jan 2020

ANDA-AQCA follow-up: Conduct & Report												
	2021 *2023											
	Jan	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**
Revise ANDA-AQCA 2019 dataset - coded site list extraction												
Formal reminder letter to participating sites for follow-up with attached individual coded site lists and site confirmations to proceed												
Participating sites to re-identify coded site lists												
Site staff to log scheduled visits for patients on site list					extension	extension	extension	extension	extension			
Distribution of Data Collection forms and resources												
ANDA-AQCA Follow-up Data Collection (during scheduled visit/phone follow-up							extension	extension	extension			
Data received from ANDA- AQCA sites												
Data entry and validation												
Data queries generated for sites												
Integration of returned data queries												
Final Data Analysis												
Final Data Reports to sites												→ Feb 2022/2024

* Note: Follow-up data collected in 2023 is dependent on additional funding

10. References

1) The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med. 1993;1993(329):977-86.
2) UK Prospective Diabetes Study Group: Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet. 1998;351:832-853.
3) UK Prospective Diabetes Study Group: Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). Lancet. 1998;352:854-865.
4) UK Prospective Diabetes Study Group: Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes (UKPDS 38). BMJ. 1998;317:703-713.
5) UK Prospective Diabetes Study Group: Efficacy of atenolol and captopril in reducing risk of both macrovascular and microvascular complications in type 2 diabetes (UKPDS 39). BMJ. 1998;317:713-720.
6) DO IT Study Group. Report of the EASD Study Group DO IT 1990/1991. Diabetologia 1991; 34 (2): I.
7) Piwernetz K, Home PD, Snorgaard O, Antsiferov M, Staehr-Johansen K, Krans M. Monitoring the targets of the St Vincent Declaration and the implementation of quality management in diabetes care: the DIABCARE initiative. The DIABCARE Monitoring Group of the St Vincent Declaration Steering Committee. Diabetic Medicine. 1993 May 1;10(4):371-7.
8) Krans HMJ, Porta M, Keen H. Monitoring instruments for quality improvement in diabetes care. G Ital Diabetologia. 1993;10:371-7.
9) Piwernetz K, Bruckmeier A, Staehr-Johansen K, Krans H. DiabCare Quality Network in Europe. Diabetes, Nutrition & Metabolism. 1993;6:311-314.
10) Diabetes Australia NSW & NSW Department of Health. Report on the 1993 NSW Diabetes Outcomes Workshop (NDOW). NSW: NSW Department of Health; 1993 Sep.
11) Rattray A, Colagiuri S, Churches T, Flack JR. NSW diabetes outcomes workshop (NDOW) data collection. Proceedings of the Australian Diabetes Society Meeting; 1995 Sep; Melbourne. Australian Diabetes Society; 1998.
12) AIHW. National Health Priority Areas Report: Diabetes Mellitus 1998. Canberra ACT: Commonwealth Department of Health and Aged Care, and the Australian Institute of Health and Welfare; 1999. 186 p. AIHW Cat. No. PHE 10.
13) Colagiuri S, Colagiuri R, Ward J. The National Diabetes Strategy and Implementation Plan 1998. Canberra, ACT: Diabetes Australia; 1998. 281 p.
14) Meteor metadata online registry [Internet]. Canberra ACT: NDDWG; 2005. Diabetes (clinical) NBPDS Diabetes (clinical) NBPDS; [cited 2017 Nov 20]. Available from: http://meteor.aihw.gov.au/content/index.phtml/itemId/304865.
15) Fleming BB, Greenfield S, Engelgau MM, Pogach LM, Clauser SB, Parrott MA. The Diabetes Quality Improvement Project: moving science into health policy to gain an edge on the diabetes epidemic. Diabetes Care. 2001;24(10):1815-20.
16) NBHW. Quality and efficiency of diabetes care in Sweden: national performance assessment. Stockholm Sweden: NBHW; 2011 May 18. Contract No.: 2014-3-18.
17) NICE. NICE quality and outcomes framework indicator: diabetes mellitus London: NICE; 2017. Available from: https://www.nice.org.uk/standards-and-indicators/gofindicators?categories=&page=2.
18) Bonney M, Harris MF, Priddin D. National Divisions Diabetes Program: Recommended GP Subset of the NDOQRIN Dataset. 1999.

19) NSW Department of Health. Principles of Care and Guidelines for the Clinical Management of Diabetes Mellitus v1.3. Sydney NSW: NSW Department of Health; 1996. 35 p.

20) Flack JR, Colagiuri S, Churches T, Brandon P. Integrated software to record, analyse, report and audit clinical diabetes data. Proceedings of Computers in Diabetes '98; 1998 Sep; Barcelona, Spain. Diabetes Nutrition & Metabolism 1998; 11:43.

21) Churches T, Flack JR, Colagiuri S, Brandon P. Integrated software to record, analyse, report and audit clinical diabetes data. Proceedings of the Australian Diabetes Society Meeting; 1998 Aug; Perth. Australian Diabetes Society; 1998.

22) Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81.

11. Appendices

Appendix 1: Development of ANDA Quality Clinical Indicators

There has been long standing worldwide interest in developing suitable diabetes datasets and methods of data collection to capture appropriate diabetes outcomes for quality improvement. As a result, collection, analysis and reporting of standardised diabetes datasets are now widely practiced. The European Association for the Study of Diabetes (EASD) Study Group DO IT (Diabetes care Optimisation through Information Technology)[6] undertook much work aimed at improving the quality of diabetes care through the appropriate use of information technology, including promoting the collection, analysis and reporting of the DiabCare dataset[7-8] for audit and benchmarking purposes. From this has come the DiabCare Q-Net initiative[9]. A similar initiative, the NSW Diabetes Outcomes Workshop (NDOW), was undertaken in Australia in September 1993 with funding from the NSW Health Department[10-11]. Forty five stakeholders including diabetes health professionals, Health Department officials and consumers met for a one day workshop and agreed on a dataset of 59 health outcome data elements that covered demographic, acute and chronic complications and self-care practice areas of diabetes care. These items became known as the NDOW dataset, and subsequently these data items have become widely promulgated for collection (using standardised definitions) across Australia.

In 1997 the Australian Diabetes Society (ADS) accepted a recommendation to adopt the NDOW dataset as its Diabetes Outcomes dataset, and formed a sub-committee (now named the National Diabetes Data Working Group (NDDWG)). This sub-committee managed the dataset and promoted quality diabetes care in Australia, through the National Diabetes Outcomes Quality Review INitiative, (NDOQRIN)). The NDDWG has taken a subset of the NDOW dataset and has promoted its collection as a minimum dataset (for quality diabetes care) in a variety of clinical practice settings.

After diabetes was named the 5th National Health Priority Area in 1996[12], work followed to improve diabetes care in Australia including the commissioning of the National Diabetes Strategy to update and replace the National Action Plan. One aspect reviewed was the need for local data on which appropriate planning could be carried out and assessment of the effect of initiatives could be undertaken. Consequently, several initiatives indicated the need for reliable data in Australia (including diabetes indicators work), as noted in the National Health Priority Areas Report: Diabetes Mellitus 1998[12]. However, data on clinical aspects of diabetes, including outcomes data, were deficient in Australia as highlighted in The National Diabetes Strategy and Implementation Plan report[13]. The NDDWG continued to promulgate the NDOQRIN dataset, and in 2002 was successful in having it accepted as the first clinical dataset to be included in the National Health Data Dictionary and Knowledgebase, Version 12. This dataset has since been enhanced, and is now online as part of the AIHW – Metadata Online Registry ('METeOR') as the Diabetes (clinical) Data Set Specification[14].

The Dataset

The NDOQRIN diabetes dataset has considerable compatibility with similar international datasets[15-17]. The NDOQRIN dataset was enhanced and used as the basis of this national initiative, aimed at improving diabetes care through a structured approach to patient management[18]. This was achieved by linking the minimum dataset to the NSW Clinical Management Guidelines for Diabetes[19],with subsequent enhancements to the dataset over the years. This minimum dataset is suitable for use in primary care (where it is known as the 'Recommended GP Subset of the NDOQRIN Dataset'), specialist practice and diabetes centre settings. Enhancements and deletion/addition of data fields have occurred over the years with feedback from participating centres on collections.

Appendix 2: ANDA-L Data collection form – baseline

Draft

ANDA-L Baseline
Australian National Diabetes Audit - Australian Quality Clinical Audit

Section 1. Patient Demographics

Participant ID. | Site ID 0 0 1 | Staff Initials (optional)

1.1 Date of birth (d d / m m / y y y y) | 1.2 Sex ☐ Male ☐ Female *If FEMALE* → 1.2.1 Currently pregnant ☐ No ☐ Yes

1.3 Date of visit (d d / m m / 2 0 1 7) | 1.4 Initial visit ☐ No ☐ Yes | 1.5 Aboriginal/Torres Strait Islander ☐ No ☐ Yes

1.6 Country of birth | 1.7 NDSS member ☐ No ☐ Yes

1.8 Ethnicity | 1.9 DVA patient ☐ No ☐ Yes

Section 2. Diabetes Type & Management

2.1 Date of diagnosis (m m / y y y y)

2.2 Type of diabetes ☐ Type 1 ☐ Type 2 ☐ GDM ☐ Don't know ☐ Other

2.3 Management method (Select all that apply)
☐ Diet only ☐ Acarbose ☐ GLP1 agonist ☐ Metformin ☐ SGLT2 inhibitor ☐ DPP4 Inhibitor ☐ Sulphonylurea ☐ Thiazolidinedione ☐ Insulin

If INSULIN → 2.3.1 Duration ____ years . ____ months

→ 2.3.2 Mode (Select all that apply) ☐ Basal ☐ Basal bolus ☐ Pump ☐ Pre-mixed insulin

Section 3. Height, Weight & Smoking Status

3.1 Weight ____ . ____ kg

3.2 Height ____ . ____ m

3.3 Smoking status ☐ Current ☐ Past ☐ Never

If current OR past smoker

3.3.1 Number of years spent smoking

☐ <5 years ☐ 5-10 years ☐ 11-20 years ☐ >20 years

Section 4. Blood Pressure

4.1 Blood pressure (most recent, measured after 5 mins sitting) ____ / ____ mmHg

4.2 Anti-hypertensive treatment ☐ No ☐ Yes

If YES → (Select all that apply) ☐ ACE Inhibitor ☐ AT2 Antagonist ☐ Beta blocker ☐ Thiazides ☐ Ca^{2+} channel blocker ☐ Other

Section 5. Diabetic Eye Disease - last 12 months

	No	Yes
5.1 Attended optometrist	☐	☐
5.2 Referred to ophthalmologist	☐	☐
5.3 Attended ophthalmologist	☐	☐
5.4 Fundus examination	☐	☐
5.5 Retinopathy	☐	☐
5.6 Laser treatment	☐	☐
5.7 Right cataract	☐	☐
5.8 Left cataract	☐	☐

Section 6. Diabetic Foot Problems

	Last 12 months No	Last 12 months Yes	Previous No	Previous Yes
6.1 Peripheral neuropathy	☐	☐	☐	☐
6.2 Foot ulceration	☐	☐	☐	☐
6.3 Foot deformity	☐	☐	☐	☐
6.4 Peripheral vascular disease	☐	☐	☐	☐
6.5 Lower limb amputation	☐	☐	☐	☐
If YES (select all that apply) →	☐ Minor ☐ Major		☐ Minor ☐ Major	

Section 7. Medications & Lipids - last 12 months

	No	Yes	Contraindicated
7.1 Aspirin	☐	☐	☐
7.2 Other anti-platelets	☐	☐	☐
7.3 Anti-coagulants	☐	☐	☐
7.4 Lipid lowering Rx	☐	☐	
If YES → 7.4.1 Statin	☐	☐	☐
7.4.2 Fibrate	☐	☐	☐
7.4.3 Ezetrol	☐	☐	☐
7.4.4 Fish oil	☐	☐	☐
7.5 Lipids measured	☐	☐	

If YES → Complete below:

		Not available
7.5.1 Total Cholesterol ____ . ____	mmol/L	OR ☐
7.5.2 LDL ____ . ____	mmol/L	OR ☐
7.5.3 HDL ____ . ____	mmol/L	OR ☐
7.5.4 Triglycerides ____ . ____	mmol/L	OR ☐

7.5.5 Were the above fasting lipids? ☐ No ☐ Yes

Section 8. Complications/Events/Comorbidities

	Last 12 months No	Last 12 months Yes	Last 12 months Not Applicable	Previous No	Previous Yes	Previous Not Applicable
8.1 Cerebral stroke	☐	☐		☐	☐	
8.2 Myocardial infarction	☐	☐		☐	☐	
8.3 CABG/Angioplasty	☐	☐		☐	☐	
8.4 Congestive cardiac failure	☐	☐		☐	☐	
8.5 End stage kidney disease	☐	☐		☐	☐	
8.6 Blindness	☐	☐		☐	☐	
8.7 Erectile dysfunction	☐	☐	☐	☐	☐	☐
8.8 Dementia	☐	☐		☐	☐	
8.9 Severe hypoglycaemia	☐	☐		☐	☐	

If YES (last 12 months) → 8.9.1 No. of episodes ☐ 1-2 ☐ 3-5 ☐ >5

8.10 Malignancy (exclude non-melanotic skin cancers) ☐ Metastatic solid tumour ☐ Non-metastatic solid tumour ☐ Not Applicable ☐ Leukaemia ☐ Lymphoma

8.11 Liver disease ☐ Mild ☐ Moderate/Severe ☐ Not applicable

Section 9. Renal Function & Blood Glucose Control - last 12 months

9.1 Urinary protein/albumin collected ☐ No ☐ Yes

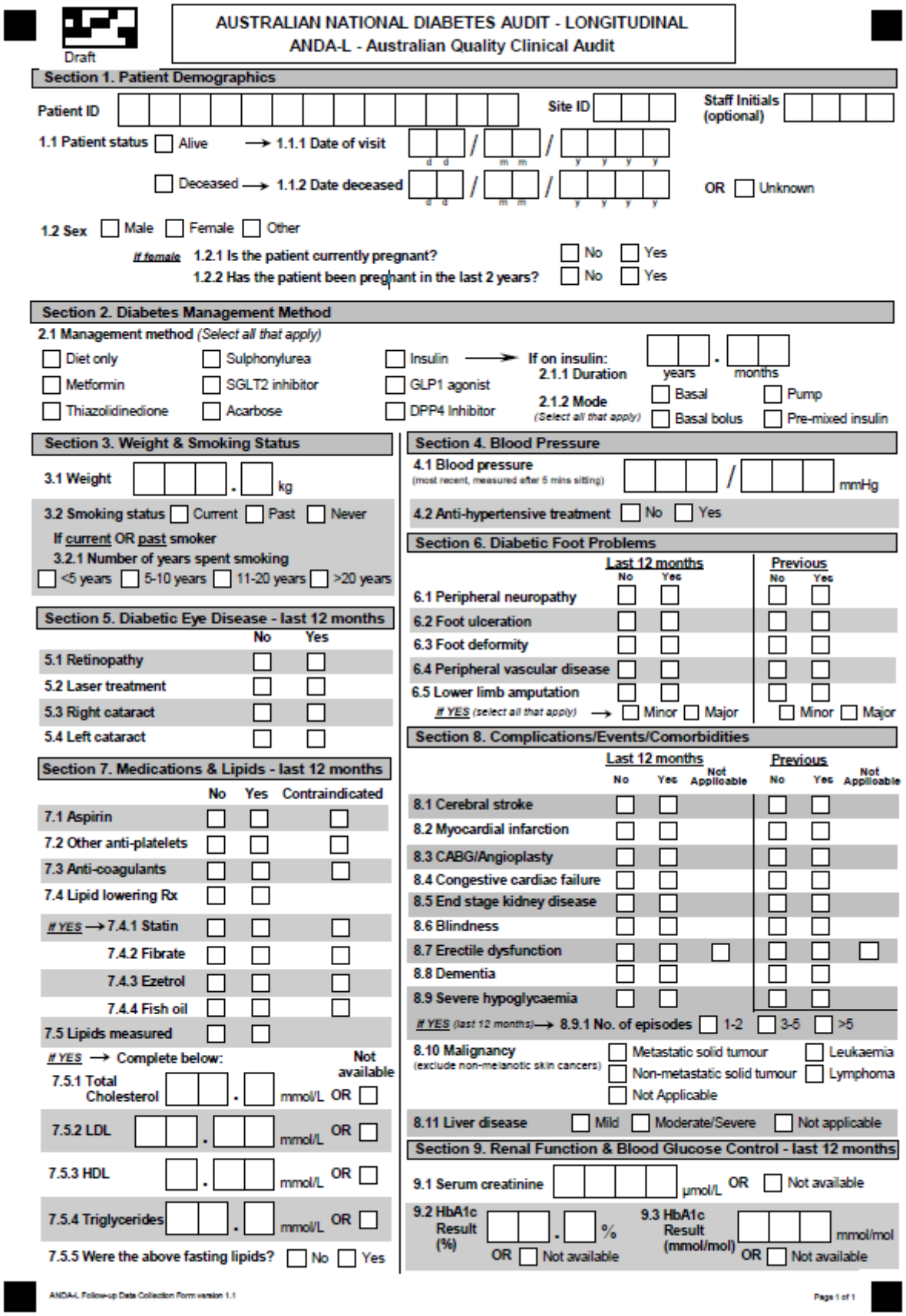
If YES → 9.1.1 Result ____ . ____

9.1.2 Units ☐ mg/L ☐ µg/min ☐ mg/24 hr ☐ ratio

9.2 Serum creatinine ____ µmol/L OR ☐ Not available

9.3.1 HbA1c Result ____ . ____ % OR ☐ Not available AND 9.3.2 ____ mmol/mol OR ☐ Not available

Appendix 3: ANDA-L Data collection form – followup



Draft

AUSTRALIAN NATIONAL DIABETES AUDIT - LONGITUDINAL
ANDA-L - Australian Quality Clinical Audit

Section 1. Patient Demographics

Patient ID | Site ID | Staff Initials (optional)

1.1 Patient status ☐ Alive → 1.1.1 Date of visit (d d / m m / y y y y)

☐ Deceased → 1.1.2 Date deceased (d d / m m / y y y y) OR ☐ Unknown

1.2 Sex ☐ Male ☐ Female ☐ Other

If female 1.2.1 Is the patient currently pregnant? ☐ No ☐ Yes

1.2.2 Has the patient been pregnant in the last 2 years? ☐ No ☐ Yes

Section 2. Diabetes Management Method

2.1 Management method *(Select all that apply)*

☐ Diet only ☐ Sulphonylurea ☐ Insulin → If on insulin: 2.1.1 Duration ☐☐ years . ☐☐ months

☐ Metformin ☐ SGLT2 inhibitor ☐ GLP1 agonist

☐ Thiazolidinedione ☐ Acarbose ☐ DPP4 Inhibitor

2.1.2 Mode *(Select all that apply)* ☐ Basal ☐ Pump ☐ Basal bolus ☐ Pre-mixed insulin

Section 3. Weight & Smoking Status

3.1 Weight ☐☐☐.☐ kg

3.2 Smoking status ☐ Current ☐ Past ☐ Never

If current OR past smoker

3.2.1 Number of years spent smoking

☐ <5 years ☐ 5-10 years ☐ 11-20 years ☐ >20 years

Section 4. Blood Pressure

4.1 Blood pressure (most recent, measured after 5 mins sitting) ☐☐☐ / ☐☐☐ mmHg

4.2 Anti-hypertensive treatment ☐ No ☐ Yes

Section 5. Diabetic Eye Disease - last 12 months

	No	Yes
5.1 Retinopathy	☐	☐
5.2 Laser treatment	☐	☐
5.3 Right cataract	☐	☐
5.4 Left cataract	☐	☐

Section 6. Diabetic Foot Problems

	Last 12 months No	Last 12 months Yes	Previous No	Previous Yes
6.1 Peripheral neuropathy	☐	☐	☐	☐
6.2 Foot ulceration	☐	☐	☐	☐
6.3 Foot deformity	☐	☐	☐	☐
6.4 Peripheral vascular disease	☐	☐	☐	☐
6.5 Lower limb amputation	☐	☐	☐	☐
If YES (select all that apply) →		☐ Minor ☐ Major		☐ Minor ☐ Major

Section 7. Medications & Lipids - last 12 months

	No	Yes	Contraindicated
7.1 Aspirin	☐	☐	☐
7.2 Other anti-platelets	☐	☐	☐
7.3 Anti-coagulants	☐	☐	☐
7.4 Lipid lowering Rx	☐	☐	
If YES → 7.4.1 Statin	☐	☐	☐
7.4.2 Fibrate	☐	☐	☐
7.4.3 Ezetrol	☐	☐	☐
7.4.4 Fish oil	☐	☐	☐
7.5 Lipids measured	☐	☐	

If YES → Complete below: Not available

7.5.1 Total Cholesterol ☐☐.☐ mmol/L OR ☐

7.5.2 LDL ☐☐.☐☐ mmol/L OR ☐

7.5.3 HDL ☐.☐☐ mmol/L OR ☐

7.5.4 Triglycerides ☐☐.☐ mmol/L OR ☐

7.5.5 Were the above fasting lipids? ☐ No ☐ Yes

Section 8. Complications/Events/Comorbidities

	Last 12 months No	Last 12 months Yes	Last 12 months Not Applicable	Previous No	Previous Yes	Previous Not Applicable
8.1 Cerebral stroke	☐	☐		☐	☐	
8.2 Myocardial infarction	☐	☐		☐	☐	
8.3 CABG/Angioplasty	☐	☐		☐	☐	
8.4 Congestive cardiac failure	☐	☐		☐	☐	
8.5 End stage kidney disease	☐	☐		☐	☐	
8.6 Blindness	☐	☐		☐	☐	
8.7 Erectile dysfunction	☐	☐	☐	☐	☐	☐
8.8 Dementia	☐	☐		☐	☐	
8.9 Severe hypoglycaemia	☐	☐		☐	☐	

If YES (last 12 months) → 8.9.1 No. of episodes ☐ 1-2 ☐ 3-5 ☐ >5

8.10 Malignancy (exclude non-melanotic skin cancers) ☐ Metastatic solid tumour ☐ Leukaemia ☐ Non-metastatic solid tumour ☐ Lymphoma ☐ Not Applicable

8.11 Liver disease ☐ Mild ☐ Moderate/Severe ☐ Not applicable

Section 9. Renal Function & Blood Glucose Control - last 12 months

9.1 Serum creatinine ☐☐☐☐ µmol/L OR ☐ Not available

9.2 HbA1c Result (%) ☐☐.☐ % OR ☐ Not available

9.3 HbA1c Result (mmol/mol) ☐☐☐ mmol/mol OR ☐ Not available

Appendix 4: ANDA- L Data dictionary

Section 1. Patient Demographics	
Medical Record No.	(Compulsory field). Enter identifier such as record number or the first 2 letters of the first name and surname and month and year of birth (e.g. FFSSMMYY) to enable you to check your records if there is a query regarding the data.
Site ID	Unique site identifier (assigned by ANDA Secretariat).
Staff initials (optional)	Site staff initials.
Date of birth	Record as **DD/MM/YYYY**. [If unknown other than year: Record as 01/01/YYYY].
Sex	Mark **Male** or **Female** indicating phenotypic (physical) sex at birth.
Currently pregnant	If sex is female, mark **Yes** or **No** if the patient is currently pregnant.
Date of visit	Record the date the patient attended as **DD/MM/2017**.
Initial visit	Mark **No** or **Yes** indicating if this is an initial visit assessment.
Aboriginal/Torres Straits Islander	Mark **No** or **Yes** indicating Aboriginal / Torres Strait Islander background.
Country of birth	Record the patient's country of birth.
NDSS member	Record **No** or **Yes** if a member of the NDSS.
Ethnicity	Record the patient's ethnicity.
DVA patient	Eligible people whose medical care charges are met by the Department of Veterans' Affairs (DVA).
Section 2. Diabetes Type & Management	
Date of diagnosis	Record as **MM/YYYY** of first diagnostic blood glucose estimation. [If date unknown other than year, record as 01/YYYY].
Type of diabetes	Mark **Type1** [IDDM] or **Type2** [NIDDM] or **GDM** or **Don't know**, or **Other** to indicate the clinical classification of diabetes.
Management method	If multiple, **tick all that apply**. See the 'Australian Blood Glucose Treatment Algorithm For Type 2 Diabetes' and the 'Table of Evidence and Properties of Glucose-Lowering Agents' for information on each drug class. These resources are found on the Australian Diabetes Society website, or with the direct link http://t2d.diabetessociety.com.au/documents/tXPPhWzq.pdf
Insulin duration	If the patient is on Insulin, record the number of years/months the patient has been on insulin.
Mode of insulin	If the patient is on Insulin, record mode of administration/s. If multiple, **tick all that apply.** *Basal: Intermediate-acting or long-acting insulin injection(s), Bolus: Very short-acting or short-acting insulin injection(s), Basal bolus: Insulin regime that utilises any type of basal insulin as well as any type of bolus insulin. Pre-mixed insulins are excluded from this category, Pre-mixed: Injection of any pre-mixed combination of intermediate insulin with either short-acting or very short-acting insulin. Pump: Mode of insulin delivery being via continuous subcutaneous insulin infusion.*
Section 3. Height, Weight & Smoking Status	
Weight	Record in **kilograms** the weight measurement without shoes or jacket.
Height	Record in **metres** the height measurement without shoes.
Smoking status	Mark **Current** or **Past** or **Never** to indicate smoking activity of any tobacco material. *Current = regular smoking over the past 3 months, Past = no regular smoking for 1 month or more, Never = never smoked*
Years spent smoking	If the patient is a **current** or **past** smoker, record the number of years spent smoking.
Section 4. Blood Pressure	
Blood pressure	Record Systolic / Diastolic (mm Hg) measured after *5 minutes sitting, (1st and 5th phases).*
Anti-hypertensive treatment	Mark **No** or **Yes** to indicate if the patient is on treatment for hypertension.
Anti-hypertensive medications	Select the anti-hypertensive medication/s that the patient is currently taking. **If on combination tablet, tick all that apply.**
Section 5. Diabetic Eye Disease – last 12 months	
Attended optometrist	Mark **No** or **Yes** to indicate if the patient attended an optometrist in the last 12 months.
Referred to ophthalmologist	Mark **No** or **Yes** to indicate if the patient was referred to an ophthalmologist in the last 12 months.
Attended ophthalmologist	Mark **No** or **Yes** to indicate if the patient attended an ophthalmologist in the last 12 months.
Fundus examination	Mark **No** or **Yes** to indicate if the patient has had an ophthalmological assessment (Direct or Indirect) in the last 12 months.
Retinopathy	Mark **No** or **Yes** to indicate if the ophthalmological assessment revealed any diabetic retinopathy in the last 12 months.
Laser treatment	Mark **No** or **Yes** to indicate if the patient has had eye laser treatment in the last 12 months.

Right & left cataract	Mark **No** or **Yes** to indicate if the patient currently has a cataract or has had one removed previously. Record for **both** eyes in the last 12 months.
Section 6. Diabetic Foot Problems	
Mark **No** or **Yes** to indicate diabetic foot problems in the last 12 months **AND/OR** previously. Answer all questions.	
Peripheral neuropathy	Mark **No** or **Yes** to indicate clinical judgement following assessment using pin prick and vibration or monofilament.
Foot ulceration	Mark **No** or **Yes** to indicate past history of foot ulceration.
Foot deformity	Mark **No** or **Yes** to indicate the presence of any foot deformity *(e.g. Hallux, hammer or claw toe, flat or high arch, Charcot's).*
Peripheral vascular disease	Mark **No** or **Yes** to indicate peripheral vascular disease. YES = absence of both dorsalis pedis **and** posterior tibial pulses in either foot.
Lower limb amputation	Amputation of toe, forefoot or leg [above or below knee], not due to trauma or causes other than vascular disease.
Minor/Major Lower Limb Amputation	If the patient has had an amputation in either lower limb, indicate if minor and/or major. *Minor = Amputation of the toe/s or foot (below the ankle), Major = Amputation above the ankle.*
Section 7. Medications & Lipids – last 12 months	
Aspirin	Mark **No** or **Yes** to indicate whether the patient is on Aspirin. Indicate whether contraindicated.
Other anti-platelets	Mark **No** or **Yes** to indicate whether the patient is on any other anti-platelet treatment (e.g. clopidogrel).
Anti-coagulants	Mark **No** or **Yes** to indicate whether the patient is on anti-coagulant treatment (e.g. Warfarin, novel anti-coagulants)
Lipid lowering treatment	Mark **No** or **Yes** to indicate whether the patient is on lipid lowering treatment. **If Yes**, indicate whether they are on Statin, Fibrate, Ezetrol and/or Fish Oil. Record if contraindicated. **If on combination tablet, tick all that apply.**
Lipids measured	Mark **No** or **Yes** to indicate if lipids have been measured in the past 12 months.
Total Cholesterol, LDL, HDL, Triglycerides	Record **absolute result** of most recent result of *total, LDL & HDL cholesterol* and *triglycerides* in the last 12 months or tick 'Not available'.
Above measured in fasting specimen	Mark **No** or **Yes** to indicate if the lipids reported in items 7.5.1 to 7.5.4 were measured in a fasting state.
Section 8. Complications/Events/Co-morbidities	
Mark **No** or **Yes** to indicate a history of complication or an event in the last 12 months **AND/OR** previously. Answer all.	
Cerebral stroke	Due to vascular disease including TIA.
Myocardial infarction	Evidenced by ECG changes, plasma enzyme changes or medical documentation.
CABG/Angioplasty	Coronary Artery Bypass Grafting surgery (CABG), Angioplasty or Stent.
Congestive cardiac failure	Symptomatic congestive cardiac failure with response to specific therapy.
End stage kidney disease	Requiring dialysis or having undergone kidney transplantation.
Blindness	Patient became legally blind (>6/60) in either eye.
Erectile dysfunction	History or treatment of failure to achieve or maintain erection sufficient for penetration. If female, tick 'Not applicable'.
Dementia	Chronic cognitive deficit diagnosed by a clinician.
Severe hypoglycaemia	Severe hypoglycaemia requiring assistance of another person to actively administer carbohydrates, glucagon, or other corrective actions.
Number of episodes	If the patient had at least one episode of severe hypoglycaemia, record the number of episodes.
Malignancy	Indicate type of malignancy **or** if not applicable. *Exclude non-melanotic skin cancers.*
Liver disease	Indicate severity of liver disease **or** if not applicable. *Mild = cirrhosis without portal hypertension, chronic hepatitis, Moderate to severe = cirrhosis with portal hypertension.*
Section 9. Renal Function & Blood Glucose Control – last 12 months	
Urinary protein/albumin collected	Mark **No** or **Yes** to indicate if Urinary protein/albumin was collected.
Urinary protein/albumin result	If Urinary protein/albumin was collected, record absolute amount of albumin [**mg/L**] or as albumin excretion rate [AER: **µg/min** or **mg/24hr**] or **Ratio**.
Urinary protein/albumin units	If Urinary protein/albumin was collected, mark the applicable units.
Serum creatinine	Record **absolute result** measurement of serum creatinine in **MICROMOLS/L** [µmol/L] or tick 'Not available'.
HbA1c result	Record **absolute result** [%] **AND** mmol/mol of the most recent Haemoglobin A1c (HbA1c) protein result in the last 12 months or tick 'Not available'.

Appendix 5: ANDA-L Participant Information Statement

Australian National Diabetes Audit Longitudinal Register (ANDA-L)
Participant Information Statement

Version 4, 27 February 2019
Full Project Title: Australian National Diabetes Audit-Longitudinal Register
Short Title: ANDA-L

Introduction
Diabetes represents the fastest growing chronic disease in Australia. One way to promote and improve the standard of diabetes care and achieve better health results for people with diabetes in Australia, is to monitor and collect health information.

What is ANDA-L and what does it do?
ANDA-L is an important activity promoting improvement in the care provided by diabetes centres. ANDA-L has been established to collect patient health information to guide diabetes centres on how to improve patient care.

Who is funding this activity? Financial support is provided by the Australian Government Department of Health.

What does my participation in ANDA-L involve?
The diabetes team at your centre will collect information about you and your diabetes treatment as part of your routine clinical care. They will complete a one page form and may access some information through your medical records to assist with its completion. Your diabetes centre will then follow-up and collect the same information from you 2 years and 4 years later. This will be conducted in the same manner during one of your routine clinic visits or you will be contacted via phone should you not have a scheduled appointment during these follow-up time points. This information will also be linked to government databases for the purposes of following ANDA-L's activities into the future.

Participation in this activity is voluntary. If you do not wish to take part in ANDA-L, you are free to withdraw at any time during the course of this activity by contacting ANDA-L Central Management.

Where will my health information be stored?
Your health information will be coded to secure your identity. The patient code linking your name to your health information will be stored electronically in a password protected database within the Monash University's secure network based in Victoria, Australia. Paper copies will be secured in a locked room at your diabetes centre and the ANDA-L site based in Victoria, Australia. No-one except your diabetes centre and the ANDA-L team will be able to gain access to your information. Access will only be used for identifying you for follow-up purposes. There is a lot of security in place to protect your information.

What health information will my diabetes centre collect for ANDA-L?
Your diabetes centre will collect information about you and your diabetes treatment. The information collected is part of your routine care. No additional information apart from the information that your diabetes team has access to during your visit is required. Information included in this collection are your name, postcode, date of birth, gender, basic information about your health status (height, weight, blood pressure), diabetes management, complications and some of your test results and medications.

Data linkage
ANDA-L would like to link your health information to the following external databases: Medicare Benefits Schedule (MBS), the Pharmaceutical Benefits Scheme (PBS) and/or National Death Index Registry (NDI). This information is additional to the information collected at your diabetes centre and will assist with following ANDA-L's activities into the future.

How does ANDA-L use my information?
The information collected for ANDA-L is used in many ways:

1. Making reports with the latest information about patients with diabetes
2. Sending reports back to each diabetes centre advising how their patients are doing NOW compared to the past and also compared to other diabetes centres
3. Understanding the quality, type and place of care people receive
4. Understanding the different treatments people get for their diabetes

5. Understanding how many people have diabetes and what health care they need so that the best health care services can be set up to look after them
6. Helping people do research so they can understand more about diabetes and the best ways to treat it and keep patients healthier.

Do I have to share my health information with ANDA-L?

Participation in this activity is voluntary. If you do not wish to take part, you have a period of 2 weeks following this routine visit to **opt out**. Please be aware that your information WILL be collected and included in ANDA-L as well as permitted to be linked to the MBS, PBS and/or NDI databases unless you contact the Central Management directly to advise that you DO NOT want your details recorded and linked. Please do not call your diabetes centre. ANDA-L manages all opt-out requests centrally. This can be done by yourself or a family member. Please note we may ask for some identifying information so we can ensure we accurately remove your information from our databases. Opting out will not affect the treatment you receive now or in the future, or your relationship with the staff caring for you.

If you decide to take part and later change your mind, you are free to **opt out** from this activity at any stage. No additional information will be collected from you. The information already collected will not be included and removed from the ANDA-L database. If you decide to **opt out** from this activity, please notify ANDA-L Central Management.

To opt out or withdraw from this activity at any stage, please contact ANDA-L Central Management on 1800 XXX XXX.

What will happen if I agree to share my health information with ANDA-L?

Your diabetes team will give you this participant information statement for you to read and consider. You do not have to do anything more. They will collect your information during your routine visit, through your medical records or may contact you via phone when following you up. Your data will be linked to the MBS, PBS and/or NDI databases for future follow up.

What are the risks for me if I agree to share my information with ANDA-L?

The main risk is a loss of privacy if your personal and private health information which is given to ANDA-L is viewed by an unauthorised person. This information would only be seen by your doctors, nurses or health carers directly involved in your care. The information given to ANDA-L is kept as safe as possible. Your identity and personal details are not accessible to the public.

Is my information in ANDA-L kept private and safe? Who can see it?

ANDA-L follows Australian Government rules about keeping your information private and confidential. There are many security measures to make sure all the information is kept very safe. The computer systems are protected. Information is transferred in a safe and secure way.

Your identity (name and other personal information) will remain confidential under a coded system and can only be accessed through your diabetes centre, the ANDA-L team and the accredited organisations that will be responsible for performing data linkage. All information will only be disclosed with your permission, except as required by law. All information that is used for reporting or research is always coded (without your name).

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact your diabetes centre if you would like to access your information. In accordance with regulatory guidelines, the information collected in this study will be securely archived and kept indefinitely.

Who can I contact for further information or if I have concerns?

For further information or any concerns regarding this activity, please contact your diabetes centre or
Email: anda@nadc.net.au
For any complaints about any aspect of this activity, the way it is being conducted or any questions about your rights as a participant, please contact the Monash Health Human Research Ethics Committee Manager, Ms Deborah Dell on **03 9594 4611**
To opt out or withdraw from this activity, please contact ANDA-L Central Management on the following FREECALL number: **1800 XXX XXX.**