Kimberley Aboriginal Health Planning Forum

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Protocol Review Evidence Used and Rationale

Protocol name: Type II Diabetes in Adults

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Name: during this review the name was changes from "Type II Diabetes" to "Type II Diabetes in Adults" to acknowledge that Type II Diabetes in children is covered in a different protocol.

Rationale:

The Type II Diabetes in Adults protocol provides Kimberley specific guidance for the screening, diagnosis & management of type II diabetes in adults. It is informed by Australian guidelines and locally produced research from the Kimberley Aboriginal Medical Services (KAMS) and the Rural Clinical School of Western Australia (RCSWA). Type II diabetes is highly prevalent in the Kimberley with prevalence estimates for adults 15 years and over in some communities between 24% and 34%. Disease occurs at a young age and prevalence accelerates quickly by the mid-thirties. Early diagnosis and glycaemic management is important to minimize long-term complications, which are also prevalent in the Kimberley (including cardiovascular disease, end-stage renal failure, foot ulcers & amputation).

Important updates in this review include:

- Specific advice for identification and management of the state called "prediabetes".
- Transition from the use of exenatide (Byetta, Bydureon) to dulaglutide (Trulicity) which is in keeping with the updated Kimberley Standard Drug List (KSDL).
- Inclusion of guidance for the use of the newest oral hypoglycaemic class, SGLT2 inhibitors, with empagliflozin available on the KSDL.
- Inclusion of an alternate DPP-4 inhibitor (linagliptin) now listed on the KSDL that does not require dose reduction in renal impairment.

Areas highlighted for review at next update:

- Prediabetes: the current prediabetes range of 5.7-6.4% may require further refinement t in the future (see below).
- Treatment algorithm: review to ensure up to date and has ongoing congruence with the Pharmaceutical Benefits Scheme (PBS). Consider management algorithms that focus on individual risk profiles.
- SGLT2 inhibitors: review of advice for use in the Kimberley.

Discussion Points:

Screening & Diagnosis

Our protocol provides guidance to use glycated haemoglobin (HbA1c) as the primary pathological test for screening of type II diabetes in Aboriginal adults 15 years and over annually.

HbA1c is now acceptable as a diagnostic test for diabetes, as endorsed by the American Diabetes Association (ADA) in 2010, the World Health Organisation (WHO) in 2011 and the Australian Diabetes Society (ADS) in 2012. The Medicare Benefits Schedule (MBS) approved annual HbA1c for the diagnosis of diabetes in asymptomatic patients at high risk in November 2014, after which time the KAHPF type II diabetes protocol was updated to reflect this. Aboriginal patients qualify for this testing based on the high rates of type II diabetes in the population.

Our current screening algorithm was reviewed in the study "Using glycated haemoglobin testing to simplify diabetes screening in remote Aboriginal Australian health care settings" by Marley et al (1) . This study found that when compared to an algorithm using glucose and oral glucose tolerance testing (OGTT), that the HbA1c algorithm simplified diabetes testing in remote areas, provided more timely diagnoses and increased case detection.

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Australian guidelines, as well as the WHO and ADA, suggest that abnormal screening tests for diabetes in an asymptomatic patient should be confirmed with a second laboratory test to establish a diagnosis of diabetes (2). However, a single elevated HbA1c result is accepted by the MBS as evidence for established diabetes, due to HbA1c being more "robust and reproducible" than blood glucose testing (3). This has informed our protocol's screening and diagnostic algorithm, which requires only one diagnostic HbA1c to diagnose type II diabetes. This algorithm also acknowledges that screening for diabetes in remote Aboriginal Australian setting is challenging, with fasting samples, OGTTs, and timely follow up after an abnormal laboratory result often difficult to obtain. Several factors contribute to this including a population that travels frequently between communities, a high burden of social and emotional distress, other life circumstances that may need to take priority over health care and telephone contact details that may not be up to date.

Our protocol encourages the use of point-of-care (POC) HbA1c testing for screening and monitoring of diabetes. POC testing allows patients to receive results within one consultation, on the same day. This is beneficial as diagnosis, education and management can be provided at the same time for our patients who may travel between communities and may not be otherwise followed up in the short-term. The publication "Cross-sectional comparison of point-of-care with laboratory HbA1c in detecting diabetes in real-world remote Aboriginal settings" (4) showed good concordance between laboratory and real-world remote setting POC HbA1c in Kimberley Aboriginal Medical Services.

HbA1c testing does pose some limitations and it is important that clinicians are aware of medical conditions that can affect the reliability of HbA1c results (5). Any condition that shortens erythrocyte survival or decreases mean erythrocyte age will falsely lower HbA1c test results (6). The presence of abnormal haemoglobin variants can cause unusually high HbA1c or unusually low HbA1c (6).

Table 1: Factors affecting HbA1c (adapted from WHO & RACGP (5, 6)).

Mechanism	**Increased HbA1c**	**Decreased HbA1c**
Erythropoesis	Iron, vitamin B12 deficiency Decreased erythropoiesis	Administration erythropoietin Administration iron, B12 Reticulocytosis Chronic liver disease
Altered Haemoglobin	Haemoglobinopathies HbF Methaemoglbin	
Glycation	Alcoholism Chronic renal failure	Aspirin Vitamin C & E Certain haemoglobinopathies
Erythrocyte destruction	Splenectomy	Haemoglobinopathies Splenomegaly Rheumatoid arthritis Drugs eg antiretrovirals, ribavirin, dapsone
Assays	Hyperbilirubinaemia Alcoholism Large doses aspirin Chronic opiate use Carbamylated haemoglobin	Hypertriglyceridaemia
Other	Steroid therapy, stress, surgery or illness in the past three months	

Random capillary glucose testing is often used in clinics in both diabetics and non-diabetics. While we believe there are limited indications for random capillary glucose testing in clinic (e.g. people with diabetes on medications that can cause hypoglycaemia, people with and without diabetes who present unwell) outlining the use of random capillary glucose testing is beyond the scope of this protocol. Screening for diabetes should be by annual HbA1c testing not by random blood glucose testing. We have provided some guidance for high random capillary glucose reading results, as these should not be ignored. A random capillary glucose reading of 5.5 or more is a risk factor for underlying undiagnosed diabetes and HbA1c testing should be performed if not done in the last 12 months (7). A random blood glucose of 11.1 or more is highly suggestive of diabetes (6) and a venous HbA1c and venous blood glucose should both be performed. This is to make sure that a fulminant hyperglycaemic process is not missed by performing HbA1c alone.

Prediabetes

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Prediabetes is a term used to describe individuals who have higher blood glucose levels than normal, but do not meet the criteria for diabetes (8). The term prediabetes is contentious among international organisations, with many guidelines still referring to impaired fasting glucose and impaired glucose tolerance to describe this group of people who are at increased risk of developing diabetes, as well as increased risk of cardiovascular disease (8). Currently, the ADA is the only group that provides guidance on using HbA1c to identify this group, giving a range of 5.7% to 6.4% (8). The National Institute for Health and Care Excellence (NICE) identify those with a HbA1c of 6.0-6.4% at high risk of progression to type II diabetes (9).

Concern has been raised that the prediabetes range of HbA1c 5.7-6.4% may be too broad, and label a large portion of the population as at risk, overwhelming health care services and diagnosing people with a condition that may not necessarily progress to diabetes (10). The management of prediabetes is widely agreed to be primarily that of lifestyle intervention – to encourage weight loss for those overweight or obese, and modify cardiovascular risk factors to reduce overall cardiovascular risk (smoking, blood pressure, hyperlipidaemia). This is management that we would encourage for all patients in the Kimberley, regardless of HbA1c, and KAHPF recommendations can be found in the Healthy Living protocol. It therefore begs the question, what else should be offered to those identified to have HbA1c levels in the prediabetes range in the Kimberley?

Our protocol recommends that these people should be offered intensive lifestyle intervention and vigilant follow up. Ideally this should be in the form of an appropriate intensive lifestyle intervention program. Currently, this is not always practically available, but there is hope for appropriate programs to become available in the future. For example, you can see "Piloting a culturally appropriate, localized diabetes prevention program for young Aboriginal people in a remote town" (11) which describes the piloting of a locally adapted community-led 8-week diabetes prevention program in Derby. Other lifestyle programs could be adapted in the Kimberley in the future, including the HEAL program by South Western Sydney PHN, and the DESMOND program from Diabetes WA. The RCSWA team is currently seeking ethics approval for an audit titled "Investigating progression of type 2 diabetes among Kimberley Aboriginal people to improve screening and prevention", which will help to determine the rate of progression from high range (6.0-6.4%) and low range (5.7-5.9%) prediabetes to type II diabetes and identify risk factors associated with progression. It is hoped that this audit can help to inform the next type II diabetes in adults protocol review, which may involve a refinement of the current prediabetes HbA1c range in order for Kimberley health services to focus resources better to prevent progression and cardiovascular disease. At this point in time, as there is wide consensus that the 6.0-6.4% HbA1c range is at particularly high risk of progression, we have highlighted the importance of this sub-group to receive intensive lifestyle intervention and vigilant follow up. These people in particular should be actively followed up, rather than only being placed on recall for repeat HbA1c in 12 months time.

Involvement of Aboriginal Health Workers & Practitioners (AHWs/AHPs) in Diagnosis and Medication Changes

Specific advice has been included in this protocol update to consider involving AHWs/AHPs when delivering a diabetes diagnosis or changing medications to assist with education and support. This advice is a direct recommendation from the study "Understanding lived experiences of Aboriginal people with type 2 diabetes living in remote Kimberley communities: diabetes, it don't come and go, it stays!" (12) in which interviewed participants described "a lack of contextually relevant education at diagnosis, and with medication changes". The study highlighted difficulties in communication between Aboriginal patients and non-Aboriginal doctors, and provided insight into the unique ability of AHWs to communicate with Aboriginal patients in a way that builds rapport and allowed the provision of education. Involving AHWs, allows for the provision of culturally specific education that can be tailored to the community and encourages continuity of care with health workers that live and continue to work in the community.

Therapeutic Protocols

First Line Agents

The biguanide metformin remains the first line agent of choice. It is safe, effective, inexpensive, helps with weight loss and may reduce the risk of cardiovascular events and death. Side effects are mainly gastrointestinal. Metformin requires dose adjustment in renal impairment and is generally ceased when eGFR <30. Consider periodic B12 testing in patients on metformin in the long term as it is associated with B12 deficiency, which can worsen peripheral neuropathy.

Second Line Agents

The choice of second and third line medications is moving towards an approach that considers an individual's unique risk profile and the risks and benefits of each medication class, rather than the use of a generically applied algorithm. This is now more relevant due to the multiple new classes of anti-diabetic agents that are available. At this stage, the PBS does not altogether allow for this individual approach due restrictions in prescribing. In future protocol reviews, an individualized approach may be more easily achieved as the PBS is updated. Clinicians, however, should be aware of the risk/benefit profiles of each class of drug and may consider these in their decision making, while still operating within the limitations of the PBS.

Sulfonylureas:

- The PBS recognizes that if sulfonylureas are contraindicated or not tolerated, another agent may be used. This should be kept in mind before prescribing, especially if the potential adverse effect of hypoglycaemia is a contraindication for prescribing.
- Weight gain should also be considered when prescribing sulfonylureas. In an overweight or obese patient, a DPP-4 inhibitor may be a more appropriate second line choice.

DPP-4 inhibitors:

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- The KSDL has been updated in 2019 to include the DPP-4 inhibitor linagliptin, which does not require dose adjustment in renal impairment.
- Sitagliptin remains on the KSDL and use is encouraged as the available combination tablet with metformin to reduce pill burden.
- There is a linagliptin/metformin combination tablet, however it is not on the KSDL and its use is not encouraged in the protocol due to the metformin being in the immediate release form. Pharmacy has noted some clinician confusion around this combination tablet (ie being prescribed as a daily dose, when it needs to be twice daily due to the immediate release metformin).
- Sitagliptin and linagliptin are subsidised on the PBS for use with either metformin or sulfonylurea (ie dual therapy) or with both (ie triple therapy) or for use with insulin.
- Side effects include nausea, hypoglycaemia (if used with a sulfonylurea), and pancreatitis.

SGLT2 Inhibitors ("Flozins") (13):

- SGLT2 inhibitors are the newest class of oral hypoglycaemic agents, and work by reducing the renal reabsorption of glucose in the proximal tubules and increasing urinary glucose excretion. They are dependent on renal function and so shouldn't be used in eGFR <45.
- SGLT2 inhibitors are listed on the PBS as second or third line agents. They can be used with metformin or sulfonylurea as dual therapy, with metformin and sulfonylurea as triple therapy, or with metformin and a DPP-4 inhibitor as triple therapy. They can also be used alongside insulin.
- There is much excitement about SGLT2 inhibitors in the global community for several reasons. They can effectively reduce HbA1c, are associated with weight loss, and most importantly several large randomized controlled trials have found statistically significant reductions in cardiovascular death in those with pre-existing cardiovascular disease. Studies are underway to determine if SGLT2 inhibitors also have a renoprotective effect.
- There are also reasons for us to exercise caution in introducing this class of medications in our population. SGLT2 inhibitors can result in increased genital infections (eg candidiasis), have been associated with euglycaemic ketoacidosis, and can cause dehydration which potentially could result in acute kidney injury. This class of medication has also been associated with increased rates of foot amputation.
- The risk of euglycaemic ketoacidosis is increased in fasting, restricted dietary intake, bowel preparation, surgery, dehydration and intercurrent illness. Euglycaemic ketoacidosis should be considered in patients taking an SGLT2 inhibitor who develop abdominal pain, nausea, vomiting, fatigue or unexplained acidosis. A normal or only modestly elevated plasma glucose level does not exclude the diagnosis (14). Capillary ketones should be checked in this situation, with levels >1.0 mmol/L suggestive. In the protocol we have suggested an unwell patient on an SGLT2 inhibitor should have capillary ketones checked, and if > 0.6 mmol/L this should be discussed with the on-call regional physician. Issues of food insecurity, excessive alcohol intake and hot weather conditions should be considered before prescribing SGLT2 inhibitors.
- The risk of potential acute kidney injury is also worth considering as the increased excretion of glucose in the urine leads to an osmotic diuresis that can cause dehydration. In the Kimberley, where weather conditions are often hot and people spend significant time outdoors, this is an important consideration.
- Any patient started on an SGLT2 inhibitor should have the risks and benefits of the medication adequately communicated to them before commencement. They also should be educated on reasons to withhold the medication (eg surgery, fasting, bowel preparation, sickness) and when to seek help for adverse effects. Renal function should be monitored after commencement.
- For these reasons, our protocol suggests consideration of discussion with the Kimberley regional physician team before an SGLT2 inhibitor is commenced. Monitoring of the cautious introduction of SGLT2 inhibitors in the Kimberley will allow us to quantify adverse events and so provide better guidance on their use in future protocol updates.
- Studies investigating the possible slowing in progression of chronic kidney disease (CKD) should be watched carefully for the potential benefit in our population, which has significant burden of CKD.

Dulaglutide

Dulaglutide (Trulicity) is a new addition to the KSDL and is expected to be the primary GLP-1 analogue used in the Kimberley. It is a once weekly subcutaneous injection. Previously, the older drug exenatide has been used in the forms of the twice daily subcutaneous injection (Byetta) and a slow release formulation given as a weekly injection (Bydureon). The main reason for switching to dulaglutide is an easier method of administration - it is delivered via a preloaded pen, that uses a small non-visible needle, and does not require drawing up. The previously used Bydureon is delivered by a large bore needle, requires drawing up, and vigorous mixing of components prior to injection by tapping the pen at least 80 times. The use of the easier to administer dulaglutide should assist with improved adherence. Dulaglutide can be used as a second line treatment with metformin if a sulfonylurea is contraindicated or not tolerated, or can be used as third line treatment in combination with metformin and sulfonylurea. It is not listed on the PBS in combination with an SGLT2 inhibitor or a DPP-4 inhibitor. Using DPP-4 inhibitors in combination with GLP-1 analogues increases the risk of side effects and is not recommended.

GLP-1 analogues assist with weight loss and have evidence for a cardioprotective effect. They can be an appropriate choice in those overweight/obese and with cardiovascular disease. The main limitation to its use are gastrointestinal side effects, with nausea, vomiting and diarrhea being common. They should therefore be carefully monitored in those with renal impairment to avoid acute kidney injury secondary to dehydration. Dulaglutide may cause pancreatitis and should not be used in patients with a personal or family history of medullary thyroid

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cancer or in those with a past history of pancreatitis. There is risk of hypoglycaemia for patients also taking insulin or a sulfonylurea. Dulaglutide can be used in moderate to severe chronic kidney disease (CKD), down to eGFR 15, which is based on trial protocols such as that in AWARD-7 (15).

Insulin

We advise insulin as a first line agent for those with initial HbA1c levels ≥12%. The ADA recommends insulin to be used as first line agent for glycaemic control if HbA1c ≥10%. We have kept our advice to consider insulin as a first line agent in extremely high HbA1c with the example of ≥12% on discussion with the Kimberley regional physician team. This should not preclude clinicians from using insulin as a first line agent in individuals with lower HbA1c's when felt appropriate.

Dose adjustment in renal impairment

Advice for metformin & gliclazide is in keeping with the KAHPF Chronic Kidney Disease protocol. We note that NICE and FDA guidance suggest cessation of metformin if eGFR <30. In practice, some nephrologists and physicians may suggest continuing low dose use of metformin in these patients due to the importance of glycaemic control to prevent further renal function deterioration. We therefore give advice for clinicians to discuss cessation with on-call specialist. We give similar advice for gliclazide as it can be used in eGFR <45, but the risk of hypoglycaemia is greater so risk must be assessed. Advice for sitagliptin is updated to align with the Australian Medicines Handbook. All dose adjustments are given in terms of eGFR to be consistent with our classification of CKD in the CKD protocol. Advice for dulaglutide not to be used in eGFR <15 is in keeping with use in the AWARD trials. Advice for avoidance of empaglifozin in eGFR <45 is in keeping with Jardiance product information.

Follow Up

- Follow up recommendations are largely in keeping with RACGP guidelines.
- MBS billing codes for POC HbA1c use are included for use in Aboriginal Medical Services as part of the Quality Assurance for Aboriginal & Torres Strait Islander Medical Services (QAAMS) program & POC HbA1c is encouraged for screening and monitoring.
- UEC and urine ACR is recommended every three months due to the high prevalence of chronic kidney disease in the region based on regional physician team advice.

Timeline:

Working Group 1st meeting: September 24th 2019

Working Group 2nd meeting: October 29th 2019

Working Group 3rd meeting: December 16th 2019

Chronic disease subcommittee: February 10th 2020

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Other Resources

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