Protocol

Australian Diabetes Clinical Quality Registry

DCQR012021
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Data Custodian
Monash University

Coordinating Principal Investigator
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Statement of Compliance
This study will be conducted in compliance with the current protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007), Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95), ASCSQH Operating Principles and technical standards for Australian Clinical Quality Registries, University research policies and procedures and federal laws governing privacy and confidentiality.

Contents

1. Abbreviations & Acronyms

ABS	Australian Bureau of Statistics
ACSQHC	Australian Commission on Safety and Quality in Health Care
ADCQR	Australian Diabetes Clinical Quality Registry
ADS	Australian Diabetes Society
AIATSIS	Australian Institute of Aboriginal and Torres Strait Islander Studies
AIHW	Australian Institute of Health and Welfare
ANDA	Australian National Diabetes Audit
ANDA-L	Australian National Diabetes Audit-Longitudinal
ANZDATA	Australian and New Zealand Dialysis and Transplant Registry
AQCA	Australian Quality Clinical Audit
AQSMA	Australian Quality Self-Management Audit
BMI	Body Mass Index
DDS-17	Diabetes Distress Score - 17-item measure
DO IT	Diabetes care Optimisation through Information Technology
CABG	Coronary Artery Bypass Graft
CQR	Clinical Quality Registry
DALY	Disability Adjusted Life Years
GDM	Gestational Diabetes Mellitus
HbA1c	Glycated Haemoglobin
HDL	High-density lipoprotein
LDL	Low-density lipoprotein
METeOR	Metadata Online Registry
MBS	Medicare Benefits Schedule
NADC	National Association of Diabetes Centres
NDSS	National Diabetes Services Scheme
NHMRC	National Health and Medical Research Council
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
PBS	Pharmaceutical Benefits Scheme
PCP	Primary Care Partnerships
PHN	Primary Health Networks
PIS	Patient Information Statement
QI	Quality Improvement
SPHPM	School of Public Health and Preventive Medicine
SFTP	Secure File Transfer Protocol
SSL	Secure Sockets Layer
REDCap	Research Electronic Data Capture
VLAD	Variable Life Adjusted Display

2. Study Sites

2.1. Study Location/s

The Australian Diabetes Clinical Quality Registry (ADCQR) will collect data from primary, secondary and tertiary diabetes health services located in Australia. A list of all participating diabetes centres and their locations will be available from the ADCQR Management Team (contact details provided in Section 7 of the protocol).

3. Introduction/Background Information

3.1. Lay Summary

Diabetes represents the fastest growing chronic disease in Australia. One way to promote and improve the standard of diabetes care and achieve better health outcomes for people with diabetes in Australia is to monitor and collect health information. Clinical registries are large databanks of health information used to assess and report on the quality of care within specific areas of the health service. Quality indicators collected by clinical registries assess whether care is safe and effective and delivered in a timely and appropriate manner.

The National Clinical Quality Registry Strategy (the CQR Strategy) aims to drive continuous improvements in the quality and value of healthcare to achieve better health outcomes for all Australians. The Australian Diabetes Clinical Quality Registry (ADCQR) will work towards the proposed vision of the CQR Strategy by:

- Collecting ongoing health outcome data for people with diabetes.
- Monitoring and reporting on the quality (appropriateness and effectiveness) of health care for people with diabetes by routinely collecting and analysing health outcome data.
- Providing clinicians, health service managers, patients and other stakeholders with ongoing feedback on clinical practice and outcomes for people with diabetes to improve the quality of care.

Diabetes centres will be invited to participate in the ADCQR by collecting and uploading health information for people diagnosed with diabetes during a specified sampling period of every year to the ADCQR's online data entry system. Data will be collected on all consecutive patients attending the service during the sampling period, and may include new participants as well as those who may have participated in previous years. Health information collected by the centre will include clinical data collected from medical records at the diabetes centre or during a clinical appointment. In addition, some sites may choose to administer and collect patient-reported data. The ADCQR will link every participant once to information held by Australian Commonwealth and State and Territory Government agencies related to the objectives of the Registry at four years after the patient is registered in the ADCQR. Linkage will provide a longitudinal assessment of the effects of diabetes centres health care practices on patient treatment and outcomes..

All data collected will be stored securely within the ADCQR which is hosted by Monash University. All authentication and authorisation related information will be encrypted and all activity will be in accordance with Monash University's Information Technology Services Security Framework policy.

3.2. Background

3.2.1. Disease Characteristics

Diabetes is a chronic and progressive disease that is characterised by elevated blood glucose levels due to relative or absolute impairment of insulin secretion and/or target tissues having reduced sensitivity to the action of insulin as well as the effects of counter-regulatory processes.[1]

While there are many forms of diabetes, the main two comprise T1DM and T2DM. Autoimmune destruction of insulin-producing beta islet cells results in T1DM, while the pathogenesis of T2DM is characterised by insulin resistance and relative impairment of insulin secretion without an autoimmune component.[1]

Diabetes leads to multisystem complications including diabetic ketoacidosis, hyperosmolar hyperglycaemic state, acute hypoglycaemia resulting from excessive exogenous insulin administration or other pharmacotherapies, as well as long-term sequelae of microvascular and macrovascular complications. The early diagnosis and management of diabetes to improve glycaemia, the metabolic profile, and vascular risk factors as well as the additional benefits beyond glycaemia reported for newer pharmacotherapies in the management of T2DM have the potential to reduce the overall burden of diabetes and its complications. [2, 3]

3.2.2. Burden of Disease

Diabetes is a chronic disease that has become one of the largest challenges facing Australia's health care system. The number of people affected by diabetes in Australia continues to grow with a recent estimate of around 280 Australians developing diabetes each day.[4] While it is estimated that approximately 1.8 million Australians are living with diabetes, only 1.4 million are known and registered on the National Diabetes Services Scheme (NDSS) in 2022, with a large proportion thought to have undiagnosed type 2 diabetes.[3-5] Of those registered on the NDSS in 2022, approximately 9% had T1DM and 86% had T2DM.[5]

Diabetes is also emerging as a global health care problem that threatens to reach pandemic levels.[6] On a global scale, the World Health Organisation has estimated that 422 million adults were living with diabetes in 2014 as compared to 108 million in 1980.[6] The global age-standardised prevalence of diabetes has nearly doubled since 1980, rising from 4.7% to 8.5% in the adult population.[7] It is a leading cause of mortality, with the International Diabetes Federation reporting 5 million deaths from diabetes worldwide in 2015.[8] In the Australian context, it was estimated in 2018 that approximately 16,700 deaths (10.5% of all deaths) were related to diabetes.[9] Of these, 28% were directly due to diabetes while 72% were associated with diabetes.[9]

The increasing prevalence and widespread impact of diabetes on individuals, communities, and the health care system therefore highlights the importance of early recognition and optimal management of diabetes and its complications.[3]

3.2.3. Management of Diabetes

The optimal management of diabetes requires a multi-disciplinary approach that addresses glycaemia and reno-cardiovascular risk factors through pharmacotherapy, lifestyle measures, and sometimes

health technologies, as well as the early detection and management of micro- and macrovascular complications.[1]

Managing blood glucose levels with oral hypoglycaemic agents, non-insulin injectable medicines, and/or insulin has been reported to lower the risk of vascular complications.[10, 11] Modern oral and non-insulin injectable agents have also been reported to provide protective reno-cardiovascular benefits that may be independent of glycaemic control.[12] The early detection and management of reno-cardiovascular risk factors is also a vital aspect of care. The lipid profile must be regularly monitored and managed with effective lifestyle interventions and pharmacotherapy when required. Screening for diabetic nephropathy should be performed regularly along with close attention to blood pressure and appropriate management strategies. Assistance with smoking cessation as well as the maintenance of appropriate body weight with nutrition, physical activity, and other approaches are also important to minimise cardiovascular risk.[13] In addition, foot care is vital for the early detection, management, and prevention of foot ulceration, deformity, vascular complications, and lower extremity amputations.[14-16]Regular follow-up with an optometrist and/or ophthalmologist for the early detection and management of ophthalmic complications of diabetes is also important to preserve vision for people living with diabetes.[17, 18]

Optimal management approaches should be individualised and consider factors such as age, comorbidities, life expectancy, and the patient's capacity to manage diabetes independently.[1, 12]

3.2.4. Variation in management of diabetes and outcomes

One of the aims to achieving better healthcare is to reduce unnecessary variation in disease management and outcomes. Variation in diabetes care is mainly described based on the concept that access and quality of care given to people with diabetes is highly dependent on various factors such as age, sex, ethnicity, co-morbidities, socio-economic factors, as well as geographical location. The aim of diabetes care should be to minimise variation and maximise evidence-based practice.[19]

Studies have shown that integrated, multidisciplinary care is crucial to improving the health experience and outcomes of people with diabetes and in particular those with more complex needs such as the elderly, people with disability, mental illness and multiple morbidities or those with a longer duration of disease.[20-22]

Various factors may affect the utilisation of healthcare services for diabetes, including characteristics of patients and healthcare providers. Such variation in utilisation may be unwarranted, and hence integrating diabetes care across the spectrum of service providers aims to refocus patient-centered care, promoting better health outcomes and fiscal sustainability.

Among those with diabetes, multifactorial interventions that improve glycaemic control, blood pressure and lipid control have been demonstrated to significantly reduce the risk of premature mortality and cardiovascular disease.[23-26] However, only 50% of people with diabetes are currently estimated to be achieving optimal glycaemic control, blood pressure and lipid levels.[27] Improvements in risk factor levels are vital to reduce diabetes-related morbidity and mortality and improve quality of life and life expectancy for people with diabetes.[3]

There are variations in health outcomes across different clinical practices and other geographical spaces, and understanding the variation at different levels of care and its magnitude could provide useful information to guide health services policy makers in designing effective interventions. These variations reflect complex interactions between demographic, socioeconomic and environmental factors. There is an increased burden of disease in lower social-economic places, or where health care is less accessible where the burden of disease [measured in terms of disability adjusted life years (DALYs) is higher than the national rate.[28]

3.2.5. Barriers and gaps in diabetes management

To be able to improve the care of people with diabetes and decrease the burden of diabetes, barriers and gaps in diabetes management must be known. Existing barriers and gaps in diabetes management include:

- *Not all people with diabetes are diagnosed and captured*.
  It is estimated from community-based samples that 3 in 10 adults with diabetes are undiagnosed. As a significant proportion of adults have established complications at the time of diagnosis, systematic efforts to screen for undiagnosed diabetes have the potential to reduce the burden of diabetes.[3]
- *Gaps in data, knowledge, information and primary care*
  Significant gaps exist in diabetes-related knowledge and decision making among practicing physicians, as highlighted by clinical guideline use.[29] Clinical guidelines and recommended cycles of care are evident, however there is need for greater comparative data to compare the quality of care and outcomes across practices. The available evidence suggests there is considerable room for improvement in clinical outcomes for people with these conditions in general practice.[30]
- *Poor outcomes in the Aboriginal and Torres Strait Islander population*
  Australia has enormous cultural and social diversity and, while diabetes is increasingly common across the country, it is particularly problematic within certain communities.[31] The Australian Health Survey (National Aboriginal and Torres Strait Islander Health Measures Survey, 2012–13) found that one in five Aboriginal and Torres Strait Islander people over the age of 25 years have diabetes. This compares with rates of between 6 and 8 per cent of the general population in the same age group (taken from the Australian Health Survey and AusDiab, respectively).[32, 33] These data demonstrate that Aboriginal and Torres Strait Islander peoples experience a disproportionate share of the burden of diabetes as a result of the considerably higher diabetes rates.

  Australia's Aboriginal and Torres Strait Islander community has one of the highest rates of type 2 diabetes and its complications both nationally and globally. Increasingly, diabetes is being diagnosed in children, adolescents and young adults[34] with rising rates of diabetes in pregnancy establishing intergenerational patterns of premature disease.[35] The prevalence and severity of diabetes-related complications among Aboriginal and Torres Strait Islander peoples is of particular concern.[36]

  To prevent diabetes and improve diabetes management, it is important to ensure that the communities have access to, and can benefit from, diabetes support, education and services

— e.g. Aboriginal Community Controlled Health Services, where they exist, or culturally competent mainstream services — as an integral part of their primary health care services. Aboriginal and Torres Strait Islander peoples may experience cultural and linguistic barriers, as well as geographic and socio-economic barriers, that limit their access to diabetes-related services and education.

- *Diverse clinical settings*
  Based on data from the Australian Bureau of Statistics (ABS), at the end of June 2002 there were 19,464 general practice (GP) and specialist medical practices in Australia, comprising 9,600 GP and 9,864 specialist practices. These medical practices are operated from 28,676 locations across Australia's metropolitan, regional, remote and rural settings.[37]

3.2.6. Australian National Diabetes Strategy

The Australian National Diabetes Strategy 2021-2030 has prioritised Australia's response to diabetes and aims to identify approaches to help reduce the impact of diabetes in the community.[31] Its vision is to strengthen all health sectors in developing, implementing and evaluating an integrated and coordinated approach to reduce the social, human and economic impact of diabetes in Australia through its principles of:

1. Collaboration and cooperation to improve health outcomes;
2. Coordination and integration of diabetes care across services, settings, technology and sectors;
3. Facilitation of person-centered care and self-management throughout their life;
4. Reduction of health inequalities and measurement of health behaviors and
5. Outcomes to guide action within the goals.

It will assist with achieving the following goals:

1. Prevention of T2DM;
2. Promoting awareness and early detection of diabetes along with early interventions with lifestyle modifications where reversibility of T2DM is possible;
3. Reduction of diabetes related complications and improvement of quality of life among people with diabetes;
4. Reduction of the impact of diabetes on the Aboriginal and Torres Strait Islander peoples and other priority groups; and
5. Strengthening prevention and care through research, evidence and data.[31]

3.2.7. Clinical Quality Registries

A proven strategy to reduce variations in outcomes and to improve survival is to measure and compare it using high quality clinical registry data. This has been successfully tested in a range of clinical areas including in the management of surgery (e.g. trauma,[38] cardiac surgery,[39] transplantation,[40] and breast surgery[41]) and in the medical management of patients (e.g. stroke care,[42] cardiac care,[43] dialysis[40] and cancer care[44]). Clinical registries provide the most effective means of collecting high quality data and are a tool for quality improvement.

Where they have been introduced at a state or national level, registries have become one of the most clinically valued tools for quality improvement.[45] The Australian Commission on Safety and Quality in

Health Care (ACSQHC) has advocated development of clinical registries.[46] Registries can improve quality of care by:

- Providing credible risk adjusted data;
- Giving clinicians information about how their outcomes benchmark with others, both locally and where appropriate internationally;
- Identifying and investigating variations in clinical practice and outcomes; and
- Providing an early warning if quality of care deteriorates.

Clinical quality registries are also important tools to appraise the implementation of clinical guidelines, aiming to improve quality of care, reduce variation and regional differences, and pursue cost-effective models of care. Previous studies have reported major improvements to patient outcomes attributed to clinical quality registries. In addition, clinical quality registries have significant utility in medical research, with lower costs than randomised controlled trials and greater external validity.[47] Monitoring of healthcare and outcomes, benchmarking, and rigorous quality improvement are thus essential to guide optimal healthcare.

In addition to being important tools in improving quality of care, clinical registries provide unparalleled ability to track how innovation in biomedical science translates into longer term outcomes in the 'real world'.[48, 49] Biomedical science laboratories are involved in identifying new mechanisms of disease, new prognostic markers, new early diagnostics and measures of response to treatment. This work is often impeded by lack of access to human populations where outcomes are systematically and accurately collected and can be related to laboratory findings.

3.2.8. Clinical registries at Monash University

The School of Public Health and Preventive Medicine (SPHPM) at Monash University has a strong track record in the development and operation of clinical and clinical quality registries at a state and national level.[50] It currently operates 24 clinical registries, including those monitoring the Victorian trauma system,[51] cardiac surgery and interventional cardiology, burns, hyperbaric medicine and blood diseases.[52] It fosters a thriving research environment supporting high quality research and researchers with extensive experience in registry methodology including recruitment, data collection, linkage and analysis underpinned by effective registry governance structures.

In 2008, Monash was requested by the ACSQHC to develop Operating Principles for Australian Clinical Registries.[53] Principles outlined in this document will guide the development of all registries in Australia, including the ADCQR.

The ability to monitor care and benchmark performance requires the collection of high-quality epidemiological data collected on people with diabetes. A registry allows the capacity to identify and benchmark against best practice, provide regular feedback to clinicians regarding their clinical outcomes, and, provide a platform for further research into diabetes management. Investment in long-term registry data will allow better analysis of outcomes on spending and health, including through post-marketing assessment of new drugs.[54]

3.2.9. Australian National Diabetes Audit

Quality improvement (QI) is integral to a well-functioning health care service. Understanding and properly implementing QI is necessary for improving efficiency, patient experience and safety, and health outcomes. Underpinning QI is a continuous commitment to collect, analyse and report on outcomes that measure variation in clinical practice and inform performance. [55-57]

The Australian National Diabetes Audit (ANDA) is a longstanding centralised quality assurance activity aiming to improve the safety and quality of care provided to people attending primary, secondary and tertiary diabetes health care services for management of diabetes. ANDA collects data on people with diabetes. There are two ANDA audits that alternate each year, one that focuses on clinical indicators known to represent the impact of diabetes (ANDA-AQCA, Australian Quality Clinical Audit) and one that focuses on self-management and quality of life for people with diabetes (ANDA-AQSMA, Australian Quality Self-Management Audit). In 2019, a longitudinal register of ANDA (ANDA-L) was initiated to prospectively follow up a cohort of patients over a fixed time period. ANDA-L offers a rich source of data to better understand the impact of clinical practice and effectiveness of available treatments on outcomes for people with diabetes attending diabetes services.

ANDA processes are efficiently run and scalable. ANDA has successfully addressed: (1) governance; (2) stakeholder engagement; (3) promoting and delivering the activity to sites from different health sectors; (4) growth of the number of participating sites and patients over time; and (5) successful pooled reporting and individual site reporting. All states are represented in this benchmarking activity. ANDA has set the foundations for extending and developing the ADCQR.

- ANDA is a well-established quality improvement activity that has been running since 1998/1999 with Monash University delivering this activity from 2013. It has a broad coverage of sites from varying heath sectors (primary, secondary and tertiary) nationally. This activity has been progressively expanding over time from having 30 sites registered in 2013, to 80 sites delivering this activity in 2019 with patient growth from 3843 to 6436, respectively. Due to the impacts of the COVID-19 pandemic in 2020-2021 (staffing constraints, staff redeployments), some diabetes centres have been unable to participate. In 2021, there were 68 sites who participated, with total patient numbers of 5062. Despite these impacts, it is anticipated that there will be growth in participation in future years, especially as the rate of people living with diabetes is increasing.
- ANDA has provided efficient analysis and reporting. Pooled reports are provided to the Commonwealth Government Department of Health for approval and are made available to the public. Site reports are sent directly to sites for benchmarking and QI purposes. The collection of information on health outcomes is validated and data completeness is maximised.
- ANDA has performed effectively against its key performance indicators (milestone deliverables) and has met its objectives to a high standard. Across the years, there have been progressive improvements in the data collection methods with a decrease in missing data. Recently, risk adjustment of key outcomes has been introduced. Work is ongoing to incorporate site feedback on data collection methods and reports. Annual reporting to the Commonwealth Department of Health and participating sites has been consistently delivered on time and on budget.

ANDA has provided the foundation for planning and designing the ADCQR, which includes merging and refining the two data collections of ANDA (ANDA-AQCA and ANDA-AQSMA) into an annual cycle. Through the formative work of ANDA and the order ranking review process undertaken by the Scientific Advisory Committee, the Australian Diabetes Society (ADS) Council and the National Association of Diabetes Centres (NADC) Committee, the ADCQR aims to capture the best elements of both datasets and benchmark with international standards to fulfil the Clinical Quality Registries Framework prioritisation criteria (developed by the ACSQHC).

3.2.10. Australian Diabetes Clinical Quality Registry

The ADCQR aims to build on the visions, principles and goals of the Australian National Diabetes Strategy and further implement, broaden and reinvigorate the concept of ANDA to a larger scale transitioning it to a broader national roll out. The focus will be on engaging the various health sectors, benchmarking and reporting, improving metrics, as well as short-term and long-term improvements in clinical outcomes and complications. Noting the limitations associated with using existing data sources to accurately track diabetes centres and people with diabetes in the ADCQR, this CQR aims to work towards linking and developing a standardised data set by merging the two existing ANDA data collections and moving towards aggregating data from different systems. In achieving the aims of the ADCQR, it is imperative that factors such as leadership and governance, workforce, information and research capacity, financing and infrastructure, partnerships and networks are in place.

The ADCQR will prospectively facilitate the monitoring of health outcomes by collecting, analysing and reporting on diabetes data indicators and work towards the proposed vision of the CQR Strategy of an integrated health system to drive improvement in patient outcomes.

The ADCQR will report on the appropriateness, effectiveness and variation in patient outcomes to participating clinicians, hospitals, jurisdictional health departments, consumers and funding bodies, and set the base for improvements in diabetes care.

The national ADCQR anticipates that a large proportion of burden will be prevented by:

- Monitoring the quality (appropriateness and effectiveness) of health care for people with diabetes by routinely collecting and analysing health outcome data.
- Providing clinicians, health service managers, patients and other stakeholders with ongoing, risk adjusted, benchmarked feedback on clinical practice and outcomes for people with diabetes to improve the standard of care.
- Monitoring the burden of diabetes related complications as well as risk factors to provide insights into the performance of national guidelines regarding risk factor management.
- Monitoring the uptake of diabetes management therapies and technologies and correlate this with markers of glycaemic control and complications of diabetes. This may provide insights into the real-world impact of diabetes management technologies.

The national ADCQR will provide invaluable data regarding the care of adults with diabetes. National benchmarking will provide feedback on the ability of health services to assist their patients reach various therapeutic targets, as well as strategically directing future services by highlighting areas of

potential need. Furthermore, it will provide a representative understanding of current clinical and biochemical outcomes in the Australian context, and will allow a more accurate assessment of the impact of government expenditure and how this can better be targeted to improve services. The national ADCQR will provide vital information on the uptake of diabetes management technologies that will allow more accurate Australian economic evaluations of these devices as well as evaluating real-world correlation of advanced technologies with biochemical and long-term clinical outcomes.

4. Study Objectives

4.1. Hypothesis

We hypothesise that a clinical quality registry established to monitor management and outcomes of people with diabetes will reduce variation in health care, and improve knowledge and health outcomes.

4.2. Registry Aims

The aim of this project is to develop a population-based diabetes clinical quality registry to optimise quality of care provided to people diagnosed with diabetes. This will be achieved by:

1. Assessing patterns of care and access to care;
2. Identifying variability in treatments/outcomes amongst people with diabetes
3. Benchmarking of process and outcome measures amongst providers of care;
4. Determining the degree of compliance (and reasons for non-compliance) with best practice-based guidelines for the treatment of diabetes;
5. Identifying factors that predict favourable and unfavourable treatment outcomes.

In addition, this diabetes clinical quality registry will improve knowledge and advance treatment by:

6. Monitoring trends in outcomes and survival over time,
7. Providing an infrastructure on which intervention or other studies can be established,
8. Determining the clinical effectiveness of treatments in a 'real world' setting
9. Providing information to assist in the credentialing of clinicians and identification of appropriate training resources.

4.3. Registry Outcomes

Establishment of the ADCQR offers the potential to make considerable inroads into our understanding of current practice in the treatment of diabetes and reasons for variation in outcomes. Understanding reasons for and reducing variation in outcomes is critical in driving improvements in the management of the disease.

The establishment of the ADCQR will achieve the following outcomes:

- Provide confidence to clinicians and institutions that they are delivering a high-quality service.
- Provide important information to inform public health policy and practice, including analysis of the cost benefit of new treatment, identification of areas of need and outcome of interventions.
- Assure the public that diabetes treatments and quality of care are performed under the oversight of a robust quality assurance programme. This will instill patient confidence and

confer a public relations advantage to diabetes centres contributing data.

- Provide consumers and people with diabetes with the opportunity to inform the ADCQR research agenda. People with lived experience (consumer representative) on the Scientific Advisory Committee will help to ensure that the Registry addresses the needs of people with diabetes and their families.
- Provide a data spine from which other studies can be undertaken. As an observational tool, it will enable hypotheses for testing through subsequent studies.
- Provide an ability to track long term effects of innovations in diabetes management.
- The Registry will be capable of being linked to other databases containing information about histopathology, genetic markers, biochemical characteristics and other newly discovered laboratory markers.

4.3.1. Federal Outcomes

The ADCQR provides an excellent example of the evolution in care highlighted by Australia's Primary Health Care 10-year plan. By allowing clinicians to utilise real world data and develop contextually appropriate models of care in chronic disease management delivery, while ensuring an appropriate and rigorous methodology to data collection and analysis, we anticipate that participation in the ADCQR will become the standard by which diabetes care is assessed in the future and becomes an integral driver in funding reform.[58]

4.4. Registry Outcome Measures

The ADCQR will collect health outcome data for people with diabetes attending a diabetes health service during a specified sampling period of every year to be benchmarked against other participating sites and according to national and international guidelines. The health outcomes collected include clinical quality indicators as well as patient-reported outcomes. Clinical quality indicators will capture health service use, treatments and outcomes that are a part of standard care, while patient-reported outcomes will collect relevant data directly from the patient and measure the patient's experience. The minimum dataset to be collected by the ADCQR is based on the two ANDA collections, and determined by the ADCQR Scientific Advisory Committee, based on clinically relevant and patient-reported outcomes. The proposed outcomes (Table 1) captured by the ADCQR may change over time in line with new guidelines, treatments and understandings of what constitutes quality of care. In addition, the proposed outcomes will be continually reviewed and adjusted to maximise completion of data and reduce the burden on participating sites and their patients.

Table 1. Proposed health outcome data to be collected

	Health Outcome	Data items required
1	**Patient demographics**	Date of birth Sex Pregnancy status Country of birth Aboriginal or Torres Strait Islander
2	**Anthropometric measures**	Height Weight Body mass index (kg/m^2)
3	**Blood pressure**	Systolic blood pressure (mmHg)

	Health Outcome	Data items required
		Diastolic blood pressure (mmHg) Antihypertensive treatment
4	**Diabetes type and management**	Year of diagnosis Type ▪ T1DM ▪ T2DM ▪ Other (secondary diabetes) Management method ▪ Acarbose ▪ Diet only ▪ DPP4 inhibitor ▪ GLP1 agonist ▪ Insulin ▪ Metformin ▪ SGLT2 inhibitor ▪ Sulphonylurea ▪ Thiazolidinedione Insulin duration Insulin mode ▪ Basal ▪ Basal bolus ▪ Pump ▪ Pre-mixed insulin Injection site rotation Blood glucose level Checks frequency T1DM – blood ketone level checks frequency as recommended
5	**Additional medications and other**	Anti-coagulants Anti-platelets Aspirin Lipid lowering therapy ▪ Statin ▪ Fibrate ▪ Ezetimibe ▪ PCSK9 inhibitors ▪ Fish oil
6	**Medication use**	Compliance with usual medications Use of complementary /dietary supplements/ over the counter therapy ▪ Awareness of use to diabetes health professional
7	**Diet**	Following recommendations and difficulties following recommendations
8	**Lifestyle**	Physical activity Smoking status Alcohol intake
9	**Health professional attendances**	Health professionals attended in last 12 months: ▪ Podiatrist ▪ Diabetes Educator ▪ Dietician ▪ Psychologist ▪ Psychiatrist ▪ Social Worker ▪ Diabetes specialist ▪ Ophthalmologist

	Health Outcome	Data items required
		▪ Optometrist ▪ Dentist ▪ Exercise psychologist
10	**Diabetic complications (within the last 12 months)**	Cerebral stroke Myocardial infarction CABG/angioplasty End stage kidney disease Foot ulceration Peripheral vascular disease Lower limb amputation Major/minor amputation Charcot foot Peripheral neuropathy Retinopathy Right/left cataract Blindness Sexual dysfunction Gastroparesis
11	**Diabetic emergencies (within the last 12 months)**	Diabetic ketoacidosis Hyperosmolar hyperglycemic state Severe hypoglycaemia ▪ No. of episodes in last 12 months Hypoglycaemic awareness
12	**Other Complications/Events/Comorbidities**	Congestive cardiac failure Chronic obstructive pulmonary disease Dementia Depression Liver Disease Malignancy Thyroid disease Admission to hospital in last 12 months COVID-19 ▪ Hospitalisation
13	**Pathology**	Glycaemic Control ▪ HbA1c (%) Renal Function ▪ Urinary protein/albumin ▪ Serum creatinine (µmol/L) Lipid Profile ▪ Total Cholesterol (mmol/L) ▪ LDL (mmol/L) ▪ HDL (mmol/L) ▪ Triglycerides (mmol/L)
14	**Vaccinations**	COVID-19 Influenza Pneumococcal
15	**Mental Health Screening and Treatment**	Screening with validated tools for: • Anxiety • Depression • Diabetes distress Treatment ▪ Antidepressants ▪ Counselling/therapy
16	**Other Patient-Reported Outcomes**	Self-assessment of health status/diabetes management Quality of life measures

5. Research Plan

5.1. Registry Design

The ADCQR is a population based observational study of people undergoing treatment and management for diabetes. The ADCQR will collect identifiable data obtained from patients, health professional consultations, medical records and data linkage on key clinical indicators and patient-reported outcomes. Data released for analysis will only be done so in a re-identified form. In publication/reporting, only de-identified grouped/aggregate data will be released. Data will be collected on patients with diabetes attending a diabetes health service during a specified sampling period of every year. The sampling period will be four weeks during the months of May/June self-selected by the participating health service, with data collected on all consecutive patients attending during this period. This may include patients who have participated in the Registry in previous years, as well as new participants. This sampling period may be extended up until the censorship date of 31 August upon agreement between sites and the ADCQR Management Team to accommodate for any delays in ethics and governance approvals, and/or reliant on the site's capacity to collect more data. The Registry is based on the ANDA cross sectional data collection and longitudinal demonstration project (ANDA-L) and is multi-centred operating across all states and territories nationally. The Registry will conform to the national operating principles for clinical quality registries as set out by the ACSQHC. The Registry is expected to be ongoing and data will be retained indefinitely. Figure 1 provides a diagrammatic overview of the core set up and activities of the ADCQR. Figure 2 provides a diagrammatic overview of the Governance structure of the ADCQR.

Figure 1. Operational overview of the Australian Diabetes Clinical Quality Registry

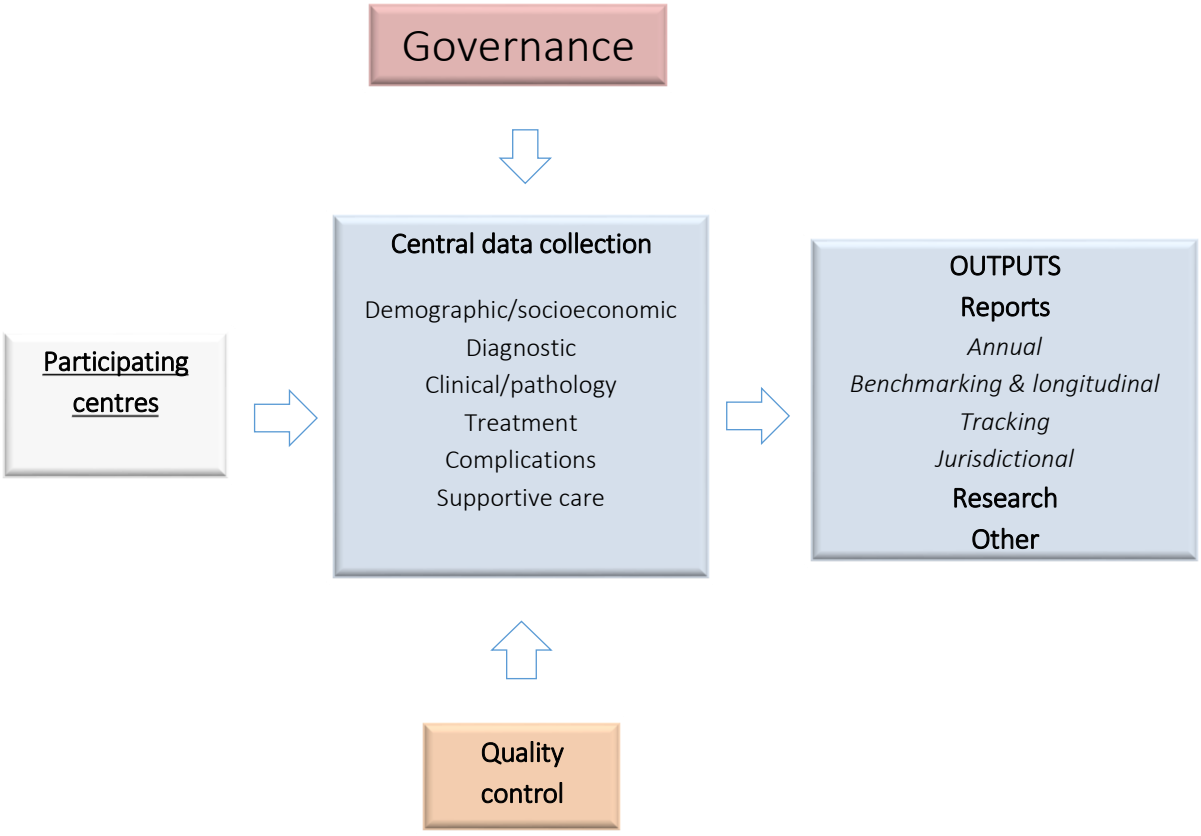
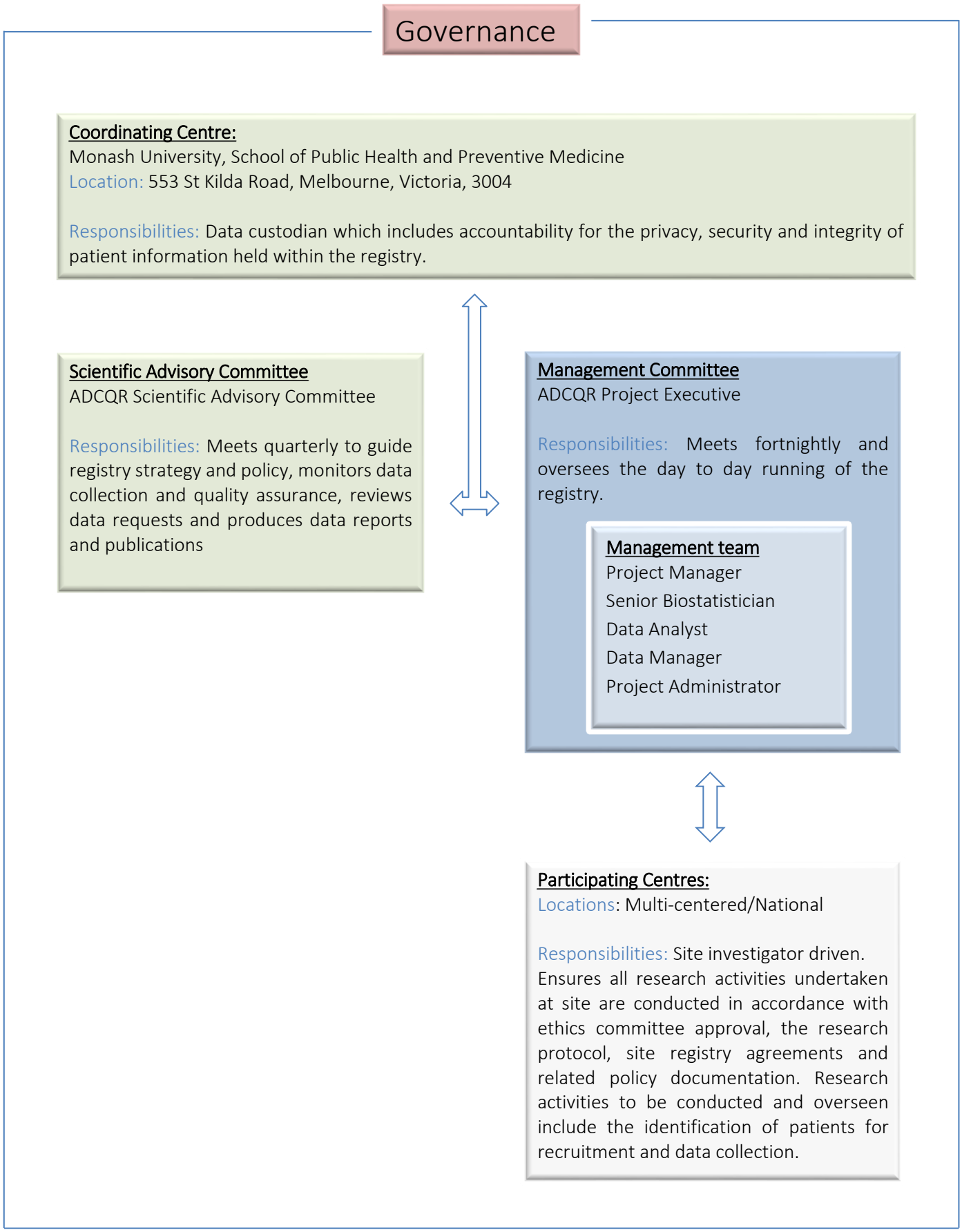


Figure 2. Governance structure of the Australian Diabetes Clinical Quality Registry



5.2. Registry Population

All adult patients diagnosed with diabetes attending a participating site are eligible to participate.

5.2.1. Inclusion criteria

The ADCQR will capture two patient cohorts:

1. Adult patients with recently diagnosed diabetes (diagnosed ≤12 months from the consult date)
2. Adult patients with a known diagnosis of diabetes (diagnosed >12 months from the consult date)

Patients who meet the following criteria will be eligible to be registered and have their data collected into the ADCQR:

- Attend a participating diabetes centre
- Aged 18 years or over
- Have T1DM, T2DM or secondary diabetes (diabetes due to other causes)
- Have the capacity to make the decision to opt-out or be included in the Registry

N.B. Female patients with established diabetes who are pregnant at the time of recruitment or during patient follow-up will be included.

5.2.2. Exclusion criteria

Patients will be excluded from the ADCQR based on the following criteria:

- Female patients with a diagnosis of gestational diabetes mellitus (GDM) (not known to have established diabetes, i.e. a diagnosis of diabetes prior to pregnancy)

5.3. Recruitment Procedure

Schema of recruitment, data collection and the opt-out process for the ADCQR is provided in Figure 3. The ADCQR consists of the following tiered/ordered recruitment components:

5.3.1. Diabetes centre recruitment

1. Expressions of interest will be distributed to diabetes centres listed with the NADC by the ADCQR Secretariat.
2. Acceptances will be logged and formal invitations sent to diabetes centres who express their interest.
3. Allocation and confirmation of unique site codes will be provided to participating sites in a double-blinded/coded manner, where only the ADCQR Secretariat can access the identified copy. Sites that have participated in past surveys will use their previously allocated unique site code. New sites will be allocated a new unique site code.

4. Distribution of the Participant Information Sheet (PIS) (Appendix 1), data collection forms and instructional study documents.

5.3.2. Patient (participant) recruitment

Participating sites will recruit patients over a consecutive four-week period over the months of May/June every year. This sampling period may be extended up until the censorship date of 31 August upon agreement between sites and the ADCQR Management Team to accommodate for any delays in ethics and governance approvals, and/or reliant on the site's capacity to collect more data. Participating site health professionals (clinicians and nurses directly involved in the care of the patient) will identify the patient's status of eligibility through their medical records and during their consult prior to recruitment (see sections 5.2.1 and 5.2.2).

Participating site health professionals will discuss this activity directly with the patient, and provide the patient with the PIS. Every year sites will provide the PIS to all patients attending their centre within the specified sampling period and who meet the inclusion criteria. This includes patients who have participated in the activity previously. This will ensure that these patients are reminded of the activity and given the information to opt-out at any time if desired.

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 the ADCQR.

5.3.3 Script for site health professionals when speaking to participants for all points of contact

To ensure consistency in communications across all participating sites, generalised scripts to inform patients about the ADCQR and the collection of patient-reported outcomes are included in Appendix 2.1 and Appendix 2.2, respectively.

5.4. Ethical Considerations

5.4.1. Opt-out process

The ADCQR will employ an opt-out process. The opt-out process has been used successfully in over 75% of clinical quality registries in Australia.[59] 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. The opt-out process 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.[60, 61]

Eligible patients will be provided with a PIS by a health professional at the participating site and will have an opportunity to ask any questions. The PIS provides details about the Registry, their right to voluntary consent and the process for withdrawal (see Section 5.4.3). To confirm patients have received the PIS, a check box on the paper collection form, web-based database and in-house clinical care database will be marked by the site staff to indicate it was given and/or the site staff will document the PIS was given in the patient medical record.

Patient data including identifiers, clinical indicators and patient-reported outcomes will be collected at the time of the patient consult at the diabetes centre/health service and entered in the ADCQR database The date of the patient consult (clinic visit) will indicate the commencement of a 14-day opt-out window. During the 14 day opt-out window, patient data will be held in a holding database. If the patient has not opted out within the 14-day window, participation will be assumed and patient data will be transferred into the ADCQR database. A waiver of consent will be applied for the collection of this data and transfer to the holding database prior to it being submitted to the Registry and participation being assumed.

5.4.2. Waiver of consent

A waiver of consent is necessary for the collection of patient data and transfer to the holding database before it is submitted to the Registry and participation is assumed.

5.4.3. Withdrawal of consent/Opt-out of the Registry

Patients will have a 14-day opt-out window before participation is assumed. Patients are able to opt-out at any time by contacting the ADCQR Management Team via the Freecall 1800 telephone number.

If a patient wishes to opt-out, the ADCQR Management Team will confirm if they want to opt-out of specific components (ie the clinical component, patient-reported outcomes or data linkage) or all components. All data collected to date will be retained in the ADCQR database, unless the patient requests for it to be removed. No further/additional data will be collected from the time of withdrawal (depending on the patient's request). Patient identifiers and demographics such as name, sex, date of birth and address will be retained to ensure participating sites do not collect data in error, and for case ascertainment purposes, unless the patient requests for this data to be removed. Patients will have the opportunity to opt-out of the activity immediately (during their consult) and no data will be

collected. For those who do not immediately opt-out and have data collected by the site staff, the opt-out options include:

1. Total opt-out: Remove all existing data collected and no data linkage
2. Partial opt-out: Remove parts of the existing data (demographics/clinical/patient reported outcomes) and no data linkage
3. Partial opt-out: Retain all the existing data and no data linkage
4. Partial opt-out: Remove parts of the existing data and allow data linkage

The ADCQR will have an active document to continually log patients who have opted-out. Participating sites will be notified of the patients who have opted-out at the point of withdrawal and advised to keep a log of these patients so no further data collection occurs in the future if these patients attend a participating site (clinic) during the data collection period.

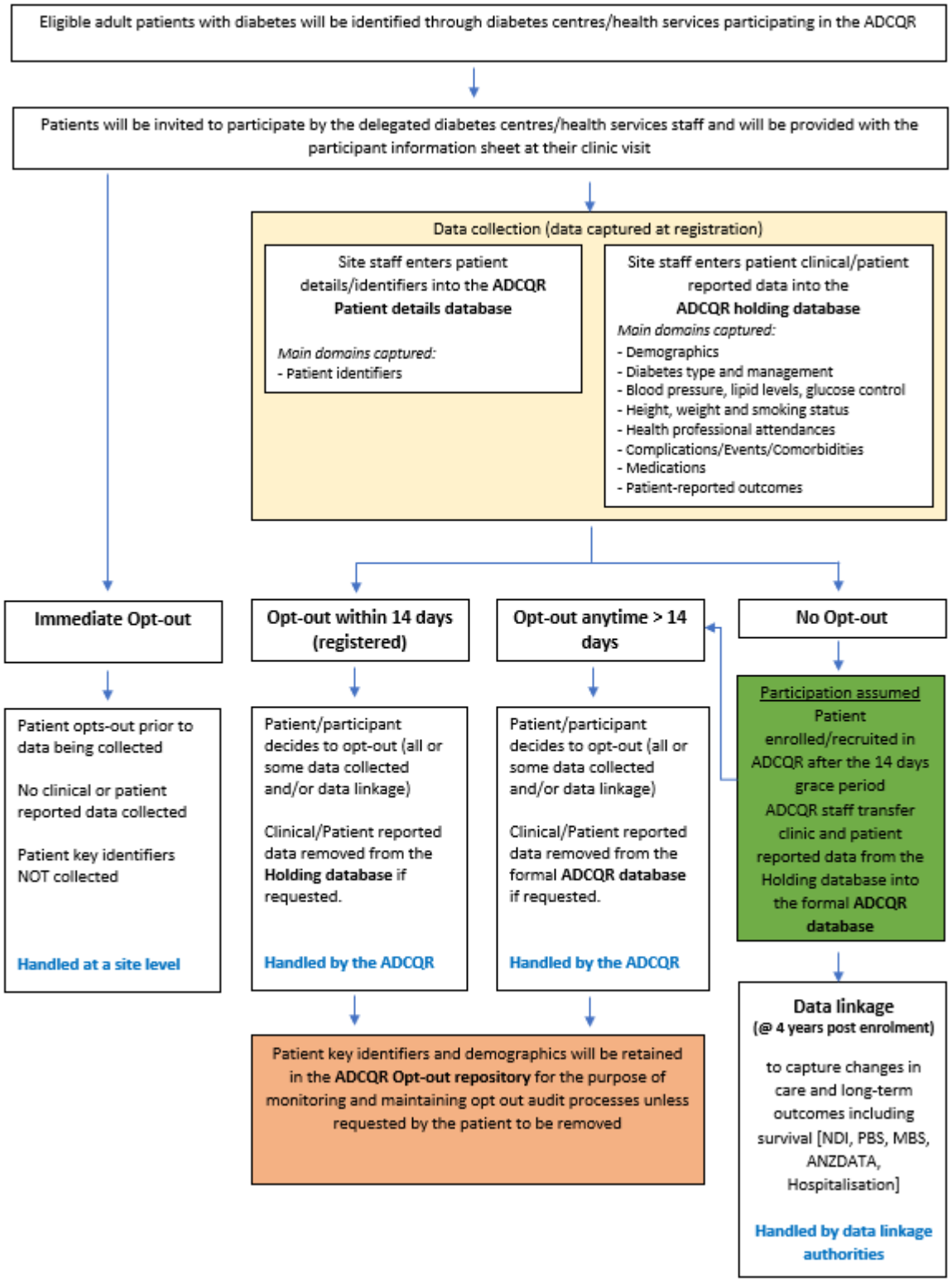
5.4.4. Aboriginal/Torres Strait Islander Considerations

The Registry 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 Registry will adhere to the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) Code of Ethics for Aboriginal and Torres Strait Islander Research[62] and the Guidelines for Ethical Research in Australian Indigenous Studies (GERAIS) produced by the Australian Institute of Aboriginal and Torres Strait Islander Studies. [63,64] These guidelines embody the best standards of ethical research and human rights and seek to ensure that research with and about Aboriginal and Torres Strait Islander peoples follows a process of meaningful engagement and reciprocity between the researcher and the individuals and/or communities involved in the research.

Consultation has been sought through a consumer advisor of the Aboriginal/Torres Strait Islander community and accepted. Information about the Registry and patient involvement has been presented to and communicated between this representative and the ADCQR Management Team.

Figure 3. Schema of the registry recruitment, data collection and opt-out process



5.5. Data

5.5.1. Data collection overview

The ADCQR data collection and timetable of data collection is outlined in Table 2 and Table 3, respectively. The reporting and analysis overview is outlined in Figure 4.

Participating sites will collect/enter patient data for a cohort of patients over a consecutive four-week period during the months of May/June of every year. This sampling period may be extended up until the censorship date of 31 August upon agreement between sites and the ADCQR Management Team to accommodate for any delays in ethics and governance approvals, and/or reliant on the site's capacity to collect more data. The cohort may include patients who have participated in the Registry in previous years, as well as new participants. Please note - the sampling period can be extended to suit the site's ability and capacity to collect more data.

This cohort captured in every year will comprise of two sub-cohorts:

1. Adult patients that are recently diagnosed with diabetes and captured from the beginning of their diagnosis (diagnosed with diabetes within the last 12 months).
2. Adult patients that have a diagnosis of diabetes greater than 12 months.

Data to be collected will include key clinical indicators and patient-reported outcomes. One data linkage to information held by Australian Commonwealth and State and Territory agencies related to the objectives of the Registry will occur at four years after the patient is registered in the ADCQR (Table 2).

Sites will collect data on patient demographics, key clinical indicators and patient-reported outcomes for the two sub-cohorts. The proposed health outcomes captured by the ADCQR include (refer to Table 1 for further details):

- 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
- Patient-reported outcomes to support the collection of data related to self-management of diabetes and quality of life.

The selection of data fields and their definitions are derived from national data specifications such as Metadata Online Registry (METeOR)[65] where they exist and from international data dictionaries where terms are not defined within the Australian context. A detailed data dictionary containing the data

elements, formats, ranges and validation rules and definitions will be maintained under document management with version control.

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

While the ADCQR will encourage all sites to collect all data electronically, not all sites have the capacity/ability to collect data via this format. The ADCQR will offer three formats for data collection with secure protocols for submission into the ADCQR:

1) Paper-based data collection – Site staff will complete data collection forms manually. Upon completion of the data collection period, sites will scan and send pdf versions of the paper forms in one batch through a secure file transfer protocol (SFTP) to the ADCQR Secretariat. Paper-based data collection forms will be retained/archived at the site according to their retention/archive policies.
2) Electronic data collection web-based interface (REDCap) stored on a secure Monash University server - Assigned site staff members will be allocated a unique username to access the database. Data will be entered in real time (during the patient consult) directly into the ADCQR holding database. After data entry completion, sites will be able to download, print and file a pdf version at their local site. Site staff will be trained to use the database and will be provided with a data entry manual to assist with good quality data collection.
3) Electronic data extraction – completed data extracted from the site will be sent in one batch through SFTP to the ADCQR Secretariat. Clinical data can only be collected through this format. Sites collecting data through this format will be unable to extract patient-reported outcomes as it is data that is collected directly from the patient. Sites will be given an option to collect patient-reported outcomes into the ADCQR via the paper based or the web-based data collection format. Where possible, Registry staff will assist sites to extract relevant data directly from their hospital systems to assist the data collection process. This may be through applications installed by third-party providers or through an upload of regular hospital data extracts.

All Registry data will be kept electronically. Paper based forms will be required to be scanned and the pdf version sent through to the ADCQR Secretariat via SFTP. These will be stored electronically, for tracking purposes, on a Monash University Server (infrastructure located in Australia). Data will be backed up daily and all traffic between the data enterer's device, the web server, database server and file server will be encrypted. All authentication and authorisation related information will be encrypted and stored securely.

Censorship dates for electronic data import into the ADCQR and paper-based data submissions through a SFTP will be 31 August of every year. This will allow sufficient time for the ADCQR Data Management Team to process, validate and analyse all data for timely pooled and site benchmarked reporting.

5.5.2. Data linkage

Data linkage provides 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 the ADCQR to follow-up its outcomes into the future.

Data linkage to information held by Australian Commonwealth and State and Territory agencies, as well as other clinical registries and pathology databases, related to the objectives of the Registry will be undertaken once, at four years after the patient is registered in the ADCQR. This will include the National Death Index (NDI), National Diabetes Services Scheme (NDSS), Pharmaceutical Benefits Scheme (PBS), Medicare Benefits Schedule (MBS), the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA) and hospitalisation data. Data linkage will be performed by accredited national and state data linkage organisations (using probabilistic linkage methods).

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. This includes the School of Public Health and Preventive Medicine (SPHPM), Monash University, who are the data custodians of the ADCQR, as well as the data custodians of the other datasets to be linked.

2. Data Linkage Organisations who link the datasets from different organisations together. There are two national accredited integrating Authorities that can perform data linkage for ADCQR data collections:
    i. Services Australia and
    ii. Australian Institute of Health and Welfare (AIHW)

    There is also a network of jurisdiction data linkage units which service each state and territory. For example, the Centre for Victorian Data Linkage (CVDL) is a state-based accredited integrating authority, acting as a trusted intermediary, with approval and collaboration of data custodians, and can undertake linkages to Victorian health and human services datasets.

3. Researchers who use de-identifiable linked data for the purposes of analysis and research/report preparations. For example, the ADCQR Biostatistics Unit within SPHPM will only have access to ADCQR deidentified linked data.

5.5.3 Internal longitudinal reporting

As per section 5.5.1, sites will collect data on all patients attending their diabetes service over a consecutive four-week period during the months of May/June of every year, which may be extended up until the censorship date of 31 August upon agreement between sites and the ADCQR Management Team. The cohort may include patients who have participated in the Registry in previous years, as well as new participants, and therefore follow-up may be periodic.

The Registry will monitor the participants captured in the Registry each year to establish the proportion of new and existing participants and ensure that the cohort captured continues to grow over time. The Registry will code all participants. As the ADCQR matures and reliant on the size of the

cohort with data captured in multiple years, internal longitudinal reporting may be undertaken. De-identified grouped/aggregate longitudinal data captured by the Registry may also be used for research purposes.

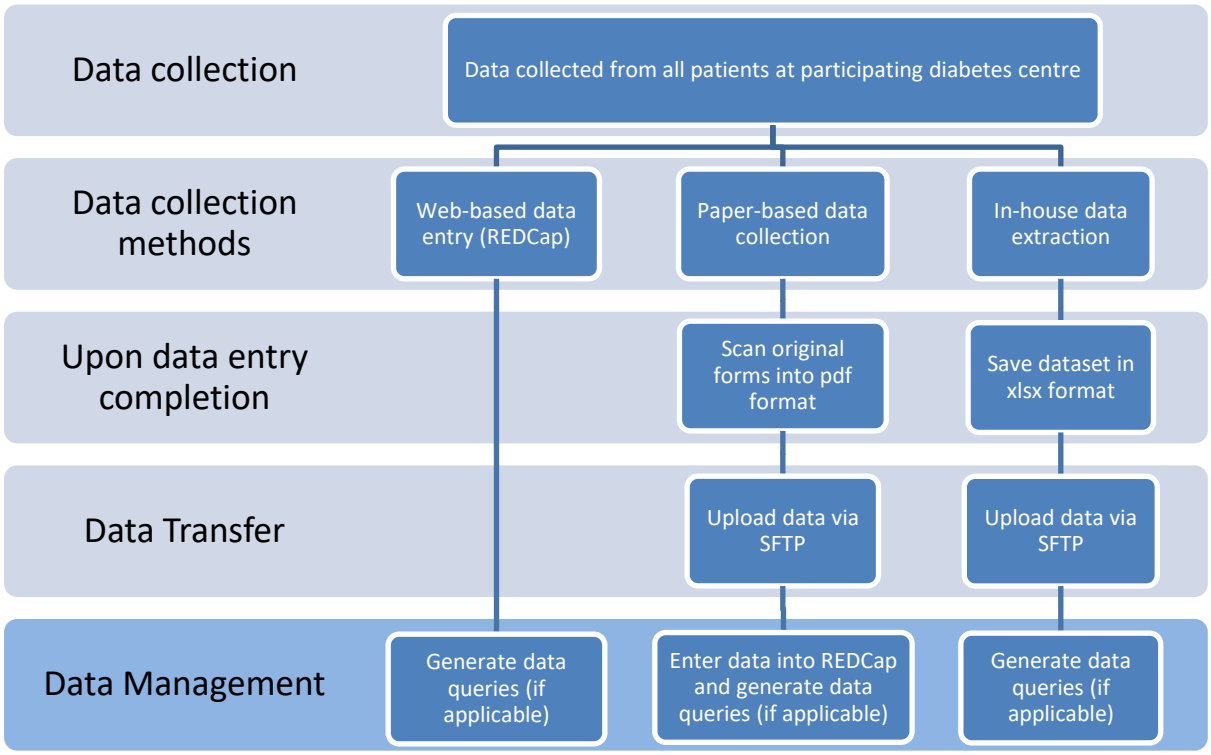
Table 2: ADCQR data collections

	Data collection of the ADCQR
Cohort	Every year the Registry will capture a cohort during the specified sampling period that may include new participants to the DQCR as well as patients who have participated in the ADCQR in previous years. (N.B. In Year 1 of the Registry's implementation, the cohort will include new participants only)
Population captured	Adults (aged ≥18 years) with T1DM or T2DM or other (secondary diabetes) and • recently diagnosed diabetes (≤12 months from their diagnosis date) • known diagnosis of diabetes (>12 months from their diagnosis date)
Data collection (sampling) period	4-8 weeks during May/June [Period can be extended up until the censorship date of 31 August]
Data collected from participating site	See Table 1 • All key clinical quality indicators Patient-reported outcomes
Avenue of data collection	• Key clinical quality indicators: Medical Records or during consult • Patient-reported outcomes: Self-reported by patient during consult
Formats for data collection	Web faced database Data extraction Paper-based
Censorship date of data upload into ADCQR	31 August

Table 3: ADCQR data collection

	Data items collected	Annual data collection sampling period	Data linkage
ADCQR data collection	**Demographics** Name, DOB, sex, address, date of diagnosis	X	
	Eligibility confirmation	X	
	Diagnosis Diagnostic test results, staging, method of diagnosis, comorbidities	X	
	Treatment/ Management Clinical indicator data (Refer to Table 1)	X	X
	Patient-reported outcomes	X	X

Figure 4: Data collection and secure file transfer overview



5.5.4. Data quality

Data completeness and accuracy will be optimised through in-built validation and completion checks in the Registry database to minimise data entry error. These include:

- Data entry controlled by form logic and limited to feasible data
- Use of in-built edit checks to ensure data meets required formats and ranges
- Use of exhaustive drop-down lists providing all possible answers to enhance accuracy and minimise free text entry where applicable.
- Use of hide and show mechanisms to guide data entry to required fields
- Use of explanatory texts to assist data entry
- Validation rules applied at the time of submission with alerts to assist with errors and missing data
- Use of a participant management system to list incomplete data and other actions required

Additional quality checks post data entry will include checks for:

- duplicate data
- cross checking data obtained from multiple sources – medical notes vs self-report
- missing data
- data consistency

Quality checks may be undertaken by the ADCQR Data Management Team for case ascertainment and data accuracy and completion at regular intervals. Data quality and completeness will be checked at a number of stages of the data management process. Errors in data quality, when identified, may be referred back to contributing sites for review.

Site staff collecting and entering data will be encouraged to conduct their own internal audits to ensure that all relevant cases are captured in the Registry and for data completeness of existing records. An assessment of the data collection requirements in light of developed clinical indicators, annual and other reporting and research requirements will be undertaken to maximise the collection of near complete, high quality data.

5.5.5. Data confidentiality

Data will be collected by the Registry in identified form to facilitate data linkage and for internal longitudinal reporting purposes. Patient identifiers will be kept in a separate database to demographic, clinical and patient-reported data. Data released for analysis will only be done so in a re-identifiable (coded) form. In publication reporting of the epidemiological and clinical characteristics of participants enrolled in the Registry, only de-identified grouped/aggregate data will be released.

Clinical quality indicators and patient-reported outcomes along with personal identifiers will be linked through the use of a unique code number that will be created and assigned by the participating site to each patient/participant entering the ADCQR. The participating site will be required to keep a record log on site in order to follow-up on any data queries that require clarification.

Patient identifiers will only be available to key staff within the ADCQR. The ADCQR Management Team will only have access to this information to maintain participant confidentiality and for opt-out audit mitigation processes.

For participating sites collecting data through the paper-based format, separate participant details forms containing participant identifiers will be required to be completed, scanned in a pdf version and uploaded via SFTP.

For participating sites opting to collect data via data extraction, personal data containing patient identifiers will be presented in Microsoft Excel along with the clinical indicator data and uploaded via SFTP. All personnel at sites involved in treating patients and providing data to the Registry will undertake training by ADCQR staff to ensure that they understand their obligations in regard to data confidentiality and privacy relating to research activities. Each Registry database user will have their own username and password to access the database. Staff at recruiting centres will only have access to their own patients at their site (or central data collectors may only have access to patients at hospitals that they have been assigned to).

ADCQR staff will be trained in confidentiality, privacy and Good Research Practice through both the University's onboarding program and through additional good research practice training.

Annual reports, benchmarking reports, other ad hoc reports and research will use aggregated data, ensuring patient confidentiality. For benchmarking purposes, reporting of comparative data will be de-identified so that sites will only be aware of their own identity in any communal graphical or other display of information.

5.5.6. Data Security

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

1. The REDCap application is hosted on the web server hosted at Monash University's managed location in Australia.
2. To ensure the data are not compromised in transit, all communication between the participating site's browser and the 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. ADCQR Secretariat, Principal Investigator or Data Manager). When ADCQR is notified that a staff member has left the project, their access to the system will be removed. ADCQR 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 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 is the responsibility of the Site Coordinator who oversees each site's operations.

Any staff with access to data will be trained by the ADCQR Management Team (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 ADCQR Management Team, which include the Monash staff working directly with the Project Manager, will have access to raw ADCQR cohort data. Table 4 outlines access to different data components housed in the database.

Table 4: Database access

Data Type	Database Access		
	Participating Sites*	ADCQR Management Team	Biostatistician
Patient identifiers	✓	✓	
Patient contact details	✓	✓	
Health outcome data	✓	✓	✓

*Participating sites will only have access to their own patient data.

5.6. Patient Risk Management and Safety

Participation in the Registry involves the collection of data from medical records, and/or health professionals, directly from the patient, and from data linkage to datasets held by the Australian Commonwealth and State and Territory agencies, and other clinical registries. This is unlikely to result in any harm to patients as the information collected during their clinical visit is part of their clinical care. Some patients/participants may experience minimal discomfort when answering questions related to patient-reported outcomes. To minimise discomfort (if any), it is at the discretion of the participating site health professional staff to assist in the completion of this component with new patients/participants. Patients/participants can also choose not to participate in this component.

Monash University values the privacy of every individual's personal and health information and is committed to the protection of personal information. In minimisation of security breaches, personal and health information is handled in accordance with the Privacy and Data Protection Act 2014 (Vic), the Health Records Act 2001 (Vic), as well as the European Union General Data Protection Regulation 2016/679 (EU) where applicable.

If awareness of a data or privacy incident is raised, including an actual or suspected data breach, it will be immediately reported to the University's Data Protection and Privacy Office.

Risk management will be reviewed during regular team meetings, monitoring the activity and expected timelines. Any issues with data collection from the participating site(s) will be addressed through communications through the ADCQR Secretariat.

5.7. Information Output

As per the 2008 ACSQHC Operating Principles, the ADCQR will produce a range of regular reports including annual reports and benchmarked reports. Figure 5 depicts the data analysis and reporting cycle for the ADCQR.

5.7.1. Annual reports

A publicly available annual report will be provided to sites detailing descriptive results presented as frequencies and percentages for categorical variables and mean and standard deviation for continuous variables. Reported characteristics include:

- Clinical characteristics - demographics, blood glucose monitoring, diabetes management, risk factors and complications.
- Patient-reported outcomes - quality of life and wellbeing, self-management of diabetes including diabetes education, and healthcare utilisation.

Data analysis and reporting for annual pooled reports may include:

- Pooled data
- Data frequency counts
- Missing data
- Descriptive report (data tables and graphs)
- Comparative statistics by year of collection

5.7.2. Benchmarked reports

Benchmarked reports comparing clinical quality indicators across sites will be provided to participating sites on an annual basis following sufficient data collection for meaningful results. Such standardised cross-sectional reports will be confidential to the recipients but presented with de-identified comparative measures benchmarked to like sized/type of services.

Where outliers exist, these will be managed by the ADCQR Scientific Advisory Committee together with ADCQR Data Management Team in accordance with Monash Universities outlier management policy. This involves analysis to determine the cause of outliers, investigating variables including data, patient case mix, resourcing, process of care and clinical for the remediation of outliers to maintain workforce and ensure safety and quality.

Data analysis and reporting for individual site data reports will include:

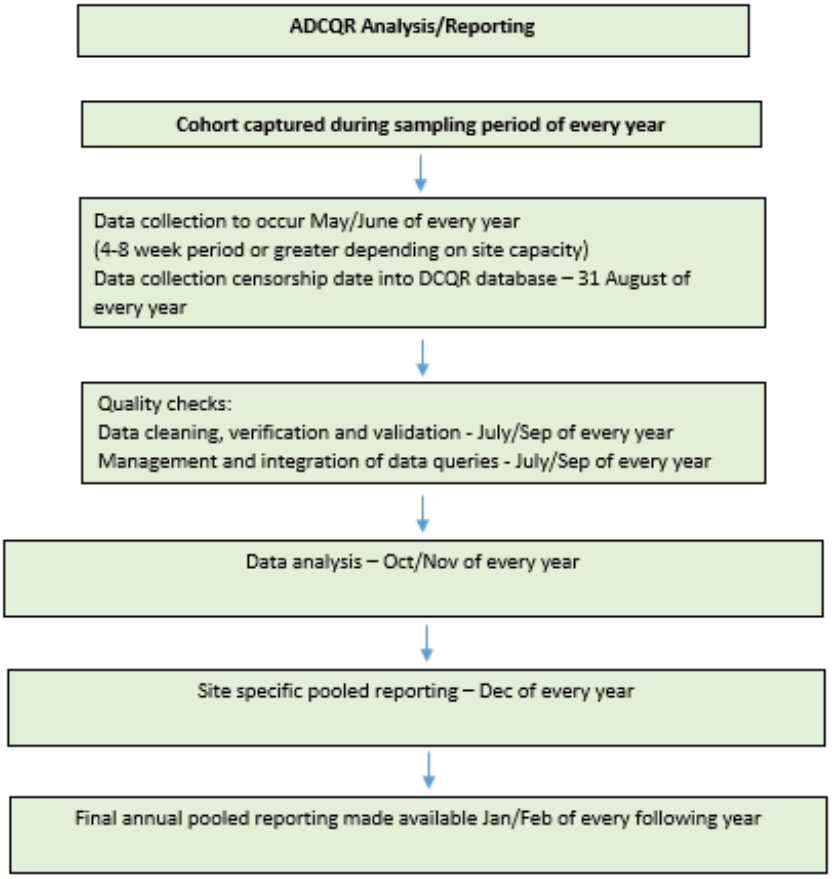
- Site report at a glance
- National benchmarking report
- Historical comparison report (if applicable)
- Descriptive report (data tables and graphs)
- Data compared against Clinical Management Guidelines for Diabetes (Clinical component only)
- Quality Improvement (QI) guide

5.7.3. Data access for research and non-research purposes

Sites will be able to access their own data through the Registry database. Ad-hoc reports may be prepared following data requests approved in accordance with the ADCQR Data Access Policy (Appendix 3). This may include access for non-research use for regulatory or other activities. Researchers may access Registry data for the purposes of undertaking their own external analysis following approval by the ADCQR Scientific Advisory Committee and Ethics Committee as per the ADCQR Data Access Policy. Where a request for data for research purposes utilises only de-identified Registry data, ethics approval for the project may be sought from a single ethics committee. All data will be released for analysis on the Monash Secure eResearch Platform (SERP), a secure environment for sharing research data for collaboration and analysis.

Monash's ADCQR Coordinating Centre is the point of contact for matters relating to access to Registry data (see Section 7 for contact details).

Figure 5: Data analysis and reporting cycle



6. Statistical Methods

6.1. Statistical Methods to be Undertaken

All analyses on the ADCQR data for the pooled reports/site benchmarked reports will be undertaken with the support of the Biostatistics Unit at SPHPM, Monash University.

6.1.1. Statistical Analysis Plan

Overall Objective

The overall aim of the Registry reporting is to provide risk-adjusted benchmarked clinical quality indicator reports to diabetes centres across Australia and to undertake appropriate longitudinal tracking of individual centres and patients over time

Primary Aim

The primary aim is to provide risk-adjusted clinical quality indicator reports to diabetes centres for a set of clinical endpoints using funnel plots, with the purpose of centres being able to benchmark their performance against others.

Secondary Aim

The secondary aim is to benchmark each centre's performance against their historical values and provide this information to allow for an early warning trend tool for any possible worsening outcomes using the variable life adjusted display (VLAD) plots.

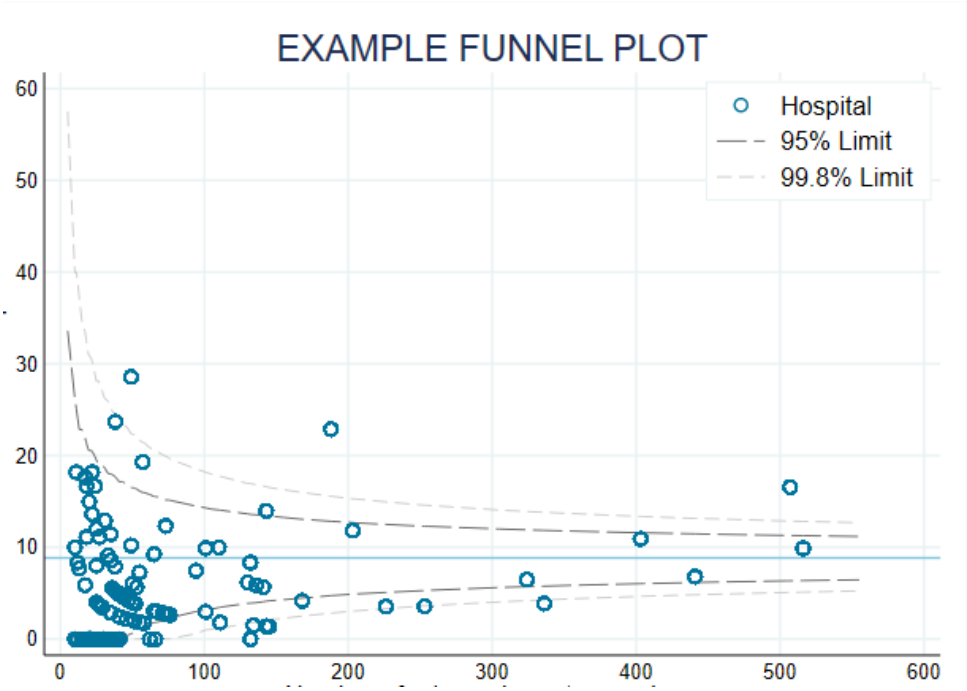
6.1.2. Statistical Methods

Benchmarking - Funnel Plots

Unadjusted and risk adjusted funnel plots will be generated for selected clinical outcomes. Funnel plot is a visual representation of how individual sites' performance compared to their peers and the overall average; it also identifies outliers (i.e. those who are performing better or worse than the average). The funnel plot contours represent two standard deviations (95% control limits) and three standard deviations (99.8% control limits) from the mean, those above and below these lines are considered outliers, with a 5% and 0.2% chance of a false positive. The binary logistic regression model will be used to identify significant risk factors. For continuous and count data, the Gaussian and Poisson distribution will be used instead. Risk-adjustment considers differences in patient-level risk-factors; it enables adjustment for confounding variables which are beyond the control of the clinician or healthcare system. The variables used in the risk adjustment model will be noted under each funnel plot.

The variables used in the risk adjustment model will be based both on clinical and statistical considerations. Based on an initial list of clinically plausible variables provided by the ADCQR Scientific Advisory Committee, the likelihood ratio test ($p<0.05$) will be used to determine covariates that are significantly and independently associated with the outcomes. Missing data on the categorical variables will be grouped as a "missing" category and included in the analyses. An example of a funnel plot is shown in Figure 6.

Figure 6. Risk-adjusted funnel plot for diabetic complications by centre/hospital

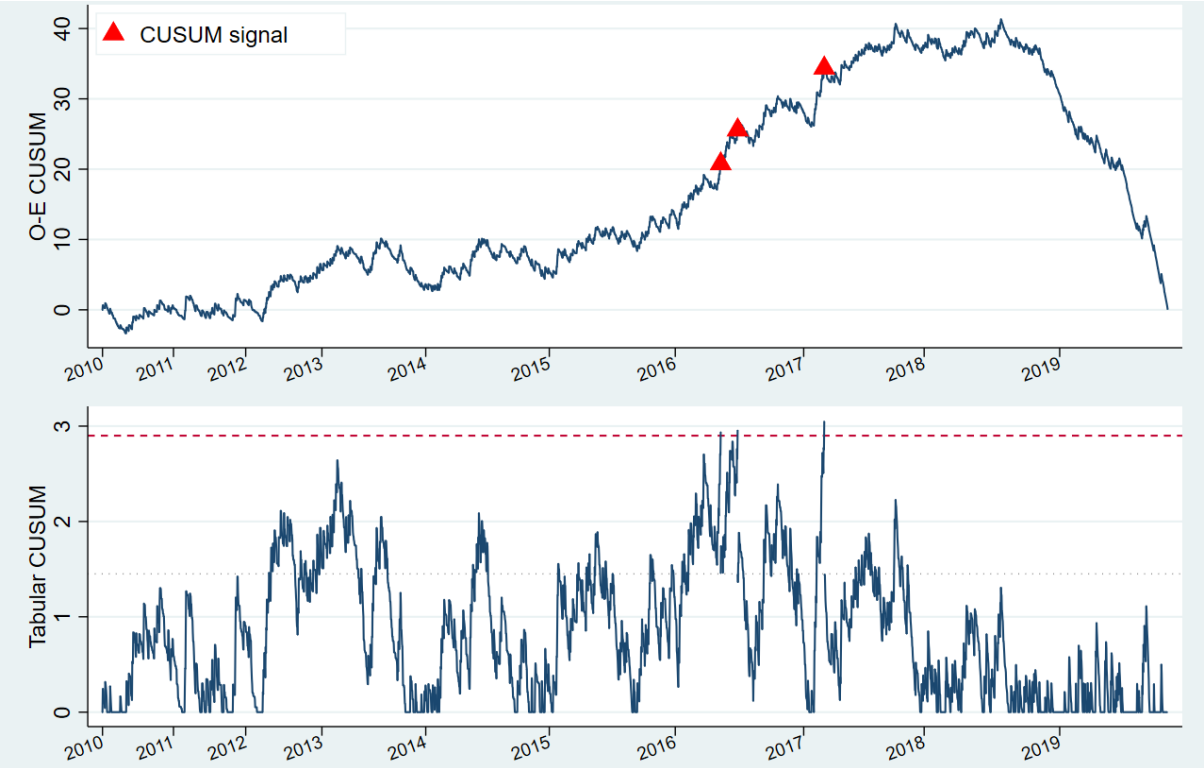


Each centre is represented by a circle that plots the number of patients by the percentage of cases with complications at that centre. The solid line represents the pooled average percentage of all observed cases with complication from all centres combined.

Site tracking - VLAD plots

Risk-adjusted Variable Life Adjusted Display (VLAD) plots will be generated for each site that has >=50 cases to ensure there is enough samples to provide a robust tracking tool. VLAD incorporates a risk adjusted probability using the same risk adjustment process described above. The VLAD then plots the difference between the observed and expected (O-E or VLAD type CUSUM), vertically aligned with tabular (sequential probability ratio) CUSUM over sequential observations over the time of visit/clinic dates. Exceeding the decision threshold on the tabular CUSUM places a corresponding marker on the O-E CUSUM, and flags a time when there is an unusually high spike in adverse outcome for the site. Following a red flag, the series get re-started to the baseline value to ensure the signal is responsive to subsequent changes in data over time. Average run length (AR0) when the process is in control and average run length when there is a signal (ARL1) will be determined through simulation analysis. An example of a VLAD plot is shown in Figure 7. Data analysis will be performed in R/ Stata software.

Figure 7. VLAD plots for diabetic complications for centre ID "XXYY"



Clinical Endpoints/ Quality Indicators

A list of quality indicators will be identified in consultation with the ADCQR Scientific Advisory Committee. These include HbA1c, number of diabetes-related complications in the past 12 months, including diabetic ketoacidosis, severe hypoglycaemia, hypoglycaemia, and hospitalisations, etc. The indicators will be ranked as primary and secondary quality indicators and operational definition of the variables (including numerators and denominators for rates) will be created.

Risk Adjustment

Risk-adjustment variables include patient age, body mass index (BMI), gender, smoking status, comorbidities, etc. A list of risk-adjustment variables will be identified from the literature and clinical input a-prior and careful consideration will also be given to the statistical quality of the data collected in the Registry (including issues of missing data and bias) before inclusion in the model. An a-priori structured process of variable selection based on the likelihood ratio test will then be utilised to select the final list of variables for risk adjustment in the model.

Subgroup Analysis

All analyses will be stratified by centre type (primary, secondary and tertiary), provided there are sufficient numbers.

Data for women with diabetes who are pregnant during the data collection period will be presented separately.

Missing Data

Missing data will be included in the model for each covariate as a separate category to preserve the overall sample size and ensure comparability between unadjusted and risk adjusted analysis. There will be no imputation of missing data as the assumption of missing at random cannot be verified.

Implications

Providing clinicians and public institutions risk-adjusted reports of their clinical outcomes is a vital public health quality assurance activity. A site receiving a report suggesting they were an underperformer can investigate the root cause. There is significant evidence from other fields of medicine that reporting benchmarked outcomes back to clinicians improves clinical outcomes.[45, 50, 66] The mechanism for this improvement is clinicians implementing evidence-based changes to their practice, based on the factors observed by the registry to be associated with better outcomes. The ADCQR will be used to monitor any changes in outcomes with time.

7. ADCQR Coordinating Centre and Management Team

The ADCQR Coordinating Centre is Monash University. Monash University Registry Staff working out of the SPHPM will project manage the Registry's core activities under direction of the ADCQR Scientific Advisory Committee.

Registry activities will include:

- Overall management of the Registry
- Management of Registry budget
- Ethical oversight and management on behalf of participating sites,
- Monitoring/audit visits to participating sites
- Training of participating sites/or inhouse data collectors
- Data management and data querying
- Maintaining data collection in a secure environment
- Data analysis
- Reporting
- Data access request management

For all registry related enquiries regarding day to day operational activities, including access to data, please contact the ADCQR Coordinating Centre.

Contact details:

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8. Organisation and Governance

8.1. Registry Responsibilities and Governance

The ADCQR is a multi-centred, investigator driven endeavour. The principal investigator (PI) at each site will be responsible for ensuring that research activities undertaken at their site are conducted in accordance with the research protocol, site Registry agreements and related policy documentation. Site research activities include recruitment of patients and data submission and will be conducted at participating hospitals by site staff, overseen by the PI at each site.

Day to day project management will be undertaken by ADCQR at SPHPM, Monash University. While Monash Registry staff will oversee all project related activities, participating hospitals will ultimately be responsible for ensuring timely and accurate data collection (where central data collection is not used). This will be supervised by the Data Manager and Project Manager who will report and provide feedback through the ADCQR Secretariat on data completion and quality to sites and the ADCQR Scientific Advisory Committee.

The ADCQR will engage key national stakeholders in diabetes research and treatment. The governance structure will be in keeping with the operating principles established by the ACSQHC. The formation of the ADCQR Scientific Advisory Committee will be broad based with representation from Monash University, allied health, clinicians, Primary, Secondary and Tertiary Health services, government bodies, Colleges [Royal Australian College of General practitioners (RACGP)], Professional Associations/Advocacy groups and consumer representatives.

The ADCQR Scientific Advisory Committee will meet four times a year and have a significant role in guiding the Registry strategy and policy, ensuring deliverables are met, identify issues and review data requests, reports and publications.

A Management Committee (Project Executive) will be established to oversee the day to day running of the Registry that will involve Monash University Registry Staff (Management Team), the data custodian and the clinical lead. Further subcommittees may be established as required.

Monash University is the data custodian. Custodianship responsibilities of Monash University entails accountability for the information held within the Registry.

8.2. Scientific Advisory Committee Membership

List of the ADCQR Scientific Advisory Committee members

Name (Role)	Position Organisation
(Chair)	As appointed
Professor Sophia Zoungas (Australian Diabetes Clinical Quality Registry Lead)	Head of School of Public Health and Preventive Medicine Monash University Head, Division of Metabolism, Ageing and Genomics
Associate Professor Sofianos Andrikopoulos (Representative for stakeholder engagements/communications)	Chief Executive Officer Australian Diabetes Society (ADS)
Ms Natalie Wischer (Representative for stakeholder engagements/communications)	Chief Executive Officer National Association Diabetes Centres (NADC)
Ms Taryn Black (Representative for stakeholder engagements/communications)	National Director- Policy Programs and Communications. Diabetes Australia (DA)
Professor Barbora de Courten (Clinical Representative)	General Physician, Monash Health
Professor Jeff Flack (Clinical Representative)	Director, Diabetes Centre Bankstown-Lidcombe Hospital
Professor Jenny Gunton (Clinical Representative)	Endocrinologist, Head, Centre for Diabetes, Obesity and Endocrinology Research (CDOER) Chair of Medicine at Westmead Hospital
Dr Gary Deed (Representative from Primary Health sector)	Chair, RACGP Diabetes Specific Interests Network
Dr Konrad Kangru (Representative from Primary Health sector)	General Practitioner Whitsunday Doctors Service
Diabetes Educator Representative	TBA
Dr Odette Pearson (Aboriginal and Torres Strait Islander representative)	Senior Research Fellow Wardliparingga Aboriginal Research Unit South Australian Health and Medical Research Institute (SAHMRI)
Ms Sally Rayner (Australian Government Department of Health)	Director, Health System Clinical and Patient Outcome Section Australian Government Department of Health Business Case Sponsor representative
Ms Megan Phelan (Australian Government Department of Health)	Policy Officer, Clinical Quality Registries Section Health Economics and Modelling Branch Health Economics and Research Division

Name (Role)	Position Organisation
	Health Systems Policy & Primary care Group Australian Government Department of Health Business Case Sponsor representative
Associate Professor Wendy Davis **(Data/science expert)**	Principal Research Fellow, The University of Western Australia
Professor Jane Speight **(Data/science expert)**	Director, Australian Centre for Behavioural Research in Diabetes
Mr Trevor Jones **(Consumer Representative)**	Nominations through consumer organisations [Limbs 4 Life]

8.3. Funding

The Australian Government Department of Health has funded the conduct of ADCQR from 2021-2022. Further funding may be sought during the life of the Registry.

9. Significance

The ADCQR endeavors to become a learning health ecosystem in diabetes care with the vision of participating services/centres continuously learning from the data collected. Its importance is in the improvements in the areas of quality and safety, and the promotion of the ADCQR for research use.

The ADCQR has the potential to improve understanding of current practice in the treatment of people with diabetes and its reasons for variation in outcomes. It will improve understanding of diabetes care and associated risk factors for complications. It will increase awareness on the gaps in the standard of care, and that early detection and specific intervention programs are required to reduce the development and impact of diabetes complications.

By working in partnership with the Australian Government, states and territories, the private sector, clinical experts, and patients, the ADCQR aims to improve quality of patient care through comparisons of health services and diabetes centres in Australia, and furthermore facilitate research.

10. Appendix

List of supporting documents

Appendix No.	Document Name
1	Master Participant Information Sheet (Explanatory statement)
2	Participating site example script
3	Data Access and Publication Policy
4	Master Participating Site Information Sheet

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