

# AN~~DA~~-AQ~~SMA~~ PROTOCOL

## **Australian National Diabetes Audit - Australian Quality Clinical Audit**

### **Protocol**

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# AN~~DA~~-AQ~~SMA~~ PRO~~TO~~COL

## **Australian National Diabetes Audit – Australian Quality Self Management Audit**

### **Synopsis**

The Australian National Diabetes Audit - Australian Quality Self Management Audit (AN~~DA~~-AQ~~SMA~~, previously ANDIAB2) is a well-established, important biennial, quality activity led by the National Association of Diabetes Centres (NADC), in specialist diabetes centres across Australia, in all States and Territories, (although in some years, some States and Territories have not submitted data). Participating specialist diabetes services (Diabetes Centres and specialist endocrinologists in private practice), receive an individualised report of their diabetes practice processes and patient outcome data compared with their peers.

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

AN~~DA~~-AQ~~SMA~~ is undertaken in specialist diabetes services but could be applied to diabetes management assessment in other clinical practice settings including primary care. The process also has potential applicability in other chronic disease settings.

Based on feedback from participants from previous ANDIAB2 collections, and review of experience in the 2012 Diabetes Collaborative, several enhancements have been made to the dataset to be collected in 2014.

## What's New?

From 2014 we will use the name Australian National Diabetes Audit – Australian Quality Self Management Audit (ANDA-AQSMA) nee ANDIAB2.

The new ANDA central coordinating/reporting centre is based at Monash Health, Diabetes and Vascular Unit, Victoria, as of 2013.

In ANDA-AQSMA 2014 we will collect the same dataset as in ANDIAB2 2012, with the following changes;

- 2 fields have been removed;
  - Lipohypertrophy present? [No/Yes/Not relevant]
  - Lipoatrophy present? [No/Yes/Not relevant]
- 2 fields have been added;
  - Do you check your blood glucose as often as is recommended? [No/Yes/Unsure]
  - If you are on injectables or insulin, do you rotate your injection sites? [No/Yes]
- 3 options added to answer for Management Method
  - Injectables
  - Injectables and Tablets
  - Insulin and Injectables and Tablets
- Answer to 'How long ago was insulin started?' will now be recorded as a categorical variable [<1 year, 1-5 years, >5 years]

Enhancements adopted in ANDA-AQCA 2013 will be carried over to ANDA-AQSMA 2014 with the addition of space for the insertion of HbA1c in both % and mmol/mol units, and country of birth [Name].

The ANDA-AQSMA 2014 Data Collection form has been reformatted to make completion of the form easier. Minor changes have been made to the Data Definitions, and additional forms required for completion of ANDA-AQSMA 2014. A full description of changes made to ANDA-AQSMA 2014 is included in the Appendix.

## 1. Background

The National Association of Diabetes Centres (NADC), who leads this initiative, is a national collective of over 60 Diabetes Centres brought together by a common desire to see improvement in the standard of diabetes care in Australia.

The NADC was established as a joint initiative by the Australian Diabetes Society and the Australian Diabetes Educators' Association after considering the outcomes of the Diabetes Control and Complications Trial (DCCT). The DCCT found that maintenance of good glycaemic control significantly reduces diabetes related complications in individuals with Type 1 diabetes, and recognised the role of multidisciplinary teams in the provision of specialist care for those people requiring intensive treatment. Subsequently the United Kingdom Prospective Diabetes Study (UKPDS) showed that maintenance of good glycaemic and blood pressure control, through a team approach, in people with Type 2 diabetes, reduced the long term complications of the disease.

As a consequence, the NADC was created to establish and promote effective health care practice and ultimately achieve better outcomes for people with diabetes. In particular, key strategies were identified including the development of standards of care and quality review initiatives, information provision, and training and support for health professionals in specialist multidisciplinary settings.

## What is a Diabetes Centre?

A Diabetes Centre is a specialist unit made up of a team of health professionals dedicated to the care of individuals with diabetes. The key functions of a Diabetes Centre are:

- patient education;
- medical treatment and clinical care of people with diabetes;
- providing training in diabetes care to other health professionals;
- providing a support and advisory service to people with diabetes and their non-specialist health professionals; and
- research into medical, scientific, social and behavioural aspects of diabetes.

For a period of over 30 years now, Diabetes Centres have been established across Australia and now number well over 60 nationwide. They can be found in most major metropolitan adult and children's hospitals and usually have a close working relationship with primary health care providers, ie. Local general practitioners and community health staff.

Diabetes Centres are an important component of the range of health care services available to people with diabetes. Whilst Diabetes Centres vary in their make up most will have :

- **endocrinologists** who provide specialist medical management, treatment and advice to people with diabetes;
- **diabetes nurse educators** who provide individual and group patient education, counselling and support services, and specialise in the clinical and nursing care of people with diabetes;
- **dietitians** whose job is to assess the individual's nutritional needs and provide advice and an appropriately tailored eating plan to suit the person's physical needs and help promote good health and good diabetes control; and
- **podiatrists** who specialise in assessing and treating diabetic foot problems as well as providing foot care education to individuals and groups.

Diabetes Centres are often referred to as *Diabetes Ambulatory Care Centres*. This is because most of the services provided by Diabetes Centres are conducted on an outpatient basis. However, the treatment and education of people with diabetes who are admitted to hospital, and in-service training for hospital staff are also important functions of Diabetes Centres.

## Who will access a Diabetes Centre?

Most patients are referred to Diabetes Centres by General Practitioners in order that their patients receive specialist assessment and treatment. Given this role, it is important to recognise that it is most likely that people attending Diabetes Centres will be those whose diabetes is less likely to be managed well. In considering the outcomes of this data collection, it is important to remember that whilst Diabetes Centres will provide assessment and treatment, ongoing responsibility for management of most people remains with the individual and their general practitioner.

Therefore, patients with diabetes referred to specialist diabetes services including Diabetes Centres and specialist endocrinologists in private practice are likely to be those with newly diagnosed disease requiring education, and those with uncontrolled diabetes or complications of the disease requiring specialist assessment and management. As such the latter patients, in particular, likely represent those individuals with more complex or complicated diabetes.

## Development of ANDA (nee ANDIAB) Quality Clinical Indicators

There has been long standing worldwide interest in attempting to define suitable diabetes datasets and methods of data collection to reflect appropriate diabetes outcomes. As a result, collection, analysis and reporting of standardised diabetes datasets is now widely practised. The European Association for the Study of Diabetes (EASD) Study Group DO IT (Diabetes care Optimisation through Information Technology)<sup>1</sup> 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<sup>2,3</sup> for audit and benchmarking purposes. From this has come the DiabCareQ-Net initiative<sup>4</sup>.

A similar initiative in Australia, in September 1993, was the NSW Diabetes Outcomes Workshop (NDOW), sponsored by the NSW Health Department as one of its Health Outcomes Funded Projects<sup>5,6</sup>. Forty five 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) Council 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 Revue 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 5<sup>th</sup> National Health Priority Area in 1996, 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<sup>7</sup>. 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 (Colagiuri et al)<sup>8</sup>.

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 (see AIHW website).

At its Annual General Meeting in Canberra (Oct 1997), the National Association of Diabetes Centres (NADC) proposed that a one month data collection be undertaken (in March 1998), using the minimum dataset defined by NDOQRIN. This dataset, managed by the NDDWG, contains demographic, clinical, biochemical and outcome data items, and, as stated above, has been proposed for collection in a variety of clinical practice settings in Australia including primary care<sup>9,10</sup>, see below (The Dataset).

## 2. The Dataset

The NDOQRIN diabetes dataset has considerable compatibility with similar international datasets including the DiabCare dataset. 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. This was achieved by linking the minimum dataset to the NSW Clinical Management Guidelines for Diabetes<sup>11</sup>, thence enhanced 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.

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 Data Collection Form**).

Definitions for each data field, including all valid field types, are printed on the reverse side of the forms (**Appendix Definitions**).

The data dictionary (indicating field type, size and transfer protocol requirements) has been updated and is made available to all sites including sites contemplating electronic data transfer from in-house databases.

## 3. ANDA Software/Database

An application of Teleform© scannable/faxable software has been integrated with a Microsoft SQL Server 2010 running under a Windows XP© operating system. The Teleform© Designer module allows paper forms to be designed and printed. Once completed, retain a copy of the ANDA-AQSMA Data Collection forms at your site and forward the original copies to the ANDA secretariat. The Teleform© Reader module assesses each form and either accepts the form (transferring data to an intermediate Access© data file), or suspends the form for verification of one or more data items that the Reader software cannot confidently identify. The Teleform© Verifier module allows an on screen version of the scanned (or faxed) image to be viewed, and corrections made where necessary. Once such corrections are made and accepted, data from these forms are also transferred to the intermediate file. Data in this file are then appended to the permanent database file. Concurrent Operating System and Software Versions are Windows XP, Access 2003 & Teleform V10.1.

The software has been written to allow individual practitioners or sites (eg a Diabetes Centre) to be registered, and for unique forms to be generated for completion by that practitioner (or site). Reports have been developed and attached to menu buttons on a user-friendly interface to enable data reporting. This includes data verification reports to ensure complete and valid data capture.

Any data extracted from practitioner or site in house databases will be transferred to via a secure file transfer protocol (SFTP) for collation and analysis alongside scanned form data.

Data will be stored in the central ANDA Database, a Microsoft Access© database held in password protected files on computers stored in a locked room at the School of Public Health and Preventive Medicine, Monash University.

## 4. ANDA Coordination

ANDA coordination and conduct will be overseen by Monash Health, Diabetes and Vascular Unit, Clayton, Victoria.

The new ANDA Secretariat based at Monash Health will coordinate the conduct of ANDA and distribution of reports.

The new ANDA Data Management and Analysis centre based at the School of Public Health and Preventive Medicine, Monash University will oversee and manage the ANDA database and complete the data analysis and reporting.

## 5. ANDA Methodology

ANDA will consist of the following steps (**Figure 1**):

1. Initial call for expressions of interest from specialist diabetes centres (potential sites).
2. Formal invitations to participate and site acceptances (participating sites).
3. Allocation of unique site codes by the ANDA secretariat in a double blind manner and distribution of data collection forms.
4. Data collection by participating sites.
5. Data entry, cleaning, collation and validation (including missing data query resolution).
6. Data analysis and reporting.

The ANDA Secretariat will invite Diabetes Centres (all levels of NADC membership including NADC Tertiary Diabetes Centres, NADC Diabetes Care Centres and NADC Affiliate Diabetes Centres) and specialist endocrinologists in private practice to participate in the ANDA-AQSMA collection for 2014.

Specialist endocrinologists may participate in one of two ways:

- (i) as part of a Diabetes Centre receiving either a 'pooled' report for all doctors, or an individual report covering patients seen by each doctor (identified uniquely within that Centre); or
- (ii) as an individual specialist in private practice independent of a Diabetes Centre.

All contact and correspondence with participating centres/specialist endocrinologists will only occur through the ANDA Secretariat.

The ANDA Secretariat will provide participating centres and specialist endocrinologists with their unique site code and hold the only copy of this code.

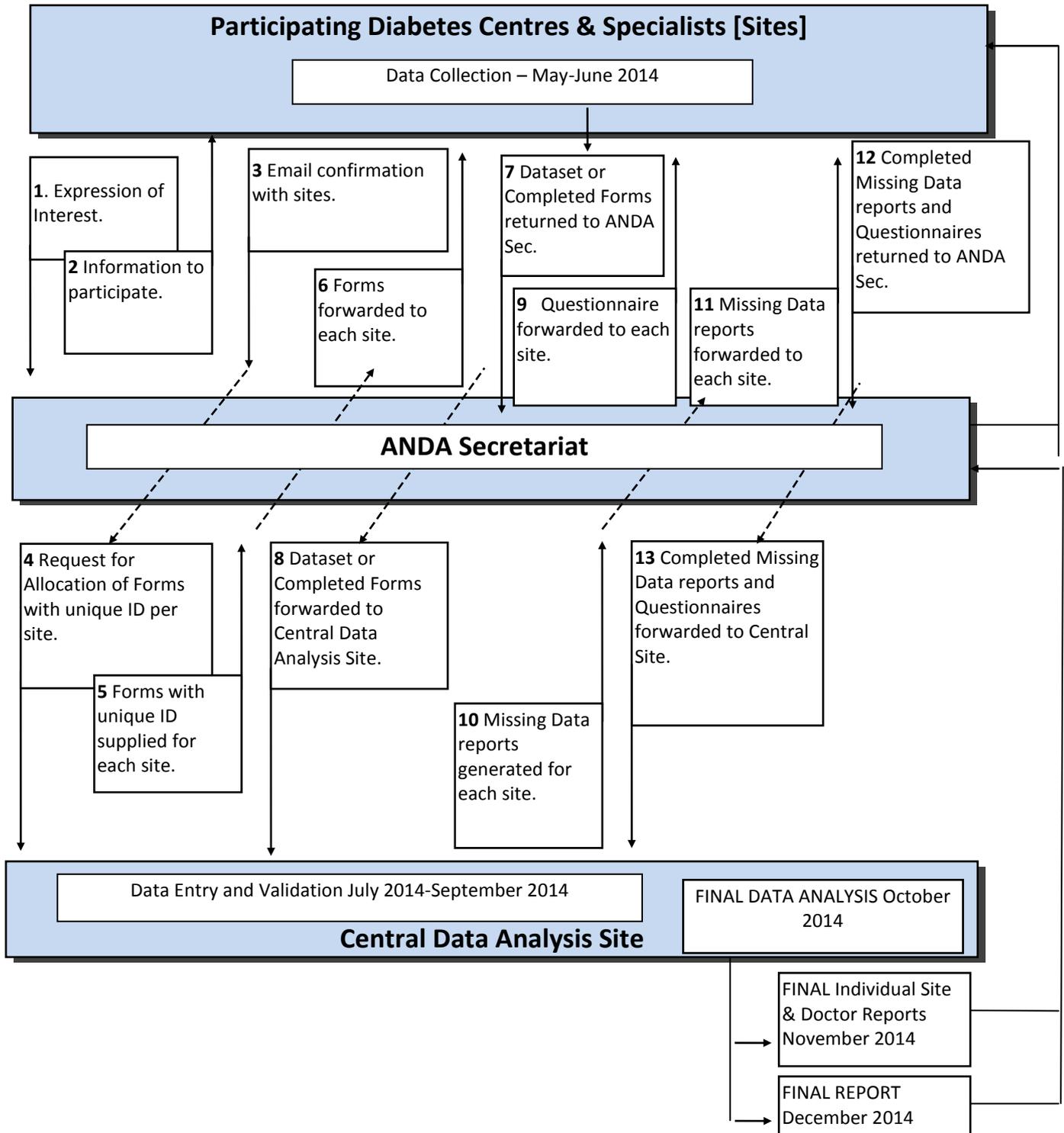
Sites that have participated in past surveys will use their previously allocated unique site code. Sites that have not participated in past surveys will be allocated a new unique site code.

The central data management/analysis unit will generate 'Master Copies' of the forms uniquely numbered for each site and/or doctor. The forms will then be provided to the ANDA Secretariat who will distribute them to each of the participating sites.

All sites will receive a "How to Fill in ANDA-AQSMA Forms" with instructions on how the forms should be completed and the data field definitions (**Appendix "How to fill in ANDA-AQSMA Forms"**).

Each participating site will be instructed to make copies (as many as required) of their unique form for use in the survey.

**Figure 1** ANDA-AQSMA Data Collection Process



### **5.1 Survey period**

Centres will conduct the survey over 4 consecutive weeks during the month of May (or at some sites, June) 2014.

### **5.2 Ethics**

As this is a doubly de-identified quality assurance activity it does not require formal ethics, however, the onus is on each centre to seek advice re local ethics requirements.

### **5.3 Survey population**

All consecutive patients attending the centre/service over the 4-week survey interval (recommended 100 patients per site, minimum 20 patients per site).

Sites using paper forms will be advised to complete a data collection form for each patient attending the centre/service. All completed forms will be copied by the sites and stored locally in a secure place. The original forms will then be sent to the ANDA secretariat. The ANDA secretariat will check and collate the original forms and deliver them to the data management centre for processing.

Sites with computerised databases will have the alternative option of extracting the appropriate data in an electronic and de-identified form and providing it directly to the ANDA secretariat through a secure web based data transfer process.

### **5.4 Data Verification and Validation**

As in previous years 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, in the pooled database, 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.

### **5.5 Data analysis/reporting**

In analysing the data, as in past surveys, the previous specified data assumptions, decisions and data 'manipulations' will be observed.

Data analysis and reporting will include:

Pooled data report

- Variable frequency counts (including % missing data)
- Variable descriptive statistics
- Comparative statistics by site (de-identified)
- Comparative statistics by year of collection

Site/doctor individual data report

- Variable frequency counts (including % missing data)
- Variable descriptive statistics
- Comparative statistics by year of collection

Reports will be presented in a standard format as tables and figures divided into the following sections:

1. Demographics and Outcomes Data at a glance report
2. Outcomes comparison report
3. Missing data report
4. Frequency counts report

### 5.6 Post survey/reporting feedback

Participating sites will be asked to complete two questionnaires: one in June/July/August, - (at completion of the data collection phase), to assess the project overall, and the other in December/January, - (after receipt of the reports) to assess the adequacy of the individual site/doctor report(s). (**Appendix Post survey/reporting Questionnaires**).

## 6. Funding

ANDA conduct in 2013 and 2014 has been funded by the Commonwealth Department of Health.

## 7. Milestones

The major project milestones are summarised in **Table 1** and superscript numbers reference **Figure 1** project components.

**Table 1: ANDA-AQCA Milestones\***

Milestones
Initial call for expressions of interest, February 2014 <sup>1</sup>
Formal invitations received, collation of site acceptances, March 2014 <sup>2</sup>
Allocation of site codes, April 2014 <sup>3,4</sup>
Generation and distribution of Data Collection Forms, April 2014 <sup>5,6</sup>
Data collection, May 2014 – June 2014 <sup>7,8</sup>
Study assessment: Post Data Collection Questionnaire <sup>9,12</sup>
Data received from ANDA-AQSMA Software sites, June 2014 – July 2014 <sup>8</sup>
Data entry and validation, July 2014 – September 2014
Missing Data reports forwarded to sites, July 2014 – September 2014 <sup>10,11</sup>
Integration of returned missing data, September 2014 <sup>12,13</sup>
Final Data Analysis, October 2014
Draft Pooled Data Report, October 2013
Final Site/Doctor Data Analysis Reports forwarded to sites, November 2014
Final Pooled Data Report, December 2014

\* See also Figure 1

## 8. References

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