A NEW ERA IN DIABETES CARE

A CALL TO ACTION REPORT TO IMPROVE TYPE 2 DIABETES CARE IN EUROPE

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EXECUTIVE SUMMARY

A large proportion of people with type 2 diabetes mellitus (T2DM) go on to develop chronic kidney disease (CKD) (~40%)¹ and cardiovascular disease (CVD) (~30%).² These secondary conditions are strongly intercorrelated³ and present a significant morbidity and mortality burden for people with T2DM.²⁴

CKD is the leading cause of end-stage renal disease and is a life-shortening condition which has a huge burden on healthcare systems.⁴⁵ There is therefore a real need to prevent the onset and progression of CKD over time in T2DM and effectively manage those people who have already developed complications.

In February 2020, a group of European primary and secondary care healthcare professionals (HCPs) with expertise in diabetes and nephrology formed the ‘A New Era in Diabetes Care’ Steering Committee, with the mission to:

- Highlight the challenges and inequalities across European countries in the prevention, monitoring and treatment of T2DM and its associated complications, with a focus on CKD and CVD
- Outline what can be done to improve quality of care and outcomes for people living with T2DM and its complications.

The Steering Committee agreed that as CVD and CKD are strongly linked, and CVD is more likely to cause early death compared with CKD, care often focuses on improving cardiovascular results rather than taking advantage of markers of kidney damage as a tool for early intervention. Therefore, the Steering Committee highlighted the lack of a structured and integrated approach for the management of people with T2DM and CKD as a barrier to high quality care. In particular, four areas were perceived to require improvement within the management process:

- Effective testing and interpretation of CKD markers
- Prescription of the appropriate treatment
- Regular review of key performance indicators / treatment outcomes
- HCP and patient education
EXECUTIVE SUMMARY

Following discussion on how to address these challenges and advance care in T2DM, the Steering Committee calls for the development of a coordinated care plan, specific to people with T2DM and CKD.

The plan prepared by the Steering Committee puts the individual at the centre of care and includes three stages; ‘Measure’, ‘Treat’ and ‘Review’ (Figure 1), to help form a collaborative relationship between the HCP and the person with T2DM, to help prevent the onset or worsening of CKD. Education for both the HCP and the person with T2DM underpins the practical elements of each step. Removing “silos” between primary and specialty care and addressing structural barriers within diverse healthcare systems across Europe emerged as critical success factors.

This meeting was held prior to the outbreak of COVID-19 in Europe. However, post-meeting, the Steering Committee believed it would be pertinent to discuss the clinical implications of COVID-19 for the treatment of people with T2DM and CKD, such as the increased appropriateness of telemedicine and caution around certain medication use.

Figure 1:
Structured care plan for patient focused prevention, monitoring and treatment of CKD in T2DM
TYPE 2 DIABETES: PATHOPHYSIOLOGY, PREVALENCE AND ASSOCIATED COMPLICATIONS

What is type 2 diabetes?

T2DM is a chronic, heterogenous condition that is generally described by abnormalities in carbohydrate and fat metabolism. The causes of T2DM are multidimensional, including both environmental and genetic components that impact insulin sensitivity of tissues (muscle, liver and adipose) and cells in the pancreas. Over time, β-cells in the pancreas that are responsible for insulin production lose function due to nutrient-induced damage, further contributing to the progression of the condition.
Who is affected by type 2 diabetes?

Diabetes is one of the fastest growing health concerns of the 21st century. T2DM can be diagnosed at any age, but it is much more common in older adults. In the UK, approximately 90% of those affected are over the age of 50 years. However, it is worth noting that there is an increasing number of younger people diagnosed, with obesity being a key contributor to this trend.

Further risk factors associated with the onset of diabetes include:

- Family history of T2DM
- Ethnicity (i.e. T2DM is particularly prevalent in those of Asian and Afro-American descent)
- Adiposity (i.e. greater body mass index or waist circumference)
- Past medical history of gestational diabetes
- Past medical history of metabolic syndrome
- Dietary factors (i.e. greater consumption of processed meat and sugar-sweetened beverages)
- Lifestyle factors (i.e. decreased physical activity, increased sedentary time, and alcohol abuse)
- Psychosocial and socioeconomic factors (i.e. lower income or lower educational status)
- Medical history (i.e. lower age at first occurrence of menstruation)
- Presence of certain biomarkers [i.e. increases in C-reactive protein and alanine transaminase]
In 2019, approximately 59 million adult Europeans (aged 20 - 79 years) were estimated to have diabetes. It is estimated that by 2045, this figure will increase to 68 million and around 90% of those cases will be T2DM. There has also been an increase in the prevalence of T2DM in people under 40 years of age, which poses a more serious health problem to the individual (extended exposure to risk factors for diabetes-related complications) and a larger issue for public health (increased healthcare utilisation / costs) than in older people. Due to T2DM’s widespread proportions, its economic burden is vast. In 2019, IDF data showed that Europe spent over USD 160 billion on diabetes-related healthcare costs. Further data on diabetes-related healthcare expenditure in individual European countries can be found in Figure 2 below.

T2DM has a significant morbidity and mortality burden - driven mainly by CVD and CKD - but also including microvascular complications (diabetic retinopathy, autonomic neuropathy, peripheral neuropathy and erectile dysfunction). The multi-morbid nature of T2DM is a contributing factor to low health-related quality of life (HRQoL) in people living with the condition, and is also largely responsible for the significant cost burden of the condition to healthcare systems.

**The personal, societal and economic burden of type 2 diabetes in Europe**

![Graph showing total diabetes-related health expenditure in 2019](image)

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**The impact of type 2 diabetes: Mortality and multi-morbidity**

T2DM has a significant morbidity and mortality burden - driven mainly by CVD and CKD - but also including microvascular complications (diabetic retinopathy, autonomic neuropathy, peripheral neuropathy and erectile dysfunction). The multi-morbid nature of T2DM is a contributing factor to low health-related quality of life (HRQoL) in people living with the condition, and is also largely responsible for the significant cost burden of the condition to healthcare systems.
**Cardiovascular disease**

CVD is a frequent comorbidity in people with T2DM, and is one of the major causes of death in these individuals. A global systematic review including data covering over 4.5 million people with T2DM showed that CVD affected 32.2% of them. Coronary artery disease and stroke were mostly responsible for a 9.9% CVD death rate. Additionally, a UK database study including over 85,000 people observed a three-fold increased risk of CVD mortality (ischaemic heart disease, pulmonary heart and circulation diseases, or cerebrovascular diseases) in middle-aged people with T2DM, compared to those without T2DM.

The economic impact of CVD in people with T2DM, and the subsequent stress on healthcare systems, is a huge socioeconomic burden. A global systematic review found that at a population level, CVD was responsible for 20% – 49% of the treatment costs of T2DM. Furthermore, the annual treatment costs for people with T2DM and comorbidities versus those without were comparatively higher: CVD (122%), coronary artery disease (107%), heart failure (59%) and stroke (322%).

**Chronic kidney disease**

There is a strong link between CVD and CKD; disease of either system often causes dysfunction in the other. During the February 2020 Steering Committee meeting, the signs of CKD, a decline in estimated glomerular filtration rate (eGFR) and presence of proteinuria, were likened to "the tank (the kidneys) of a car leaking oil. If not fixed, the engine (the heart) would ultimately seize up and stop working."

Approximately 40% of all people with T2DM will develop CKD, which is also referred to as diabetic kidney disease (DKD) in this population. CKD can negatively impact health in several ways, including increased risk for a wide spectrum of complications resulting from a weakened immune system, anaemia, high blood pressure and depression. Over time, CKD can progress to stage renal disease (ESRD), which can be fatal. ESRD was responsible for over 950,000 global deaths in 2013.

Treatment for ESRD (and late-stage CKD) – renal replacement therapy (RRT) – is costly. RRT includes dialysis and transplantation. On a per-person per-year basis, dialysis can cost between €40,000 - €80,000, and transplantation between €10,000 - €20,000. This makes healthcare costs for ESRD disproportionately expensive, with 2% of Western Europe’s entire health expenditure being spent on just 0.1% of the population. It is no surprise that CKD in people with T2DM has been labelled a ‘worldwide medical catastrophe’. 
Why action is urgently needed

T2DM and its complications pose a significant burden at both an individual and European societal level. Healthcare systems must work to prevent an increase in people with T2DM presenting with severe life-shortening and financially burdensome complications; and at ever-younger ages.

CKD, in particular, requires urgent intervention. The Steering Committee agreed that as CVD is more likely to cause early death compared to CKD, care often focuses on improving cardiovascular outcomes rather than focusing on management of CKD. Due to the strong correlation between CVD and CKD, disregarding warning signs from the kidney can significantly increase the likelihood of earlier onset of CVD. Enhancing renal outcomes in people with T2DM is likely to improve HRQoL and to reduce the financial burden on healthcare providers.
BARRIERS TO EFFECTIVE MANAGEMENT OF PEOPLE WITH TYPE 2 DIABETES AND CHRONIC KIDNEY DISEASE

The Steering Committee represented countries from across Europe, yet there was consensus on the barriers to effective management of people with T2DM and CKD in this region.

There are numerous guidelines available for the management of CKD in T2DM, developed by the International Diabetes Federation (IDF), the American Diabetes Association / European Association for the Study of Diabetes (ADA / EASD), the European Society of Cardiology (ESC), the European Renal Best Practice (ERBP), and the Kidney Disease Improving Global Outcomes (KDIGO). The availability of numerous consensus documents can make deciding the ‘best’ evidence-based approach to T2DM and CKD care a more difficult process. This is especially the case in primary care, where clinicians are already managing a wide spectrum of diseases.

Fundamentally, the Steering Committee all agreed on the current lack of a structured care plan established for people with T2DM and CKD. This lack of a defined approach contributes to inequality in care from clinic-to-clinic and patient-to-patient, depending upon the individual HCP’s knowledge of the various, often complex, clinical guidelines. The Steering Committee determined that there are four critical care components that require improvement.
Effective testing and interpretation of chronic kidney disease precursors

The 2019 ESC and 2017 IDF guidelines both recommend that people with diabetes (Type 1 and 2) are screened annually for CKD by assessing estimated eGFR and urinary albumin to creatinine ratio (UACR).\textsuperscript{23, 24} In reality, this guidance is often overlooked across Europe; approximately half of people with T2DM in Italy and The Netherlands are not regularly screened for albuminuria,\textsuperscript{25, 26} with some Dutch people never receiving a UACR test.\textsuperscript{25} Moreover, a survey conducted in the UK found that 54\% of GPs and nurses do not conduct annual UACR tests, with 75\% underestimating the impact of CKD on CVD mortality risk.\textsuperscript{27}

In their experience, the Steering Committee indicated that screening for CKD typically takes place in primary care, although there are exceptions, such as in Italy, where it is generally conducted by a diabetologist. Regardless, the Steering Committee agreed there is a general lack of understanding across Europe of what screening results indicate for the kidney, further exacerbated by an absence of guidance from the laboratory regarding test results and their potential renal implications. In addition, some people with T2DM may be oblivious of the link between T2DM and CKD or the methods to test for CKD, meaning they do not prepare to provide a sample, or are not equipped to request one from their clinician.

A 24-hour urine sample was the traditional screening method for CKD in people with T2DM. However, it can be difficult for someone to accurately collect a 24-hour sample, and HCPs may feel it is not worthwhile submitting a sample that does not accurately reflect this 24-hour window, therefore missing a treatment opportunity. As early diagnosis is an essential factor of CKD management,\textsuperscript{28} it is important that this therapeutic window is not missed. UACR is now a recommended screening technique for CKD and requires only one sample, either done in the early morning or randomly. Further, eGFR should be estimated using creatinine-derived formulations, such as the Chronic Kidney Disease Epidemiology Collaboration Equation (CKD-EPI). The Steering Committee were all in agreement that these screening methods are key to preventing the progression of CKD.

The onset of the COVID-19 pandemic poses a specific challenge to people with T2DM who are more likely to have worse clinical outcomes than the general population as a result of catching the virus,\textsuperscript{29} and may be fearful of using healthcare resources. Additionally, pressures on healthcare systems has resulted in many non-emergency appointments being cancelled or postponed.\textsuperscript{30} The Steering Committee commented that this may mean CKD screening opportunities are missed. They unanimously agreed that annual screening for CKD should continue to take place while also protecting people with T2DM by following the relevant shielding guidelines and using telemedicine where appropriate.
Currently, there is some difference in the guidelines regarding the appropriate treatment to prescribe. Either metformin is recommended as the first-line treatment for T2DM, followed by a drug with cardiovascular or renal benefit, such as a sodium-glucose co-transporter-2 inhibitor (SGLT2i) or glucagon-like peptide-1 receptor agonist (GLP-1RA) in the presence of established / high risk of CVD / CKD. Further, a drug with cardiovascular or renal benefit can be initiated in drug-naïve people with T2DM with established / high risk of CVD / CKD. Additionally, an angiotensin converting enzyme inhibitor (ACEi), angiotensin-receptor blocker (ARB) or SGLT2s is recommended in people with T2DM and heart failure to reduce the risk of heart failure hospitalisation and CV death. The Steering Committee speculated that differences in guidelines may be attributed to the relatively higher cost of glycaemic treatments with greater cardiovascular and renal benefit than typical first-line treatments. In response to this, the Steering Committee members agreed that cost-effectiveness analyses of SGLT2is and GLP-1RAs should be updated to include potential financial savings achieved by delaying the need for dialysis in people with T2DM who progress to ESRD, and hospitalisation in those who develop heart failure and other cardiovascular diseases. The Steering Committee commented that the T2DM treatment paradigm is still heavily focused on glycaemic control and may neglect renal and cardiovascular outcomes. Committee members agreed that dipeptidyl peptidase-4 inhibitors (DPP-4is) may be too regularly prescribed in the second line, despite the fact they do not have significant renal and cardiovascular benefits. In the past, there were some concerns about the side effects of SGLT2is, indicated in high profile reports such as that by the Food and Drug Administration in 2018. However, the ‘A New Era in Diabetes Care’ Steering Committee were in agreement that the cardiovascular and renal benefits outweigh the side effects of SGLT2is and GLP-1RAs, that are usually minor and easy to manage (such as urogenital infections). There are also several recent reviews which concur on the risk-benefit profile of this drug class. The group also felt that informing people with T2DM of these potential side effects from the outset may also help to alleviate their concerns about treatment. With the emergence of COVID-19, there are some worries regarding the use of ACEis and antidiabetic drugs. The mechanism of action of ACEis and the method of cell entry for coronavirus has resulted in some speculation that ACEis may increase the infectivity of COVID-19. However, as of Spring 2020, there is little scientific evidence to support this claim and the risks of abandoning ACEi treatment are well documented. While improving glycaemic control is important for both long-term health outcomes and to reduce the risk of severe COVID-19 disease, there are some specific treatment considerations that should be made. Although metformin-associated lactic acidosis and SGLT2i-associated hyperglycaemic diabetic ketoacidosis are rare events, the risk of these occurring would suggest that these drugs be suspended in people with T2DM and severe COVID-19 symptoms to prevent dehydration and sick day rules followed. In general, it is suggested that hydration is closely monitored in those on metformin, SGLT2is and GLP-1RAs with manageable COVID-19 symptoms. It is important to note that these suggestions are based upon medical literature while awaiting the results of randomised clinical trials, and do not form validated clinical recommendations.
There is a need for standardised key performance indicators (KPIs) in diabetes care, both at a national level, and across Europe, due to their major influence on quality improvement. The Steering Committee highlighted the necessity of collaboration between HCPs and organisations such as the Primary Care Diabetes Europe to benchmark KPIs to review and improve monitoring, treatment and outcomes in people with T2DM and CKD. The Steering Committee also recognised clinical inertia as a common challenge faced by HCPs and people with T2DM. Clinical inertia refers to the failure of HCPs to initiate or intensify therapy when needed. Multiple factors can lead to clinical inertia, but this phenomenon happens most often during periods of treatment change, where management becomes more complex, which is typical for a person with T2DM with a recent diagnosis of CKD. As it is linked to progression of secondary complications of the principal disease, the Steering Committee felt that more needs to be done to address the problem of clinical inertia. The COVID-19 pandemic is likely to further impact adherence and clinical inertia. The Steering Committee agreed that digital innovations such as telemedicine could be used to maintain regular reviews of treatment where clinical appointments are unnecessary or inappropriate.
The Steering Committee saw effective professional education as the foundation of high-quality healthcare but noted that it was lacking in the T2DM and CKD therapy area. The group identified some HCP teaching techniques as being "too passive to be effective", such as PowerPoint-based learning, and commented that these types of sessions may not always draw a high attendance or have sufficient impact on improving practical care. Conversely, simulation debriefing in healthcare (replacing or amplifying real scenarios with interactive guided experiences) can significantly improve technical and non-technical skills, vital signs assessment and situational awareness.39

The Steering Committee highlighted the need to effectively monitor treatment adherence as an important measure to improve T2DM care. Strict control of blood glucose is an essential component of high-quality care in T2DM.40 Glucose-lowering/antidiabetic drugs are recommended for those who are unable to achieve glycaemic targets with lifestyle changes alone.40 Good adherence to treatment can have significant benefits for health outcomes, and is linked to a reduction in hospitalisation and all-cause death in people with chronic disease.40 However, significant numbers of people with T2DM do not follow their agreed treatment plans. While numbers vary across studies, a systematic review observed that optimal treatment adherence for oral antidiabetic drugs dropped as low as 36% over 6 – 24 months.41

People with T2DM often have varying levels of knowledge and education around their condition and its related complications. In some cases, people are unsure of their HbA1c, blood pressure and lipids levels, or expect the HCP to provide this information. As diabetes self-management education has been shown to improve glycaemic control, one of the strongest predictors for diabetes-related complications,42 the Steering Committee acknowledged its importance in improving care for people with T2DM and CKD.
BEST PRACTICE EXAMPLES

Despite the general barriers to high quality care in T2DM and CKD, the Steering Committee members were often part of local or national initiatives that aimed to provide best practice, whether focused on T2DM or CKD. The following examples represent such initiatives as presented by members of the Steering Committee.
As a nephrologist who helps manage dialysis patients, Professor David Wheeler wanted to get involved in the management of people with T2DM and CKD at an earlier stage of their condition. He believed this would lead to more opportunities to provide evidence-based therapies, highlight concerns and manage CKD risk factors to prevent progression. In response to this, Professor Wheeler, along with colleagues at the St Pancras Kidney, Diabetes and Eye Centre, runs a virtual CKD consultancy service for the 35 primary care practices in Camden, London.

The virtual CKD consultancy service is embedded within EMIS Web, the online system used to hold patient data from local primary care practices. With patient permission, he and his team can access patient data sets for any primary care referral. This information allows them to understand the treatment course of individuals with T2DM, and visualise their eGFR and UACR fluctuations over time, with an average turnaround time to provide advice of one week.

Using the online system, Professor Wheeler can provide any necessary advice to the GP and determine whether care should be escalated, or if no current action is needed. If he feels that the person needs secondary care, the most frequent option is “to bring the patient to St Pancras Hospital where there is a dialysis unit; we discuss any lifestyle changes and treatments that could prevent them from ending up on a dialysis machine”.

Professor Wheeler highlighted that he receives referrals at various stages of CKD. In some cases, there are very early signs of CKD and this provides the best possible opportunity for the HCP to prevent the condition progressing. The advice and guidance provided by the Virtual CKD Clinic has been and continues to be well received by the primary care clinics it serves.
Professor Ronan Roussel was involved in the ANODE randomised control trial, the assessment of a fully automated Web-based educational tool designed to help people with obesity and T2DM improve their diet and increase physical exercise.

Obesity is a risk factor for CVD, as well as T2DM. Primary intervention – education that promotes a healthy diet, weight loss and increases in physical activity – is widely believed to be the foundation of treatment for obese people with T2DM. However, in reality, the required tailored and high-intensity care is often difficult to achieve due to a lack of resource and high cost. Additionally, Professor Roussel commented on "medical deserts", geographical regions that isolate people from face-to-face education programmes.

The ANODE programme collected baseline lifestyle habits, provided education on nutrition and exercise techniques, techniques and generated balanced and healthy recipes tailored to the user’s preferences through an online portal. Users were asked to log into the programme at least once a week. Following 16 weeks of intervention, body weight, waist circumference and HbA1c had significantly improved in ANODE users.

Web-based interventions, such as ANODE, show promise in relieving some of the burden posed by T2DM on individuals and healthcare systems. Critically, web-based interventions require minimal human input, cutting cost and increasing access to hard-to-reach populations.
Leicester Diabetes Centre (LDC) developed an education programme that aimed to upskill primary care HCPs around cardiovascular, renal and metabolic patient needs. This involved working with Specialist Nurses, Practice Nurses and GPs in these three key areas and reviewing how they interact.

Effective Diabetes Education Now (EDEN) was established in 2012 as a wide-scale transformation programme to address the skill gaps and changing models of care in HCP diabetes knowledge. EDEN aimed to enable delivery of effective care and education for people with diabetes and long-term conditions, and was part of a collaboration between the local Leicester Clinical Commissioning Groups and the team at the Leicester Diabetes Centre.

The EDEN clinical team are experts in education and academia, and include Specialist Nurses, GPs and other allied HCPs. They have delivered over 450 face-to-face training events to over 8000 HCPs. Nearly all HCPs who attended said their clinical confidence increased after training.

EDEN provides a variety of training materials, including:
- Face-to-face training – Interactive workshops
- Digital resources – E-learning, webinars and downloadable resources
- ‘Train the Trainer’ – A comprehensive programme to enable widespread dissemination of clinically relevant educational materials
- Bespoke programmes – Customised programmes and partnerships in collaboration with a range of individuals

EDEN module topics have included:
- Injectable therapies
- Foot care
- CaReMe (Cardiovascular, Renal and Metabolic)
- CKD
- Haemodialysis care

Specific CKD sessions have focused on:
- How to raise discussion with patients who have a declining eGFR
- Education on the importance of UACR samples to support with predicting and delaying onset of future complications
- What is contraindicated in CKD and diabetes? Which drugs need dose reduction or withdrawal and at what stage?
As co-founders of TREND-UK (Training, Research, Education for Nurses Working in Diabetes), Professor June James and fellow Consultant Nurse Debbie Hicks develop and produce free-to-access educational materials, for both HCPs and people with T2DM. They have produced some specific material on CKD in T2DM, to help describe the condition and guide diagnosis and treatment.

In 2019, Professor James, Nurse Hicks and Professor James Burton (Consultant Nephrologist – Leicester) and colleagues conducted six UK-wide road shows for diabetes specialist nurses, practice nurses working in diabetes, GPs, and pharmacists. The roadshows were well attended and positively received; a second series of five roadshows are planned for Autumn 2020.

As part of this programme, and with the support of Professor Burton and Dr Rob Gregory (Consultant Diabetologist – Leicester), the TREND team designed an HCP document titled “Type 2 Diabetes and Chronic Kidney Disease”, which was produced and distributed at national meetings and through the roadshows.

The HCP document includes background information on how the kidneys work, CKD, symptoms of the condition and its complications. There is also detailed information on the definition of CKD through eGFR and albuminuria, the importance of screening using these methods and the treatments that are available.

In addition, the TREND-UK website includes a leaflet for people with diabetes and a guide to diabetes medicines management in CKD for HCPs, which is updated as drug licenses change.

www.trend-uk.org
In Spain, the public healthcare system allows for IT systems to be used across primary and secondary care. The Nephrology Department has a mailbox (incorporated into the IT system) that receives all the primary care referrals to be evaluated by nephrologists, and include a person’s renal markers (eGFR and UACR). Based on these results, the single reviewer (in this case, Dr Jose Luis Górriz) then decides whether further specialist renal care is needed.

If care should be escalated, a face-to-face appointment can be made with the nephrologist, usually in cases where renal results are more concerning i.e. requiring treatment. In patients with mild DKD (slight increase in albuminuria or slight decrease in eGFR), recommendations, lifestyle changes and treatment adjustments are provided for follow-up by primary care.

Dr Górriz converts around 80% of referrals to a face-to-face meeting, and 20% are conducted via telephone. On average, an appointment is sent in less than one week (mean 3.8±4.5 days) and the patient is seen in less than 14 days.
The redGDPS Foundation refers to a group of Spanish primary care HCPs with a special focus on improving the care of people with T2DM. Their main activities include:

- Producing publications that provide guidance for practice and the latest updates in the T2DM field
- Training courses
- Research grants and donations to non-government organisations
- Collaboration with patient associations and scientific societies

In particular, redGDPS organise and run a mixture of face-to-face and online training courses aimed at primary care clinicians. Their face-to-face events are held in the evening on several dates throughout the year. The sessions discuss a variety of topics, from treating hyperglycaemia to managing microvascular and macrovascular complications. They also focus on the practical aspects of care, and use real clinical cases to frame common problems faced in practice. redGDPS now run a master’s degree at the Francisco de Victoria University, Madrid, in ‘Care and education for people with T2DM’, which aims to improve the professional competence of primary care clinicians towards people with T2DM.

As well as providing education, redGDPS are actively involved in their own projects and studies. Previous work includes PERCEDIME2 (An epidemiological study to evaluate the prevalence of CKD in people with T2DM in primary care) and PREDAPS (A study to determine the risk factors of diabetes and vascular complications in prediabetic patients). redGDPS are currently working on two projects; to examine clinical inertia and adherence to treatment in primary care, as well as a deep dive into the prevalence, evolution and characteristics of diabetic foot.

redGDPS has also created tools to help primary care clinicians in practice. The InsuTOOL is an app widely available online that helps HCPs choose the most suitable insulin treatment regimen for each individual patient.
THE PROPOSED SOLUTION

A STRUCTURED CARE PLAN FOR PATIENT-FOCUSED PREVENTION, MONITORING AND TREATMENT OF CHRONIC KIDNEY DISEASE IN TYPE 2 DIABETES

The Steering Committee highlighted the need for a structured and integrated care plan to better prevent, monitor and treat CKD and CVD in people with T2DM. This plan outlines several calls to action for HCPs and people with T2DM and CKD based on the challenges identified by the Steering Committee, putting people with T2DM at the centre of care.

This novel framework includes three stages; 'Measure', 'Treat' and 'Review' and establishes a collaborative relationship between HCP and person with T2DM and CKD. Education for stakeholders is the necessary driver throughout the framework and is required to practically implement each step.
Effectively test and interpret albuminuria

- All people with T2DM should be screened annually for CKD by assessment of eGFR and UACR
- Replace the 24-hour urine sample with UACR
- Laboratory results should highlight if a sample is abnormal to trigger a HCP response
- Embed albuminuria into electronic healthcare records to guide the HCP to prescribe the right drug at the right time for the person

Use shared decision-making to create an appropriate care plan

- Discuss factors that may affect treatment choice i.e. HbA1c, blood pressure, kidney function, weight, comorbidities, risk/benefit ratio, current medication, treatment regimen, cost
- Use mutually agreed targets to drive progress in health outcomes
- Discuss the risks and benefits of treatment
- Move the treatment paradigm to provision of beneficial renal and CVD outcomes
- Be aware of the changes COVID-19 may bring into practice

Monitor and review the care plan to ensure goals are being met

- Review the care plan regularly (3-6 months)
- Check for progression of CKD and decline in renal function
- Assess achievement of other goals and discuss any areas that have not been met
- Investigate glycaemic control and assess level of adherence to treatment
- Make mutual changes to the care plan and execute swiftly to prevent clinical inertia
- Use telemedicine where appropriate to maintain treatment adherence and reduce clinical inertia
**Educate: raise awareness of chronic kidney disease and its signs**

**HCPs should be:**
- Knowledgeable of the impact of CKD on health outcomes, especially the heightened CVD risk.
- Familiar with eGFR and UACR as clinical measures / indicators in relation to renal dysfunction and CKD. After confirming the eGFR / UACR values, HCPs should know when (eGFR decline / UACR increase)* and how (referral to secondary care) to respond.
- Aware of the importance of annual screening for CKD in people with T2DM, as is stated in the ESC and IDF clinical guidelines, and should be able to implement this into everyday clinical practice.

**People with T2DM should be:**
- Educated on the link between T2DM and CKD, CVD, and other microvascular complications related to diabetes when they are originally diagnosed with T2DM.
- Aware that an annual urine test is necessary and understand why this is required/what this aims to measure. This patient empowerment will allow someone with T2DM to push for regular screening and better self-manage their condition.

**Measure: effectively test and interpret albuminuria**

- People with T2DM should be screened annually by assessment of eGFR and UACR.
- UACR should replace the 24-hour urine sample, as the latter is practically difficult to accurately measure in a clinical setting.
- The laboratory should clearly highlight if a urine sample is abnormal before returning it to the clinic / relevant physician.
- Albuminuria results with normal ranges should be embedded into electronic healthcare records to guide the HCP and flag the appropriate guidelines when an abnormal sample returns from the lab. This would allow the HCP to prescribe the right drug for the right person at the right time.

*While laboratory staff are not HCPs, they should be educated on what eGFR / UACR values represent abnormal results so they can report this back to the clinic.*
Educate: increase understanding of the treatment model

HCPs should:
- Use short ‘forum-style’ debriefs to review actual clinical T2DM and CKD cases and share best practice examples / look for opportunities to improve the care they provide
- Receive back-to-basics training on what CKD is, the current clinical evidence in the area and practical implication of the guidelines
- Be aware of the most recent cardiovascular and renal data around SGLT2is and GLP-1RAs
- Be aware of the implications of prescribing ACEis and antidiabetic drugs in the presence of COVID-19

People with T2DM and CKD should be:
- Informed of the lifestyle changes that will benefit renal health
- Educated on the available treatments, their benefits / risks and the importance of correctly administering their therapy to maximise outcomes

Treat: use shared decision-making to create an appropriate care plan

The HCP and person with T2DM and CKD should:
- Discuss factors that may affect treatment choice, i.e. HbA1c level, blood pressure, kidney function, weight, comorbidities, risk / benefit ratio, current medication, treatment regimen, cost
- Mutually agree targets that should drive progress in health outcomes
- Discuss the risks and benefits of treatment so that a shared decision can be made based on both of their preferences
- Move the treatment paradigm beyond only lowering HbA1c to medications that also provide beneficial renal and CVD outcomes
EducatE: keep on track

HCPs should be:
- Aware of the impact of clinical inertia and poor adherence on treatment outcomes
- Conscious of the importance of identifying and measuring KPIs in T2DM / CKD
- Mindful of potential adherence issues if glycaemic control is poor

People with T2DM and CKD should be:
- Encouraged to bring any queries or issues with treatment to their consultation

Review: monitor and review the care plan to ensure goals are being met

- The care plan should be reviewed regularly, every 3 – 6 months, as stated in the ADA / EASD Decision Cycle for Glycemic Management in the 2018 guidelines
- The HCP should check for progression of CKD and decline in renal function. Additionally, any other mutual goals should be discussed
- Following this discussion, relevant changes should be made to the care plan to prevent clinical inertia
- Use telemedicine to replace out-patient appointments where appropriate, especially during the COVID-19 lockdown
- On a regional / national scale, KPIs (e.g. number of people with declining eGFR / number of people with doubling creatinine levels / number of people progressing to ESRD) could be used to benchmark progression of CKD. Collaborating with societies, such as the Primary Care Diabetes Europe, may help to establish these KPIs
PUTTING THE PLAN INTO ACTION

This solution to improve the management of CKD in people with T2DM must be tested before widespread roll-out can be achieved. A potential first step to roll this out could include choosing pilot clinics across Europe for the ‘Structured care plan for patient-focused prevention, monitoring and treatment of CKD in type 2 diabetes’, where its success amongst HCPs and people with T2DM and CKD will be evaluated. As mentioned in the care plan, KPIs should be established, such as ‘number of people with doubling creatinine levels’, to monitor its effectiveness.

CONCLUSION AND CALLS TO ACTION

T2DM-related complications, including CKD and CVD, pose a significant risk to both people with the condition and the healthcare systems that serve them across Europe. More needs to be done to prevent the progression of CKD and its subsequent impact on morbidity and mortality. In order to advance healthcare in this field, the ‘A New Era in Diabetes Care’ Steering Committee convened in February 2020.

The group highlighted and prioritised unmet needs in care for T2DM and CKD; identifying effective screening for CKD; prescription of the appropriate treatment, regular review of KPIs; and HCP and patient education as most important. The Steering Committee suggested that a ‘Structured care plan for patient-focused prevention, monitoring and treatment of chronic kidney disease in T2DM’ would be a beneficial tool to HCPs and could help prevent progression of CKD in people with T2DM and worsening health outcomes. The plan would focus on effectively and appropriately measuring, treating and reviewing, with tailored HCP and patient education as the facilitator for each step.

Moving forward, the plan will potentially be piloted in a clinical setting to evaluate its European-wide potential. Now is the time to do more for people with T2DM and CKD and focus on implementing the calls to action from this report into everyday clinical practice.
References

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