



**DIABETES:**  
protect our future

# Diabetes: A National Public Health Priority

**Proposal for a National Strategy for Diabetes**

**2015-  
2020**

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The aim of this strategy is to implement measures aimed at preventing diabetes, expanding treatment options and improving the integrated management of diabetes so as to prevent or postpone the onset of diabetes-related complications

## **FOREWORD**

Diabetes is a common chronic condition in the Maltese population. It is for this reason that Government has made diabetes one of its key priorities.

*Inkomplu ntejbu u nwessgħu s-servizzi li jingħataw lid-dijabetiċi*

*kemm fuq livell ċentrali kif ukoll bħala kura fil-kommunita'.....*

I therefore have the pleasure to launch this document which contains a series of proposals that together will help us to address diabetes effectively at a national level. This document has been compiled by a steering group that carried out a needs assessment based on evidence and focus groups to prepare a number targets. Our aim is to try and reduce the impact that diabetes has on individual, their families and society.

We are therefore proposing to intensify our efforts to address risk factors for diabetes and promote the earlier diagnosis of diabetes. All persons with diabetes shall receive quality care according to a national standard. We will expand the range of treatment modalities available and set up systems for screening, prevention and early diagnosis of complications. Patients will be empowered to take a more active role in the management of their condition. Education and support will be key hallmarks alongside clinical excellence that will enable us to attain better outcomes for persons with diabetes. Health care providers in specialised clinics, in the community in the public and private sectors will complement each other to provide seamless integrated care.

I trust the document will serve to promote a constructive and healthy debate on the measures being proposed to reach higher levels of care and better outcomes for the benefit of all persons with diabetes and their families.

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## GLOSSARY

BIRO	Best Information through Regional Outcomes (Diabetes Information system project)
BMI	Body Mass Index
CSII	Continuous Subcutaneous Insulin Infusion
CVD	Cardiovascular Disease
DHC	Paediatric Diabetes Healthcare
DNS	Diabetes Nurse Specialist
DPA	Directorate of Pharmaceutical Affairs
DPP	Diabetes Prevention Program
DPS	Finnish Diabetes Prevention Study
eGFR	Estimated Glomerular Filtration Rate
EHES	European Health Examination Survey
EHIS	European Health Interview Survey
ESRF	End Stage Renal Failure
EUCID	European Core Indicators in Diabetes
EUROPOP	European Population projection figures
GFL	Government Formulary List
GFLAC	Government Formulary List Advisory Committee
GIGT	Gestational Impaired Glucose Tolerance
GDM	Gestational Diabetes Mellitus
GP	General Practitioner
HWL	Healthy Weight for Life Strategy
IFG	Impaired Fasting Glucose
IGR	Impaired Glucose Regulation



IGT	Impaired Glucose Tolerance
ICT	Information and Communication Technologies
ISPAD	International Society of Paediatric and Adolescent Diabetes
LSA	Learning Support Assistant
MDT	Multidisciplinary Team
MI	Myocardial Infarction
MONICA	Multinational MONItoring of trends and determinants in Cardiovascular disease study
NCD	Non-communicable disease
NSO	National Statistics Office
OPU	Orthotics and Prosthetics Unit
PACS	Picture Archiving and Communication System
PDS	Paediatric Diabetes Service
POYC	Pharmacy of Your Choice
T1DM	Diabetes Mellitus Type 1
T2DM	Diabetes Mellitus Type 2
WHO	World Health Organization
WTE	Whole Time Equivalent

## EXECUTIVE SUMMARY

Diabetes Mellitus is a chronic disease that occurs when the pancreas is unable to produce enough insulin, or when the body cells cannot make proper use of the insulin produced, due to reduced sensitivity. Diabetes is an important cause for morbidity in Malta with around 10 per cent of the population above 18 years estimated to be living with this condition. The incidence in Malta is expected to continue rising in all age groups, making diabetes a growing health problem. Diabetes has a significant impact on the quality of life of persons with diabetes and their families, especially when complications arise. The high burden of diabetes among the Maltese population calls for a national diabetes strategy. The overall aim of this strategy is to emphasise prevention and early diagnosis of diabetes, expand treatment options and further develop the integrated care and management of diabetes so as to prevent or postpone complications. Support for persons with diabetes and their families at all stages is considered an important aspect of the service framework being proposed.

Many of the risk factors leading to Type 2 diabetes, which is the common form of diabetes, are modifiable. Examples are obesity, unhealthy diet, physical inactivity and smoking. Evidence has shown that in the case of diabetes prevention, measures do work and that the onset of diabetes can be prevented or postponed if a healthier lifestyle were to be adopted. Prevention strategies require a whole of society approach in order to succeed. A higher level of public awareness about diabetes and measures to avoid Type 2 diabetes is necessary. Educating the public about diabetes, its risk and seriousness and promoting a healthy lifestyle could potentially avert the projected increase in diabetes incidence.

Screening for diabetes involves the identification of asymptomatic individuals who are at high risk of developing the disease and through appropriate screening tests. Diagnosing diabetes in its early stages or in the so-called pre-diabetic stage may delay the onset of diabetes and is important to reduce the risk of complications. This strategy therefore proposes an opportunistic screening program at national level through the testing of fasting blood glucose at least every two years for individuals over 45 years and other groups at increased risk of developing diabetes.

The provision of care for individuals with diabetes involves various professionals. The diabetes clinic at Mater Dei Hospital is the hub for specialist care of persons with diabetes. Over the years, a shared care programme has been developed in partnership with the health centres primarily to offer care and support for persons with uncomplicated Type 2 diabetes. This strategy proposes to continue to build on the strengths of the existing clinical care programmes whilst seeking to address the gaps that have been identified. In order to attain consistent high quality outcomes there the strategy recommends investment in additional human resources. This will enable strengthening of the multi-disciplinary team approach particularly in those professions where critical shortages are known to exist. Health care

professionals will be empowered and equipped to offer care in line with a national service framework. For high standards of care to be achieved, investment in innovative treatment, equipment and information systems is considered necessary. The aim is to ensure that patients receive optimal care in all health care settings since it is recognised that the private sector also plays an important role in the care of persons with diabetes. The key emphasis in both children and adults will be primarily geared towards preventing complications through risk factor modification and control. This will be complemented by setting up of systematic screening and follow up for the early detection of complications at a stage where they are amenable to effective intervention.

Patient self-management is a key skill to effectively manage and care for diabetes. It requires patients to understand and know their health condition and to be able to independently control their blood glucose levels. This strategy addresses self-management by placing the patients in the centre of healthcare. It includes actions on patient empowerment, education, health literacy, accessibility of medicines and supplies. Psychosocial support for persons with diabetes will also be strengthened. A legal framework to ensure that persons with diabetes are guaranteed the highest standards of care and that society takes all steps possible to prevent the onset of diabetes and its complications will be developed.

In order to tackle the burden of diabetes effectively, comprehensive and complete information regarding the epidemiology of the disease is necessary. This strategy recommends the setting up of a national register for all persons with diabetes in Malta and Gozo. Additionally, further research will be supported.

This strategy was developed by a Steering Group which included representatives of the major stakeholders involved in diabetes and its management. Its work was guided by the input of over 50 experts who shared their views and put forward their proposal during a series of focus groups held over past months.

Government is presenting this proposal for wide consultation prior to finalising the first ever national strategy for diabetes in line with its electoral programme proposal to bring about improvement in the quality of life for persons with diabetes and their families.

# **CHAPTER 1: INTRODUCTION TO THE NATIONAL DIABETES STRATEGY 2015-2020**

According to the World Health Organisation (WHO) 347 million people worldwide have diabetes and the prevalence is rising faster than expected (WHO, 2013).

Diabetes Mellitus is a chronic disease that occurs when the body's response to insulin is diminished, either due to reduced sensitivity to Insulin, or due to reduced production of Insulin. Insulin is a hormone produced by the pancreas that regulates blood sugar concentration when this rises after a meal, or decreases while fasting. Large swings in sugar concentration are detrimental to health, and lead to both short- and long-term effects. Hyperglycaemia, or raised blood sugar, may seriously damage body tissues such as of the kidneys, nerves, and blood vessels especially when this has been ongoing for a long time. Hypoglycaemia or reduced blood sugar causes the brain to cease functioning properly, and unless corrected immediately may lead to coma and eventually death.

## **TYPES OF DIABETES MELLITUS**

### **TYPE 1 DIABETES**

This is caused by the body's immune system destroying insulin-producing cells in the pancreas. This leads to a reduction in the potential for the body to produce insulin requiring administration of insulin (injected).

### **TYPE 2 DIABETES**

In this type of Diabetes, there is gradual increase in resistance of the body's tissues to the effects of insulin. There is a more gradual onset than Type 1 diabetes (T1DM) and is most common in middle-aged and elderly, however it is becoming more common in younger people too (Rosenbloom, Joe, Young, & Winter, 1999).

There are a number of modifiable risk factors for Type 2 Diabetes (T2DM) including obesity, smoking and inactivity. Hence, apart from starting oral hypoglycaemic agents, first-line management includes dietary changes and exercise.

### **GESTATIONAL DIABETES**

This is the onset of diabetes during pregnancy in an individual with no previously known diabetes but certain risk factors such as obesity and smoking. This is caused by insulin resistance during pregnancy and might herald the onset of T2 DM.

## DIABETES IN MALTA

In 2010, a pilot European Health Examination Survey (EHES) was conducted in which blood glucose measurements were taken to estimate the prevalence of diabetes. 9.8% of the study population (population aged 18 years and over) were found to have Diabetes. The prevalence of elevated blood glucose increased sharply after the age of 40. Between the ages of 41 and 60, 12.2% of the study sample had elevated blood glucose, while this rose to 21.6% of the population older than 60 (Directorate for Health Information and Research, 2010).

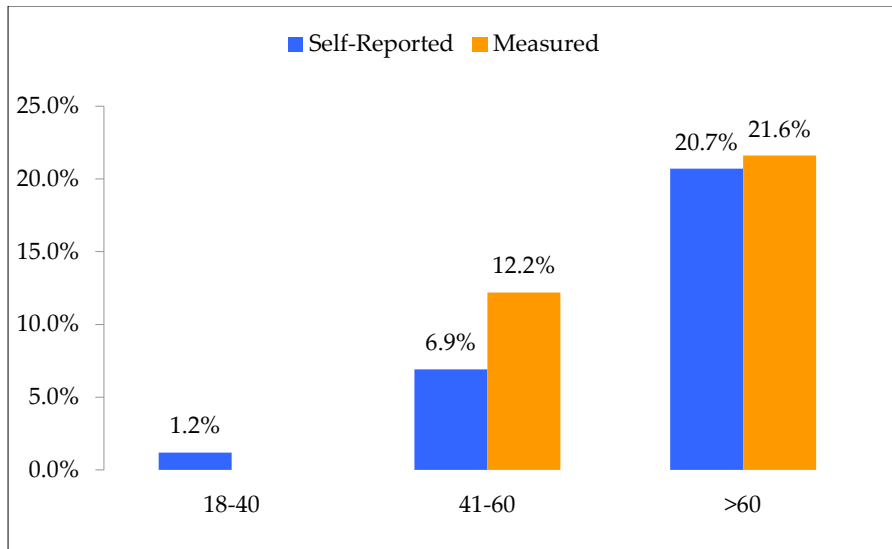
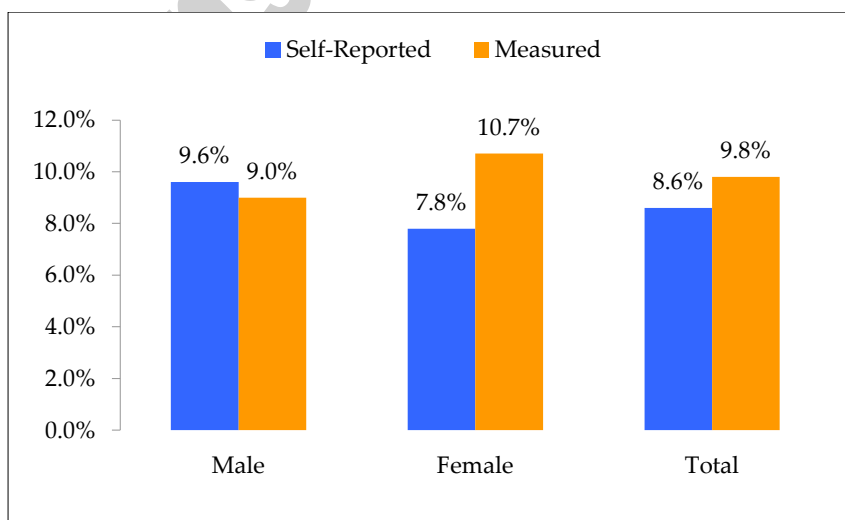


FIGURE 1: SELF-REPORTED (2008) AND MEASURED (2010) PREVALENCE OF ELEVATED BLOOD GLUCOSE BY AGE (Directorate for Health Information and Research, 2010)

According to the European Health Interview Survey (EHIS) conducted 2 years previously in 2008, the self-reported prevalence of Diabetes was 8%, and 6% of the population were taking medications for Diabetes (Department of Health Information and Research, 2008).



**FIGURE 2: SELF-REPORTED (2008) AND MEASURED (2010) PREVALENCE OF ELEVATED BLOOD GLUCOSE BY GENDER** (Directorate for Health Information and Research, 2010)

According to the International Diabetes Federation, 10.1% of all 20-79 year olds in Malta suffer from Diabetes. This places Malta in the first quartile within the European region. A mean diabetes-related expenditure of 1535 USD per diabetic is quoted with an estimate of 12000 undiagnosed diabetics in the population (International Diabetes Federation, 2013).

The last population based prevalence study on diabetes was the MONICA study conducted under the auspices of WHO in 1984. This study had estimated prevalence of diabetes in persons aged 15+ in Malta at 7.7% (A. G. Schranz, 1989).

The above data, whilst having certain limitations, clearly shows diabetes to be a relatively large and still growing health problem in Malta.

## MORTALITY DUE TO DIABETES

In 2012, the Standardised Death Rate due to Diabetes was 6.0 per 100,000. This figure has been decreasing mainly due to a change in coding practices whereby diabetes mellitus is increasingly seen as a contributory cause of death rather than the underlying cause of death, along with hypertension, hypercholesterolaemia and other risk factors for ischaemic heart disease. The average age of death due to Diabetes Mellitus was 69 years in males and 79 years in females, compared to the general population's median age at death of 77 years and 82 years respectively (Directorate for Health Information and Research, 2012).

## DIABETES IN PREGNANCY

In 2012, 22 mothers were reported as having Insulin Dependent Diabetes and 14 mothers having non- Insulin Dependent Diabetes prior to the pregnancy. There were 179 mothers registered with impaired glucose tolerance or gestational diabetes but none required treatment with insulin (Department of Health Information and Research, 2012).

Gestational Diabetes is the second-most frequent pathology encountered during pregnancies between 2001 and 2010 (2.4% of maternities) (Department of Health Information & Research, 2012).

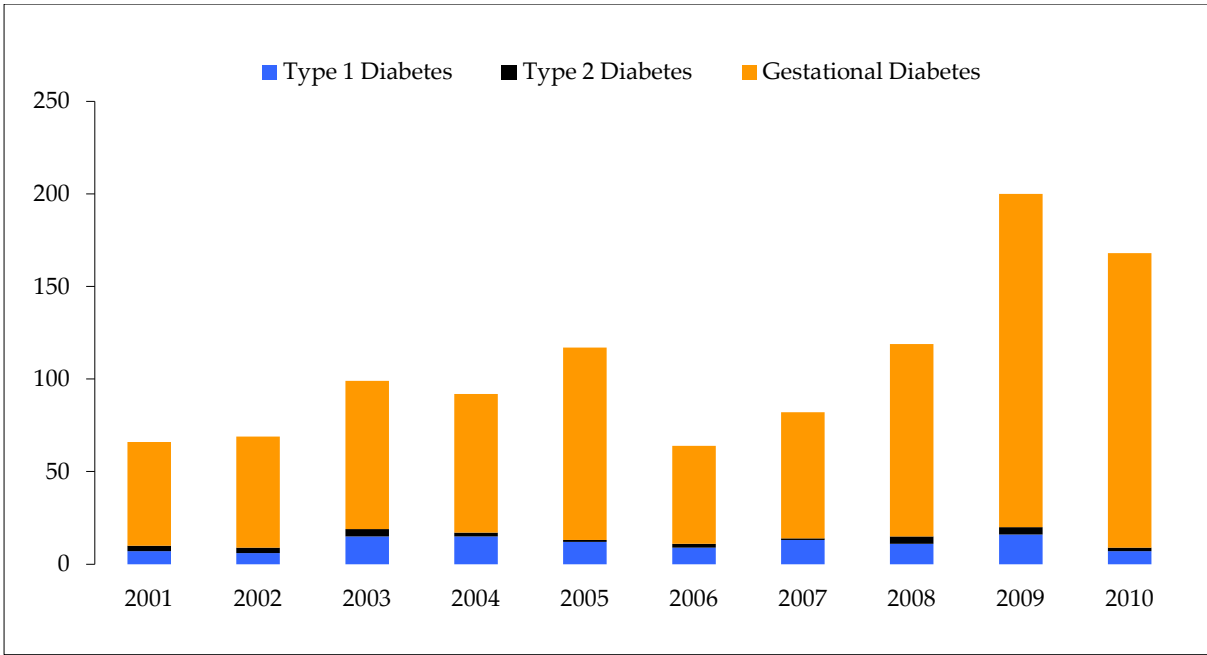
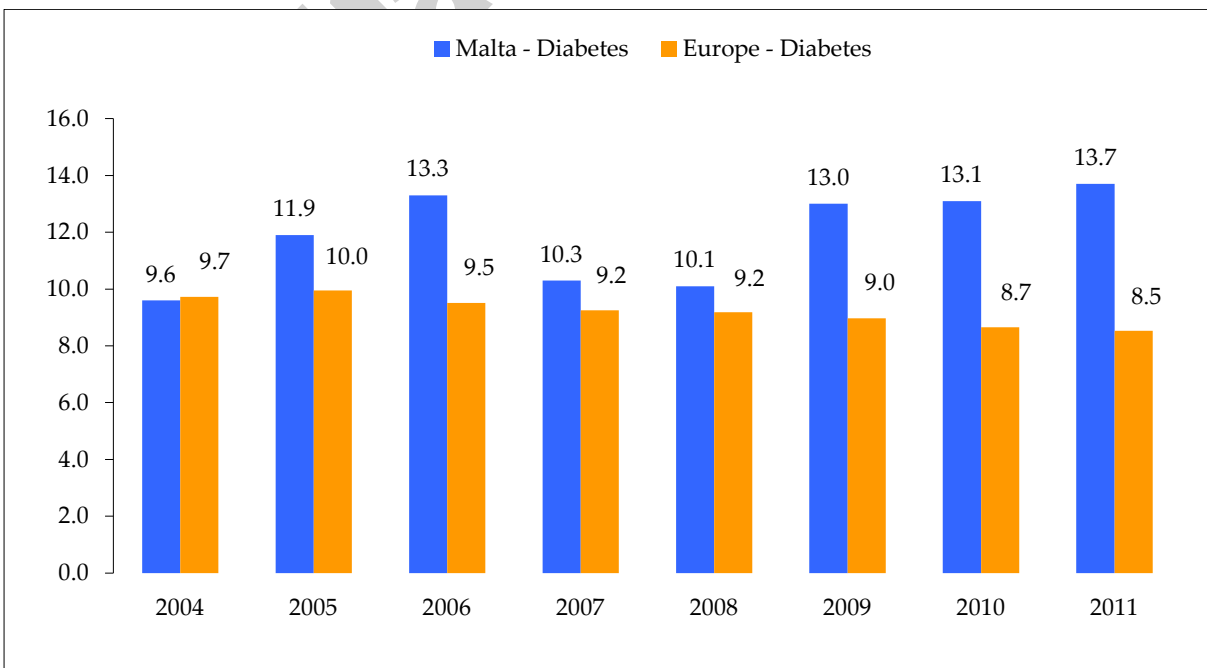


FIGURE 3: MATERNAL PATHOLOGY DURING PREGNANCY (Department of Health Information & Research, 2012)

## HOSPITAL STAY

The average length of stay in hospital for Diabetes Mellitus was the highest in the EU in both 2010 and 2011, rising from 13.1 to 13.7 days respectively. The EU average was 8.7 days in 2010 and 8.5 days in 2011 (EUROSTAT, 2013).



**FIGURE 4: IN-PATIENT AVERAGE LENGTH OF STAY (DAYS) FOR PATIENTS WITH DIABETES MELLITUS COMPARING MALTA TO EUROPE (EUROSTAT, 2013)**

## UNCONTROLLED DIABETES

The age and sex-standardised rate of hospital admissions due to uncontrolled diabetes was 160 per 100,000 population which is comparable to the EU15 average of 159 per 100,000 in 2009 (OECD, 2012).

## RISK FACTORS FOR DIABETES

### AGE

Since T2DM is commonly diagnosed in middle age and is most prevalent in older people, the changing demographics will have an impact on the prevalence of Diabetes.

### SOCIO-ECONOMIC FACTORS

Factors such as obesity, physical inactivity, unhealthy diet, smoking and poor blood pressure control are all associated with increased risk of developing diabetes. These are more prevalent in individuals suffering from social deprivation and are hence linked (Wilkinson & Marmot, 2003).

### MODIFIABLE RISK FACTORS

Obesity: When compared to EU member states, Malta has the highest rate of obesity amongst males and the third highest rate amongst females. 69% of males and 49.1% of females were overweight and obese (Department of Health Information and Research, 2008).

Unhealthy diet: The Health Promotion & Disease Prevention Directorate is in the process of developing a National Food Consumption Survey which will give a good indication of Maltese eating habits. Based on previous surveys, the national obesity strategy has 6 targets for nutrition which include: reducing the frequency of intake of processed meats, sweets, pastries and sugared soft drinks, increasing the intake of fish and vegetables, and reducing the mean daily intake of animal fat (Superintendence of Public Health, 2012).

Physical Inactivity: The 2002 and 2005 *Eurobarometer* studies on Physical Activity and Health and Food respectively report Malta as scoring the lowest in a comparison undertaken with the EU-15 (2002) and EU-25 (2005) member states for the number of days of moderate and vigorous physical activity, lowest duration of physical activity during the day and lowest average walking time during the week (EUROSTAT, 2013).



Smoking: 19.2% of the Maltese population aged 15 or older smoke daily (EU average 23.9%). (Department of Health Information and Research, 2008; EUROSTAT, 2013) In the 2007 European School Survey Project on Alcohol and Other Drugs study, conducted among Form 5 students, 26% of children reported smoking cigarettes in the previous 30 days. 3.4% of children have their first cigarette when less than 9 years old and the age at which the highest number of children smoked their first cigarette is 14 years (*European School Survey Project on Alcohol and other Drugs*, 2007).

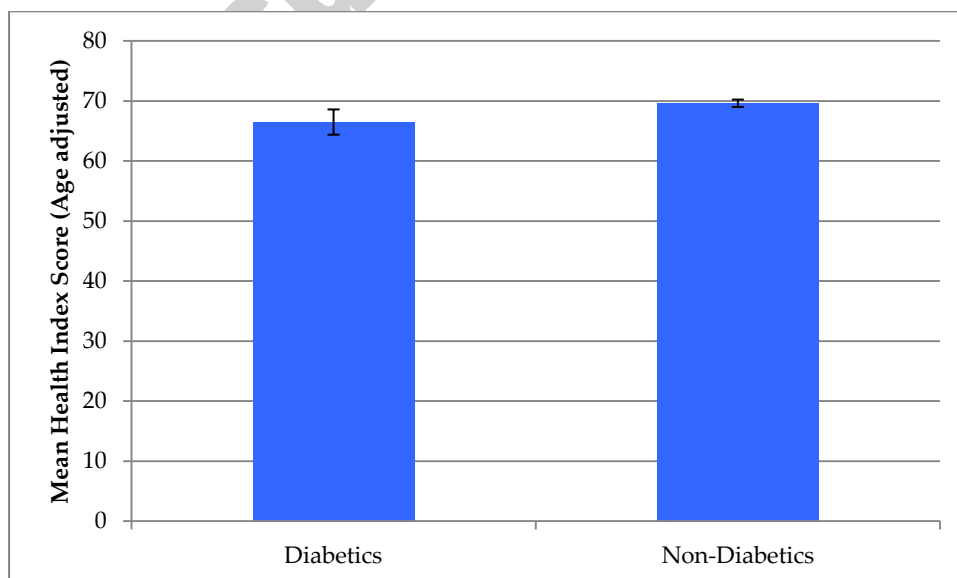
According to the latest Health Behaviour in School Children study, Malta scored third from the top in terms of 13-year-olds who smoke at least once (11% of girls and 9% of boys)(WHO Europe, 2006).

## HEALTH IMPACT OF DIABETES

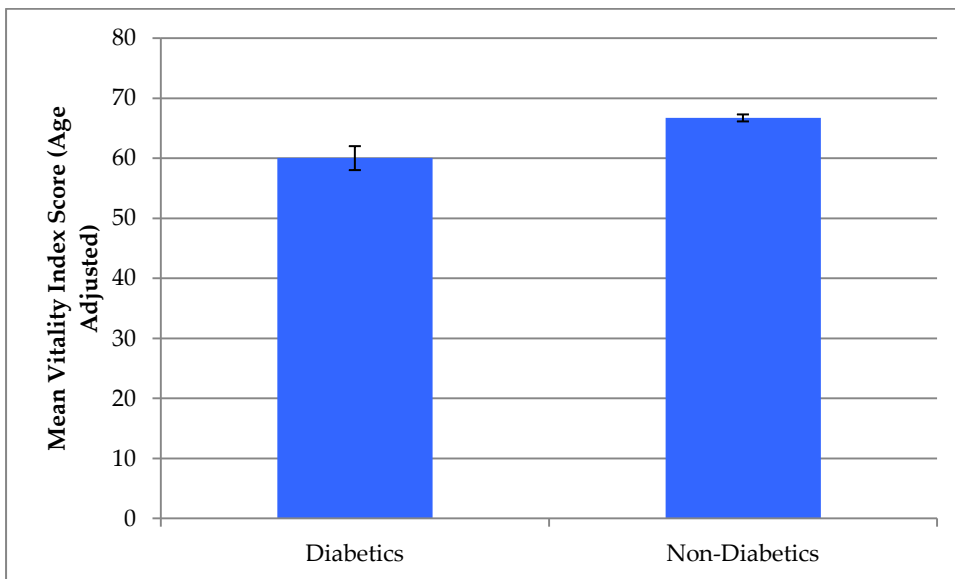
### GENERAL EFFECTS ON HEALTH AND WELLBEING

Diabetes is associated with a variety of other conditions affecting health. In fact, local data from the Health Interview survey reveals that the age-adjusted means of both the Mean Health Index (Figure 5) and the Mean Vitality Index score (Figure 6) are significantly lower in people with diabetes when compared to those without (Self-reported) (Department of Health Information and Research, 2008).

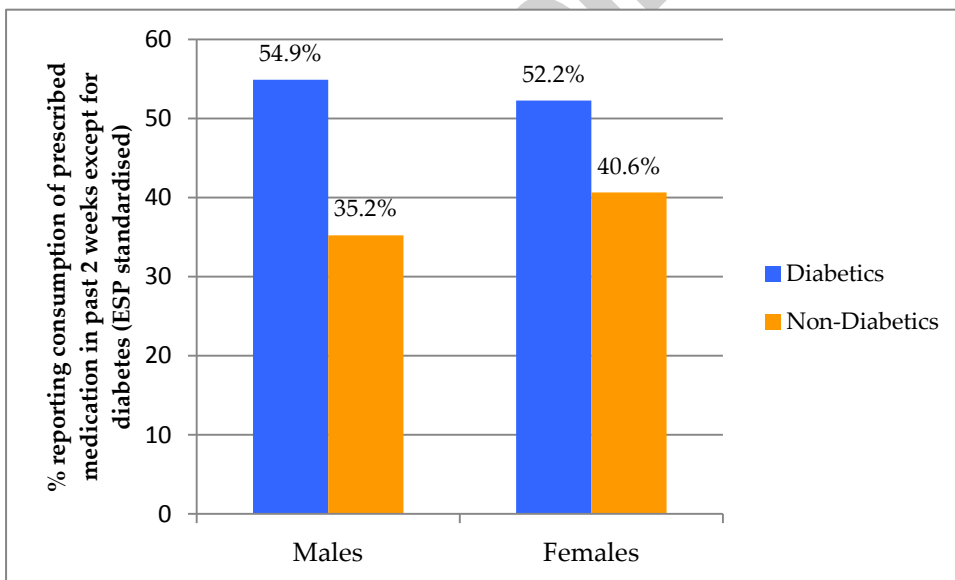
Another measure of morbidity caused by Diabetes is the self-reported need for prescribed medications in diabetics versus non-diabetics, after the diabetic medication itself is excluded. While 55% of male diabetics are on some prescribed medication, only 35% of non-diabetics are. This difference is slightly smaller in females but still significant (Department of Health Information and Research, 2008) (Figure 7).



**FIGURE 5: MEAN HEALTH INDEX SCORE (AGE-ADJUSTED) IN PEOPLE WITH AND WITHOUT DIABETES**  
(Department of Health Information and Research, 2008)



**FIGURE 6: MEAN VITALITY INDEX SCORE (AGE-ADJUSTED) IN PEOPLE WITH AND WITHOUT DIABETES**(Department of Health Information and Research, 2008)



**FIGURE 7: PROPORTION OF PEOPLE REPORTING CONSUMPTION OF PRESCRIBED MEDICATION IN THE PAST TWO WEEKS EXCEPT FOR DIABETIC MEDICATION (ESP STANDARDISED) IN DIABETICS VS. NON-DIABETICS BY GENDER** (Department of Health Information and Research, 2008)

## CARDIOVASCULAR DISEASE

Damage to arteries occurs in the presence of prolonged high glucose concentrations. This leads to a variety of cardiovascular diseases such as heart disease, stroke and peripheral

vascular disease. People with diabetes have about twice the risk of developing a range of cardiovascular diseases, compared with those without diabetes, (Sarwar et al., 2010) and are likely to die due to them; cardiovascular disease is a major cause of death and disability in people with diabetes, accounting for 44 per cent of fatalities in people with Type 1 diabetes and 52 per cent in people with T2DM (Morrish, Wang, Stevens, Fuller, & Keen, 2001). Local data also shows that persons with Diabetes have a higher all-cause mortality rate after a myocardial infarction, than persons without diabetes (Gruppetta, Calleja, & Fava, 2010). In addition, people with T2DM have a two-fold increased risk of stroke within the first five years of diagnosis compared with the general population (Jeerakathil, Johnson, Simpson, & Majumdar, 2007).

## **KIDNEY DISEASE**

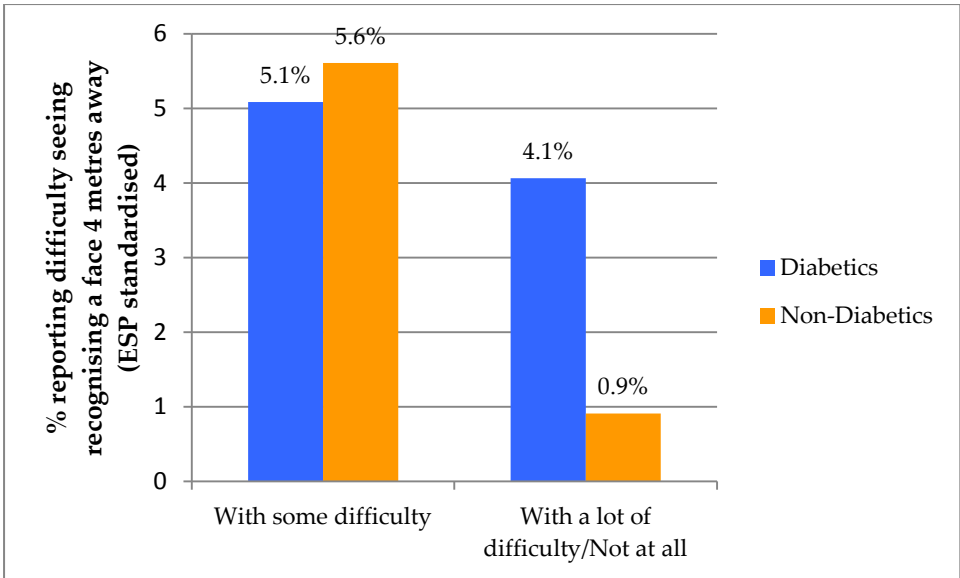
The damage caused by high blood sugar concentrations also affects small vessels in the kidneys. They start working less efficiently which may eventually result in kidney failure. Keeping blood glucose levels as near normal as possible and blood pressure well controlled can greatly reduce the risk of kidney disease developing as well as other diabetes complications (Stratton et al., 2000). Despite this, diabetes is the single most common cause of end stage renal disease, (Locatelli, 2004) and around one in three people with T2DM eventually develops overt kidney disease (Remuzzi, Benigni, & Remuzzi, 2006).

Kidney disease is the second most common cause of death in diabetics, accounting for 21 per cent of deaths in T1DM and 11 per cent of deaths in T2DM (Morrish et al., 2001).

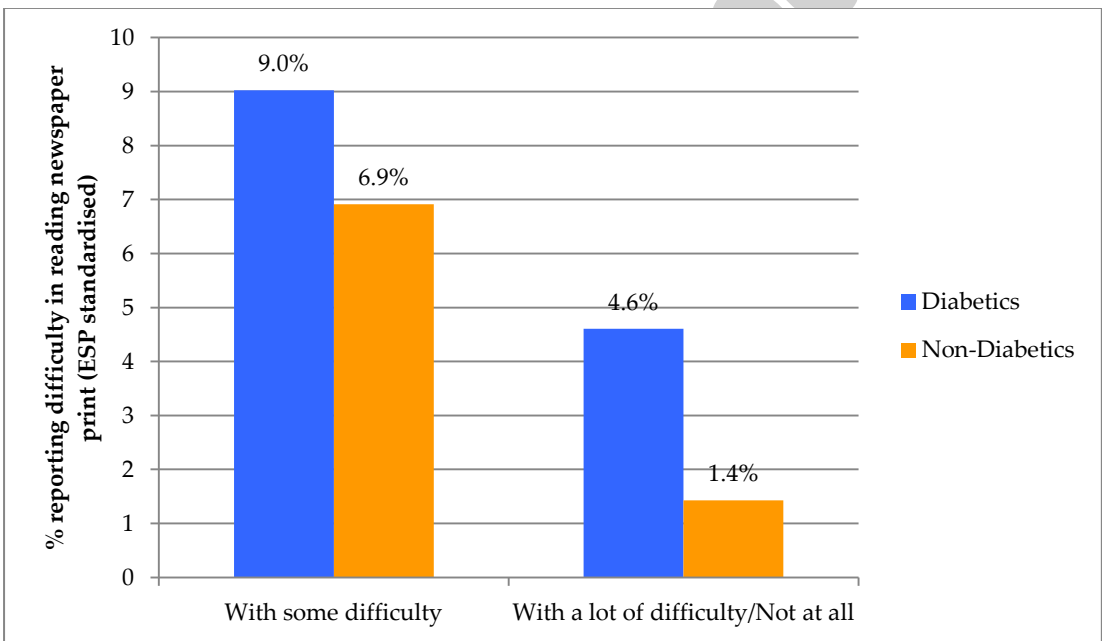
## **EYE DISEASE**

Blood vessels in the retina of the eye can also be damaged. This leads to compromised vision and may even lead to blindness if untreated (Retinopathy). Within 20 years of diagnosis nearly all people with T1DM and almost two thirds of people with T2DM (60 per cent) have some degree of retinopathy, and people with diabetes are 10 to 20 times more likely to go blind than people without diabetes (Infeld & O'Shea, 1998). People with diabetes are also twice as likely to suffer from cataracts or glaucoma as the general population (Ederer, Hiller, & Taylor, 1981).

The Health Interview Survey in 2008 asked respondents to state whether they could recognise a face 4 metres away, or read newspaper as a measure as a measure of short-/long-sightedness respectively. (Figure 8, Figure 9) Diabetic subjects were found to be more likely to report having a lot of difficulty or even being completely unable to do so than non-diabetics (Self-reported) (Department of Health Information and Research, 2008) ( $p < 0.05$ ).



**FIGURE 8: PROPORTION OF PEOPLE REPORTING ABILITY TO RECOGNISE A FACE 4 METRES AWAY (ESP STANDARDISED) IN PEOPLE WITH AND WITHOUT DIABETES**



**FIGURE 9: PROPORTION OF PEOPLE REPORTING ABILITY TO READ A NEWSPAPER (ESP STANDARDISED) IN DIABETICS VS. NON-DIABETICS**

## AMPUTATION

The biggest cause of amputations in persons with diabetes is due to peripheral artery disease. Worldwide, the rate of leg amputations in people with diabetes is over 15 times higher than in people without diabetes (A. J. M. Boulton, 1997). It is a cause of great morbidity and also a risk factor for premature death since up to 70 per cent of people die within five years of having an amputation as a result of diabetes (Schofield et al., 2006).

## MENTAL HEALTH

Emotional health and wellbeing can be affected by coping with diabetes and as a side effect of some medication.

The prevalence of depression is approximately twice as high in people with diabetes as it is in the general population (Katon et al., 2004).

Locally, people with diabetes are more likely to report symptoms of chronic anxiety or depression when compared to non-diabetics (Self-reported) (Figure 10) (Department of Health Information and Research, 2008).

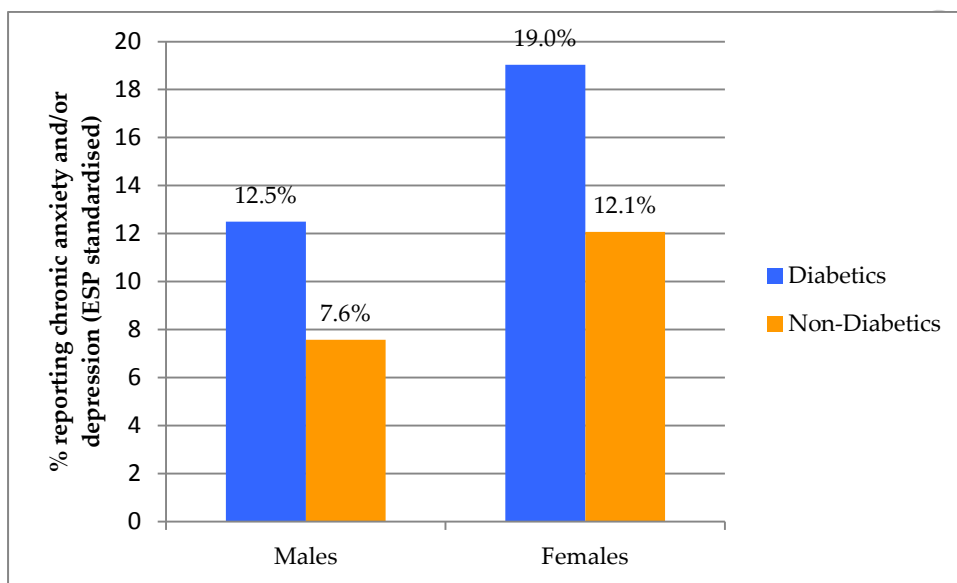


FIGURE 10: PROPORTION OF PEOPLE REPORTING CHRONIC ANXIETY AND/OR DEPRESSION (ESP STANDARDISED) IN PEOPLE WITH AND WITHOUT DIABETES (Department of Health Information and Research, 2008)

## NEUROPATHY

Due to the damage to nerves that diabetes causes, some patients suffer from chronic nerve pain.

Neuropathies (or nerve damage) may affect up to 50 per cent of patients with diabetes (A. J.M. Boulton, 2005), which may lead to Charcot deformities which impact greatly on the quality of life.

## SEXUAL DYSFUNCTION

The same neuropathy can result in erectile dysfunction.

The reported prevalence of erectile dysfunction is between 35 per cent and 90 per cent among men with diabetes (Malavige & Levy, 2009).

## COMPLICATIONS IN PREGNANCY

A foetus of a pregnant mother who is also a diabetic or develops diabetes during pregnancy is at a greater risk for complications such as macrosomia (excessive birth-weight) which may lead to complications during labour, neonatal hypoglycaemia and stillbirth (González-Quintero et al., 2007). Uncontrolled or unrecognised diabetes in early pregnancy can also lead to congenital malformations and miscarriages.

## PROJECTIONS (FUTURE HEALTH PROFILE)

According to the latest projections by the International Diabetes Federation, the local prevalence of Diabetes is expected to rise unless drastic action is undertaken to address this. The rise in prevalence together with Malta's changing demographics also means that Maltese diabetics will get older and hence more prone to morbidity (International Diabetes Federation, 2013).

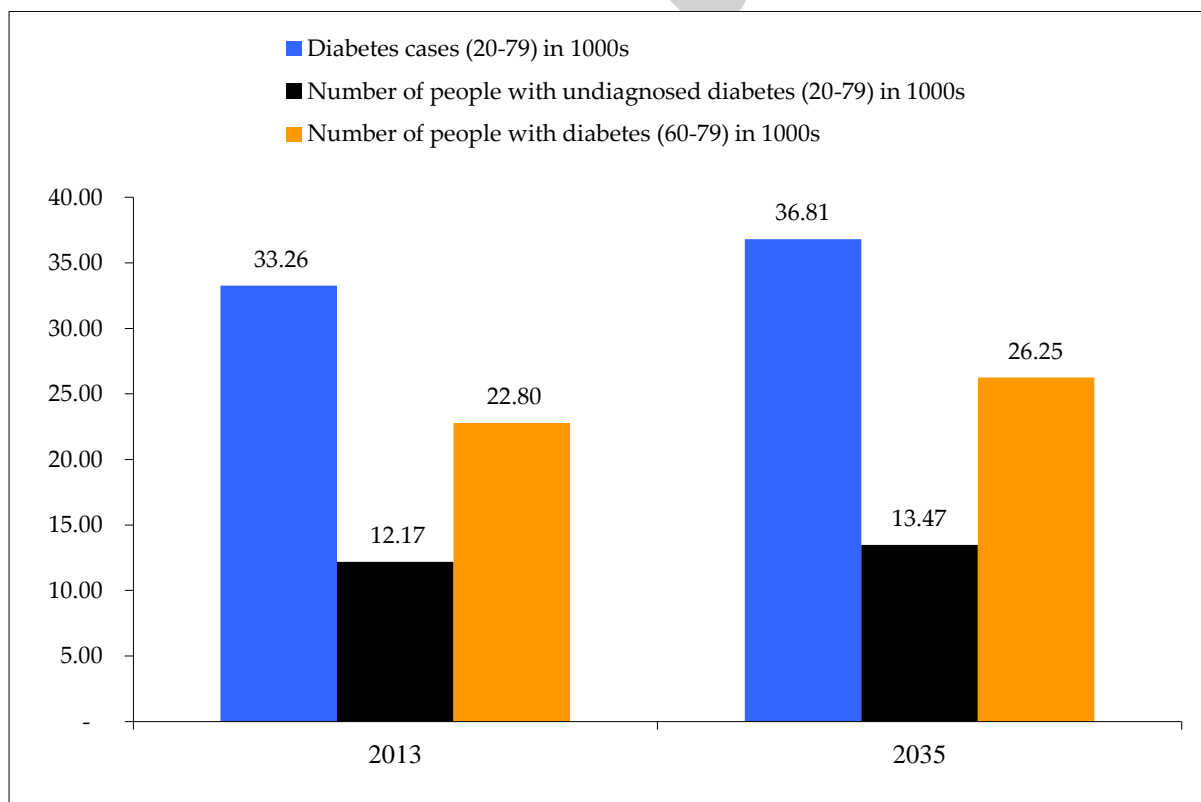


FIGURE 11: IDF PROJECTIONS FOR NUMBER OF DIABETES CASES (TOTAL, UNDIAGNOSED AND IN 60-79 YEAR AGE GROUP) IN 2035 (International Diabetes Federation, 2013)

Figure 12 shows the local projected prevalence of diabetes. This was produced by applying the current age-standardised rates to NSO's projected population demographics.

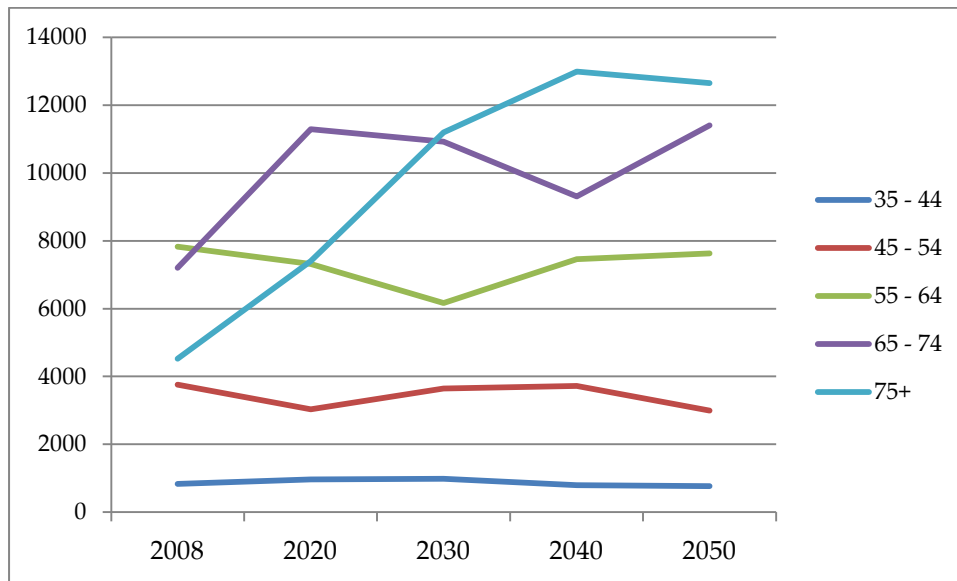


FIGURE 12: PROJECTED PREVALENCE OF DIABETES BY AGE GROUP. (Calleja, 2005)

NOTE: Projections assume that the age specific prevalences of self-reported diabetes remain the same from that reported in 2008. Projection calculated using 2010EUROPOP population figures for Malta.

## COSTS (ADAPTED FROM THE EC WEBSITE) (European Commission, 2014)

There are 3 categories of costs associated with diabetes:

**Directs costs:** Diabetes is costly for the health care systems because of its chronic nature and particularly because of the gravity of its complications.

**Indirect costs:** Diabetes causes a loss of productivity because of disability, sick leave, early retirement and premature death. These costs are borne both by firms and by insurance companies. Indirect costs are often higher than direct costs. A similar survey made in Latin America shows that indirect costs are 5 times higher than direct costs. The same tendency was observed in the United States of America.

**Intangible costs:** Diabetes influences the quality of life of patients (suffering, anxiety, and discrimination sometimes). It can also affect their social life and their leisure time. Their mobility can also be reduced because of the disease.

Diabetes complications require hospitalisation most of the time. 50% of people with diabetes suffer from at least one complication. Hospitalisation represents the biggest proportion of

the direct costs. It implies admission to hospital, laboratory analysis, the work of medical staff, specific therapies, and investments to assure the best quality of care for affected people. The length and the frequency of this hospitalisation also increase the charges for health systems. By contrast, drug costs (insulin, anti-diabetic drugs) to treat T2DM are relatively low. To sum up, diabetes complications represent a huge cost for health care systems.

## LOCAL COSTS

In Malta, the annual excess cost for hospital, primary care and specialist visits for persons with diabetes versus those without diabetes has been calculated using EHS 2008 data. It is estimated to be at least €9 million, the bulk of which is due to more frequent and longer inpatient stays.

## THE RATIONALE FOR A NATIONAL DIABETES STRATEGY FOR MALTA

Diabetes is an important cause of morbidity in the Maltese population. Its incidence is rising in all age groups. Diabetes has a significant impact on the quality of life of the individuals affected as well as their families. Furthermore, diabetes is an economic burden to society.

Some types of diabetes are preventable. Prevention strategies require a whole of society approach as is proposed in the WHO health policy Health 2020. Persons with diabetes have the potential to lead an active and fulfilled life. The support from society in terms of provision of high quality health care that is free at the point of use as well as removal of barriers for engagement in work and leisure activities are important aspects of any diabetes strategy.

The high prevalence of diabetes in Malta warrants a national strategy. Whilst acknowledging and building upon the existing strengths, a national strategy allows us to focus on the gaps and propose measures to address them.

This will ensure coordinated action from health authorities, health care providers, health care professionals, patients and civil society in order to bring about a coordinated and consistent approach to diabetes prevention and care in Malta. The establishment of a cross party Parliamentary Working Group on diabetes has served to heighten the profile of the disease and its impact on society. Members of the steering group tasked with the drafting of this proposal for a national strategy were invited to contribute to the work of the Parliamentary Working Group. The consultations held by the Parliamentary Working Group greatly facilitated and supported the work of the steering group and every effort was made to incorporate the main recommendations that came out of the deliberations of the



Parliamentary Working Group as well as the final report in the preparation of this document.

This document is intended as a proposal for consultation. It outlines Government's vision to tackle diabetes and proposes measures to achieve this vision in partnership with all of society. The content of this document has been informed by reviews of international and local literature, input from members of the Diabetes Steering Group and a series of focus groups that included patients, clinicians and other experts.

The national diabetes strategy forms part of a series of health policies all of which are geared towards reduction of the burden of chronic non-communicable disease in society within the framework of the national health systems strategy.

Consultation Document

## CHAPTER 2: CURRENT SITUATION IN DIABETES CARE

### PROVISION OF CLINICAL SERVICES FOR DIABETES

All adult persons with diabetes irrespective of the aetiology and classification of their diabetes have access to specialist care provided within the diabetes clinic at Mater Dei Hospital. This clinic has been established for several decades previously at St Luke's Hospital and has been the reference point for all health care professionals and patients with regards to diabetes care offering services in line with International recommendations and standards for the management of patients with diabetes. Services are provided by specialised doctors, nurses and allied health professionals both on an outpatient and inpatient basis. Adults with T1DM, gestational diabetes, maturity onset diabetes of the young (MODY) and other rare types of diabetes as well as persons with complications from T2DM are all seen within the specialist clinics at Mater Dei Hospital since this is the appropriate clinical setting to care for these conditions. Children with diabetes are seen by a Consultant Paediatrician and Endocrinologist at the Children Outpatients.

When complications develop, other professionals are involved in the care of the person with diabetes depending on the nature of the complication. Ophthalmologists, renal physicians, vascular surgeons, cardiologists, physiotherapists, podiatrists, and tissue viability nurses are key in the care of persons with diabetes who develop complications.

Over the past few years in order to meet the increasing demand as the prevalence of diabetes increases as a result of the demographic transition and other factors, a shared care diabetes program has been developed between Mater Dei Hospital as the specialist referral centre for all adult persons with diabetes and the health centres in primary care. In this shared care programme primarily patients with uncomplicated T2DM are seen by a General Practitioner (GP) with a special clinical interest, in primary care. Patients are also seen at prescribed time intervals by the specialist in diabetes and fast track referral scheme are in place to allow patients to be seen in between scheduled specialist appointments should the necessity arise.

Services to prevent eye complications through preventive retinal photography have been in place in a hospital setting for several years. More recently funduscopy cameras have also been installed in the community. Likewise podiatrists offer foot screening, examination and management in both the hospital and community settings.

Currently persons with diabetes in Malta can choose to be managed either through the public health sector or through the private sector. In the private sector patients are managed by their private GP or by their private diabetes specialist through a system of professional referral as the need arises. The significant contribution of private primary care in the Maltese health care system means that for a number of patients private primary care providers play a key role in the care of persons with diabetes. In many cases, a combination of service providers may be responsible for care of persons with diabetes across hospital and primary care and across public and private settings.

All persons with diabetes are also encouraged to attend structured diabetes education sessions carried out by diabetes nurses, doctors, dietitians and podiatrists. Sometimes referral for psychological review is also required.

Seamless communication and coordination of all aspects of patient care therefore represent a particular challenge in the management of diabetes which requires the specialised input of several health care professionals.

## UTILISATION OF SERVICES

The Diabetes Clinics in Health Centres are mostly run by Family Doctors with a special interest and training in Diabetes. The number of attendances has been steadily increasing over the years (Figure 13). Persons with Diabetes are seen in a holistic manner, and a number of routine investigations and examinations are performed at least every 6 months. Persons with Diabetes are referred to the clinics by referral from Family Doctors in the community (both public and private), and also from Mater Dei Hospital.

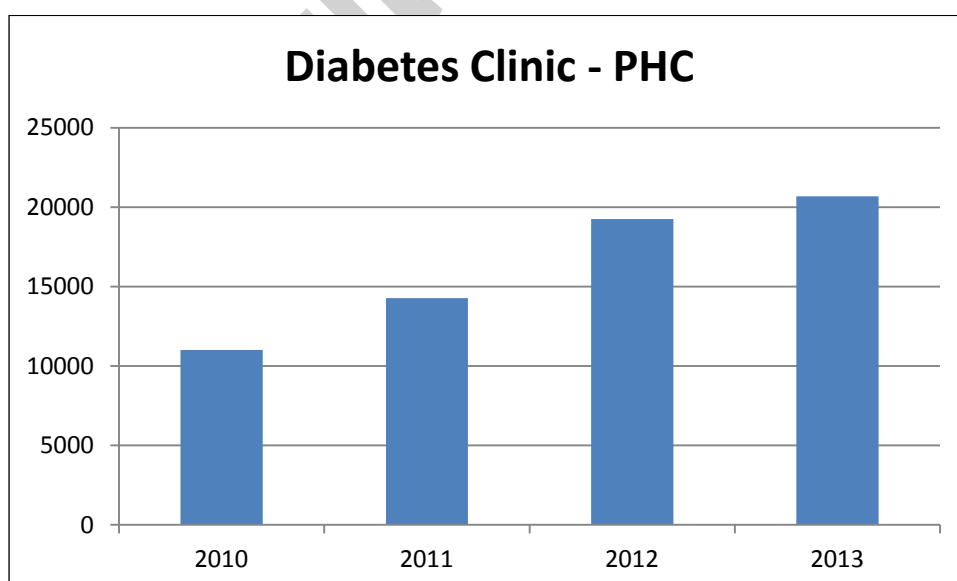


FIGURE 13: NUMBER OF ATTENDANCES AT THE DIABETES CLINICS IN PRIMARY HEALTH CARE (Directorate of Health Information and Research, 2013)

They are also referred once a year for podiatry and ophthalmologic assessment at the Health Centres that offer Podiatry and Ophthalmology services. Recent data shows that while most of this protocol is being adhered to, there are still some areas that require work. Over a 12 month period, only 71% of persons received eye screening, 59% had a podiatry appointment, and only 14% had their urine tested for microalbuminuria. (Montebello, 2014)

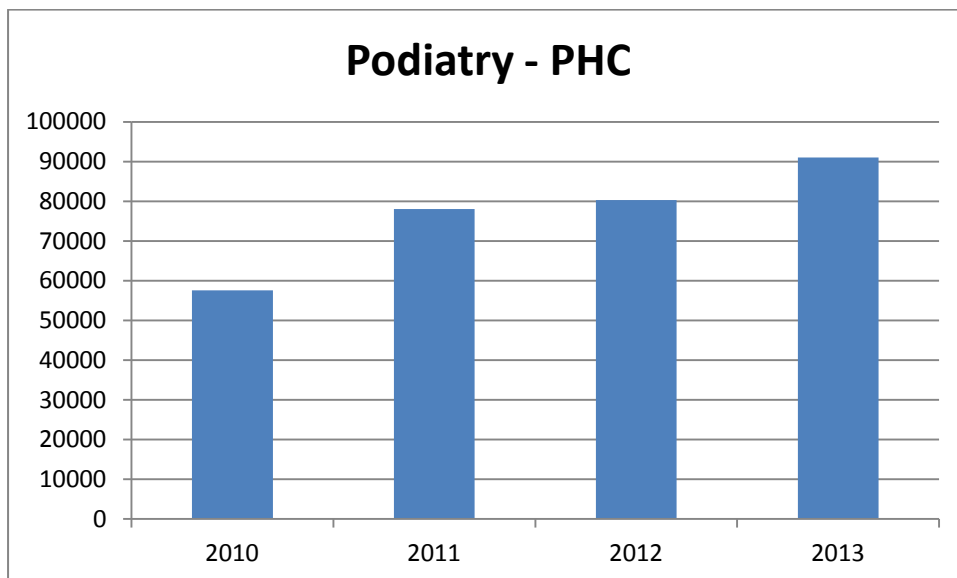
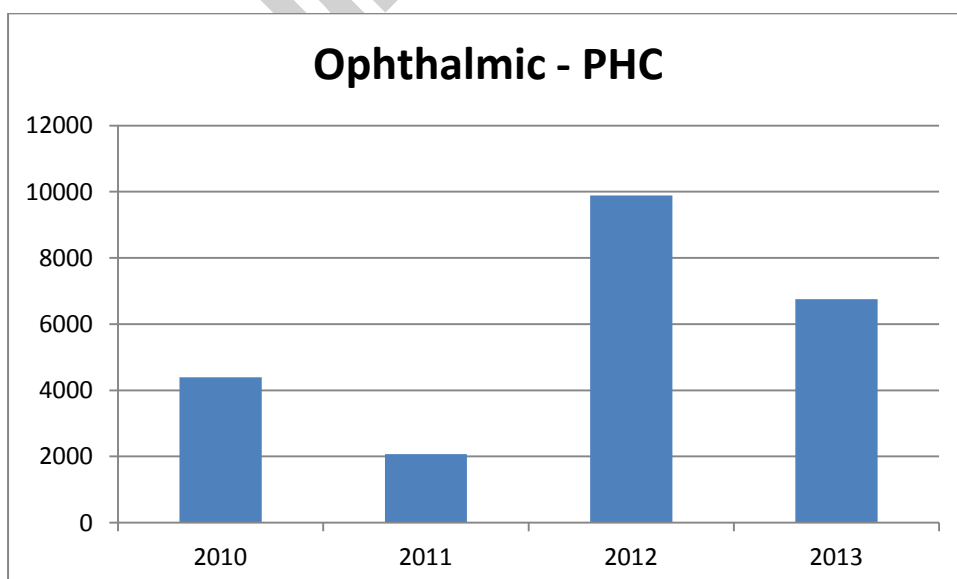


FIGURE 14: NUMBER OF ATTENDANCES AT THE PEDIATRY CLINICS IN PRIMARY HEALTH CARE (Directorate of Health Information and Research, 2013)

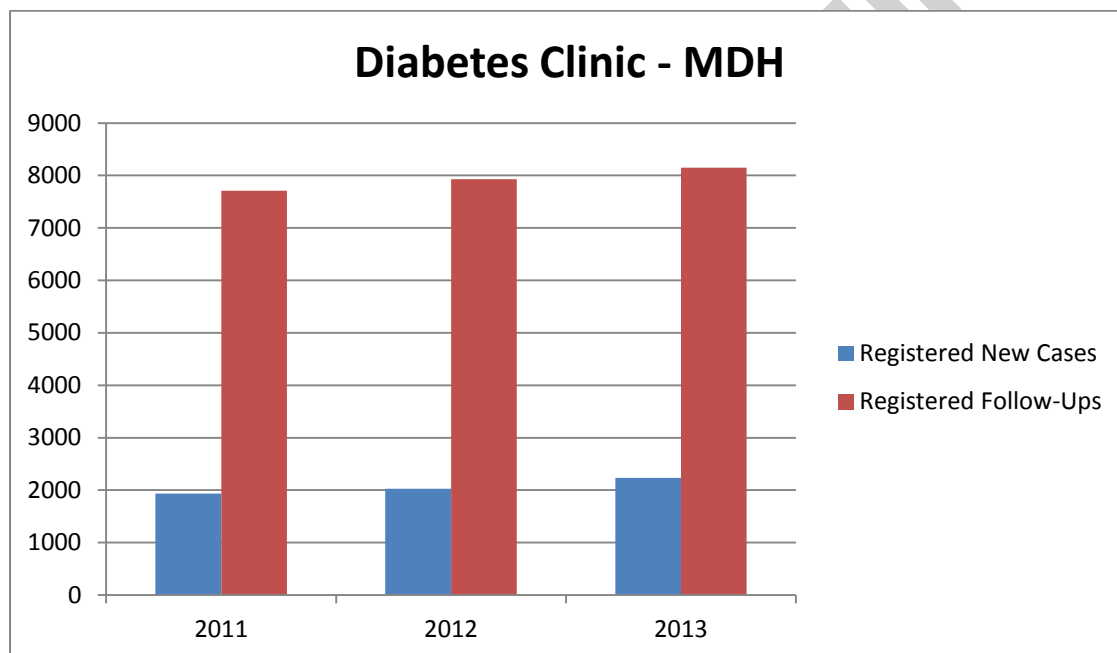
The Podiatry clinics in many Health Centres do not only deal with diabetic foot problems but are inundated with other referrals of varying clinical significance.



**FIGURE 15: NUMBER OF ATTENDANCES AT THE OPHTHALMIC CLINICS IN PRIMARY HEALTH CARE**  
(Directorate of Health Information and Research, 2013)

Apart from the need for regular review by specialised podiatrists and ophthalmologists, there is a need for better assessment and earlier referral for mental and dental health, and diabetic neuropathy. Formalised screening protocols and referral pathways would help diagnose complications earlier, and improve rates of foot and eye complications. This will need to be coupled with education sessions to health care professionals and service users alike.

Currently, every person who attends the Diabetes Clinic in the community is reviewed by a diabetes specialist at a prescribed time interval depending on the clinical requirements. The clinics at Mater Dei Hospital are consultant-led. There are currently four Consultant Endocrinologists (and one part-time) who each run a Diabetes Clinic to deal with the ever-increasing number of referrals (Figure 16).



**FIGURE 16: NUMBER OF ATTENDANCES AT THE DIABETES CLINIC AT MATER DEI HOSPITAL** (Directorate of Health Information and Research, 2013)

Diabetes Awareness Sessions at Mater Dei Hospital are organised by three Practice Nurses specialised in Diabetes. These three nurses are tasked with providing structured education to all persons with diabetes in Malta. Due to the fact that there are an estimated 30,000 persons with Diabetes in Malta, they are very limited and often only take place upon initial diagnosis with the main focus being on patients starting insulin.

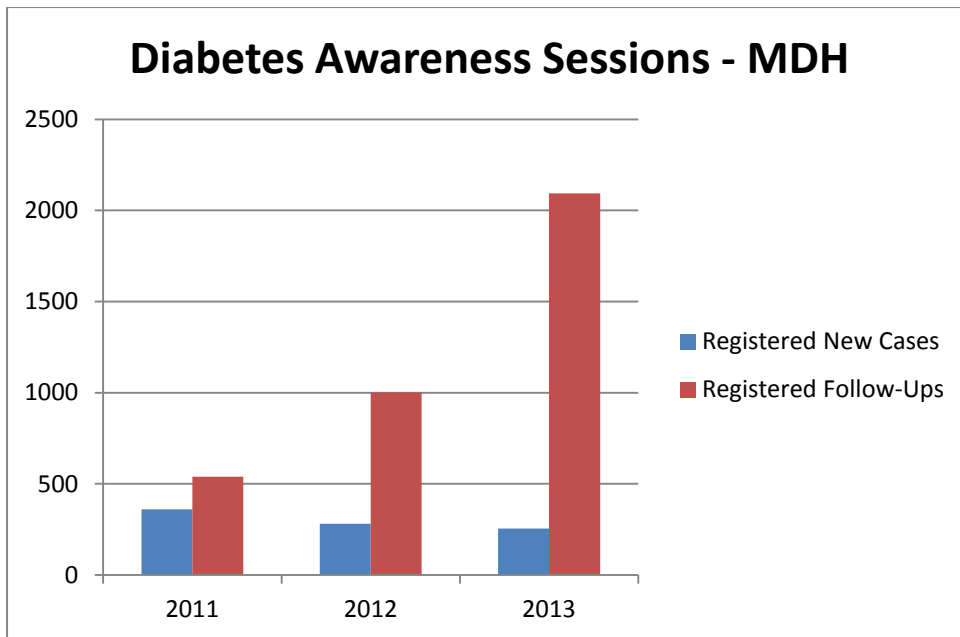


FIGURE 17: NUMBER OF ATTENDANCES FOR DIABETES AWARENESS SESSIONS AT MATER DEI HOSPITAL (Directorate of Health Information and Research, 2013)

There are also Diabetic Retinopathy and Podiatry clinics at Mater Dei Hospital, who see cases referred from the consultant clinics, other healthcare providers, and also self-referrals.

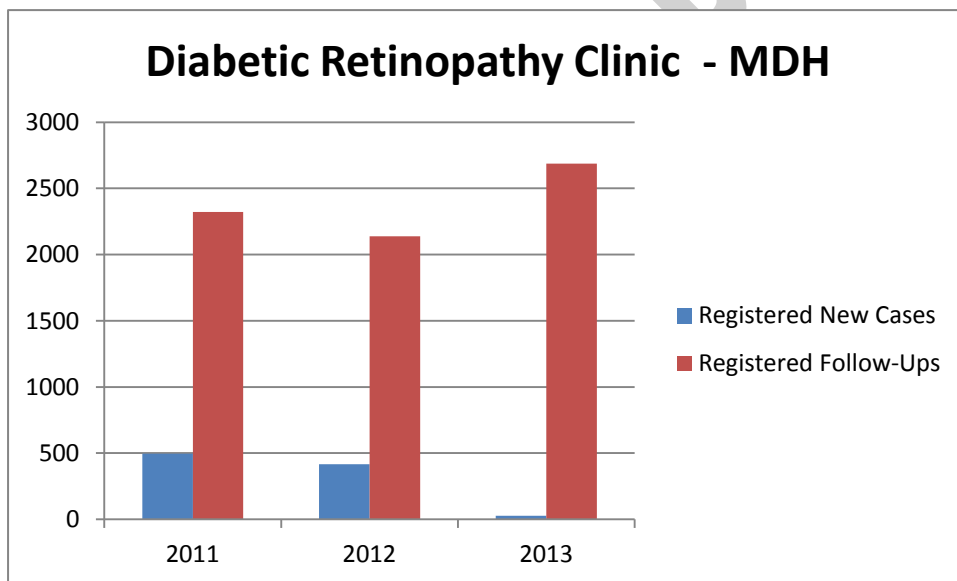
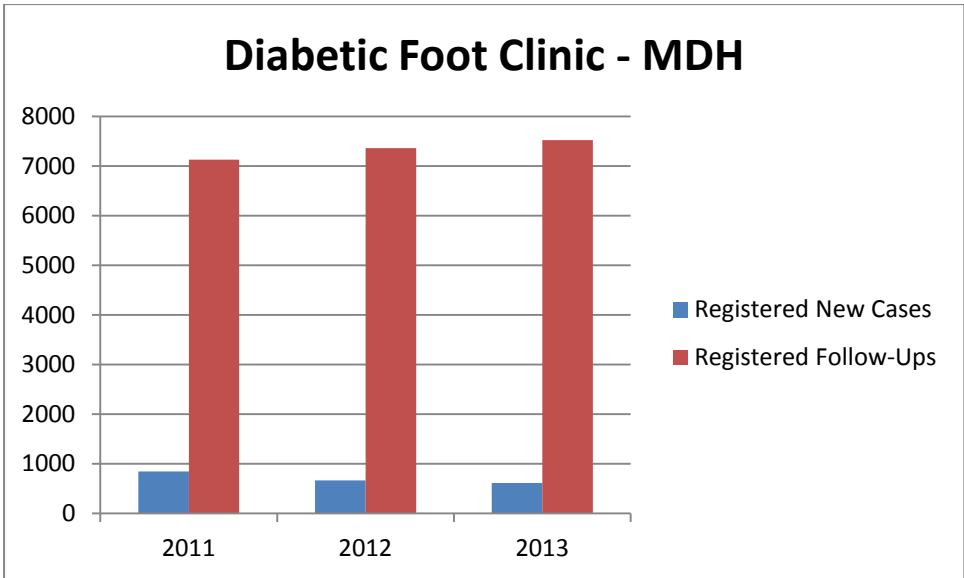
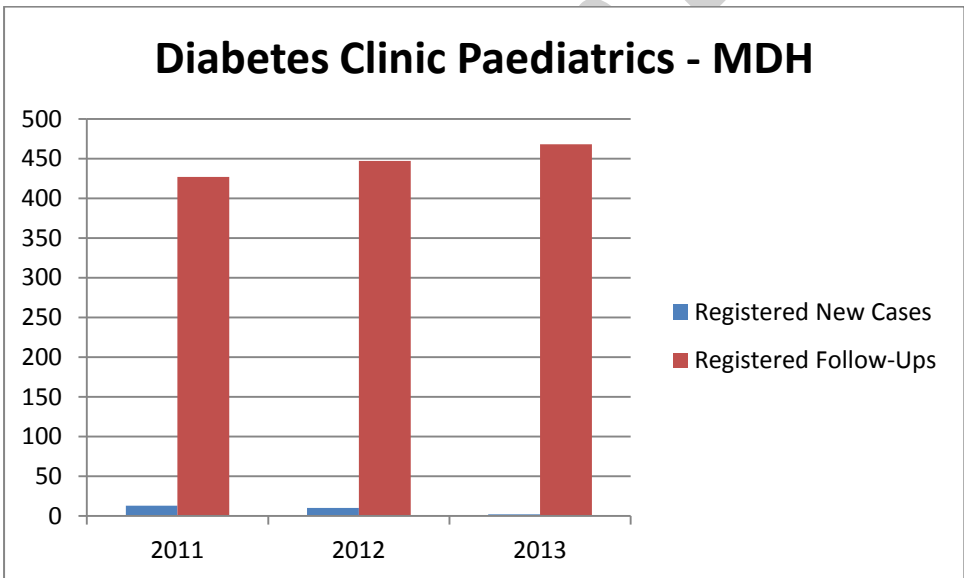


FIGURE 18: NUMBER OF ATTENDANCES AT THE DIABETIC RETINOPATHY CLINIC AT MATER DEI HOSPITAL (Directorate of Health Information and Research, 2013)



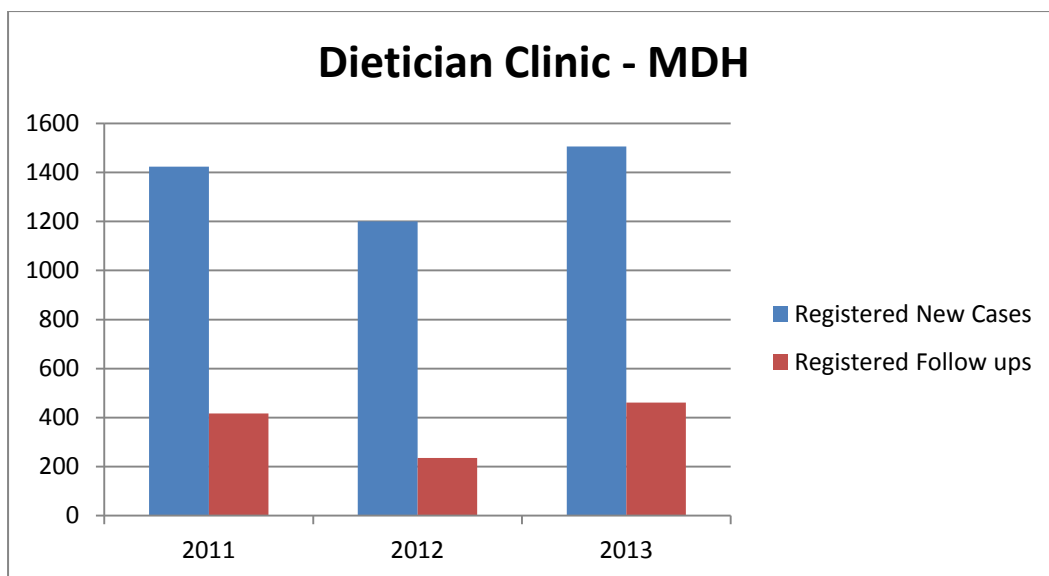
**FIGURE 19: NUMBER OF ATTENDANCES AT THE DIABETIC FOOT CLINIC AT MATER DEI HOSPITAL**  
(Directorate of Health Information and Research, 2013)

There is one Consultant Paediatric Endocrinologist who sees all children and adolescents under the age of 16 years in Malta with diabetes who are referred to him. The number of new cases shown in Figure 20 is lower than the actual number since new cases are admitted to hospital for metabolic stabilisation, and then seen as follow-ups at the outpatient clinic.



**FIGURE 20: NUMBER OF ATTENDANCES AT THE PAEDIATRIC DIABETES CLINIC AT MATER DEI HOSPITAL**  
(Directorate of Health Information and Research, 2013)

Children with T1DM who transition from paediatric to adult care experience a big change in the intensity of their follow-up. This comes at a time when they may be passing through a number of personal, physical and emotional changes. There is a need for a dedicated clinic for these to make sure there is seamless continuation of care.



**FIGURE 21: NUMBER OF ATTENDANCES AT THE DIETITIAN CLINIC AT THE MATER DEI HOSPITAL** (Directorate of Health Information and Research, 2013)

Nutrition management is fundamental for the prevention of T2DM and the effective management of all types of diabetes. Due to a limited dietetic workforce most of the diabetic patients referred are seen at an initial consultation and not followed up as shown in Figure 21. This decreases the effectiveness of dietary intervention.

## HUMAN RESOURCES

The number of attendances in the various clinics is increasing every year, and the existing complement of human resources falls far short of reaching the recommended international standards to guarantee high quality services and expand the services offered through the formation of multidisciplinary teams to deal with challenging cases. It would also be possible to dedicate more time per appointment. Diabetes is a complicated chronic condition, requiring a lot of time to discuss the issues encountered. The need for a one-stop shop where service users can visit multiple related healthcare professionals in one day and one physical location emerged as a service gap during the needs assessment carried out in the preparation of this strategy.

## DIETITIANS

The nutrition and dietetic service in Malta and Gozo is under developed when compared to other EU countries (average of 15 dietitians per 100,000). Currently the workforce consists of 3 full-time dietitians and 1 part-time dietitian dealing with all medical cases that require dietetic intervention. There are currently no dietitians who are dedicated to the care of



diabetic patients only. The recommended number of specialised dietitians to cover diabetes alone in all levels of healthcare is of at least 7 full-time dietitians.

## **DIABETES NURSE SPECIALISTS**

In Malta, there are currently only two nurses taking care of persons with diabetes. The recommendations regarding the number of diabetes nurse specialist are:

Children: According to the Royal College of Nursing (UK) as well as the SWWEET group recommend a maximum caseload of 70 children should be given per Diabetes Nurse Specialist.

Adults: According to the Diabetes UK Task and Finish Group the minimum core staffing levels for an area with a population of 400.000 with an average of a 10% prevalence of diabetes, is at least 10 Diabetes Nurse Specialists.

## **PSYCHOLOGISTS**

A need for dedicated psychologists to care for persons with diabetes has been identified.

- Health psychologists who help newly diagnosed persons with diabetes to change their lifestyles to cater for their changed needs such as with cognitive behaviour therapy.
- Counselling psychologists who help persons with diabetes and their families to accept their new health state, and grief the loss of health and onset of complications, when they occur.
- Psychological support for staff, especially for those who deal with the complications of diabetes.
- Dedicated psychologists to support diabetic children and their families.

## **ORTHOTICS AND PROSTHESIS**

It has been shown that whilst the number of amputations overall has been decreasing, there is still much room for improvement. Furthermore persons who suffer minor amputations require immediate and appropriate care and support in order to prevent further deterioration. The current infrastructure and services are insufficient to meet the needs of the service users. The premises for the Orthotics dept. are reportedly not of good enough quality to adequately cater for the clients' needs due to inaccessibility. A location with dedicated parking spaces immediately outside the facility is an important consideration.

Basic orthotist services should be available wherever a one-stop-shop/clinic is based. Nevertheless, the current number of orthotists (1) is difficult to maintain such a clinic concept. Whilst some investment in this area has been carried out there remains a critical

need for additional human resources, equipment and funding to offer timely quality services to this vulnerable group of people with diabetic foot complications.

## **PODIATRISTS**

As illustrated earlier in Figure 15, the number of referrals to Podiatry clinics is increasing every year. With a rising prevalence and an improved adherence to the recommended yearly screening, these figures are expected to continue rising too, requiring additional resources.

## **INFORMATION SYSTEMS FOR DIABETES**

A diabetes clinical information system has been in place for a number of years at the diabetes clinic at the hospital previously St Luke's and now Mater Dei. This system which was developed specifically for diabetes has been in place since the 1990s and was last updated in 2014. Currently it holds data for over 23,000 patients and this data could be used as a basis to create a national diabetes register given the richness of clinical data that is available.

Unfortunately the data is not complete as not all diabetes clinicians make use of the system and the system is not available to the private sector hence patients receiving their care exclusively in the private sector are not captured. Recently the software has also been made available to doctors running the diabetes clinics in health centres. The system as yet is not connected to other clinical IT systems.

Having an ICT-based register of persons with Diabetes would allow for a recall system, whereby the service user is reminded to attend screening at the recommended time intervals. This system would need to be implemented across the health system (both public and private) to standardise the quality of care given.

An ICT system capable of ensuring integrated diabetes care across community and hospitals and with access for both public and private health systems would allow for improved continuity of care among different health care professionals, data capture and follow-up. It would also allow for outcome indicators to be calculated more precisely enabling a system of performance management to be set up. This will be important to monitor the progress being registered in diabetes outcomes as a result of the investment through this strategy. The current diabetes information system could serve as a good framework for such a system until such time as an electronic health record would become available at which point the existing system would be integrated into the overall clinical record.

## CURRENT QUALITY OF DIABETES CARE

In order to assess how well the system is performing at managing Diabetes, a set of indicators were calculated according to the Final report European Core Indicators in Diabetes project (EUCID) 2008 (DG Health and Consumer Protection, 2008).

### METHODOLOGY AND SOURCES

A database of persons currently receiving free treatment for diabetes was created to serve as the baseline denominator for performance measurement. This was created by extracting a list of ID card numbers from the POYC database in mid-May 2014 consisting of those persons who were dispensed one or more of the items related to Diabetes. This includes all the Insulins, Oral Hypoglycaemic Agents, Glucose strips, Insulin pens and needles. This was cross-referenced with the mortality register to exclude all persons who have since passed away. This yielded a list of 25,721 persons.

### RESULTS

All the indicators use the above-mentioned 25,721 persons as the denominator, and have been calculated by cross-referencing with data from MDH Laboratory Information Service for laboratory values. The mid-year population of 2012 (National Statistics Office, 2012) was used to calculate national prevalence.

Age group	<15	15-24	25-34	35-44	45-54	55-64	65-74	75-84	>85
Proportion	0.2%	0.4%	0.6%	1.5%	4.4%	11%	21%	23%	18%

FIGURE 22: TABLE SHOWING THE PROPORTION OF PERSONS WITH DIABETES IN MALTA BY 10-YEAR AGE-GROUPS (PHARMACY OF YOUR CHOICE, 2014)

The above table shows the epidemiological profile of persons registered on the POYC database as taking one or more medications related to Diabetes. This means that about one-fifth to one-fourth of the Maltese aged above 65 are taking medications for diabetes. The true prevalence is probably even higher if one had to account for all those who are undiagnosed, or not captured in this survey since they are not on the POYC database. In fact the pilot Health Examination Survey carried out in 2010 had indicated that the likely prevalence in the adult population is around 9%.

Age group	<15	15-24	25-34	35-44	45-54	55-64	65-74	75-84	>85
Proportion	0.5%	0.4%	0.8%	2.4%	7.0%	16%	26%	27%	21%

FIGURE 23: TABLE SHOWING THE PROPORTION OF PEOPLE IN MALTA WHO HAVE IMPAIRED FASTING GLUCOSE (FBG  $\geq 6.1$  MMOL/L) BY 10-YEAR AGE-GROUPS (PATHOLOGY DEPT. MDH, 2014)

This table shows the distribution of Fasting Blood Glucose measurements from the hospital Laboratory Information System between April 2012 and April 2014. Population-based

interventions will aim to reduce the proportion of people having raised fasting blood glucose in each age group.

Age Groups	<15	15-24	25-34	35-44	45-54	55-64	65-74	75-84	>85
% with HbA1c tested in last 12 months	84%*	73%	68%	62%	69%	73%	73%	69%	54%
Hb-A1c > 7%	53%* *	74%	64%	64%	64%	58%	53%	48%	43%

\*The % of children tested with HbA1c in the above table refers only to venous measurements worked at the hospital lab. In reality, the % is 100% since all children get an HbA1c measurement 3-4 times per year with a Point of Care analyser.

\*\* Glycaemic control in children is defined as HbA1c < 7.5% (not < 7% as in adults), and 53% were above this limit in 2013.

FIGURE 24: TABLE SHOWING THE PERCENTAGE OF PERSONS WITH DIABETES IN MALTA WHO HAD THEIR HbA1c LEVELS TESTED IN THE LAST 12 MONTHS, AND THE PROPORTION OF WHICH WERE ABOVE 7%(Pathology Dept. MDH, 2014; Pharmacy of Your Choice, 2014)

The above table shows the proportion of persons with diabetes who have had an Hb-A1c test done within the previous 12 months. While adherence is high in children, it is at its lowest in the middle-aged and the very elderly. Hb-A1c control (defined as <7%) is at its lowest in young adults, and improves with age. This is a common phenomenon seen in other countries too (DG Health and Consumer Protection, 2008). These figures compare favourably with those of other (Ali et al., 2013; Chittleborough, Baldock, Phillips, & Taylor, 2010; Donovan & McIntyre, 2010; Yong, Phillipov, & Phillips, 2007). However, our objective is to continue to improve further.

Age groups	<15	15-24	25-34	35-44	45-54	55-64	65-74	75-84	>85	
% with total cholesterol tested in last 12 months	Not indicated		62%	64%	69%	74%	75%	70%	52%	
total cholesterol > 5 mmol/l			37%	40%	40%	32%	30%	28%	31%	
% with LDL-cholesterol tested in last 12 months			62%	63%	68%	74%	75%	70%	52%	
LDL > 2.6mmol/l				54%	54%	54%	44%	40%	38%	41%
% with HDL-cholesterol tested in last 12			62%	64%	69%	74%	75%	70%	52%	

months								
% of those tested with HDL < 1.25 mmol/l		32%	49%	56%	49%	42%	37%	39%

FIGURE 25: TABLE SHOWING THE PERCENTAGE OF PERSONS WITH DIABETES WHO HAD A LIPID PROFILE TEST WITHIN THE PREVIOUS 12 MONTHS, AND THE PROPORTION OF RESULTS WHICH WERE OUTSIDE THE RECOMMENDED RANGES (Pathology Dept. MDH, 2014; Pharmacy of Your Choice, 2014)

The above table shows similar rates as for Hb-A1c testing, with low rates of adherence in the middle-aged and the very elderly.

## ADMISSIONS DUE TO COMPLICATIONS FROM DIABETES

While admissions for lower limb ulcers and gangrene are not always due to Diabetes, the vast majority of them are. Diabetic Ketoacidosis/Hyperglycaemic hyperosmolar syndrome and hypoglycaemia are three other complications that can arise from inadequate glycaemic control. A substantial proportion of other admissions (e.g. acute coronary syndrome, strokes and infections) are also related to diabetes.

	2010	2011	2012	2013
DKA/HHNS	59	88	100	91
LL Ulcer/Gangrene	192	290	223	322
Hypoglycaemia	180	203	214	184

FIGURE 26: NUMBER OF DISCHARGES FROM MATER DEI HOSPITAL DUE TO COMPLICATIONS OF DIABETES PER YEAR (Clinical Performance Unit, n.d.)

## LIMITATIONS OF THIS DATABASE

This is a list of all living persons (as of mid-May 2014) who were entitled to one or more of the above-mentioned items. These items are specific for people with Diabetes<sup>1</sup>.

By cross-referencing with Mater Dei (St Luke's pre 2007) Hospital Activity Analysis over the past ten years, it has been calculated that over 21% of all persons with a discharge diagnosis of diabetes in Malta are not on this database. These are persons who are not receiving free medications/supplies either because they are not entitled to obtain them free of charge through the public health system or because they choose to buy their own medicines/supplies, or because they do not need medication (usually when metformin is contraindicated or not tolerated).

<sup>1</sup> With the exception of Metformin which may also be given for Polycystic Ovarian Syndrome

# CHAPTER 3: PREVENTING THE ONSET OF TYPE 2

## DIABETES

### INTRODUCTION

'Prevention is better than cure' was never more befitting than in the case of diabetes. Epidemiological studies have shown that the Maltese population has a relatively high prevalence of carbohydrate metabolism disorders in persons over 15 years. This higher prevalence is corroborated by increased rates of Maltese pregnant women with an impaired glucose metabolism. It is well established that these women are at an increased risk of development of T2DM or impaired glucose tolerance later on in life (Savona-Ventura & Savona-Ventura, 2013).

Persons are diagnosed as having diabetes according to blood glucose levels set at the threshold at which they are at an increased risk of developing micro vascular, cardiovascular complications and premature mortality<sup>2</sup> (Roglic, Resnikoff, Strong, & Unwin, 2006). The situation is unfortunately not as simple as this, there is a grey area where they may be hyperglycemic above the 'normal' ranges but below the threshold classifying diabetes<sup>3</sup>. This category of people are often termed 'pre-diabetics' and are at increased risk of developing diabetes and its complications.

The major drivers for T2DM are modifiable risk factors such as high rates of overweight and obesity in adults and children.

An integrated approach to tackling chronic diseases is the way forward. This is based on the fact that there are common risk factors and co-existence of a number of chronic diseases in a person. In Europe it was estimated that >35% of men over the age of 60 years will have two or more chronic diseases contemporaneously. An integrated, patient-centred approach to prevention will cut costs over managing the patient for each condition separately capitalizing on scarce resources and having a greater impact on the individual's health (OECD, 2012).

At the same time care needs to be taken to focus on diabetes prevention on those persons deemed to be at high risk of developing this disease.

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<sup>2</sup> Current WHO diagnostic criteria –fasting plasma glucose  $\geq 7$ mmol/L or an oral glucose tolerance test that measures venous plasma levels 2 hours after a 75g oral glucose load  $\geq 11.1$  mmol/L is considered diabetic

<sup>3</sup> FBG: $<6.1$ mmol/L or 2-hr glucose  $<7.8$ mmol/L

# MODIFIABLE RISK FACTORS FOR DEVELOPING DIABETES

## OVERWEIGHT/ OBESITY

Excess weight is widely acknowledged to independently increase the risk of developing diabetes. The magnitude of this association has been widely investigated and various strengths of association have been quoted. There is general consensus that at a body mass index (BMI) of 23kg/m<sup>2</sup> there is no additional risk of developing diabetes attributable to weight. particularly Above a BMI of 29kg/m<sup>2</sup> the risks are markedly increased whilst with a BMI of 25-29kg/m<sup>2</sup> persons were found to have twice the risk of those with a BMI of 23kg/m<sup>2</sup>. Excess weight earlier on in life was also found to be associated with an increased diabetic risk (Chan, Rimm, Colditz, Stampfer, & Willett, 1994) . A meta-analysis of well-powered studies of this association have found that when adjusting for the three main confounding variables (age, family history of T2DM and physical activity), the relative risk of developing diabetes was 7.28 for obese persons and 2.92 for overweight persons (Abdullah, Peeters, de Courten, & Stoelwinder, 2010). Furthermore, Wald et al. designed an algorithm to determine the percentage body weight loss that was found to neutralize one's excess diabetic risk related to weight. A 10% reduction in weight would approximately half the risk of developing diabetes whereas a 20% reduction in body weight would decrease this risk by approximately three quarters. The BMI level at which the risk for diabetes is least is 22kg/m<sup>2</sup>. There is thus significant public health impact of adequate weight control at a population level as regards the diabetic risk (Wald, Bestwick, & Morris, 2012).

## PHYSICAL INACTIVITY

A number of large cohort studies provide strong evidence for the value of physical activity in reducing the incidence of T2DM. Although we know that physical inactivity is an independent risk factor for diabetes, the exact values are specific to the study population. In the USA it was estimated that 13% of T2DM in men and 29% of T2DM in women was attributable to lack of physical activity whilst in Finland this ranges from 3% to 7% (Al Tunaiji, Davis, Mackey, & Khan, 2014). Although both obesity and the lack of physical activity were found to be independent risk factors for diabetes, the former was found to confer the larger risk (Rana, Li, Manson, & Hu, 2007). Physical activity in itself results in lower rates of obesity and therefore the role of physical activity in preventing diabetes should not be underestimated.

## GESTATIONAL DIABETES

It is well established that women who have experienced gestational impaired carbohydrate metabolism disorders such as gestational impaired glucose tolerance and gestational diabetes (GDM) are at an increased risk of developing T2DM later on in life. A local eight

year follow up cross sectional study has shown the risk for women with GIGT/GDM was 3.6-6.7 times higher than for the general population ( a G. Schranz & Savona-Ventura, 2002). Factors that were shown to increase the risk of progression to prediabetes and also to T2DM included weight gain and increased waist circumference post partum (Huopio et al., 2014). Targeting women with elevated fasting glucose levels during pregnancy may prove to have the greatest effect for the effort required. This is a golden opportunity to target effective lifestyle interventions amongst this high risk group. One must not forget that the offspring of these women are also considered to be at an increased diabetic risk due to the altered *milieu interieur* to which they were exposed. Therefore establishing healthy attitudes will benefit both the mother and the child.

## **TOBACCO**

Three large prospective studies suggest that smoking is associated with the development of T2DM in men and women (Kawakami, Takatsuka, Shimizu, & Ishibashi, 1997; Rimm et al., 1993) consistent with evidence linking smoking and insulin resistance. In a study on middle-aged British men, the risk of T2DM was significantly increased in cigarette smokers compared with never-smokers, despite their lower body weight. The relationship was stronger after adjustment for BMI and persisted after additional adjustment for other potential confounders (Wannamethee, Shaper, & Perry, 2001). Sufficient evidence exists to indicate that cigarette smoking is an independent and modifiable risk factor for T2DM.

## **HIGH BLOOD GLUCOSE (PREDIABETES)**

High blood glucose is a substantial risk factor for diabetes and in the long run, heart disease and stroke. Impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) are two states of abnormal glucose metabolism that are collectively known as prediabetes. Current estimates are that up to 70% of persons with IFG/IGT may progress to diabetes (Knowler et al., 2002; Nathan et al., 2007).

In persons with diabetes, cardiovascular risk increases in a linear fashion with hyperglycaemia. The Whitehall study showed a definite graded relationship between increasing levels of hyperglycaemia above a threshold level and coronary mortality (Brunner, Shipley, Witte, Fuller, & Marmot, 2006).

## **METABOLIC SYNDROME**

Abdominal obesity may be associated with clustering of cardiovascular and metabolic risk factors which constitute the metabolic syndrome. This includes hypertriglyceridemia, low high-density lipoprotein and cholesterol levels, high blood pressure, and elevated levels of fasting glucose. Patients with even minimal abnormalities in any 3 of the 5 risk factors for the metabolic syndrome are at heightened risk for developing CVD or diabetes. The risk for



disease increases over time as the number of metabolic syndrome characteristics accumulates and hence early management is warranted (Smith, Allwright, & O'Dowd, 2007).

## EVIDENCE FOR PREVENTING THE ONSET OF DIABETES

As outlined below, there is robust evidence that in the case of diabetes, prevention does work. Evidence exists for the effectiveness and benefits of diabetes prevention, earlier diagnosis and better care of the diagnosed patient.

Numerous studies have shown how lifestyle intervention when applied consistently in the form of dietary advice and/or the introduction of sustained physical activity to a population of high risk individuals, results in the delay or actual prevention of T2DM.

One of the earliest studies in this regard is known as the Malmö study. Middle aged men with normal glucose tolerance and others who were known to have impaired glucose tolerance at baseline were assigned to continue as usual whilst others were prescribed a lifestyle intervention composed of six months' of supervised physical training and dietary treatment. This study showed a lower incidence of T2DM amongst the group who had undergone the lifestyle intervention with an increased reversal of impaired glucose tolerance to normal levels. Mortality at 12 year follow up was also found to be better for this latter group (Eriksson & Lindgärde, 1991). The Da Qing study period in contrast lasted for 6 years and this attempted to determine the relative effect of either a dietary intervention or an intervention involving increased physical activity on the development of diabetes. They found that diet reduced the incidence by 31%, exercise by 46% and a combination of both resulted in a reduction of 42% (Pan et al., 1997).

The Finnish Diabetes Prevention Study (DPS) was the first randomized control trial that studied the effect of lifestyle intervention of a group of obese/ overweight participants with impaired glucose tolerance at baseline. After two years of this trial it was concluded that the intervention group had less than half the risk of developing diabetes as compared to the non-intervention group. This impact of the lifestyle change was found to persist for at least four years after the intervention was terminated. This cumulative attenuation of the individual's risk was seen with the achievement of each health promoting goal including weight loss, increased physical activity, increased dietary fibre and decreased intake of total and saturated fats (Lindström et al., 2003, 2006). The Diabetes Prevention Program (DPP) is another larger randomized clinical trial in which individuals of various ethnicities and of diverse cohorts were randomised to one of three intervention groups. One included placebo treatment, one included treatment with metformin whilst the latter was a lifestyle intervention group.

The participants of the intensive lifestyle intervention group were required to lose at least 7% of their initial body weight through a healthy diet and 150 minutes of moderate intensity physical activity per week. Individualised, targeted sessions were delivered through a carefully organized, standard curriculum. The results were clear- the group that was assigned the intensive lifestyle modification program had a 58% less risk of developing diabetes as compared to the placebo group. It is important that lifestyle interventions are patient centred rather than the one-size-fits-all approach and they must also be culturally adapted to the context within which they are to be used. Studies have shown that interventions advocating an improvement in diet alone or an increase physical activity alone or a combination of the two have been found to be equally effective.

## OBJECTIVES

To prevent the development of T2DM by targeting the modifiable risk factors including: overweight and obesity, physical inactivity, smoking, dyslipidaemia and hypertension

To improve the health outcomes of people with diabetes by early diagnosis, self-management and lifestyle interventions

## GUIDING PRINCIPLES

### **ADOPT A WHOLE OF SOCIETY AND WHOLE OF GOVERNMENT APPROACH**

Diabetes is largely caused by the way we live and work. It is not caused by the health system and cannot be solved by the health system alone. Lifestyle choices are strongly influenced by trade, marketing, fiscal policies, education, transport and urban environment, media and agricultural practices. The whole of society and whole of government approach should underpin effective strategies to prevent the onset of risk factors related to diabetes and to improve the health outcomes of diabetes. This approach underpins both the Noncommunicable Disease Strategy and the Healthy Weight for Life Strategy. In order to be effective, actions resulting from the Diabetes Plan must include intersectoral action and be congruent with actions resulting from the NCD and HWL Strategies.

### **LIFE COURSE APPROACH**

The risk causes of noncommunicable diseases including diabetes accumulates throughout life, starting from *in utero* through childhood and adolescence, adulthood into old age (Aboderin et al., 2002). The main factors at different stages of life include:

**foetal life** – foetal growth, maternal nutritional status and socio-economic position at birth  
**infancy and childhood** – breastfeeding, unhealthy diet, lack of physical activity, obesity, socio-economic position

**adolescence** – unhealthy diet, lack of physical activity, obesity, alcohol and tobacco use

**adult** – known behavioural and biological risk factors

Evidence is accumulating that effective policies addressing these risks can prevent NCDs.

The risk of developing diabetes is influenced by biological or social factors acting at all stages of the life course, including the exposure to gestational maternal diabetes and high birth weight. Obesity, high blood pressure and dyslipidaemia track from childhood through adolescence and young adulthood, leading to atherosclerosis and in many cases diabetes.

## FOCUS ON EQUITY

Equity is the absence of avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically. Health inequity encompasses both health determinants and access to resources to maintain or improve health outcomes. The determinants of health affect people's opportunities to make and sustain healthy choices, including their ability to choose healthier diets and undertake regular physical activity, and their capability of maximising health outcomes while living with diabetes. Strategies for diabetes prevention will aim to contribute towards the reduction of health inequalities by reaching out to vulnerable and hard to reach groups.

## NATIONAL STRATEGIES WORKING IN SYNERGY TO PREVENT DIABETES

Several public health strategies published over the past years focus on reducing the prevalence of risk factors relating to diabetes. The Strategy for the Prevention and Control of Non-communicable Diseases (NCD) aims to limit the prevalence of persons with diabetes among those aged 34 years and over to 10% by 2020. Some of the actions aimed at reducing the prevalence of T2DM and its complications in the general population include the provision of education on healthier lifestyles, the promotion of healthy diets in schools and the lowering of the prevalence of excess weight especially in those with a history of first degree relatives with T2DM. The NCD strategy also focuses on secondary prevention to ensure the reduction of excessive weight in persons with diabetes and lifestyle modification, to improve the level of education and self-management in persons with diabetes and to encourage exercise among these persons. It promotes the role of primary care teams in providing primary and secondary prevention (Health Promotion and Disease Prevention Directorate, 2010).

The Food and Nutrition Policy and Action Plan (2014) identifies nutrition as a major modifiable determinant of chronic disease. This action plan takes population based approaches and individual targeted interventions through collaborative health-in-all policies and whole-of-government approach involving all levels of government and relevant stakeholders (Health Promotion and Disease Prevention Directorate, 2014b).

The Healthy Weight for Life (HWL) Strategy points out that overweight and obesity are responsible for about 80% of cases of T2DM. This strategy focuses on action related to nutrition and physical activity across the life course and within different settings. It requires a whole of government and whole of society approach in order to achieve effective actions and to reach its targets by 2020 (Superintendence of Public Health, 2012).

In addition other strategies focussing on policy strengthening the sports culture within the population, including increasing access to high quality sports facilities have also resulted in new opportunities for physical activity for different age groups in localities all over both islands (Malta Sports Council, 2006). A national Health Enhancing Physical Activity Strategy will be formulated in 2015.

The Healthy Eating Lifestyle Plan regulates food and drink consumed on school premises including during special activities and those provided from school tuck shops. It promotes the concept of the health promoting school by giving guidelines on both nutrition and physical activity and encouraging the integration of the school as a health resource within the wider community (Ministry for Education and Employment, 2014).

The Breastfeeding Policy builds on previous work done to make breastfeeding the cultural norm, by involving the whole family, health professionals, employers, educators and retailers to encourage exclusive breastfeeding till six months and as long as both mother and child wish to continue thereafter.

## CURRENT PREVENTION SERVICES

Our health care system uses different methods at population and individual level to reduce the risk factors related to diabetes and its complications. The Health Promotion and Disease Prevention Directorate focuses on the potential to prevent diabetes by lifestyle interventions and community education to empower people to change their behaviour. These include the provision of nutrition, physical activity and tobacco telephone helplines, increasing awareness and behaviour change by various media and in different settings, community outreaches and named campaigns. The directorate offers free weight management groups and aerobic sessions in many localities, as well as smoking cessation groups. These groups are run by trained facilitators. The uptake of these services is very good with over 2000 people attending these classes in 2013.

Service	No of classes	No of participants
Aerobics	42	981
Weight Management	41	757
Smoking Cessation	19	421

FIGURE 27: SERVICE UTILISATION OF AEROBICS, WEIGHT MANAGEMENT AND SMOKING CESSATION CLASSES (Health Promotion and Disease Prevention Directorate, 2014a)

Specific events are held on a regular basis addressing the prevention and early pickup of diabetes, both in general events, within the workplace and using publications or social and traditional media.

The Directorate is specifically involved in promoting the intersectoral approach to involve other governmental departments and the whole of society to contribute to the well being of the population. Another area is working to promote an enabling environment whereby the healthier choice is the easier choice for all the population.

The Primary Care Department, apart from running specific diabetes clinics, also focuses on providing one to one advice on the preventable risk factors during other clinics.

## RECOMMENDATIONS FOR ACTION

### POPULATION LEVEL INTERVENTIONS

Population level interventions focus at targeting modifiable risk factors to reduce the risk of developing diabetes. Actions already being implemented through other public health strategies have not been addressed in detail here.

The main actions include:

#### *Pregnant women:*

- Pregnant women should be screened for impaired glucose tolerance (Health Promotion and Disease Prevention Directorate, 2010)

#### *School-aged children:*

- During the school years, the improvement of life skills education, the promotion of physical activity within the school and community, the provision of safe and healthy foods in schools, and the restriction of marketing and access to foods high in fats, sugar and salt must be strengthened. Parents and teachers are essential co-participants in these life choices. These interventions are addressed in both the HWL Strategy (2012) and the Healthy Eating Lifestyle Plan (HLP) in schools (2014)

### *Food industry and access to foods:*

- Establishment of a task Force led by the Ministry responsible for Health to develop action plans on the introduction of agreed mechanisms to reduce salt and sugar, limit saturated fat and eliminate trans-fat content in local food products (Superintendence of Public Health, 2012)
- To conduct feasibility studies on the introduction of sin taxes as well as incentives and subsidies for increased accessibility and affordability of healthy food are proposed (Superintendence of Public Health, 2012)
- The introduction of regulatory measures to restrict access by children to nutritionally-inappropriate meals and energy-dense snacks and drinks from outlets located in the vicinity of schools (Superintendence of Public Health, 2012)
- Improved food labelling in order to facilitate healthier choices during food purchase.

### *Advertising:*

- To regulate audiovisual advertising, such as advertising of unhealthy foods especially that directed at children (Superintendence of Public Health, 2012)

### *Education:*

- Implement an integrated social marketing programme which provides strong messages about the risks, seriousness and impact of T2DM and focuses on the preventability of the disease. This needs to be sector specific, focusing on general public, the workforce
- Ensuring that health professionals (especially family doctors, midwives, nurses and pharmacists) have adequate knowledge and skills and appropriate online tools to help and support their patients to undertake and maintain behaviour change and making healthier choices

## **INTERVENTIONS FOR INDIVIDUALS AT HIGH RISK OF TYPE 2 DIABETES**

- Early detection of hyperglycaemia through the implementation of blood glucose tests for persons over 40 years will be encouraged through opportunistic screening following systematic protocols (Chapter 4: Policies for Early Diagnosis)
- Reducing the number of overweight persons especially those with 1<sup>st</sup> degree relatives with T2DM (Health Promotion and Disease Prevention Directorate, 2010) and those with IGT and IGF
- Lifestyle intervention needs to focus on nutrition, physical activity, weight loss and weight maintenance, management of hypertension, dyslipidaemia and smoking cessation (National Institute for Health and Care Excellence (NICE), 2009). An integrated intensive, programme is to be developed and delivered by a multiprofessional team within the community. This programme will be modelled on the most effective interventions reported in the scientific literature. Measures need to be taken to facilitate access particularly for persons at highest risk with low means.

Results will be monitored and the programme will be evaluated at regular intervals. Attention will be given to ensure the inclusion of persons who are socially excluded

- Develop formalized post-partum follow-up and prevention programmes for women who were diagnosed with gestational impaired carbohydrate metabolism disorders, with referral to lifestyle intervention programme and yearly or as required follow-up according to agreed guidelines

## **INTERVENTIONS FOR INDIVIDUALS WITH TYPE 2 DIABETES**

Well-designed and well-implemented programmes are likely to be cost-effective for people with diabetes and should be offered to every person and/or their carer at the time of diagnosis, with annual reinforcement and review (National Institute for Health and Care Excellence (NICE), 2009).

Education for people with diabetes will focus on improving their knowledge, skills and confidence, enabling them to take increasing control of their own condition and integrate effective self-management into their daily lives. High-quality structured and sustained educational programmes can have a beneficial effect on health outcomes and can significantly improve quality of life.

Health literacy will focus on specific areas as recommended in the Non Communicable disease prevention and control strategy (Health Promotion and Disease Prevention Directorate, 2010) by:

- Ensuring optimum glycaemic control
- Dietary and lifestyle change
- Exercise
- Medication
- Prevention of microvascular complications
- Control of glycaemia
- Control of blood pressure
- Monitoring and screening
- Prevention of coronary heart disease and macrovascular complications
- Control dyslipidemia
- Dietary and lifestyle changes including hypertension control and
- Smoking reduction
- Intensive Lifestyle intervention Programme for people with Diabetes

Self-management Courses are usually composed of small groups led by lay trainers or life coaches usually over a period of time (six weeks up to one year) (Lorig et al., 1999). They are a tool used to increase knowledge and skills of people with chronic diseases so that they are more in control of the symptoms and use appropriate strategies to deal with their disease. The course includes discussion on both nutrition and physical activity, achieving behaviour

change, pain management, drug and other therapies, communication and relaxation skills. Self-management courses for people living with diabetes should also include advice on maintaining optimal glycaemic control, control of hypertension, dyslipidaemia and regular screening for heart, eye, kidney and foot complications (Health Promotion and Disease Prevention Directorate, 2010).

*It is therefore recommended that:*

*Newly diagnosed persons with diabetes who are motivated to undergo an intensive lifestyle management programme be given the opportunity should be supported. Such programmes would need to meet certain quality criteria and could include online resources and support, annual reinforcement and review, social media and telephone automated reminders after the initial intensive programme ends. Such programmes may be developed and delivered by Government but may also be established in partnership with accredited private sector providers.*

Consultation Document



## CHAPTER 4: POLICIES FOR EARLY DIAGNOSIS

*Our overall goal is to identify high risk individuals and diagnose T2DM as early as possible.*

T2DM is associated with serious complications and shortens life. Its prevalence is increasing rapidly worldwide as well as in Malta partly due to the demographic changes and partly attributed to the increase in morbid obesity. No cure for diabetes is available. One logical response is therefore to diagnose the condition as early as possible. Diabetes is often asymptomatic in its early stages. Yet appropriate management and glycaemic control at the outset serve to postpone complications and improve quality of life. Besides the obvious benefits of avoiding or postponing complications for the affected individuals and their families, several studies have shown economic and societal benefit through the implementation of programmes which promote early diagnosis.

Earlier diagnosis consists of identifying high risk individuals and offering them appropriate diagnostic tests. The application of diagnostic tests to asymptomatic individuals also enables individuals with Impaired Glucose Regulation (IGR) to be identified. These persons will also benefit from lifestyle intervention. In some individuals IGR is reversed whilst in others at least the progression to T2DM is slowed down.

Recommendations on screening asymptomatic adults for T2DM vary. The American Diabetes Association recommends that adults who are overweight or obese and have at least one additional diabetes risk factor should be screened for T2DM and prediabetes; for adults without risk factors, screening should begin at age 45. More conservatively, the U.S. Preventive Services Task Force recommends screening among those with elevated blood pressure only, but makes no recommendation for other adults.

The application of health care processes to asymptomatic individuals through some kind of screening programme is not a decision to be taken lightly since there are consequences for the individuals who participate in such programmes as well as the wider cost-benefit issues. The principles (Wilson and Jungner criteria) which apply to any screening programme should therefore be examined closely also in the case of diabetes.

T2DM fulfils a number of positive criteria which make it favourable to screen high risk populations:

- a large and growing disease burden
- a well understood natural history
- a long asymptomatic pre-diabetic state which includes impaired glucose regulation
- the disease screened for is treatable and benefits from early treatment
- a high ratio of previously undiagnosed diabetics

- several low cost, safe and reliable tests which may be used to screen high risk individuals

On the negative side, there is no clear consensus on who should be screened, which test to be used and which periodic interval to apply. The evidence regarding outcomes with earlier diagnosis is also somewhat unclear.

Studies carried out in different populations have yielded variable results depending on the prevalence of diabetes in the population studied as well as the response to lifestyle intervention and pharmacotherapy in the early stages of the disease.

The best consensus appears to indicate that whilst population based screening is not justified in terms of numbers needed to screen, there is value in screening for the disease in high risk groups.

In Malta, whilst the actual true prevalence of diabetes is presently unknown, findings from a self-reported national health interview survey in 2008 and a small pilot health examination survey in 2010 indicates that the prevalence of diabetes could be expected to range between 6 and 10%. Furthermore, one out of every five persons found to have diabetes as the time of the pilot health examination survey was not known to be suffering from the condition previously.

## WHY DO WE SCREEN?

We screen to identify persons with T2DM, to identify persons who are at high risk for developing T2DM and who have IGR and to advise persons to embark on lifestyle intervention changes that will postpone the emergence of diabetes or its complications.

## WHO SHOULD WE SCREEN?

Studies tend to agree that screening should be targeted towards high-risk individuals. Various risk assessment scores (Finnish, Cambridge,) have been tested and found to be positive predictors for individuals at high risk. Whilst these are relatively simple and quick to apply, the most consistent factors that predict the likelihood of diabetes are the following:

- Obesity (BMI >30 kg/m<sup>2</sup>)
- Family history (first degree relative)
- Age >45 years
- Raised blood pressure (Systolic >130 mmHg) and /or heart disease
- Previous occurrence of diabetes in pregnancy

- Use of drugs that predispose a patient to T2DM, including: nicotinic acid; glucocorticoids; thyroid hormone; beta-adrenergic antagonists; thiazides; phenytoin; pentamidine; anti-psychotic agents; interferon-alpha therapy.

Screening persons with one or more of the above mentioned risk factors can be cost-saving (Chatterjee et al., 2013). Among diagnostic models containing various risk factors, a model containing obesity alone was the best predictor of undiagnosed diabetes. Opportunistic screening for T2DM in primary care could initially therefore target middle-aged and older adults with obesity (Klein Woolthuis et al., n.d.).

## WHERE SHOULD SCREENING TAKE PLACE?

Opportunistic disease screening is the routine, asymptomatic disease screening of patients at the time of a physician encounter for other reasons. While the prevalence of unrecognized diabetes in community populations is well known, the prevalence in clinical populations is unknown. The available literature favours that screening takes place in a clinical setting. Clinical opportunistic screening is one mechanism for making the diagnosis before symptoms are reported. Almost two-thirds of new cases of T2DM can be detected before symptoms are reported, at reasonable cost by opportunistic screening in the primary care setting (Pereira Gray, Evans, Wright, & Langley, 2012; van den Donk et al., 2011).

There is also substantial potential for case-finding in a medical centre outpatient setting (Edelman et al., 2002).

## DIAGNOSTIC CRITERIA

The confirmation of T2DM is most commonly defined according to World Health Organization diagnostic criteria (Roglic et al., 2006).

### DIABETES

Fasting plasma glucose	≥7.0mmol/l (126mg/dl) <b>or</b>
2-h plasma glucose <sup>4</sup>	≥11.1mmol/l (200mg/dl)

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<sup>4</sup> Venous plasma glucose 2-h after ingestion of 75g oral glucose load. If 2-h plasma glucose is not measured, status is uncertain as diabetes or IGT cannot be excluded.

## IMPAIRED GLUCOSE TOLERANCE (IGT)

Fasting plasma glucose <7.0mmol/l (126mg/dl) **and**  
2-h plasma glucose  $\geq$ 7.8 and <11.1mmol/l (140mg/dl and 200mg/dl)

## IMPAIRED FASTING GLUCOSE (IFG)

Fasting plasma glucose 6.1 to 6.9mmol/l (110mg/dl to 125mg/dl) **and (if measured)**  
2-h plasma glucose <7.8mmol/l (140mg/dl)

## THE SCREENING TEST

Various tests have been studied as screening tests for T2DM and IGR. It is being proposed that fasting venous blood glucose be utilised as the screening test for IGR and T2DM.

## THE ECONOMIC RATIONALE

Whilst no local studies on the cost effectiveness of screening have been carried out, the relatively high prevalence in Malta would make the cost effectiveness ratios reported in the literature more favourable. Costs of the screening tests as well as the prescription of generic metformin over a three year period in the US all turned out lower than resultant health system costs for no screening. The economic costs of hyperglycaemia are substantial. Early detection would allow management to prevent or delay development of diabetes and diabetes-related complications. Screening appears to be cost-saving compared to no screening from a health system perspective, and potentially cost-neutral from a societal perspective (Chatterjee et al., 2013; Chatterjee, Narayan, Lipscomb, & Phillips, 2010). The benefits of early detection and treatment accrue more from postponement of complications and the resulting improvement in quality of life than from additional life-years (Hoerger, 2014).

## PROPOSED WAY FORWARD

Clinical opportunistic screening for pre-diabetes / T2DM followed by diet and exercise, (or metformin treatment) has been shown to be cost-effective. Government is proposing to formally introduce this programme as a national standard for clinical practice in primary care. Opportunistic screening may also be carried out in specialist clinical settings where the reason for the encounter may be unrelated to diabetes including emergency attendances or

admissions for problems unrelated to diabetes. Persons will receive reminders to have their blood glucose levels checked at least every two years.

## RESOURCES

For the programme to successfully deliver lifestyle changes there needs to be investment in the training of dietitians and exercise physiologists needed to deliver such lifestyle change interventions (Bertram, Lim, Barendregt, & Vos, 2010). Additional laboratory resources will be required to carry out the increased number of tests. However the screening will otherwise comprise part of the normal clinical practice through GP visits in private family practice or health centres depending on the patient's preferred care provider.

## RECOMMENDATION

*It is therefore being proposed that opportunistic screening should be offered every two years at least to all adults who fulfil at least one of these risk factors:*

- Obesity over 18 years (BMI  $\geq 30$  kg/m<sup>2</sup>)
- Age >45 years
- Raised blood pressure (Systolic >130 mmHg) and /or heart disease
- Previous occurrence of diabetes in pregnancy
- Use of drugs that predispose a patient to T2DM, including: nicotinic acid; glucocorticoids; thyroid hormone; beta-adrenergic antagonists; thiazides; phenytoin; pentamidine; anti-psychotic agents; interferon-alpha therapy.
- Persons between the age of 18 and 44 with a family history of diabetes and who are overweight may also be offered opportunistic screening

Opportunistic screening may be carried out within primary health care centres or at private family doctors or may also be offered during encounters with specialist or hospital care for issues unrelated to diabetes.

All health care professionals who encounter persons who have at least one of these risk factors are encouraged to ask about screening for diabetes in the past 12 months and to refer persons for opportunistic screening.

Consideration will be given to the setting up of a mHealth alert system for diabetes screening as part of the forthcoming mHealth strategy since a gentle reminder has been shown to improve uptake.

## SCREENING

This will be carried out with a Plasma Glucose test (ideally fasting)

If patient is not febrile or acutely ill:

- Results random 7.8 mmol/l or fasting <5.6.mmol/l – patient reassured and asked to repeat in a year's time
- Result 5.6.mmol/l-7.0 mmol/l – repeat FBG +/-OGTT
- Result >7.0mmol/l – repeat FBG +HbA1c

#### *Diagnosis*

- Normoglycaemia – reassure and indicate date for repeat test
- IGR – referral for intensive lifestyle intervention programme and follow up 12 months later
- T2DM - enrol in national diabetes information system to engage in preventive screening programme and care

## SCREENING FOR GESTATIONAL DIABETES

Diabetes in pregnancy can have serious consequences for both mother and baby if undiagnosed and untreated. Systematic screening for diabetes in all pregnant mothers will continue to be undertaken. A national standard of care for screening, management of the condition in pregnancy and follow up after pregnancy will be developed to ensure that all pregnant mothers get the best possible care. Documentation on the screening tests performed and their outcomes will be maintained by all antenatal care centres.

# CHAPTER 5: ENSURING ACCESS TO INNOVATIVE QUALITY TREATMENT

## INTRODUCTION - DEFINING ACCESS TO MEDICINES AND DEVICES FOR DIABETES

Ensuring access to diabetes treatment is a costly, complex and resource-consuming challenge. It is also only one element in high-quality comprehensive diabetes care (International Diabetes Federation Europe, 2011). Access to health technology is determined by ensuring that products required to respond to the population's health needs, are provided where and when they are needed, in an adequate format and according to proper protocols, at a price that would not cause financial hardship to the community or the individual. Access to medicines and medical devices can be achieved by ensuring availability, accessibility and affordability.

*Our main goal is to implement a plan of expansion to provide access to those innovative treatments which have been shown to improve health outcomes and quality of life in persons with diabetes whilst giving due attention to the impact of such expansion on the overall financial sustainability of our health system.*

*We shall also increase access to devices that promote self monitoring and self management of diabetes to encourage patient participation in the management of their condition and foster an outcome oriented and preventive culture.*

## GUIDELINES FOR THE TREATMENT OF DIABETES MELLITUS

### TYPE 1 DM

T1DM is characterised by a complete deficiency of insulin production. Without a regular and reliable supply of insulin, people with T1DM will not survive (International Diabetes Federation Europe, 2011). An intensified insulin regimen is required in these patients consisting of both basal and prandial insulin.

Insulins may be divided into the following classes (BMJ GROUP AND THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN, 2013):

- *Conventional human insulins:*  
Intermediate-acting (basal) e.g. isophane insulin

- Short-acting (prandial) e.g. soluble insulin
- *Insulin analogues:*
  - Long-acting (basal) e.g. degludec, detemir and glargine
  - Rapid-acting (prandial) e.g. aspart, glulisine and lispro.

Both conventional human insulins and insulin analogues may be used in patients with T1DM (BMJ GROUP AND THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN, 2013). The long-acting insulin analogues are recommended in patients with severe or nocturnal hypoglycaemia and who are using an intensified insulin regimen (Scottish Intercollegiate Guidelines Network (SIGN), 2010). The insulin regimen should be tailored to the individual patient to achieve the best possible glycaemic control without disabling hypoglycaemia.

## **TYPE 2 DIABETES**

T2DM occurs due to reduced secretion of insulin, or peripheral resistance to the action of insulin (insulin resistance), or due to a combination of both. Depending on the status of the condition, T2DM can be treated with lifestyle changes and/or oral and non-insulin injectable drugs and/or insulin therapy.

The treatment pathways for patients with T2DM differ amongst different international guidelines (AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS (AACE), 2013; Inzucchi et al., n.d.; National Institute for Health and Care Excellence (NICE), 2009; Scottish Intercollegiate Guidelines Network (SIGN), 2010). However, the following principles are common amongst these guidelines.

Lifestyle modification with emphasis on diet, exercise and continued education is a key pillar in the management of T2DM in any of the clinical pathways that may be pursued.

T2DM is a chronic progressive disease – requirement for multiple medications to achieve targets increases with time due to decreasing beta-cell function in the pancreas. Thus most patients will require combinations of drugs in order to lower blood glucose levels.

The HbA<sub>1c</sub> target should be individualised according to several patient factors including age, co-morbid conditions, diabetes duration, risk of hypoglycaemia, patient motivation, adherence and life expectancy.

The choice of therapy should also be individualised and a patient-centred approach should be employed. Choice is determined on numerous factors including patient characteristics, profiles of the medications themselves (Table 1) and availability/affordability of the different options.

Patient factors that influence the choice of drugs include other co-morbidities e.g. kidney, liver and heart disease; ease of use and patient preference.



Drug factors that influence the choice of therapy include contra-indications and side-effects of the drugs themselves. Particular consideration is given to the hypoglycaemia and weight gain potential of these drugs. These two side-effects can adversely affect patient safety, adherence and cost.

Metformin remains the first-line drug in T2DM if there are no contra-indications to it. Deployment of metformin at population level is a commonly used indicator of appropriate health system performance in relation to diabetes. Available data indicates that we have a fairly good rate of deployment of metformin in Malta, yet the pathway will continue to emphasise the place of metformin as the first line drug for T2DM.

The choice of the second-line drug following metformin is not very well backed up by studies and long term data. Thus various combinations using one or two additional oral or injectable agents are reasonable and recommended interchangeably. The aim is to achieve the patient's target level of glycaemic control without significant side-effects.

Many patients with T2DM may ultimately require insulin therapy (alone or in combination with other drugs) as the disease progresses.

The management of hyperglycaemia should be put in the context of the overall management of the cardiovascular risk of the patient. Management of hypertension and hyperlipidaemia is a key component of successful diabetes care programmes (and ensuring successful outcomes).

Class	Compound(s)	Cellular mechanism	Primary physiological action(s)	Advantages	Disadvantages	Cost
Biguanides	<ul style="list-style-type: none"> <li>Metformin</li> </ul>	Activate AMP-kinase	<ul style="list-style-type: none"> <li>↓ Hepatic glucose production</li> </ul>	<ul style="list-style-type: none"> <li>Extensive experience</li> <li>No weight gain</li> <li>No hypoglycaemia</li> <li>Likely ↓ CVD events (UKPDS)</li> </ul>	<ul style="list-style-type: none"> <li>Gastrointestinal side effects (diarrhoea, abdominal cramping)</li> <li>Lactic acidosis risk (rare)</li> <li>Vitamin B<sub>12</sub> deficiency</li> <li>Multiple contraindications: CKD, acidosis, hypoxia, dehydration, etc.</li> </ul>	Low
Sulphonylureas	<ul style="list-style-type: none"> <li>Glibenclamide</li> <li>Gliclazide</li> <li>Glimepiride</li> </ul>	Close K <sub>ATP</sub> channels on beta cell plasma membranes	<ul style="list-style-type: none"> <li>↑ Insulin secretion</li> </ul>	<ul style="list-style-type: none"> <li>Extensive experience</li> <li>↓ Microvascular risk (UKPDS)</li> </ul>	<ul style="list-style-type: none"> <li>Hypoglycaemia</li> <li>Weight gain</li> <li>? Blunts myocardial ischaemic preconditioning</li> <li>Low durability</li> </ul>	Low
Metglitinides (glinides)	<ul style="list-style-type: none"> <li>Repaglinide</li> </ul>	Close K <sub>ATP</sub> channels on beta cell plasma membranes	<ul style="list-style-type: none"> <li>↑ Insulin secretion</li> </ul>	<ul style="list-style-type: none"> <li>↓ Postprandial glucose excursions</li> <li>Dosing flexibility</li> </ul>	<ul style="list-style-type: none"> <li>Hypoglycaemia</li> <li>Weight gain</li> <li>? Blunts myocardial ischaemic preconditioning</li> <li>Frequent dosing schedule</li> </ul>	High
Thiazolidinediones	<ul style="list-style-type: none"> <li>Pioglitazone (not available in Malta)</li> </ul>	Activate the nuclear transcription factor PPAR-γ	<ul style="list-style-type: none"> <li>↑ Insulin sensitivity</li> </ul>	<ul style="list-style-type: none"> <li>No hypoglycaemia</li> <li>Durability</li> <li>↑ HDL-C</li> <li>↓ Triacylglycerols</li> </ul>	<ul style="list-style-type: none"> <li>Weight gain</li> <li>Oedema/heart failure</li> <li>Bone fractures</li> <li>? ↑ Bladder cancer</li> </ul>	High

				(pioglitazone) <ul style="list-style-type: none"> <li>• ?↓CVD events (ProACTIVE, pioglitazone)</li> </ul>	(pioglitazone)	
$\alpha$ -Glucosidase inhibitors	<ul style="list-style-type: none"> <li>• Acarbose</li> </ul>	Inhibit intestinal $\alpha$ -glucosidase	<ul style="list-style-type: none"> <li>• Slows intestinal carbohydrate digestion/absorption</li> </ul>	<ul style="list-style-type: none"> <li>• No hypoglycaemia</li> <li>• ↓Postprandial glucose excursions</li> <li>• ? ↓CVD events (STOP-NIDDM)</li> <li>• Non-systemic</li> </ul>	<ul style="list-style-type: none"> <li>• Generally modest HbA<sub>1c</sub> efficacy</li> <li>• Gastrointestinal side effects (flatulence, diarrhoea)</li> <li>• Frequent dosing schedule</li> </ul>	Moderate
DPP-4 inhibitors (gliptins)	<ul style="list-style-type: none"> <li>• Sitagliptin</li> <li>• Vildagliptin</li> <li>• Linagliptin</li> </ul>	Inhibit DPP-4 activity, increasing postprandial active incretin (GLP-1, GIP) concentrations	<ul style="list-style-type: none"> <li>• ↑ Insulin secretion (glucose-dependent)</li> <li>• ↓ Glucagon secretion (glucose-dependent)</li> </ul>	<ul style="list-style-type: none"> <li>• No hypoglycaemia</li> <li>• Well tolerated</li> </ul>	<ul style="list-style-type: none"> <li>• Generally modest HbA<sub>1c</sub> efficacy</li> <li>• Urticaria/angio-oedema</li> <li>• ? Pancreatitis</li> </ul>	High
GLP-1 receptor agonists	<ul style="list-style-type: none"> <li>• Exenatide</li> <li>• Exenatide extended release</li> <li>• Liraglutide</li> <li>• Lixisenatide</li> </ul>	Activate GLP-1 receptors	<ul style="list-style-type: none"> <li>• ↑ Insulin secretion (glucose-dependent)</li> <li>• ↓ Glucagon secretion (glucose-dependent)</li> <li>• Slows gastric emptying</li> <li>• ↑ Satiety</li> </ul>	<ul style="list-style-type: none"> <li>• No hypoglycaemia</li> <li>• Weight reduction</li> <li>• ?Potential for improved beta cell mass/function</li> <li>• ? Cardiovascular protective actions</li> </ul>	<ul style="list-style-type: none"> <li>• Gastrointestinal side effects (nausea/vomiting)</li> <li>• ? Acute pancreatitis</li> <li>• C cell hyperplasia/medullary thyroid tumours in animals</li> <li>• Injectable</li> <li>• Training requirements</li> </ul>	High

SGLT2 inhibitors	<ul style="list-style-type: none"> <li>• Canagliflozin</li> </ul>	Inhibit sodium-glucose co-transporter 2	<ul style="list-style-type: none"> <li>• ↓Glucose re-absorption in the renal proximal convoluted tubule</li> <li>• ↑ Urinary glucose excretion</li> </ul>	<ul style="list-style-type: none"> <li>• No hypoglycaemia</li> <li>• Weight reduction</li> </ul>	<ul style="list-style-type: none"> <li>• Urinary infections</li> <li>• ? Bone loss</li> </ul>	High
Insulins	<ul style="list-style-type: none"> <li>• Human Regular</li> <li>• Human NPH</li> <li>• Aspart</li> <li>• Glulisine</li> <li>• Lispro</li> <li>• Degludec</li> <li>• Determir</li> <li>• Glargine</li> <li>• Pre-mixed (several types)</li> </ul>	Activate insulin receptors	<ul style="list-style-type: none"> <li>• ↑ Glucose disposal</li> <li>• ↓ Hepatic glucose production</li> </ul>	<ul style="list-style-type: none"> <li>• Universally effective</li> <li>• Theoretically unlimited efficacy</li> <li>• ↓Microvascular risk (UKPDS)</li> </ul>	<ul style="list-style-type: none"> <li>• Hypoglycaemia</li> <li>• Weight gain</li> <li>• ? Mitogenic effects</li> <li>• Injectable</li> <li>• Training requirements</li> <li>• 'Stigma' (for patients)</li> </ul>	Variable <sup>a</sup>

**TABLE 1: PROPERTIES OF GLUCOSE-LOWERING AGENTS THAT MAY GUIDE TREATMENT CHOICE IN INDIVIDUAL PATIENTS WITH T2DM. THE DRUGS LISTED ARE MEDICINAL PRODUCTS FOR HUMAN USE AUTHORISED TO BE PLACED ON THE MARKET IN MALTA THROUGH THE NATIONAL AND EUROPEAN PROCEDURES**

<sup>a</sup>Depends on type (analogues>human insulins) and dosage.

CKD, chronic kidney disease; CVD, cardiovascular disease; DPP-4, dipeptidyl peptidase 4; GIP, glucose-dependent insulinotropic peptide;

GLP-1, glucagon-like peptide 1; HDL-C, HDL-cholesterol; LDL-C, LDL-cholesterol; NPH, isophane insulin; PPAR, peroxisome proliferator-activated receptor; ProACTIVE, Prospective Pioglitazone Clinical Trial in Macrovascular Events (Dormandy et al., 2005); SGLT2, sodium-glucose co-transporter 2;

STOP-NIDDM, Study to Prevent Non-Insulin-Dependent Diabetes Mellitus (Chiasson et al., 2003; Stratton et al., 2000)

Consultation Document

## CURRENT LOCAL AVAILABILITY OF ANTI-DIABETES DRUGS ON THE MALTA GOVERNMENT FORMULARY LIST (GFL WEBSITE)

### INSULINS

Entitlement to free medication through the public health sector outside a hospital setting is based on the principle of social solidarity and occurs through a system based on criteria linked to disease or means by virtue of the Social Security Act Cap 318 Article 23 and the amendment of this act - Act No. 1 of 2012 and the **Fifth Schedule** of the same Act. Those patients suffering from chronic conditions usually fall under **Schedule V** (Yellow Card), whilst those with limited means generally pertain to the **Schedule II** (Pink Card).

#### *Human insulins - soluble insulin, isophane insulin and biphasic insulin*

They are all available in vial form (for use with an insulin syringe) and cartridge form (for use with an insulin pen). The human insulins in vial form can be used in all types of diabetes without restriction. However, human insulins in cartridge form are protocol-regulated. They are only available to patients with T1DM or to those who suffer from T2DM and have accompanying visual disturbance.

#### *Insulin glargine and insulin aspart – analogues approved for patients with type 1 diabetes only*

The current entitlement protocol for glargine states that patients should have been for at least six months on a multi dose regimen of conventional insulin; they should be testing their blood sugar on a four times a day basis for at least three months; and that their blood glucose monitoring reveals frequent fluctuations in blood sugar with a minimum average of two nocturnal hypoglycaemic episodes per week.

The current entitlement protocol for aspart states that patients should have been for at least 6 months on a multi-dose regimen of conventional insulin; must be testing their blood sugar on a four times a day basis for at least three months; and that the blood glucose monitoring reveals frequent fluctuations in blood sugar with a minimum average of two postprandial hyperglycaemic episodes per week.

### ORAL AGENTS AND NON-INSULIN INJECTABLES

There are only three oral agents on the Malta GFL – metformin, glibenclamide and gliclazide. These drugs are issued to patients via the Schedule V or Schedule II entitlement system.

There are currently no non-insulin injectables on the Malta GFL.

## **PROPOSED WAY FORWARD**

The restrictions applied on the Government Formulary are primarily based on affordability given that the high prevalence of diabetes in the Maltese population necessitates a substantial financial outlay each time a new therapeutic agent replaces an older one. However, Government has recognised that there is a clear need to expand the range of medical treatments available in order to achieve improved outcomes for persons with diabetes. A phased programme of expansion will take place over the duration of this strategy. A yearly expansion plan will be established in line with a budgetary framework. The diabetes formulary will be subject to annual review with proposals for further modification being made as part of the implementation of the strategy.

## **PROPOSED ENTITLEMENT PATHWAYS FOR FREE MEDICATIONS OBTAINED THROUGH THE PUBLIC HEALTH CARE SYSTEMS FOR THE MANAGEMENT OF DIABETES MELLITUS**

Three entitlement pathways, namely T1DM, T2DM and Painful Diabetic Neuropathy have been developed by Consultant Diabetologists. These were reviewed by the Directorate of Pharmaceutical Affairs (DPA). These pathways are being evaluated by the Government Formulary List Advisory Committee (GFLAC). The pathways are based on guidelines but cost of drugs is a major influence on the decisions taken to develop these pathways.

### **TYPE 1 DIABETES ENTITLEMENT PATHWAY**

- The foundation of the management of T1DM should consist of insulin therapy and lifestyle modifications.
- Metformin can be added in patients who are overweight or obese.
- Insulin analogues have advantages over conventional insulins. Long-acting insulin analogues cause less hypoglycaemia (including nocturnal) than the intermediate-acting human insulins due to their peakless response for approximately twenty-four hours. Rapid-acting insulin analogues are superior to short-acting human insulins because they are more predictable and also reduce post-prandial hyperglycaemia. The current entitlement protocols do not reflect this. Having to start patients with T1DM on conventional insulin and then switching to the analogues after six months has the following disadvantages:
  - hypoglycaemia and post-prandial hyperglycaemia in the first 6 months;
  - insulin glargine can be started on diagnosis of diabetes even if the patient is on intravenous insulin. This means that transition from intravenous to fixed

insulin regimen is faster than with the conventional isophane insulin. This translates into shorter hospital stays;

- re-training of patients, parents and relatives after 6 months from diagnosis to educate on use of analogues when the switch from conventional to analogues is made. This involves a patient safety issue.
- introducing two changes at the most stressful time for patients and their families adding considerably to the psychosocial disruption they already face.

*Thus it is being proposed that the current entitlement protocols for insulin analogues are opened up so that they can be given to all patients with T1DM who are deemed to require them by the diabetologist as soon as the condition is diagnosed.*

Whilst it is recognised that there may be a few patients who would benefit from the administration of insulin using the continuous subcutaneous insulin infusion (CSII) system this can only be successfully established in the setting of a CSII service. This service would not be sustainable without the enrolment of a team consisting of clinicians, diabetes nurse specialists and dietitians.

*It is therefore being proposed that this issue is assessed through a Health Technology Assessment (HTA) at a later stage once the necessary specialised human resources are made available and undergo specialised training.*

## **TYPE 2 DIABETES ENTITLEMENT PATHWAY**

- Lifestyle modifications and education remain the backbone of the management of T2DM.
- Metformin will continue to be the first line drug to be used in T2DM unless there is documented intolerance from or contra-indications to its use.
- *Deletion of glibenclamide from the Malta GFL will be considered since this is a long-acting sulphonylurea that causes significant hypoglycaemia. Gliclazide being a shorter-acting sulphonylurea will replace its use.*
- Conventional Insulin therapy will continue to be given to any patient with T2DM clinically deemed to require it at any point during the progress of the disease.
- The proposed pathways recommend that second line drugs that may be given to patients with T2DM when metformin alone is ineffective or when metformin is contra-indicated or not tolerated include:
  - sulphonylureas (if renal function is normal)
  - repaglinide (if renal function is impaired)
  - sodium-glucose co-transporter 2 inhibitors (if patient is obese).
- Where the second-line drugs are not effective or cannot be used, third-line agents to be considered will include drugs from the following classes:
  - DPP4-inhibitors



- Long-acting GLP-1 receptor agonists in obese patients
- Insulin analogues

Pathways will be drawn up in such a way that priority to access the above third line treatment will be given to those groups of patients where the capacity to benefit is deemed greatest given the substantial price difference between second and third line drugs.

## **PAINFUL DIABETIC NEUROPATHY ENTITLEMENT PATHWAY**

Painful diabetic neuropathy is a complication of diabetes mellitus. In mild to moderate pain analgesics like paracetamol and non-steroidal anti-inflammatory drugs can be used. When pain is severe and interferes with the patient's lifestyle a tricyclic anti-depressant may be indicated.

In cases where tricyclic anti-depressants are contra-indicated (e.g. heart disease) or when they are not tolerated, other drugs like duloxetine and pregabalin may be used (BMJ GROUP AND THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN, 2013). Duloxetine is not available on the Malta GFL. Pregabalin is available but it is only given for free to patients who suffer from epilepsy, malignancy or trigeminal neuralgia.

Thus it is being proposed that:

- *Duloxetine is introduced on the GFL (to be used when tricyclic anti-depressants are contra-indicated or not tolerated).*
- *The protocol for pregabalin includes painful diabetic neuropathy as an indication for free entitlement of the drug. In this case pregabalin would be used if three months of therapy with duloxetine fail to control the pain.*

## **HYPODERMIC EQUIPMENT FOR INSULIN ADMINISTRATION**

There is a currently quota for the amount of insulin syringes given to patients free of charge. Pink card holders get 10 syringes per month whereas patients who have a yellow card for diabetes are entitled to 30 syringes per month.

It is recommended that:

*Government engages in dialogue with the relevant stakeholders including POYC pharmacies and waste management services in order to consider the development of a system that incentivises safe return of used equipment. This could include the provision of a safe disposal bin for every patient started on insulin. The aim is to arrive at a situation where patients are entitled to the number of syringes they require on a monthly basis.*

## MONITORING DEVICES FOR DIABETES MELLITUS

The current entitlement criteria for blood glucose monitoring strips are age-dependent:

- Patients who are under 18 years of age are entitled for four strips daily.
- Patients who are over 18 years of age are entitled for fifty strips per month.
- Pregnant females over 18 years of age are entitled for one hundred strips per month.

It is being proposed that four blood glucose strips daily are given to all patients with T1D irrelevant of the age.

## CONCLUSION

The cost of ensuring access to diabetes medicines and devices should be considered as an investment by all of society to alleviate the human and financial burden of poorly controlled diabetes and its complications. The social and indirect costs (such as the loss of productivity due to illness) of diabetes-related complications may be even greater than their direct cost to health systems (International Diabetes Federation Europe, 2011). Government through this strategy is determined to make access to diabetes care be seen as an investment to promote a healthier and more productive society, and is a contributor to long-term economic growth.

# CHAPTER 6: NATIONAL SERVICE FRAMEWORK FOR PERSONS WITH DIABETES IN MALTA

## PURPOSE

The management and care of persons with diabetes in Malta has developed over the years in line with the St Vincent Declaration. The hub for specialist care and management of diabetes and its complications is the Diabetes Clinic at Mater Dei Hospital. Over the past years, efforts have been made to develop a shared care programme with primary care through the health centres. Both the care given at Mater Dei and health centres is supported by nurses and allied health professionals. Private general practitioners and specialists in private practice also play an important role in the care and follow up of persons with diabetes.

The needs assessment conducted to inform the preparation of this first national strategy gave indications about the gaps and barriers that currently prevent us from achieving the optimal service response that persons with diabetes rightly deserve. The purpose of this national service framework is to present the vision for an optimal health service response for persons with diabetes. Measures to address the identified gaps and barriers which will allow us to attain this optimal service response in a consistent way across all health services in Malta are proposed.

*Our vision is that of a coordinated, integrated, multidisciplinary service of consistently high quality for all persons with diabetes*

The focus of this chapter is on adults with diabetes. A chapter outlining the specific needs of children is presented separately.

## RESULTS FROM THE NEEDS ASSESSMENT

The needs of persons with diabetes will differ significantly between one person and another as well as over time in the same individual as the condition progresses or as the individual may have different needs across the life course. This presents a challenge in drawing up a service framework that acknowledges the requirement of meeting the needs of individuals who are primarily well and in whom main goal is to prevent disease and complications later on in life to other individuals in whom the disease has advanced and who require highly intensive rehabilitation, long term treatment and support. The framework has therefore been developed reflecting the level of need and intensity of service support that may be required by different individuals. At all stages of the care approach, the focus will be on ensuring

access to high quality treatment and support that is evidence based and appropriate to manage diabetes, prevent complications and improve quality of life for persons with the condition.

The main thrust of the service framework is to ensure that all persons with diabetes are monitored regularly to ensure risk factor modification including good glycaemic control to avoid complications. Persons with uncomplicated T2DM should be cared for primarily in a community setting through shared care between trained general practitioners and diabetes specialists. This will allow the diabetes clinic based at Mater Dei Hospital to dedicate its resources towards the fulfilment of its mission as a tertiary referral centre for all patients with diabetes identified as requiring regular and intensive specialist care provision. The development and elaboration of detailed care pathways for patients with different needs has been identified as a key component for the successful implementation of consistently high quality care across hospital and community and between public and private sectors.

The shared care programme for patients with uncomplicated T2DM has been recently updated. One important addition has been the possibility for private sector practitioners to participate in this programme.

Protocols with clear referral, diagnostic and follow up pathways for other persons with diabetes will be developed in the coming months.

## WHERE ARE WE NOW?

A snap shot of the current services provided has been presented in Chapter 2. The needs assessment which formed a basis for the diabetes strategy was furthermore based on information derived from two main pillars:

- Epidemiology and health service performance indicators
- Corporate stakeholder approach

## EPIDEMIOLOGY AND HEALTH SERVICE PERFORMANCE INDICATORS

Routine data collections systems for diabetes presently do not exist at a national level. This gap was a limitation in conducting an in-depth epidemiologic analysis. However the Diabetes database which was established in the 1990s at the diabetes clinic at St Luke's and was transferred to Mater Dei Hospital contains detailed electronic records on over 23,000 patients. Whilst the information is not complete, it provides a good snap shot of diabetes management and complications in Malta. Recently this database has been made available to trained GPs working in the diabetes clinics at the health centres. The further rolling out of access rights to GPs and specialists trained in the use of this application, in both the public

and private sector would enable a more complete epidemiological and service management profile to be drawn up.

Other sources of information utilised were the European Health Interview Survey 2008, the European Pilot Health Examination 2010 and information derived from various service and entitlement databases. This information allowed us to map the current burden of disease and projected growth in disease burden over the coming years. The information also gave an indication of the performance of our health system in the areas of diabetes. There is room for improvement when it comes to reaching targets to prevent complications. A number of small clinical service audits have also highlighted areas of good practice as well as targets for improvement.

## **CORPORATE STAKEHOLDER APPROACH**

A series of expert focus groups were organised in order to better understand the gaps and barriers being experienced in the current approach to diabetes services and assist with identifying the main priorities for service improvement over the coming years. The following are a brief summary of the main recommendations that emerged from an analysis of the feedback collated from the focus groups:

- Further strengthen awareness, literacy and education campaigns using modern approaches and resources targeting the general public, persons with diabetes, health care professionals and other persons who may come into contact with diabetes through their workplace
- Strengthen fight against obesity
- Develop national standards for screening, diagnosis and for management of persons with diabetes including prevention of complications
- Increased role for primary care doctors including private GPs in the organised care of persons with diabetes in line with national standards
- Creation of a real multidisciplinary team approach in the management of diabetes
- Organised call and recall system for foot and eye screening in persons with diabetes
- Intensive psychological support at the time of diagnosis, and whenever clinically indicated
- Gradual increase in numbers of medical specialists and nurse specialists
- Significant and urgent increase in dietitians and psychologists
- Increased access to supplies including glucose monitoring strips, syringes and dressings
- Upgrading of medicines formulary to provide much needed access to newer medicines and insulins
- Significant investment in orthotics and prosthetics in premises, resources and supplies

- Increase in availability of clinic space in primary care and hospital as well as increase in theatre time

#### *Children and adolescents*

- Support in schools
- Care transitioning from paediatric to adult health services

The epidemiological analysis and the local corporate stakeholder analysis served to anchor the international guidelines and evidence on appropriate strategies for the prevention and management of diabetes within the local context.

## AN INTEGRATED SERVICE OF HIGH QUALITY

Diabetes is known to be associated with increased risk of long-term complications. These include microvascular disease, such as retinopathy, neuropathy and diabetic nephropathy. There is also increased risk of developing macrovascular disease (coronary heart disease, peripheral vascular disease and cerebrovascular disease).

Health care services for persons with diabetes shall have the aim of preventing complications as well as ensuring holistic support and well being. There is a good infrastructure that has been developed over the years particularly the shared care programme between the diabetes clinics in health centres and the specialist referral centre in Mater Dei Hospital which provides a starting point on which to continue to build.

The main challenge ahead is to move from a system of passive surveillance to a system where all persons with diabetes are actively invited for monitoring of preventable complications. Another important aspect is the strengthening of the human resources complement to ensure that persons deemed to be at greater risk or who are in need of additional support are able to obtain the necessary care and assistance promptly with regular in-depth support.

## PHILOSOPHY OF CARE

Persons with diabetes need the care and support of a multidisciplinary team of professionals. In the ideal situation, the services should revolve around the patient in a one stop shop approach. Given the current shortages in human resources, it is recognised that this may not be always possible. However persons with diabetes should at least be given the opportunity to be seen by all members of the multidisciplinary team in line with their clinical needs.

T2DM is a common chronic condition whose prevalence is set to increase particularly in view of demographic trends. The philosophy of care being recommended is that of management in the community based upon continuity, active follow up, quality documentation and rapid links to specialist advice and care.

## TYPE 2 DIABETES - SHARED CARE BASED ON CONSISTENCY, QUALITY AND CONTINUITY

The needs of persons with T2DM will vary depending upon their age, disease progression and existence of other comorbidities. This may require the tailoring of individualised care. However there are key common principles that apply to all persons with T2DM in our efforts to avoid or delay the emergence of complications.

Consistency, comprehensiveness and active surveillance shall be the hallmarks of the diabetes care programme. In order to fulfil these objectives, the department of primary care and the diabetes centre at Mater Dei Hospital have updated their shared care programme which is presented as an annex to this strategy. Although a minimum national standard of care is prescribed, patients are also free to choose where and how they wish to receive care for their diabetes. The aim is to create a system that integrates care provision between hospital and the community and between the public and private sectors.

## DIAGNOSIS AND EARLY STAGES OF TYPE 2 DIABETES

The diagnosis of T2DM is often a chance finding arising from a routine health check carried out through one's family doctor or health centre. Persons diagnosed with T2DM should receive the best support and care possible immediately upon a confirmed diagnosis.

*It is therefore being proposed that persons with newly diagnosed T2DM are enrolled in the national diabetes prevention and management system. This enrolment can be performed through the regional health centres.*

In line with this proposal newly diagnosed patients by public or private general practitioners are to be referred to the health centres where the nurses in charge of managing the diabetes clinics ensure that the patient is enrolled in the national diabetes information system. Appointments are made for specialist assessment and review by a diabetologist as well as initial screening for diabetic retinopathy and podiatry review. Baseline investigations and measurements are taken and recorded. Both public and private general practitioners shall retain the right to refer patients directly to the Mater Dei diabetes clinic, if this is clinically indicated to do so.

The choice to access treatment in the private sector at all stages remains with the patients who can indicate the name of the private family doctor of his choice who will continue to provide routine follow up as well as a private diabetologist. All patients irrespective of whether they choose to have their care in a public or private setting will be invited to participate in the national diabetes programme. In the shared care programme all persons with T2DM diabetes are invited to enrol in a national screening programme for prevention of complications. Through such enrolment, patients shall be invited at pre-established intervals for preventive screening encounters. This will guarantee that all persons with diabetes have annual blood tests to ensure good glycaemic control, monitor renal function and blood lipids. These results are recorded in the system and provided to the patient's general practitioner. This will avoid duplication of tests. The system will ensure that examinations or tests carried out in the private sector are not repeated unnecessarily in the public sector. Through this programme patients shall be invited to undergo regular screening through clinical examination, blood investigations, eye screening and foot screening as outlined in the shared care programme annexed to this document. In this manner it is ensured that all persons with diabetes benefit from a national standard of care. The importance of screening for complications will also be addressed in the educational campaigns.

Active follow up and surveillance will be focussed particularly on persons who do not appear to be attending for structured follow up.

All patients enrolled in the shared care programme still retain the right to be seen by a specialist for their diabetes care. Besides the scheduled routine follow ups at the prescribed time interval appropriate for their clinical condition, urgent fast track referrals from both private and public GPs participating in the shared care programme will be facilitated to ensure prompt access for patients who need to be given urgent specialist attention.

Access to medicines will be in accordance with entitlement pathways which are described in Chapter 5. The introduction of new anti-diabetes drugs on the government health formulary requires that these drugs are used optimally in our patients with diabetes.

The Pharmacy of Your Choice Scheme will continue to play an important role in the care of persons with diabetes through the provision of advice pertaining to medicines and their side effects, assistance with queries regarding self management and recognition of non-compliance or need for medication review. The pharmacist is also an integral part of the multi disciplinary team and should take the opportunity to reinforce the need for enrolment into the diabetes information system, regular attendance for screening and for updates on matters relating to diabetes self management.

Clinical pharmacists are in a position to collaborate with other health-care professionals and can use their expertise to manage and monitor diabetes treatment plans. They have a role in the approach to patient-centred care and can intervene on initiation, dosing, monitoring and



discontinuation of drug therapy. In the hospital setting clinical pharmacists can intervene on the wards or during out-patient clinics e.g. diabetes clinic. On the wards they actively participate in medication selection as part of the medical team. They also perform medication reconciliation which is a formal process whereby pharmacists work together with patients, families and care providers to ensure that accurate and comprehensive medication information is communicated consistently across transitions of care <sup>4</sup>. The absence of structured medication reconciliation processes has been identified as a major medication safety issue at Mater Dei Hospital (MDH).

In the out-patient clinics clinical pharmacists can offer interim drug therapy visits, patient education, treatment adherence monitoring, health barriers assessment and prevention screening<sup>6</sup>. Utilization of pharmacists as an essential part of the healthcare team to prevent and manage disease in collaboration with other clinicians can improve quality, contain costs, and increase access to care.

Recognition of pharmacists as healthcare providers, clinicians and an essential part of the healthcare team is appropriate given the level of care they can provide. A suitable complement, reflective of the range of care that can be provided by pharmacists, is needed to develop and sustain patient oriented, quality improvement services.

*It is proposed that all general practitioners will be empowered to apply for free front line medicines for the treatment of diabetes to avoid unnecessary bureaucracy for patients.*

*It is proposed that pharmacists be engaged more actively in the care of persons with diabetes both through their role in the community as well as through a strengthened complement in clinical hospital based pharmacy.*

*Diabetologists will continue to play a key role, together with general practitioners and other health care professionals, as this has been shown to result in superior outcomes.*

## SELF MANAGEMENT AND EDUCATION

Successful outcomes in diabetes depend to a great extent on the role patients play in managing their condition on a daily basis. At the initial stages of diagnosis, it is fairly common for patients to pass through the recognised stages of grief for the “loss of health”. At the same time during this initial stage patients have to learn about their condition, lifestyle changes, medicines, self monitoring, management and avoidance of complications. It is the duty of every health care professional seeing diabetic patients including doctors, nurses, pharmacists, podiatrists, dietitians to provide patients education and counselling during clinical encounters. Furthermore structured patient education particularly at the time

of diagnosis or treatment transition is also needed. Education needs to be reinforced at regular intervals.

The current programme is administered by diabetes specialist nurses. However it is recognised that further efforts need to be carried out to tailor education on self management according to the person's level of health literacy. Low levels of uptake of the programme have been identified and therefore use of modern communications media should be considered as an alternative to ensure the delivery of the key messages as well as specific outreach. The education programme should be delivered by all members of the multidisciplinary team covering different topics.

*It is therefore recommended that the diabetes self management and education programme be reviewed and renewed with the aim of rendering it more accessible and including a more multidisciplinary approach. This will require an increase in the complement of trained diabetes specialist nurses and dietitians.*

The provision of education should be based on adult learning principles that promote active learning – ideally provided within a group format, unless this is considered inappropriate. Structured programmes should be provided by appropriately trained multidisciplinary teams including, as a minimum, a dietitian and a diabetes specialist nurse (or practice nurse experienced in diabetes) who understand the principles of patient education. This is complementary to one-one patient education undertaken by health care professionals attending to patients with diabetes; doctors are particularly encouraged to ensure that their patients are appropriately literate about their diabetes during clinical encounters.

## DIETARY CARE PLANNING AND DIABETES

Nutrition management is fundamental for the prevention of T2DM and the effective management of all types of diabetes. All people with newly diagnosed diabetes should be assessed by a registered dietitian, who will provide a tailored and individualised dietary care plan based on the latest evidence of effectiveness.

People taking hypoglycaemic drugs and insulin will need further advice on dietary management to balance their food intake and physical activity levels with their medication. Dietary changes need to be agreed at a pace suited to the individual – monthly follow up appointments are recommended in the initial stages after diagnosis or at times of transition, such as when medication is changed. People with diabetes who present with possible eating disorders (e.g. bingeing etc) should be referred to a clinical psychologist and dietitian for a joint programme of care.

Patients need regular updating and it has been shown that when patients accept their condition they are more receptive to educational interventions.

It is therefore important that all patients with T2DM as well as those with T1DM receive regular educational session on diabetes management and control through the course of their disease. Such sessions also serve as an opportunity for patients to ask for advice and to identify persons who may require additional support from dietetic or psychological services.

Persons with diabetes shall be invited to attend regular educational updates organised in different localities to improve access. This will necessitate significant manpower expansion .Educational material will be prepared using different media to reinforce the importance of self management for persons with diabetes.

## INTENSIVE LIFESTYLE CHANGE MANAGEMENT SUPPORT PROGRAMME

Educational programmes are not sufficient to ensure assimilation of the required information and motivation to engage in a healthy lifestyle. Evidence shows that persons who engage with an intensive lifestyle management support programme can achieve better levels of glycaemic control.

Upon initial diagnosis, patients will be assessed for their suitability to participate in an intensive lifestyle change management support programme. Such a programme would consist of dietary one to one sessions, psychological assessment and opportunities for physical training and activity. These programmes will be initially developed on a pilot basis and evaluated for their outcomes and cost-effectiveness in the local content depending on the results obtained.

## ONGOING CARE AND SUPPORT

Ongoing care and support for persons with T2DM shall primarily take place in the community through the shared care approach with the involvement of both the public and private sector depending upon the patient's choice.

In order to achieve best outcomes and to make best use of resources, it is envisaged that patients with uncomplicated T2DM will be cared jointly by general practitioners trained in diabetes care and by diabetologist. The frequency of these visits will be as clinically required, but all patients should be seen at least once annually. Patients with brittle diabetes, diabetes during pregnancy or complications shall be cared for primarily by diabetologists. The patient shall have the right to choose between private and public care.

At annual follow up, patients will have routine clinical review and investigations in line with the national standard for diabetes care. All results are to be captured in the diabetes information system. Appointment for eye and foot screening are organised and appointments for specialist review are made on a routine or urgent basis depending upon clinical findings.

During follow up visits, patients are also specifically encouraged to attend follow up educational sessions and maybe referred for dietetic or psychological advice as required.

## DRUG TREATMENT

*Access to new medications is an essential component in minimizing the risk of complications (see Chapter 5: Ensuring access to innovative quality treatment)*

## SCREENING TO PREVENT EYE COMPLICATIONS

Diabetes increases the risk of cataracts and of damage to the retina of the eyes (diabetic retinopathy). In Europe, cataracts accounted for of 13.8-21.6% blindness in 2010, whilst diabetic retinopathy accounted for 3.7-4.2% (Bourne et al., 2013). The prevalence of blindness secondary to retinopathy has decreased in many parts of the world because of regular eye screening. In the UK, where a national diabetic retinopathy screening is in place, 56.0% of T1DM subjects have retinopathy and 11.2% have sight-threatening retinopathy; the corresponding figures for T2DM are 30.3% and 2.9% respectively (Thomas et al., 2014). The importance of such regular screening lies in the fact that diabetic retinopathy is often asymptomatic until it has caused irreversible damage and visual loss.

All persons enrolled in the national diabetes information system will be assessed and monitored regularly to ensure good glycaemic control. This will already assist in the preventing microvascular disease but alone it is not enough. The situation today is such that not all persons with diabetes are carrying out appropriate and regular screening for eye complications.

It is being proposed that as part of the educational sessions and campaigns, persons with an initial diagnosis of diabetes are made aware of the important of attending screening since Argon laser treatment works best when patients are still asymptomatic.

Through enrolment in the national diabetes information system and shared care programme, active screening of ALL persons with diabetes can start to be performed as opposed to the current passive and disjointed screening programme where patients visit either their GP, physician, optometrist or ophthalmologist or none.

Screening will be performed through an annual assessment using the retinopathy screening fundus cameras that have recently been installed in health centres as well as the fundus cameras available at Mater Dei Hospital. All persons enrolled in the national diabetes information system will receive an annual invitation for screening and assessment. A mobile fundus camera will also be introduced to ensure better outreach and uptake.

Fundus images shall be taken by trained ophthalmology nurses or other trained health care professionals and reviewed by ophthalmologists or optometrists using standard criteria. Persons with suspicious or definitive pathology will be referred to the ophthalmic department at Mater Dei Hospital through an agreed fast track system. The possibility of introducing new technologies, such as optical coherence tomography (currently only available at Ophthalmic clinic at Mater Dei Hospital) will be explored.

## SCREENING TO PREVENT FOOT COMPLICATIONS

Patients with T2DM mellitus were found to be nearly 400 times more likely to undergo an initial minor toe (transphalangeal) amputation and had almost a 12-fold increased risk of a below-knee amputation (Humphrey et al., 1994). More than 60% of lower-extremity amputations are believed to be attributable to T2DM (Humphrey et al., 1994). The 25-year cumulative incidence of lower-extremity amputation in people with T1DM was estimated (in the Wisconsin study) to be 10.1% (Sahakyan, Klein, Lee, Myers, & Klein, 2011). Diabetes is also associated with worse outcomes in hospitalised patients with foot problems (Nirantharakumar, Saeed, Wilson, Marshall, & Coleman, n.d.). In patients undergoing lower extremity bypass surgery, it is associated with worse outcome (Wallaert et al., 2012), longer hospital stay and higher costs (Malone et al., 2014).

There is a need for a proper national foot screening programme to become established where all persons with diabetes are offered appointments in their local health centres for podiatric foot assessment with risk stratification and follow up intervals based on that risk assessment. All patients will have an initial assessment and yearly thereafter.

Patients who are found to have neuropathic or vascular problems shall be referred for in-depth review, intensive screening and further management at the Podiatry Centre. If vascular pathology that requires immediate intervention is confirmed, patients will be referred through a fast track system for a full vascular assessment at Mater Dei Vascular Unit.

***This care pathway has been in place for the past four years and demonstrated good results. The focus must now be on ensuring that ALL persons with diabetes receive screening and regular follow up as well as management and support for the appropriate and immediate treatment of diseases.***

## SCREENING TO PREVENT KIDNEY COMPLICATIONS

Diabetes is the leading cause of kidney disease. Diabetic kidney disease is the medical term for kidney disease caused by diabetes. Diabetic kidney disease affects both kidneys at the same time.

Diabetic kidney disease increases mortality even at its early stages (Arun et al., 2003; Neil et al., 1993). It is now the major cause for the need of dialysis in many countries (Foley & Collins, 2009) and the proportion of dialysis patients who are diabetic continues to rise (Van Dijk et al., 2005). Although outcomes of dialysis in diabetic subjects have improved (Van Dijk et al., 2005), mortality is still quite high with a median survival of 3.84 years in T1DM and 2.16 years in T2DM (Bell et al., 2014). Dialysis is associated with significant health care costs in all patients, but costs are even higher in diabetic subjects by about 27% (Foley & Collins, 2009).

The priorities to prevent kidney disease are:

### **PRIORITY 1: OPTIMAL DIABETIC SUGAR CONTROL**

Intensive management of blood glucose or glycaemic control has shown great promise for people with diabetes, not only to prevent kidney disease but also in those in the early stages of chronic kidney disease. Regular monitoring, lifestyle changes and medication are all important to help persons with diabetes achieve good control.

### **PRIORITY 2: SCREENING FOR DIABETIC KIDNEY DISEASE WITH THREE SIMPLE TESTS:**

- Blood pressure test. This test must be done at every health care visit.
- Albumin and creatinine measurement. A sample of urine for a urine albumin-to-creatinine ratio test should be done at least once a year. An elevated result is a warning sign of kidney disease.
- Estimated glomerular filtration rate (eGFR) test. This blood test measures how much blood the kidneys filter each minute. A reduction in the eGFR may indicate kidney damage or kidney failure. This test is performed at least once a year.

### **PRIORITY 3: IDENTIFICATION AND CONTROL OF HIGH BLOOD PRESSURE**

High blood pressure is the other leading cause of kidney disease in people with diabetes. High blood pressure can also be a result of damage from kidney disease. In persons with diabetes, the presence of hypertension may mean that the kidneys are already damaged. Even a small rise in blood pressure can quickly make kidney disease worse.

*All patients enrolled in the national diabetes information system and receiving regular follow up through the diabetes clinics will have these three screening tests applied.*

*Patients with abnormal findings will be referred to the diabetologist who shall have the facility to consult immediately with the nephrologist through a fast track system where this is required.*

## SPECIALIST INTENSIVE CARE THROUGH AN MDT APPROACH

The shared care programme based primarily in a primary care / community setting is intended for persons with uncomplicated T2DM.

Persons with T1DM, Gestational Diabetes, maturity-onset diabetes of the young (MODY), other rare forms of diabetes, early onset T2DM and T2DM with complications or which is difficult to control require management of their diabetes given within a specialist setting with regular follow up from all members of the multidisciplinary team.

Dietary and psychological consultations should be considered as part of the routine follow up for persons requiring close monitoring and support.

Documentation of all care episodes will be maintained through the diabetes information system.

Tailored educational sessions in small groups or one to one will be organised as required particularly for persons going through life transitions and for young women in relation to planning pregnancy.

## MANAGEMENT IN THE ACUTE CARE SETTING

Despite the best of intentions and all efforts to offer quality seamless care, persons with diabetes may experience complications necessitating hospital admission. These may be unrelated to the diabetes itself such as in the case of some need for elective surgery or may be a direct consequence of the diabetes such as in the case of hypoglycaemia or hyperglycaemia.

With reference to episodes of hypo- and hyperglycaemia every effort will be made to avert or avoid these in the first place. When they do occur, patients will be managed in line with hospital evidence-based guidelines with all the necessary attention being given to patient safety during the admission and to subsequent medication review / lifestyle and educational support in order to prevent subsequent admissions.

Persons with diabetes who are admitted to hospital for day or surgical procedures will be managed in line with evidence based protocols that have been drawn up for this purpose.

## PRACTICAL ADVICE AND SUPPORT

Persons with diabetes, particularly those who are dependent on insulin will often encounter a crisis or a new situation which they feel ill-equipped to deal with.

In such circumstances, timely advice given over the phone may avert a visit, an admission or trigger the need for an urgent consultation. At present, an informal arrangement on a voluntary basis has been in place. Given the burden on the providers of the service and the growing numbers of patients / relatives who could benefit from such a service it is felt that a more formal arrangement ought to be established.

*It is therefore being proposed that a 24/7 diabetes helpline be set up for persons on insulin. This will be staffed by trained nurses who can provide advice and support on the phone.*

## PSYCHOSOCIAL SUPPORT

The Health Interview Survey conducted in the Maltese islands in 2008 showed that persons with diabetes have a higher prevalence of anxiety and depression. This has also been reported in the international literature. As highlighted by the Parliamentary Working Group on Diabetes, further epidemiological studies are needed to study this association locally, especially on the effect this may have on the development and mental health of children and young people. Depression can affect the individual's motivation to comply with diet and treatment leading to complications and further contributing to stress and anxiety. All health care professionals involved in the care of persons with diabetes should be trained to recognise the signs and symptoms of anxiety and depression. Persons deemed at risk or in need of support should be referred to the psychologist or psychiatrist as may be required.

Persons experiencing personal or social difficulties in their life may also find it difficult to cope with their diabetes. A properly staffed psychological service should be available to support persons with diabetes passing through a crisis which can also negatively affect their management of diabetes. T1DM and adolescents are particularly at risk.

Persons who are socially excluded also need to be actively supported through the efforts of psychologists and social workers since failure to address their social problems will not allow for the attainment of successful outcomes in the management of their diabetes.



*Greater awareness of the need for referral to psychologists and social workers and accessible referral pathways for other health care professionals caring for persons with diabetes need to be established. The development of core psychosocial services for persons with diabetes as part of the multi disciplinary team need to be established and resourced as a matter of priority.*

## DIABETES INFORMATION SYSTEM

The capture of data on all patients with diabetes at a national level in a single information system allows active surveillance through personalised invitations for screening in order to encourage a high attendance. It will also allow measurement of progress in attaining the set targets of the strategy, regular evaluation and benchmarking with other health care systems. Therefore every effort should be made to ensure the capture of data for all persons with diabetes in the current information management system. This will require training and rolling out of access. In addition *diabetes will be considered as a priority area for early investment in the forthcoming e and m health strategies. Until such time, use can continue to be made of the current diabetes system with access being rolled out to all persons involved in the care of patients with diabetes. It will be important to ensure that the data available in this system would be eventually integrated in the electronic medical record once this is developed at national health system level.*

Initially it is proposed that investment is made in a call/recall system that can allow patients to receive reminders to attend appointments, have blood investigation and access retinal and foot screening programmes. This system will be invaluable in identifying persons who are not being followed up and instituting active surveillance and outreach.

## CHOICE

Freedom to choose one's health care provider will remain an important principle since the doctor-patient relationship is key to a successful outcome in the management of diabetes. Whilst patients will be offered the opportunity to access good quality health care offered free of charge through the diabetes clinics in health centres, it is recognised that some patients will prefer to remain under the care of their own private general practitioner or private specialist. It is nonetheless strongly recommended that all patients enrol in the national diabetes information system in order to access the opportunity for structured monitoring and screening on a yearly basis. In between, patients may continue to be seen by their private doctor who will work in tandem with the diabetes clinics in the health centres or Mater Dei to ensure the close follow up of the patient in the primary care setting in line with the national standard of care.

## VASCULAR COMPLICATIONS

Persons experiencing vascular complications should be able to access the necessary treatment without delay. This could include access to antibiotics and special dressings. Currently, access to such items is restricted and not all patients are able to afford to buy them. Even in the case of patients who are entitled, it often takes some time for the items to be approved and this can be detrimental to the outcome.

*It is therefore recommended that a thorough review of the procedures to access antibiotics and dressings for ulcers and gangrene take place with a view to facilitating access to such supplies.*

Patients often need to be provided with specialist footwear following minor phalangeal amputations. The current system often gives rise to considerable delays in the delivery of appropriate footwear to high risk patients with the result that they are admitted for further amputations while awaiting delivery of footwear some of whom end up losing a limb unnecessarily.

Increased human resources and operating theatre time are required to address the vascular problems associated with diabetes in an effective and timely manner. In tandem with a foot screening programme and availability of treatment and supplies, it will be possible to further reduce the rate of amputations in persons with diabetes.

## ORTHOTICS AND PROSTHESIS

Persons who undergo surgery require appropriate support and rehabilitation. One of the key sources for such care is the Orthotics and Prosthetics Unit. This unit which is currently still housed at St Luke's Hospital is severely under resourced. The process currently being followed is that when patients need orthotics they are referred to the Orthotics and Prosthetics Unit. Once the patients are given an appointment at OPU, the orthotics are ordered from abroad. This is resulting in a long waiting time (approximately 12 weeks) and a high cost.

It is believed that this can be reduced if the orthotics are fabricated in Malta. With an initial cost of around €50,000 the orthotics can be fabricated in Malta in real time and with a cost of around €10 each pair. The orthotics could be supplied to the patient within a week and thus we will be providing a much improved service at a fraction of the current cost. Investment in human resources and equipment would be required but this will lead to more timely and efficient service provision. An increase in the budget allocated to the OPU is needed to address the issue of making the necessary orthoses and prostheses available in a more timely manner.

The unit at St Luke's Hospital is in need of replacement or refurbishment. This will go a long way to improve the care experience of persons who are already in a very difficult psychosocial situation as they are dealing with grief for loss of a body part as well as coping with newfound disability.

*It is therefore recommended that priority investment is made in new premises, equipment and human resources in order to allow a quality orthotic and prosthetic service to be provided in a cost effective manner and with a better overall patient experience.*

## KIDNEY COMPLICATIONS

A number of persons with diabetes will unfortunately develop diabetic kidney disease. Persons who are deemed at risk of requiring renal replacement therapy should be referred to a clinic which will help educate and prepare them psychologically for this difficult transition in care.

*It is therefore proposed that a pre dialysis clinic be established with education and support through a multi disciplinary team.*

Persons with diabetes requiring dialysis will receive the best support and care possible through the renal unit at Mater Dei Hospital. Recently the unit has extended its hours of service in order to continue to better meet the patients growing service needs.

## EYE COMPLICATIONS

A number of persons with undiagnosed diabetes unfortunately present de novo with vascular eye complications. This should be addressed through the setting up of the diabetes screening programme.

Furthermore eye complications can be treated more easily if diagnosed when the patients is still asymptomatic. The establishment of an organised eye screening programme for all persons with diabetes and prompt referral in cases where suspicious pathology is found will enable eye complications to be tackled earlier and more aggressively.

There is a need to educate persons with diabetes about the benefits of early laser therapy. The overall goal is to continue to reduce the incidence of blindness associated with diabetes.

## ALLIED HEALTH

The role of allied health practitioners in the support of persons with diabetes ranges from primary prevention through education, to diagnosis in the laboratories, to provision of support at all stage of the illness. The allied health professionals play an important role in the management and improvement of care outcomes for diabetes. The main areas identified for priority investment in human resources are for dietitians, prosthetists and orthotic technicians.

## GOZO

Gozitan residents who are diabetic also deserve the best standards of care and management for their condition. Although some outreach is presently performed there is a need to increase the presence of specialists on the island. This may be achieved with the additional investment in human resources as identified in the strategy. Whilst Mater Dei Hospital remains the tertiary referral centre for all persons with diabetes in the Maltese islands, it is also important that for uncomplicated T2DM, Gozo also joins the shared care programme as this will allow routine follow up to be carried out to the same standard as being advocated for patients in Malta.

## ELDERLY PERSONS WITH MULTI MORBIDITY

Diabetes affects more than one in four persons over the age of 60 in Malta. The management of diabetes in the elderly must be carried out in the background context of other conditions. Care plans must be carefully developed where the treatment of hyperglycaemia should not be carried out in isolation but should be balanced with the risks of hypoglycaemia, falls fractures etc. Access to drugs which have a low hypoglycaemia risk is also important in this regard.

Elderly persons who are home bound and in need of support for insulin administration should be provided with simple regimes that are easy to administer and that can facilitate self care and adherence.

## **CHAPTER 7: FOCUS ON QUALITY OF LIFE: THE PATIENT PERSPECTIVE**

In keeping with the WHO definition of health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”, the care for persons with diabetes needs to encompass not only the biological aspects of the disease, but psychosocial aspects too. The goal is to increase the self-reliance and levels of self-care of persons with diabetes.

### **CURRENT SUPPORT SERVICE**

The Diabetes Support Team consisting of the consultant, the diabetes nurse specialist, the dietitian, the podiatrist and the psychologist should work hand in hand from the time a person is diagnosed with diabetes and followed regularly by the whole team emphasising a multidisciplinary approach to care. The current lack of sufficient human resources does not allow such multi disciplinary regular follow up to take place. Two diabetes nurse specialists need to provide education sessions for all newly diagnosed persons with diabetes and their families, ongoing education to persons with established diabetes, and lectures to health and other professionals. Besides delivering diabetes education, the specialist nurses offer support on emergency issues, staff training and assisting in general when their clinical services are required.

This leads to a situation where presently newly diagnosed persons with diabetes are being bombarded with information when they are still in a state of denial and shock, and hardly capable of absorbing all that is being passed on. Additional investment in trained human resources for patient education would allow a smooth and continuous learning process such that all patients are empowered to be self-reliant and provided with an ongoing information and educational service throughout the course of their disease.

The setting up of a 24/7 support service would help persons who need quick advice such as about insulin doses over the phone.

Persons with newly diagnosed T2DM do not have access to a dietitian before 9 – 12 months after being diagnosed – a situation where these persons are left to fend for themselves for too long before they are given the proper information on how their dietary habits have to change. Dietary guidelines should be addressed immediately at diagnosis in order to introduce a healthy diet early on, especially when weight loss is required in obese persons.

Persons with diabetes and their families also require access to routine visits offered by psychologists. Such a service would greatly benefit all persons who are affected by diabetes: parents with children who are diagnosed with diabetes, the children themselves, adolescents, young adults and persons of all ages. Some of these have no-one to turn to to express their innermost struggle and difficulties. Couples have encountered marital problems when their child becomes diagnosed with diabetes, older patients have had to deal with anger, frustration, denial, depression and rebellion all on their own, sometimes leading them to become anti-social and unresponsive to their own wellbeing. Children and adolescents have to tackle bullying, denial of their condition so that they do not stand out as different from their friends, leading some to stop taking their insulin resorting to drugs and hiding their condition even from their most intimate friends and partners.

## EDUCATION

Patient Diabetes Education (PDE) has been shown to improve outcome indicators and ultimately the quality of life of persons with diabetes. They are effective by improving diabetes knowledge, lifestyle and psychosocial outcomes. Holding these sessions in the community would be more accessible, and reduce the stigma associated with hospital-based care.

Education should be an integral part of the management of all people with diabetes: from around the time of diagnosis, on an ongoing basis, based on annual assessment of need, and on request. A trained multidisciplinary team can provide education to groups of people with diabetes, or individually if group work is considered unsuitable. Where possible, family members or friends should be included. These should be lead by health-care professional with specialist training in diabetes and delivery of education for people with diabetes. It should be accessible to all people with diabetes, taking account of culture, ethnicity, psychosocial, and disability issues. Education can be delivered in the community, and in different languages. Techniques of active learning should be used, adapted to personal choices and learning styles. The use of modern communications technologies may advance the methods of delivery of diabetes education (Cilia, 2007).

## TRANSITION OF CARE

There is a discrepancy in the care given to children who are 16 years and under, and those who are in their late teens. This arises due to the transition of care from the Children's Clinic to the adult diabetes clinics. At a time when these persons are passing through physical, emotional and lifestyle changes, they are thrust from a familiar atmosphere to one where they are expected to fit in with the rest of the diabetic patient population. Transition should

be gradual and the handover done over a period of time. For this reasons it is proposed that a joint clinic should be adopted to gain the patient's confidence from one consultant to another. Adolescents who are 18 and over should be encouraged to attend the clinic alone without the supervision of the parents in order to induce a more congenial atmosphere where the patient can be more relaxed and can open up without the fear of their parents' opinion.

## AVAILABILITY OF MEDICINES

Entitlement for new medications and blood glucose strips quota are being evaluated by the relevant authorities and there will be improvements in this area soon.

A representative of persons with diabetes should be on the board for the introduction and change of protocol and meters so that the problems faced by the service users will be addressed.

## SCHOOL

Persons living with diabetes are encountering a number of problems which are brought about due to their medical condition. One of the most serious problems is the situation faced by children and their parents at school.

The current service of school nurses is insufficient to meet the needs of children with diabetes. These nurses visit schools at specified times, and are hence unavailable for emergencies, or to help give insulin at the adequate time. In fact, young children are often assigned a Learning Support Assistant (LSA) to help them in case of need. This risks labelling these children unnecessarily, since they are not in need of assistance to learn unless they have other medical or learning difficulties.

Talks are currently underway between the Maltese Diabetes Association, the Department of Education and the Commissioner for Children's rights to bring about a change in the current system. Having children miss hours of school simply because there is no one who is empowered to immediately treat a hypoglycaemic episode is creating problems, and could be easily resolved if someone responsible has been trained and followed a recognised First Aid course.

Children who are capable of self monitoring and injecting are also encountering problems at school. Often there is not an identified place where the student can go to monitor and inject. This is often done in the common toilet, a place which is hardly ideal. Some children have also been asked to go to the headmaster/mistress office to inject there. Schools should have

the set-up to allow students to monitor and inject without hassle and should be in a position to help those students who need supervision.

In 2014, the Maltese Diabetes Association together with the paediatric diabetes team issued an Educational Folder to be used by parents, headmaster/mistresses, teachers and LSA's who have children with diabetes in their school/class. The folder aims to give the basic information on diabetes in children. It is also illustrated for easy reference. With the permission of the Department of Education the folder is being forwarded to all public and private schools.

## WORK/EMPLOYMENT

Persons living with diabetes do not only have rights but also duties and this is not always highlighted. It is important to instil in the person with diabetes that they should not hide their condition. The person with diabetes has to make their condition known to their immediate friends and colleagues at work. They should be informed on the symptoms of hypoglycaemia and how to remedy it in cases of emergency. The employer on their part can take the necessary steps to ensure employee wellbeing by ensuring that the employee is not hindered in taking the necessary measures to control their diabetes, such as by providing a private space where they can monitor and inject.

Educating the general public on diabetes and removing the taboo attached to this condition would also address discrimination when it comes to job interviews. Persons with diabetes can and do live normal everyday lives if they are well-controlled. Prospective employers should not be wary of employing persons with diabetes especially if they are provided with proof that the person is well controlled.

It must be emphasised that there are certain jobs which cannot be carried out by persons with diabetes regardless of how well they are controlled due to the risks to the safety of others e.g. pilots, drivers of heavy vehicles, the Police Force and The Armed Forces.

Whatever the circumstances, it is important to carry identification on the medical condition. The Maltese Diabetes Association distributes, free of charge, Identification ID stating that the holder is a person with Diabetes. This would help prevent instances where someone with hypoglycaemia is mistaken to be under the influence of mood-altering substances. Initial first aid would also be more effective if those who assist or paramedics know that the person has diabetes. In addition, the Department of Diabetes and Endocrinology and the Diabetes Education Unit also give out identification cards with patients' details, emergency contact details and current treatment and dose written on the card.



## HEALTH LITERACY

Persons living with diabetes and their carers are duty-bound to learn about the condition in order to be better able to take care of themselves, understand what is being said to them and therefore avoid or postpone as long as possible complications. The Maltese Diabetes Association and the Diabetes Clinic at Mater Dei Hospital both hold educational talks on Diabetes. These are however poorly attended. We must find new means to reach out to deliver key messages and to motivate persons to practise good self care. The media is also an important partner in raising awareness for the general population.

## DEALING WITH COMPLICATIONS

Quality of life deteriorates once a person with diabetes develops complications due to a changed lifestyle. The burden on the person and the immediate family cannot be quantified. They have to adjust to their new medical condition, frequent visits to their doctors and admissions to hospital. They might also perceive themselves as an added burden to the family, especially with regards to costs involved in the procurement of medicines and items which are not covered by the government formulary, therefore putting an extra financial burden on the family. For example, the treatment of osteomyelitis, a known complication of diabetes, requires prolonged treatment with expensive antibiotics which is not affordable for many persons. These end up having an amputation, simply because they did not adhere to the treatment prescribed. Entitling these persons to free antibiotics and the necessary dressings would help reduce complications.

In low income families, clinician recommendations might be completely disregarded due to the lack of resources. Such circumstances are especially evident in families with small children and pensioners. In cases where persons with diabetes depend on their family members to administer the necessary care, they might become more frustrated because they have lost their independence and become a burden on their wife, husband, children or other dependants. This change in circumstances could lead to family conflict because the person becomes irritable and frustrated and perceived as not appreciating the sacrifices the family members are doing on their behalf. The situation worsens when the persons' complications start to affect their employment. The person might need to ask for shorter working hours or work-load or be transferred to a different section in the work place, which could result in reduced hours of work and a reduction in income. When these persons need to be boarded out or fired because they are no longer fit for work, the situation becomes critical and in this instance the persons needs a more holistic management as medical intervention is not enough. Often these persons need a friendly ear to turn to, someone who is willing to hear them out and encourage them to keep going and not give up.

## LEGAL FRAMEWORK

One of the main proposals put forward by the Parliamentary Working Group on Diabetes is the development of a legislative instrument that addresses a number of issues highlighted in this chapter and elsewhere. While the strategy outlines what government is going to do, legislation is necessary for some aspects where enforcement is required.

Such an instrument would have the aim to lower any existing barriers and facilitate the full participation of persons with diabetes in societal activity. The members of the Working Group shall be collaborating with the Parliamentary Secretariat for Health to develop this instrument during this legislature and will be taking this instrument through the legislative process at the political level.

Consultation Document

## CHAPTER 8: PAEDIATRIC DIABETES IN MALTA

### EPIDEMIOLOGY OF CHILDHOOD DIABETES IN MALTA

T1DM is one of the commonest chronic conditions in childhood. The incidence of T1DM in Malta during the period 2006 - 2010 in children under the age of 14 years was calculated to be 21.86/100,000/year, with the highest incidence registered in the 5 - 9 year old age group (Formosa, Calleja, & Torpiano, 2012). An annual increase in incidence over this period has been registered in children under ten years. The reasons for this increase in incidence are unknown and this phenomenon has also been observed in other countries (Gale, 2002).

Age group	Mean incidence (per 100,000 per year)	Annual increase in incidence
0 - 4.9	21.7	+39% per year (p = 0.04)
5 - 9.9	30.4	+31% per year (p = 0.026)
10 - 14	16.1	- 6.5% (p = 0.66)

TABLE 2: INCIDENCE OF DIABETES IN CHILDREN 2006-2010 (SOURCE: DATABASE MAINTAINED BY PAEDIATRIC DIABETOLOGIST MATER DEI HOSPITAL AUGUST 2014)

Most children presented with classical symptoms such as increased thirst and an increase in the frequency and volume of urine.

Mode of presentation	Proportion (%)
Subacute symptoms (polyuria, polydipsia)	57.9
Diabetic ketoacidosis	41.0
Asymptomatic hyperglycaemia	1.1

TABLE 3: MODE OF PRESENTATION (SOURCE: DATABASE MAINTAINED BY PAEDIATRIC DIABETOLOGIST MATER DEI HOSPITAL AUGUST 2014)

### PERFORMANCE AND OUTCOMES

According to ISPAD recommendations, young people with T1DM should achieve an ideal HbA1c target of < 7.5% (IFCC < 58 mmol/mol) (Rewers et al., 2009). Analysis of 2013 data showed that almost 44% of diabetic children making use of the paediatric diabetes service at Mater Dei Hospital managed to achieve this target:

HbA1c (%)	Proportion of patients (%)
< 7.5	43.8
7.5 – 8.0	26.6
8.1 – 9.5	25
> 9.5	4.6

**TABLE 4: HbA<sub>1c</sub> AS AN INDICATOR OF OUTCOME (SOURCE: (FORMOSA N, TORPIANO J: UNPUBLISHED AUDIT))**

The mean HbA<sub>1c</sub> by age-group was as follows:

<b>Age (years)</b>	<b>Mean HbA<sub>1c</sub> (%)</b>
0 – 10.9	7.53 (±0.16)
11 – 16	7.85 (±0.25)

**TABLE 5: MEAN HbA<sub>1c</sub> BY AGE GROUP**

These results are very encouraging, especially when compared to other countries in the European Union. In England and Wales, only 17.4% of children and young people with diabetes achieved an HbA<sub>1c</sub> of < 7.5% during the period 2011 - 2012 (Royal College of Paediatrics and Child Health, 2013). In order to achieve even better results in Malta, it is necessary to make the following changes as already outlined above:

## ENSURING QUALITY SERVICES FOR CHILDREN WITH DIABETES

The first diabetes clinic in a Government hospital (St Luke's Hospital) was set up in 1963. For several years, all diabetic patients regardless of age were managed by physicians specialised in adult internal medicine working in the Department of Medicine. In 2006, the responsibility of care of diabetic children was transferred to the Department of Paediatrics with the appointment of a Consultant Paediatric Endocrinologist. Since that time, the Paediatric Diabetes Service (PDS) has been involved in the care of 181 children with diabetes, 95% of whom had T1DM. The upper age limit within the paediatric diabetes service was initially 14 years, but this was extended to 16 years in 2011. There are currently around 140 children under the age of 16 years with diabetes (94% with T1DM) who make use of the paediatric diabetes service.

Children with new-onset T1DM and their families require intensive diabetes education by a paediatric diabetes healthcare (DHC) team to provide them with the necessary skills and knowledge to manage this disease. The complex physical, developmental and emotional needs of children and their families necessitate specialized care to ensure the best long-term outcomes. Newly-diagnosed patients are admitted to hospital for an average of 5 - 7 days for metabolic stabilisation as well as intensive education of the family regarding diabetes care. During this initial period of hospitalisation, each individual patient's family receives an intensive, structured programme of education that takes up 20 hours or more. This includes the following subjects:

<b>By specialist doctors</b>	<b>By diabetes nurse specialists</b>	<b>By dietitian</b>
Nature of diabetes	Use of glucagon	Meal planning

Diabetes complications Ketones and their monitoring Diabetic ketoacidosis Diabetes co-morbidities Basics about carbohydrates Insulin action profiles Hypoglycaemia management Hyperglycaemia management Sick day rules	Use of insulin pens Self blood glucose monitoring	
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TABLE 6: LIST OF DIABETES EDUCATION SUBJECTS COVERED BY HEALTHCARE PROVIDERS

On average, each child is reviewed around six times a year, although newly-diagnosed patients are seen much more frequently in the first few weeks after discharge from hospital. Very young children (e.g. under 6 years of age) also require more frequent review. Relatively few patients miss outpatient appointments. In order to ensure that no children are lost to follow-up, those who miss appointments are contacted by phone and another appointment is given at the first available opportunity. A separate visiting consultant clinic is also held at Gozo General Hospital every 3 - 4 months in conjunction with the consultant paediatricians at that hospital.

The introduction of point-of-care capillary blood testing for glycosylated haemoglobin (HbA1c) in 2012 has allowed the measurement of HbA1c every 2 – 3 months on all young children with diabetes. This has been found to be very useful in the management and education of young people with diabetes.

The care and management of children and adolescents with diabetes is also focused towards preventing complications later on in life. The following table shows the recommended screening programme for children with diabetes as recommended by the International Society for Pediatric and Adolescent Diabetes (Donaghue et al., 2014):

Complication	Start of screening	Screening methods and frequency
Retinopathy	From age 10 and after 2 - 5 years' diabetes duration	Annually: Direct ophthalmoscopy through dilated pupils by experienced observer, or fundal photography.
Nephropathy	From age 10 and after 2 - 5 years' diabetes duration	Annually: First morning urine albumin-creatinine ratio (ACR). An abnormal result should be confirmed in at least 1 of 2 subsequent urine collections.
Neuropathy	From age 11 and 2 years' diabetes duration	Annually: History and examination.

Macrovascular disease	After age 10	Annually: Blood pressure. Every 5 years: Fasting blood lipids.
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**TABLE 7: RECOMMENDED SCREENING PROGRAMME (COMPLICATIONS) FOR CHILDREN WITH DIABETES (INTERNATIONAL SOCIETY FOR PEDIATRIC AND ADOLESCENT DIABETES)**

T1DM may also be associated with a number of co-morbidities. The following table shows the recommended screening for these conditions as recommended by the International Society for Pediatric and Adolescent Diabetes (Kordonouri et al., 2014):

Co-morbidity	Start of screening	Screening methods and frequency
Growth failure	At diagnosis	Every 6 - 12 months: Auxology.
Thyroid dysfunction	At diagnosis	Every 1 - 2 years: Thyroid function and serum anti-thyroid peroxidase antibodies.
Coeliac disease	At diagnosis	Every 1 - 2 years: Serum tissue transglutaminase and/or endomysial IgA antibodies. Antibody-positive patients should be referred to a paediatric gastroenterologist for further evaluation.
Lipodystrophy	6 months' diabetes duration	Every 6 months: Examination.

**TABLE 8: RECOMMENDED SCREENING PROGRAMME (CO-MORBIDITIES) FOR CHILDREN WITH DIABETES (INTERNATIONAL SOCIETY FOR PEDIATRIC AND ADOLESCENT DIABETES)**

## STAFFING LEVELS

The numbers of health care staff caring for children with diabetes in Malta are as follows:

Category	Current staff level	Recommended staff level for paediatric diabetes service [Kirk et al 2012, de Beaufort et al 2012, Royal College of Nursing 2006]
Paediatric diabetes specialist	2 (1 Consultant + 1 Resident Specialist) – practising paediatric diabetology, paediatric endocrinology as well as general paediatrics	1 Whole Time Equivalents (WTE) per 100 patients
Diabetes nurse specialist	2 for all Maltese diabetics (estimated 35,000)	1 WTE per 70 -100 patients
Dietitian	Ad hoc support	0.5 WTE per 100 patients
Psychologist	Ad hoc support	0.3 WTE per 100 patients
Social worker	None	0.2 WTE per 100 patients

TABLE 9: CURRENT HUMAN RESOURCES CARING FOR CHILDREN WITH DIABETES IN MALTA

## RESOURCING HEALTHCARE FOR CHILDREN WITH DIABETES

The management of childhood diabetes, especially T1DM, is extremely complex. Young children with diabetes should be managed by a multidisciplinary team (MDT) lead by a doctor specialised in paediatric diabetes care. Although patients in Malta are reviewed regularly by medical specialists at Mater Dei Hospital, they are not actually being seen by a MDT. Access to a dietitian and a psychologist is limited since there are no dietitians or psychologists working primarily with children who have diabetes.

The Royal College of Nursing recommends that the complement of diabetes nurse specialists (DNS) in a paediatric diabetes service should be 1.0 WTE per 70 diabetic children (Royal College of Nursing, 2005). This means that the paediatric service at Mater Dei Hospital should have two full time diabetes nurse specialists. Currently children with diabetes are supported by the two diabetes nurse specialists who are expected to cater for the entire diabetic population in Malta and Gozo.

All children with T1DM should receive counselling from a registered dietitian with a special interest in paediatric diabetes. Children with diabetes should follow a healthy diet as recommended for children without diabetes. This involves consuming a variety of foods. There is no evidence that one form of nutrition therapy is superior to another in attaining age-appropriate glycaemic targets. Appropriate matching of insulin to carbohydrate content may allow increased flexibility and improved glycaemic control. The effect of protein and fat

on glucose absorption must also be considered. Nutrition therapy should be individualized (based on the child's age, nutritional needs, eating habits, lifestyle, ability and interest) and must ensure normal growth and development without compromising glycaemic control. This plan should be evaluated regularly and at least annually. Currently, children with diabetes only see a dietitian infrequently and erratically because there are too few dietitians in the public health service. This has been identified as a major service gap in a recurrent manner throughout the needs analysis conducted in the drawing up of this diabetes strategy.

As diabetes care can be very demanding on affected children and their families, these should also be reviewed on regularly by a psychologist. It is not sufficient to have ad hoc access to a psychologist present. Anticipatory guidance and lifestyle counselling should be part of routine care, especially during critical developmental transitions (e.g. upon school entry, leaving secondary school). Psychologists should regularly initiate discussions with children and their families about school, psychological issues, substance use, obtaining a driver's license and career choices.

Achieving the appropriate human resource complement to cater adequately for children with diabetes has been identified as an immediate priority. Increasing the competent health professional workforce as outlined above is a necessary prerequisite to allow service improvements to be made, better support and care to be given to patients and the introduction of innovative services such as an insulin pump service.

*It is therefore recommended that steps are taken to train and recruit professionals so as to bring the staff complement for the paediatric diabetes service in line with internationally recognised levels.*

## INSULIN THERAPY FOR CHILDREN WITH TYPE 1 DIABETES

Maltese children with T1DM under the age of 16 years are on the following insulin replacement regimens.

<b>Insulin regimen</b>	<b>Proportion (%)</b>
Conventional twice-daily regimen (using human insulin preparations)	25
Multiple daily insulin regimen (using insulin analogues)	75

TABLE 10: CURRENT INSULIN THERAPY (SOURCE: DATABASE MAINTAINED BY PAEDIATRIC DIABETOLOGIST MATER DEI HOSPITAL AUGUST 2014)

The protocol for use within the public health service currently obliges clinicians to start newly-diagnosed children with diabetes on human insulin preparations. This means that all



children have to start on a conventional twice-daily regimen, which is considered to have several disadvantages (increased risk of hypoglycaemia, increased risk of poor glycaemic control, higher levels of glycosylated haemoglobin, more adverse long-term outcomes, etc.). Current practice in centres of excellence around the world is to start children with T1DM on a multiple daily insulin regimen (i.e. using insulin analogues) or an insulin pump from the time of initial diagnosis. These regimens are associated with tighter glycaemic control, fewer hypoglycaemic episodes, better quality of life and fewer long-term complications related to diabetes.

The vast majority of young diabetic patients on a conventional twice-daily insulin regimen experience poor glycaemic control and/or significant and recurrent hypoglycaemic events.

*It is therefore recommended that children with diabetes may be started immediately on an insulin analogue if this is deemed the best clinical option for that particular individual.*

Any future introduction of an insulin pump service for children must be planned properly in advance and necessitates the availability of sufficient numbers of trained human resources (see above). As the paediatric diabetes service currently lacks a proper MDT and is insufficiently staffed, plans to introduce an insulin pump service must be kept in abeyance due to the increased input and care that would be required by patients utilising a pump service. Failure to introduce a service within the necessary safety standards would place patients at high risk.

*It is therefore recommended that a detailed assessment of all the legal, workforce and resource requirements be carried out and steps to develop such a service only commenced if and when the necessary resources are in place.*

## PROVISION OF FREE MEDICAL SUPPLIES

Children with diabetes are entitled to receive the following items free-of-charge through the public health service. The provision of these supplies is important to help children and their families in the daily management of their condition and the monitoring of blood glucose several times a day has been shown to improve long-term outcomes.

Item	Quantity
Insulin cartridges	As required
Insulin injection pens	As necessary
Disposable injection pen needles	As required
Glucose meter	1 device supplied at the time of diagnosis
Blood glucose test-strips	4 strips per day
Alcohol-impregnated swabs	As required
Glucagon vial and syringe	As necessary

TABLE 11: LIST OF ITEMS PROVIDED FREE OF CHARGE TO CHILDREN WITH DIABETES

## SCHOOL

Children spend a substantial part of their day at school. This includes both winter and summer schools. Children with diabetes are also encouraged to participate in out of school activities such as sports activities since these are important to help their integration and self esteem besides keeping their blood glucose better controlled.

During school hours, most children need to check their blood glucose at least once (e.g. just before their midday break), and a number of them may also need to take an insulin dose just before they eat their school lunch. Most children above eight years are able to understand the basics of diabetes care, check their own blood glucose with their glucose meter and are also competent in self-administration of subcutaneous insulin injections. On the other hand, younger children have to rely on a responsible adult who has some knowledge of diabetes care. Very few schools employ a resident nurse able to help and/or supervise students with diabetes in blood glucose monitoring and insulin administration.

In order to bypass this problem, many parents are requesting the service of a learning support assistant (LSA) for their children, even when they do not have any learning difficulties. Although the majority of LSAs have proven to be very helpful in monitoring diabetic children at school, it is currently not their remit to do so. A good number of parents also request a community nurse to visit their children at specific times (e.g. just before the school midday break) in order to perform a blood glucose measurement. There are several disadvantages in this practice. One problem that has been encountered is that community nurses may be delayed by traffic or previous patients they would have attended to, and would only arrive at the diabetic child's school quite late during the school-break, so that the child's lunch would be delayed.

This situation emerged as an important and critical gap in the current support given to children with diabetes. The objective is to achieve a situation where every school has at least one person who is trained and certified competent in performing blood glucose measurement and administering insulin. Whilst it is acknowledged that the ideal situation would be to have a resident nurse in every school, the current demand for nurses in other areas within the health sector do not appear to make this option feasible in the short term. Other solutions could therefore involve another professional working within the school such as a teacher, a learning support assistant, and an administrative member of staff or the employment of a carer. The persons designated to carry out this function would have to attend a specific training course and be certified competent initially and at regular intervals. The performance of these duties if required due to the presence of children with diabetes attending that particular school would need to be listed as additional specific duties within

the job description which they are authorised to perform by virtue of their training certification.

## ADOLESCENCE AND CARE TRANSITIONING

Diabetes control may worsen during adolescence. Factors responsible for this deterioration include adolescent adjustment issues, psychosocial distress, intentional insulin omission and physiological insulin resistance. A careful multidisciplinary assessment should be undertaken for every child with chronic poor metabolic control to identify potential causative factors, such as depression and eating disorders, and to identify and address barriers to improved control. Furthermore adolescents with diabetes should receive regular counselling about sexual health and contraception. Unplanned pregnancies should be avoided, as pregnancy in adolescent females with T1DM with suboptimal metabolic control may result in higher risks of maternal and foetal complications.

The time of care transitioning from the paediatric diabetes service to the adult diabetes service is a sensitive one for adolescents with diabetes and their families. Besides the difficulties of managing their diabetic condition which arise during this period, adolescents also need to cope with the changes brought about through the healthcare system as their care is taken over by the adult diabetic service. The change of physician or team can have a major impact on disease management and metabolic control in the person with diabetes with some young adults defaulting follow-up during the transition from paediatric to adult diabetes care services and being more likely to experience hospitalization for DKA during this period. Organized transition services are important to avoid such episodes.

The transition has been described as “traumatic” since from a relatively sheltered service catering for less than 200 persons, adolescents with T1DM find themselves being cared for in a service that has to cater for around 30,000 persons with diabetes.

*It is therefore being recommended that a joint transition care clinic be established immediately such that patients are seen on one or more occasions by the paediatric and adult diabetologist jointly before formal transfer takes place. It is also recommended that a specialised multidisciplinary clinic for adolescents and young adults with T1DM be developed. It is recognised that this may take some time to organise as additional staff resources will be required.*

Adolescents frequent places of leisure where self management of diabetes may be compromised due to lack of access to a clean, secure and hygienic environment. Operators of leisure and social facilities for young people should be made aware of the needs of adolescents with diabetes and efforts should be made to provide safe facilities where monitoring and insulin administration may take place safely.

## CHAPTER 9: RESEARCH AND SURVEILLANCE

*Our overall goal is to promote research into all aspects of diabetes and build an appropriate surveillance system to monitor diabetes incidence and prevalence as well as to document intermediate and terminal outcomes in order to continuously improve the quality of service for persons with diabetes.*

### RESEARCH

Diabetes is one of the commonest chronic conditions currently affecting the Maltese population. Research serves to provide the necessary evidence that allows innovation with the objective of preventing or delaying diabetes or its complications. Whilst international evidence is very important in guiding standards of clinical practice, contextual factors profoundly affect incidence and management of diabetes. Therefore the need for local research that translates and tests international evidence in the local context is required. Much local research has taken place over the past years. Often this is not properly disseminated particularly if it is not published in impact factor peer reviewed journals.

The main priorities for research in diabetes that have been identified in the preparation of this strategy are the following:

- Local genetics of diabetes and interaction between genetic predisposition and risk factors in the environment
- Reasons for increasing incidence of T1DM
- Motivational factors and compliance with diet /treatment regimens
- National Prevalence study of diabetes
- E health/ M health and diabetes management

Through the national diabetes strategy, it is proposed to better organise and coordinate the efforts, resources and expertise available in order to ensure larger more effective research projects. Diabetes has been identified as one of the priority areas for research funding in the health sector over the coming years. Government bodies, academic institutions, practising clinicians, industry and NGOs are encouraged to come together and pool their resources towards research projects which can have significant impact at both national and international levels. *[Government is promoting a whole of society approach with a novel perspective to strengthen the availability of resources and the quality of research in public health and health services and diabetes will be a priority subject area in this new venture.]*

### PSYCHOSOCIAL RESEARCH

Successful prevention and management of diabetes requires that patients are actively educated and empowered to work as partners with clinical professionals in the management of their condition.

## PUBLIC HEALTH AND HEALTH SERVICES RESEARCH

Prevalence data for persons with diabetes is sorely lacking at a national level. The last fully fledged prevalence study took place under the auspices of the WHO MONICA project in the mid-1980s. A scientific prevalence study is required to understand the current epidemiology of diabetes in the Maltese islands. The significant societal transitions being experienced also leave an impact on the epidemiology of diabetes. A special focus on distribution of diabetes in society will be incorporated in the prevalence study in order to investigate any inequalities and high risk areas / population sub groups.

This will enable better planning for health services in the area of diabetes as well as economic modelling related to the projected burden of disease. A diabetes prevalence study will be conducted in 2015-2016. The findings from this study will serve to inform further actions and priorities in the coming years in the area of diabetes.

Innovative models of health promotion and health services organisation and delivery for persons with diabetes need to be developed in order to achieve better results and outcomes for individuals and for society as a whole. These include research on use of technology including ICT to deliver enhanced preventive and supportive services for persons with diabetes.

## SURVEILLANCE

There is a pressing need to establish the necessary infrastructure for surveillance of diabetes at a national level. Whilst for other chronic illnesses such as cancer, the existence of a truly national register for the past twenty years has allowed the reasonably accurate monitoring of incidence and outcomes this has yet to be developed for diabetes.

A system of surveillance enables epidemiological trends to become immediately visible such that an appropriate response may be carried out in terms of service planning as well as public health interventions. It may also help to shed light on possible aetiological factors.

At present a number of databases holding information on persons with diabetes are known to exist. Some of these have been painstakingly developed through personal initiatives over a number of years while other exist for other reasons and hold valuable information on persons with diabetes as part of a larger information management system. It is now time to

make a step further through a setting up of a national diabetes register. In order for such a register to function effectively this needs to be linked to an electronic clinical system accessible to all health care professionals who look after persons with diabetes. This is considered to be a key foundation in enabling the development of a truly integrated care system with integration between professionals, between institutional and community care, between health and social care and also across public and private sectors.

In the development of such a system, due attention will be given to ensure that privacy rights of individuals are duly protected as stipulated under the Data Protection Act.

A national diabetes register built on modern ICT infrastructure will be instrumental in assisting with clinical management particularly with ensuring that all persons with diabetes attend for eye and foot screening in order to ensure that nobody falls through the system with organised call / recall and follow up particularly of persons who may be at increased risk due to psychological or social issues.

The diabetes register together with an integrated electronic patient management system which will be developed as part of Government's forthcoming e / m health strategy will allow the measurement of performance indicators on an annual basis tracking improvements along the years. A national diabetes register will allow the monitoring of intermediate and terminal outcomes from diabetes in a standardised manner thereby promoting and facilitating the comparison of health system performance indicators in diabetes with International reputable sources.

## RECOMMENDATIONS

- Setting up of a multi disciplinary diabetes research network
- Dissemination of local research on diabetes
- Funding for a national diabetes prevalence study
- Development of a national diabetes register linked to integrated electronic patient records
- Participation in international research studies that promote innovate systems of managing diabetes and empowerment of patients

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