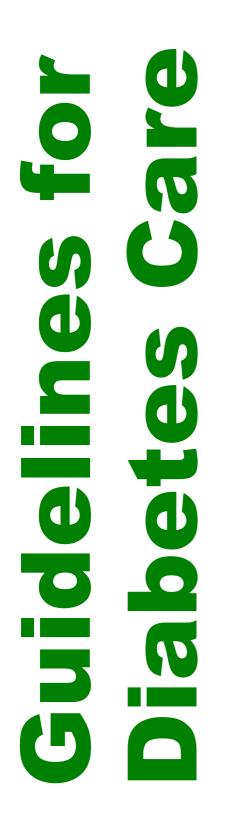
# A Desktop Guide to Type 2 Diabetes Mellitus

European Diabetes Policy Group 1998-1999

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International Diabetes Federation European Region



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# A Desktop Guide to Type 2 Diabetes Mellitus

-		page
Acknowledge	ments	2
Preface		4
How Do I :		
	e and classify hyperglycaemic states	
1	Diagnose diabetes and hyperglycaemic risk states	5-6
	Assign vascular risk resulting from hyperglycaemia	5-6
Ensure e	effective delivery of care	
2	Organize a person's diabetes care	7
3	Conduct a diabetes consultation	8
4	Monitor diabetes care	9
5	Monitor my performance	10
Promote	effective self-care through education	
6	Empower people, and assess patient education	11
	Provide skills, motivation and understanding	12
	Advise on life-style issues	13
7	Provide self-monitoring and self-management skills	14
Control k	blood glucose, blood lipids, blood pressure	
8	Define and use targets, and tackle smoking	15-16
9	Provide nutritional advice	17
10	Advise on physical exercise	18
11	Use glucose lowering therapies	19-20
12	Use lipid lowering therapies	21
13	Use blood pressure lowering therapies	22
14	Integrate arterial risk management	23
Detect a	nd manage diabetes complications	
15	Ischaemic heart disease	24
16	Kidney damage	25
17	Eye damage	26
18	Foot problems	27-28
19	Nerve damage	29
Manage	special problems	
20	Pregnancy in women with Type 2 diabetes	30-31
21	Surgery in people with Type 2 diabetes	32
European Dia	betes Policy Group	34
Statement of	duality of interest	34
Index		35

## Preface

#### A desktop guide

In 1989 the European NIDDM Policy Group published its first Desktop Guide for the management of Non-insulin-dependent (Type 2) Diabetes, and in 1993 that document was revised on behalf of the St Vincent Declaration Initiative.

The current Desktop Guide builds on those guidelines, in the light of newer understandings, and attempts to provide a more direct and more accessible format. Our aim here is to provide Guidelines which can offer easy access to high quality and better integrated care, while reducing health inequalities.

The greater emphasis on arterial risk factor management, rather than just good blood glucose control, is given particular prominence.

Furthermore, this time language that can be followed by the educated person with diabetes has been used, remembering that "the primary resource for diabetes care is the person with diabetes themselves, supported by enthusiastic and well-trained professionals".

#### Evidence

In an attempt to maintain clarity, accessibility and usefulness, the current Desktop Guide remains didactic in its approach. However, a source document to be published later will go further than the previous guidelines in referencing the evidence and strength of the recommendations given here.

#### Aims of diabetes care

The aim of these Guidelines is to enable people with diabetes to have a life of normal length and fulfilment through :

- provision of skills to adapt life-style to ensure optimum health;
- development of understanding to allow coping with new challenges, and to give maximum flexibility;
- control of risk factors for arterial disease, and for eye, kidney and nerve damage;
- early detection and management of any existing vascular damage.

#### A way forward

The 1998-1999 European Diabetes Policy Group has worked on both the major types of diabetes – the sister publication on Type 1 diabetes appeared last year. The working group came from richer and poorer nations throughout Europe, and included people with diabetes, as well as members of multi-disciplinary teams.

#### European Diabetes Policy Group, 1999

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## **1** Diagnosis of Hyperglycaemic States

# Management classification – hyperglycaemic states

#### **Diagnostic background**

The purpose of diagnosis is to identify those at risk of developing the complications of diabetes, both arterial (macrovascular) and microvascular, as well as to deal with any symptoms The levels of blood glucose vary for these different risks, and determine management

- 1. Symptomatic (biochemically confirmed)
- 2. At risk of arterial and microvascular damage
- 3. At risk of arterial damage from hyperglycaemia and of progression to diabetes
- ⇒ "Diabetes"
- ⇔ "Diabetes"
- ⇒ "Impaired Glucose Tolerance ( IGT )"
  - "Impaired Fasting Glycaemia (IFG)"

#### **Diagnostic algorithm**

#### 1. Symptomatic or glycosuria or incidental hyperglycaemia

- ⇒ Check random venous plasma glucose ( see below for capillary / venous equivalents )
  - *If* >11.0 mmol/l ( ≥200 mg/dl ) ⇔ "Diabetes"
  - *If* >5.5 mmol/l ( ≥100 mg/dl ) *then* proceed to next step (2.) ( and review cause of symptoms )

#### 2. Random or fasting screening glucose >5.5 mmol/l ( ≥100 mg/dl )

- ⇒ Check fasting venous plasma glucose
  - If ≥7.0 mmol/l ( >125 mg/dl ), repeat and if confirmed ⇔ "Diabetes"
  - If >6.0 mmol/l ( $\geq$ 110 mg/dl) do oral glucose tolerance test (OGTT)
  - *If* >5.0 mmol/l ( >90 mg/dl ), consider yearly reassessment of arterial risk factors, including plasma glucose
  - OGTT (venous plasma glucose):
    - *If* 2-h >11.0 mmol/l ( ≥200 mg/dl ) ⇒ "Diabetes"
    - If 2-h  $\leq$ 11.0 mmol/l ( <200 mg/dl ) and  $\geq$ 7.8 mmol/l (  $\geq$ 140 mg/dl )  $\Rightarrow$  "IGT"
    - If fasting >6.0 mmol/l ( $\geq$ 110 mg/dl) and 2-h <7.8 mmol/l (<140 mg/dl)  $\Rightarrow$  "IFG"

#### Diagnostic equivalents for plasma and blood

	Plasma gluco	Plasma glucose*		Whole blood glucose	
	Venous* mmol/l mg/dl	Capillary mmol/l mg/dl	Venous mmol/l mg/dl	Capillary mmol/l mg/dl	
Fasting		_	-	-	
"Diabete	s″ ≥ 7.0 >125	≥ <b>7.0</b> >125	> 6.0 ≥110	> 6.0 ≥110	
"IFG"	> 6.0 ≥110	> 6.0 ≥110	> 5.5 ≥100	> 5.5 ≥100	
OGTT 2-h					
"Diabete	s″ >11.0 ≥200	≥12.2 ≥220	≥10.0 ≥180	>11.0 ≥200	
"IGT"	$\geq$ 7.8 $\geq$ 140	$\geq$ 8.9 $\geq$ 160	≥ 6.7 ≥120	$\geq$ 7.8 $\geq$ 140	

#### \* preferred measure

OGTT: 75 g glucose in 300 ml water over 3-5 min

## **Diagnostic aids and cautions**

- 1. Fasting glucose estimations require a certainty of no previous calorie intake
  - > be suspicious if HbA<sub>1c</sub> not consistently elevated
  - > if suspicious repeat after 2-h supervision, or consider OGTT
  - diagnosis cannot be based on a single abnormal glucose estimation in the absence of symptoms
- 2. Venous plasma glucose estimation is preferred
  - for convenience, equivalents for whole blood and capillary glucose estimations are given on previous page
- 3. HbA<sub>1c</sub> (glycated haemoglobin) can be useful in clinical diagnosis
  - > provided that confirmatory venous plasma glucose estimations are obtained
  - provided the assay is DCCT standardized, an HPLC chromatogram is reviewed for presence of abnormal haemoglobins, and erythrocyte turnover is not abnormal
  - > approximately, HbA<sub>1c</sub> >7.5 %  $\approx$  fasting plasma glucose  $\geq$ 7.0 mmol/l ( >125 mg/dl ) >6.5 %  $\approx$  fasting plasma glucose >6.0 mmol/l (  $\geq$ 110 mg/dl )
- 4. Diagnostic procedures should not be performed :
  - > in the presence of acute illness or after trauma or surgery
  - > during short courses of blood glucose raising drugs
- 5. Diagnostic tests should be interpreted with reservation :
  - > in people on long-term blood glucose raising drugs
  - > in people with reversible endocrine conditions
  - > in pregnant women (see section 20)
- 6. If suspicion or high risk of diabetes, but fasting glucose normal, do OGTT, particularly in the elderly
- 7. The above procedures are not applicable to people with **hepatic cirrhosis** or other extreme forms of peripheral insulin resistance
  - in people with normal fasting but elevated post-prandial glucose levels, diagnose according to 2-h OGTT criteria

## 2 Framework of Diabetes Care

#### A framework for quality diabetes care

Ensure provision of the following :

- > A diabetes team (professionals) with up-to-date skills, including :
  - doctors
  - diabetes nurse specialists/assistants and educators
  - nutritionists (dieticians)
  - podiatrists ( chiropodists )

#### A solid infrastructure

- easy access for people with diabetes
- protocols for diabetes care
- facilities for education and foot care
- information for people with diabetes
- structured records
- recall system for Annual Review / eye surveillance
- access to quality-assured laboratory facilities
- database / software for quality monitoring and development
- continuing education for professional staff

#### A range of services

- for regular review (often 3-monthly)
- for Annual Review
- for education
- for foot care
- for eye surveillance
- emergency advice line
- access to heart, renal, eye, vascular specialists
- joint obstetric service

#### A system of quality development

- feedback from people with diabetes on service performance
- regular review of service performance (see section 5)

## **3** The Diabetes Consultation

#### **Consultation infrastructure**

Make available for consultations the following :

- diabetes team members
- time and space
- > printed information for the individual with diabetes
- > records and means of communication to other health professionals

## **Consultation process**

Include t	he following :		
🖙 Weld	ome		
F	Friendly greeting a	and	early establishment of rapport
🖙 Prob	lems review		
l l	dentification of :	≻	recent life-events / new symptoms
		≻	new difficulties in self-management of diabetes
F	Review of :	≻	self-monitored results; discussion of their meaning
		≻	dietary behaviours, physical activity, smoking
		≻	diabetes education, skills, and foot care
		≻	blood glucose, lipid and blood pressure therapy and results
		≻	other medical conditions and therapy affecting diabetes
ſ	Management of :	≻	arterial / foot risk factors identified at Annual Review
		≻	complications and other problems identified at Annual Review
🖙 Anal	ysis and plannin	g	
ļ	Agreement on :	≻	main points covered
		≻	targets for coming months
		≻	changes in therapy
		≻	interval to next consultation
🖙 Reco	ording		
(	Completion of :	≻	structured record / patient-held record

### **Annual Review**

Include additionally, a	at Annual Review, surveillance of the following :
Symptoms	ischaemic heart disease, peripheral vascular disease neuropathy, erectile dysfunction ( <i>see section 19</i> )
Feet	footwear, deformity / joint rigidity, poor skin condition, ischaemia, ulceration, absent pulses, sensory impairment ( <i>see section 18</i> )
Eyes	visual acuity and retinal review (see section 17)
Kidney damage	albumin excretion and serum creatinine (see section 16)
Arterial risk	blood glucose, blood pressure, blood lipids, and smoking ( <i>see section 8</i> )
Attendance	podiatry / ophthalmology / other, as indicated

# 4 Organization of Clinical Monitoring

## Schedule for clinical monitoring at different types of visit

Review topics	Initial review / referral	Regular review	Annual Review
Background history			
Social history / life-style review			
Long-term / recent diabetes history			
Complications history / symptoms			
Other medical history / systems			
Family history diabetes / arterial disease			
Drug history / current drugs			
Current skills / well-being			
Diabetes self-management			
Self-monitoring skills / results			
Vascular risk factors			
$HbA_{1c}$ (glycated haemoglobin)			
Lipid profile		If problem	
Blood pressure		If problem	
Smoking		If problem	
*Urine albumin excretion		If problem	
Examination / complications			
General examination			
Weight / body mass index			
Foot examination		If problem	
Eye / vision examination		If problem	
Urine protein			
Serum creatinine		If problem	
* not required if proteinuria			

## 5 Monitoring Quality of Care

## Protocol for quality development and monitoring of performance

Aggregate	the data gathered at Annual Review onto a database
Choose	indicators ( see below ) to reflect outcome as well as process of care
Analyse	data in line with published recommendations
Compare	performance with pre-determined standards or other providers of diabetes care
Review	performance at regular meetings of your diabetes team performance of education programmes
Act	to design and implement action plans for improvement

## Examples of indicators for quality development and monitoring

Measure :	Calculate :	
Intermediate outcomes		
HbA <sub>1c</sub>	Percent with HbA <sub>1c</sub> >7.5 and >6.5 %	
Albumin excretion	Percent with abnormal albumin excretion	
Eye damage	Percent with retinal damage	
True outcomes		
Amputation above ankle	Incidence	
Myocardial infarction	Incidence	
Stroke	Incidence	
Foot ulceration	Incidence	
Risk factor control		
Hypertension	Percent with blood pressure ≥140/85 mmHg	
Smoking	Percent people still smoking	
Process of care		
Eyes screened	Percent people examined in year	
Education performed	Percent people seeing nurse educator in year	
Feet examined	Percent people examined in year	
These are examples; many other indicators are possible		

## 6 Patient Education

It is the responsibility of the diabetes team to ensure that the person with diabetes can follow the life-style of their educated choice, achieved through the three elements of empowerment: knowledge, behavioural skills, and self-responsibility

#### Patient education – Taking responsibility

Assess whether the person with diabetes :

- > has the knowledge and behavioural skills necessary for optimum self-care
- makes early and effective responses to everyday problems
- > has the confidence to obtain the best input from the diabetes health-care team

#### Ensure that empowerment is :

- > a primary objective of your consultations and education programme
- > supported by availability of diabetes publications and other information sources
- > the active policy of your diabetes service

#### Provide :

- > positive encouraging responses to requests for information and understanding
- > a copy of the European Patients' Charter
- or a similar national or local statement of rights and roles
- > a copy of the person's diabetes health-care record
- > information on the results and meaning of all investigations

#### Consider :

> need for assisted self-care for those with cognitive or physical impairment

#### Patient education – Assessment

#### **Use** :

- review of diabetes skills ( self-monitoring, food identification )
- biomedical measures ( changes in body weight, glycated haemoglobin )
- evidence of appropriate behaviours
   (footwear, physical activity, smoking cessation, membership of diabetes associations)
- assessment of life-style, emotional adjustment, and perceptions of barriers to life-style activities and self-care
- perceptions of desired short-term goals (glucose control, weight), and long-term vulnerability (to arterial disease)
- knowledge ( as a basic measure )
- > diabetes-specific well-being and health profile assessments (as global measures)

#### Perform assessment :

- as part of routine care visits, by direct enquiry
- > more formally, as part of Annual Review, or on first contact

## Patient education - Goals

Aim to optimize :

- knowledge of diabetes, its progressive nature, and the aims of its management
- ability to define personal health-care targets
- motivation and attitudes to self-care
- behaviours which interact with diabetes management
- empowerment in using the skills of health-care and other professionals.

#### Aim to provide skills to :

- manage nutrition and physical activity
- and develop strategies for meeting them
- hypoglycaemia
- use the professional members of the diabetes care team effectively
- monitor and use the results of therapy
- > understand and agree health-care targets, > avoid self-destructive behaviours and deal adequately with stress
- > manage complications of therapy including > ensure appropriate use of glucose-lowering therapies
  - empower self-management during intercurrent illness
- > respond to new problems in diabetes care > cope appropriately with the late tissue
  - damage of diabetes

#### Patient education – Provision

Integrate education into regular clinical care by providing your own curriculum and programme

**Ensure** that the diabetes team has personnel adequately trained in patient education

Assess special needs of each individual (see above)

Be aware of needs of special groups (language problems, physical / mental disabilities)

**Provide** education within three time frames :

- At and shortly after diagnosis :
  - basic information on healthy eating, physical exercise, and smoking cessation •
  - supportive information on the nature and outcomes of diabetes •
  - the minimum skills to obtain control over the new situation
- In the months following diagnosis :  $\geq$ 
  - a comprehensive coverage
  - topics covered previously, plus
    - targets of therapy, eating at home and away
    - complications of diabetes, arterial risk factors, foot care •
    - employment, insurance, driving and travel
- In the long term :  $\geq$ 
  - reinforcement periodically after annual evaluation (see previous page)

Include carers and family members as appropriate

Use group education to uncover problems and provide solutions and behavioural change through peer example

Review, evaluate, and improve the impact of your education programmes regularly

#### Patient education – Life-style issues

#### Assessment

Ask regularly about diabetes interfering with :

- employment
- social and leisure activities
- > travel

#### **Topics**

#### Employment

#### Provide :

- individualized advice
- > counselling and contacts for those affected by a change to insulin therapy

#### Insurance and driving licences

*Be aware* of where appropriate and up-to-date premiums can be obtained

#### Provide :

- advice to patients wishing to enter into insurance contracts
- rapid and appropriate reports on request
- > informed comment and advice on legal restrictions on licences

#### Travelling

Provide advice :

- > on the need for valid travel insurance
- > on special health risks in visited countries
- > as appropriate for those using insulin (see *Desktop Guide to Type 1 Diabetes, 1998*)

Review coping skills for acute illness, especially gastroenteritis, and hypoglycaemia

The aims of patient education and training are to provide information in an acceptable form, in order that people with diabetes develop the knowledge to self-manage their diabetes and to empower them to make informed choices in their lives

## 7 Self-monitoring of Blood Glucose Control

#### Use and assessment of self-monitoring

Advise use of self-monitoring for :

- > education on effects of diet and physical activity on blood glucose
- > assurance of satisfactory blood glucose control
- > coping with illness and new situations
- > insulin dose adjustment and hypoglycaemia management where relevant

Assess skills ( and meters if used ) yearly or if problems with self-monitoring

Evaluate reliability of self-test results ( if indicated ) by :

- ⇒ consistency with the results of glycated haemoglobin estimation
- ⇒ comparison with acute results obtained at consultation
- ⇒ review of the quality of self-test record diaries

#### Achieving effective self-monitoring

#### **Use** :

- For all people with Type 2 diabetes
- > blood reagent strips / meters, or self-urinalysis according to individual need

Provide appropriate training and regular review of technique

#### Recommend :

- $\Rightarrow$  results are recorded ( with date and time )
- ⇒ different patterns of testing according to need :
  - urine glucose post-prandially 1-7 times a week if results consistently negative and glucose control targets met ( *see section 8* )
  - blood glucose 1-4 times a day according to need if glucose control is deteriorating or if using insulin therapy (see *Desktop Guide to Type 1 Diabetes, 1998*)
  - blood glucose 4-8 times a day during illness, life-style changes, in pregnancy
- ⇒ tests 1-2 h after meals and not just pre-prandially
- ⇒ testing to cope with variations in eating or activity
- ➡ urine glucose testing if blood glucose monitoring is indicated but not possible, or if the patient does not wish to continue with it

## 8 Assessing Blood Glucose, Blood Lipid, and Blood Pressure Control

#### Using assessment levels to set targets

Use the assessment levels (next page) for glucose, lipids, and blood pressure :

- > as an integral part of diabetes care do not manage diabetes on symptoms alone
- > to indicate need for further intervention
- > as the basis for short-term and longer-term individualized targets
- > as an educational tool to help the person with diabetes

Ask yourself the following at consultations :

⇒ Is it possible for the individual to approach each target more closely, without a counterbalancing deterioration in quality of life?

#### Be concerned about targets :

⇒ Failure to attempt to reach agreed targets is inadequate care, unless this would lead to deterioration in quality of life

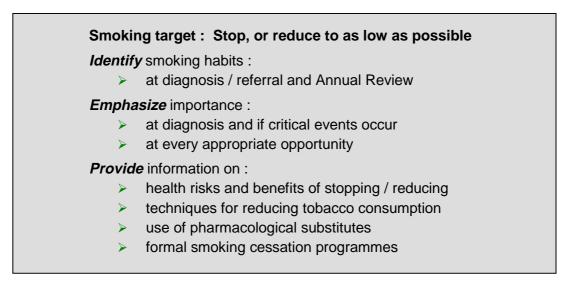
#### Assessment of blood glucose, blood lipid, and blood pressure control

#### Measure :

- ⇒ glycated haemoglobin 2-6 monthly
- the blood lipid profile ( total, LDL, and HDL cholesterol, and triglycerides ) 2-6 monthly if previously above assessment levels ( see next page ), otherwise annually
- ⇒ blood pressure at each consultation unless known to be below assessment levels

*Use* the assessment levels (next page) to set individual blood glucose, blood lipid and blood pressure targets, depending on overall risk and what it may be possible to achieve within a foreseeable time period

*Modify* individual targets at least yearly in the light of past success, and if any change in clinical circumstances



	Low risk	Arterial risk	Microvascular risk
HbA <sub>1c</sub> (DCCT standardized) %Hb	≤6.5	>6.5	>7.5
Venous plasma glucose			
Fasting/pre-prandial mmol/l mg/dl	≤6.0 <110	>6.0 ≥110	≥7.0 >125
Self-monitored blood glucose			
Fasting/pre-prandial mmol/l mg/dl	≤5.5 <100	>5.5 ≥100	>6.0 ≥110
Post-prandial (peak) mmol/l mg/dl	<7.5 <135	≥7.5 ≥135	>9.0 >160

## Blood glucose control assessment levels

Fasting capillary blood glucose is around 1.0 mmol/l (18 mg/dl) lower than venous plasma; post-prandial capillary blood glucose is the same as venous plasma

#### **Blood lipid control assessment levels**

	Low risk	At risk	High risk
Serum total cholesterol mmol/l mg/dl	<4.8 <185	4.8-6.0 185-230	>6.0 >230
Serum LDL cholesterol mmol/l	<3.0	3.0-4.0	>230
mg/dl Serum HDL cholesterol	<115	115-155	>155
mmol/l mg/dl Serum triglycerides	>1.2 >46	1.0-1.2 39-46	<1.0 <39
mmol/l mg/dl	<1.7 <150	1.7-2.2 150-200	>2.2 >200

## Blood pressure control assessment level

Low risk (mmHg) <140/85

## 9 Providing Nutritional Advice

#### **Reviewing dietary management**

Review dietary management regularly :

- $\Rightarrow$  Is healthy eating (see box) a normal part of life-style?
- ⇒ Is calorie intake appropriate to desired body weight?
- Solution ⇒ Is alcohol intake moderate? Could it be exacerbating hypertension or hypertriglyceridaemia? Could it be contributing to early or late hypoglycaemia? Is this understood by the person with diabetes?
- ⇒ Is money being spent unnecessarily on special 'diabetes' food products?
- Does calorie distribution reflect the patient's life-style and preferences, as well as glucose lowering therapy and regional eating habits?
- Do raised blood pressure or kidney damage suggest a benefit from special recommendations (protein intake <0.8 g/kg, salt intake <6 g/day, respectively)?</p>

Make recommendations and review eating :

- > at diagnosis
- > at each consultation if overweight or vascular risk factor control sub-optimal
- > formally every other year as a routine, or more often as required
- on beginning insulin therapy
- on request

Nutritional management is an integral part of initial and continuing education programmes

#### **Healthy eating**

*Advise* carbohydrate intake should be higher, and fat intake lower than that of most Europeans, but not different from recommendations for the population in general :

- Saturated fat : <10 % of calories</p>
- Polyunsaturated fat : <10 % of calories</p>
- > Carbohydrate : use foods containing soluble fibre in a carbohydrate rich diet
- Simple sugars : need not be rigorously excluded from the diet, but should be limited
- Protein : <15 % of calories</p>
- > Monounsaturated fat : use to maintain palatability and balance calorie intake
- > Total calories : as required for normal body mass index
- > Fresh fruit / vegetables : encouraged as part of meal-time calorie intake
- > Alcohol : if desired, as part of total daily calorie intake

Individualize intake to match needs, preferences and culture

## **10 Physical Exercise**

#### Assessment of physical activity

#### Review :

- > activity at work, and in getting to and from the workplace
- > physical activity practice and opportunities in domestic activities and hobbies
- the possibility of formal physical exercise on a regular basis Examples :
  - ⇒ brisk walking 30 min per day
  - ⇒ active swimming for 1 h three times a week

#### Management

Advise that physical exercise :

- > can benefit insulin sensitivity, blood pressure, and blood lipid control
- > should be taken at least every 2-3 days for optimum effect
- > may increase the risk of acute and delayed hypoglycaemia

Manage physical exercise using :

- ⇒ formal recording of levels of physical activity
- identification of new exercise opportunities ( see box above ), and encouragement to develop these
- ⇒ appropriate self-monitoring, additional carbohydrate, and dose adjustment of glucose lowering therapy for those using insulin or insulin secretagogues

#### $\Rightarrow$ warnings :

- about delayed hypoglycaemia, especially with more prolonged, severe, or unusual exercise for those using insulin therapy
- that alcohol may exacerbate the risk of hypoglycaemia after exercise
- about risks of foot damage from exercise
- need to consider ischaemic heart disease in those beginning new exercise programmes

Dietary management, physical activity, and drug therapies are partners in the battle to achieve and maintain low risk blood glucose, blood lipid and blood pressure levels

## **11** Therapy for High Blood Glucose Concentrations

# Life-style management of raised blood glucose levels should be given a good trial before beginning glucose lowering drugs

$\Box$	Patient education :	see section 6,	page 11
⇒	Self-monitoring :	see section 7,	page 14
⇒	Blood glucose targets :	see section 8,	page 16
⇒	Dietary management :	see section 9,	page 17
⇒	Physical exercise :	see section 10,	page 18

#### Using oral glucose-lowering drugs (for insulin therapy see next page)

#### Begin oral agent therapy when :

- > an adequate trial of life-style intervention / education has been given
- $\succ~~either$  ( usually ) : HbA\_{1c} >6.5 %, fasting venous plasma glucose >6.0 mmol/l (  $\geq$ 110 mg/dl )
- or (occasionally) if thin and no other arterial risk factor : HbA<sub>1c</sub> >7.5 %, fasting venous plasma glucose ≥7.0 mmol/l ( >125 mg/dl )

#### **Use** :

- > metformin
- insulin secretagogues ( sulphonylureas and repaglinide )
- >  $\alpha$ -glucosidase inhibitors
- thiazolidinediones and related PPARγ-agonists

#### **Choice of agents**

**Metformin**: strong evidence base in the overweight, lowers LDL cholesterol, but gastrointestinal side effects in some patients; dose titration may help tolerance

 contraindicated (risk of lactic acidosis) if renal impairment, overt liver disease, or severe cardiac failure; monitor renal function at least yearly

Sulphonylureas : good evidence base, provided patient has useful islet B-cell function

hypoglycaemia a significant problem glibenclamide > glipizide = chlorpropamide > gliclazide > tolbutamide ( some other agents lack data ); avoid glibenclamide / chlorpropamide particularly if renal impairment or in the thin insulin-sensitive patient ( especially if elderly )

**Repaglinide** : new rapid-acting insulin secretagogue; possible advantage in hypoglycaemia avoidance and control of post-prandial glucose excursions

α-Glucosidase inhibitors : effective control of post-prandial hyperglycaemia, but poorly tolerated by many patients; dose titration may help tolerance

**PPAR**γ-agonists : new agents, offering effective glucose-lowering particularly in combination with insulin and insulin secretagogues

 contraindicated if any history of liver disease, and require organized monitoring of liver function tests until hepatic safety assured

A number of new drugs are currently entering clinical practice; we anticipate the need to modify the above advice as the role of such drugs becomes better understood

## Maintaining good blood glucose control with oral glucose-lowering drugs

#### Expect :

- ⇒ continuous deterioration of glucose control with time
- $\Rightarrow$  a need to increase therapy and add new agents with time
- $\Rightarrow$  insulin therapy to be needed in many patients after a variable number of years

#### **Monitor** (see section 4, Clinical monitoring – page 9):

- > dietary quality and quantity, physical exercise level
- > HbA<sub>1c</sub> ( or fasting venous plasma glucose ), and self-test results
- body weight
- > other vascular risk factors ( blood lipids, blood pressure )

#### Adjust therapy :

- ⇒ Increase dose of individual agent at each visit up to maximum tolerated / effective dose, if targets are not met
- ⇒ Decrease dose of individual agent, if therapy-related problems arise, or if glucose control well into the non-diabetic range

#### Combination therapy

- ⇒ Add another agent of therapy when maximum dose of current drugs reached
- ⇒ Use triple therapy when control targets cannot be reached on maximum tolerated doses of two agents
- (For combination therapy with insulin see next box)

#### Insulin therapy in Type 2 diabetes

**Begin** when HbA<sub>1c</sub> has deteriorated to >7.5 % after maximum attention to dietary control and oral glucose-lowering therapy ( unless poor life-expectancy and asymptomatic )

- ⇒ Arrange dietary review when starting insulin therapy
- Review ( or start ) self-monitoring of blood glucose before starting insulin
- $\Rightarrow$  Continue therapy with metformin / insulin secretagogues / PPAR $\gamma$ -agonists

#### **Use** :

- NPH insulin at night with oral glucose-lowering drugs in people with good insulin secretory reserve
- > pre-mixed insulin twice daily in the majority of people
- twice daily NPH insulin in people with high pre-breakfast blood glucose concentrations relative to their HbA<sub>1c</sub>

#### Adjust therapy :

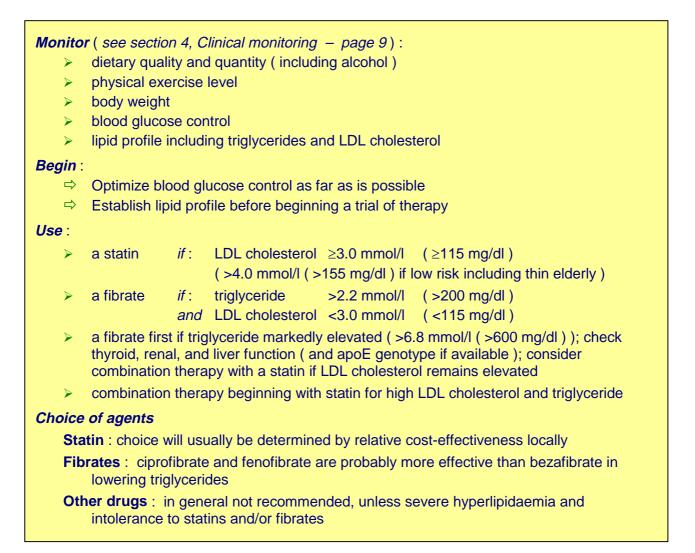
- frequently at first, using self-monitored results, until insulin dose is adequate to reach blood glucose targets (see section 8), or hypoglycaemia becomes a risk
- ⇒ Consider more intensive insulin regimens
  - in the more active patient if control remains sub-optimal
  - if control remains sub-optimal due to hypoglycaemia ( but not if due to insulin insensitivity )
  - to assist achievement of more flexible life-styles
  - See Desktop Guide to Type 1 Diabetes, 1998

## 12 Therapy for Abnormal Blood Lipid Concentrations

# Life-style management of abnormal blood lipid profiles should be given a good trial before beginning lipid lowering drugs

⇒	Patient education :	see section 6,	page 11
⇒	Blood lipid targets :	see section 8,	page 16
⇒	Dietary management :	see section 9,	page 17
⇒	Physical exercise :	see section 10,	page 18

## Using blood lipid lowering drugs



## 13 Therapy for Raised Blood Pressure

Life-style management of raised blood pressure should be given a good
trial before beginning anti-hypertensive drugs

⇒	Patient education :	see section	6,	page 11
⇒	Blood pressure targets :	see section	8,	page 16

□ Dietary management : see section 9, page 17

⇔ Physical exercise : see section 10, page 18

#### Using anti-hypertensive drugs

*Monitor* (see section 4, Clinical monitoring – page 9):

- > dietary quality and quantity (including alcohol), physical exercise, body weight
- > sitting blood pressure (after 5 min rest, 1st and 5th phase)

Use : family doctor / occupational health services to obtain monthly records patient-held record card to provide cumulative record of progress self-monitoring devices if available

#### **Use** :

- > single agent therapy at rising doses until target achieved (or intolerance)
- > multiple therapy if targets not reached on maximum doses of single agents
- once daily drug administration regimens

#### Available drug classes

ACE-inhibitors : good evidence base in diabetes, advancing renal disease, cardiac failure

- monitor renal function / K<sup>+</sup> (risk of renal artery stenosis with arterial disease)
- $\beta$ -Adrenergic blockers : good evidence base in diabetes and useful where angina or previous myocardial infarction
  - avoid combination with thiazides (metabolic deterioration), and if peripheral vascular disease. Ask about tiredness and impotence

Calcium channel antagonists : some evidence base in diabetes and in advancing renal disease

- use only long-acting preparations
- \* fluid retention a problem with some agents (avoid if history of foot ulceration)

Thiazides : some evidence base in diabetes

use low doses only and avoid combination with β-adrenergic blockers (metabolic deterioration). Ask about impotence

Loop diuretics : useful synergistic action with ACE-inhibitors

α-Adrenergic blockers : effective blood pressure lowering and metabolically beneficial

use only long-acting drugs (postural hypotension)

Angiotensin II receptor blockers : no special advantages

#### Choice of agents – summary

Multiple therapy is often required; add loop diuretic to ACE-inhibitor, and avoid thiazides with β-adrenergic blocker; otherwise most combinations neutral

Many older and less expensive agents are as effective as newer agents

If abnormal albumin excretion, particularly if progressive, begin with ACE-inhibitor, or calcium channel antagonist if ACE-inhibitor not tolerated

If ischaemic heart disease, consider  $\beta$ -adrenergic blocker first

# 14 Managing Arterial Risk Factors

## Integrated management of arterial risk

blood glucose	*	and the second			
	Ŧ	blood lipids * blood pressure			
smoking	*	body weight / abdominal adiposity			
family history	*	albumin excretion rate * arterial / heart symptoms			
at diagnosis					
yearly					
	if abno	ormal or treated			
risk level as :					
	<ul> <li>established disease, <i>or</i> any two arterial risk factors</li> <li>risk : established disease + any arterial risk factor</li> </ul>				
very nightisk.		y three arterial risk factors			
as follows :					
High risk	manage blood glucose, blood lipids, blood pressure to assessment levels				
Very high risk	manage blood glucose, blood lipids, blood pressure to lowest possible risk levels				
Smoking	mana	age problem aggressively ( see box, section 8 )			
e people :					
		t disease / stroke from the time of diagnosis			
about not smoking and smoking cessation programmes (see box, section 8)					
	iting (	see box, section 9)			
a programme of regular physical exercise ( <i>see section 10</i> ) glucose, lipid, and blood pressure lowering therapy as indicated					
low-dose aspirin for those in the <i>High risk</i> or <i>Very high risk</i> categories					
selective $\beta$ -adrenergic blockers if known ischaemic heart disease					
-	g.o				
		therapy post-menopausally ( if agreed )			
	at diagnosis yearly more frequently i <i>isk level as</i> : Average risk : High risk : Very high risk : 'as follows : High risk Very high risk Very high risk Smoking people : about the risks o about not smokir about healthy ea be : a programme of glucose, lipid, an low-dose aspirin selective β-adrer	at diagnosis yearly more frequently if above isk level as : Average risk : any of High risk : estat Very high risk : estat or an as follows : High risk mana levels Very high risk mana poss Smoking mana poss Smoking mana people : about the risks of hear about not smoking and about healthy eating ( be : a programme of regula glucose, lipid, and bloc low-dose aspirin for th selective β-adrenergic er :			

## **15** Ischaemic Heart Disease

Ischaemic heart disease develops in over three-quarters of people with Type 2 diabetes, and kills half of them.

It is often silent, often accompanied by cardiac failure, and is less amenable to surgical intervention than usual

#### Assessment and diagnosis

#### Investigate if :

- classical angina or suspicious symptoms
- unexplained breathlessness
- > cardiac failure, cardiomegaly, or cardiac rhythm disorder
- arterial thrombotic event

The threshold for investigation is lower if albumin excretion rate is abnormal

#### Investigate by :

- standard 12-lead ECG and chest X-ray
- cardiac ultrasound scan
- exercise stress ECG
- angiography / stress echo if indicated

#### Management

#### Intensify :

- > management of arterial risk factors (see section 14)
- education on life-style management including smoking (see sections 6, 8-10)

#### Review :

- > choice of blood pressure lowering drugs (indication for  $\beta$ -adrenergic blockers)
- use of aspirin / other anti-thrombotic therapy ( all patients )
- use of cardiac failure drugs (indication for ACE-inhibitors)

#### Advise :

early coronary bypass therapy / angioplasty / stenting if indicated

#### **Use** :

intravenous insulin to control blood glucose levels after admission for myocardial infarction

#### Consider :

bormone replacement therapy in post-menopausal women ( if agreed )

## 16 Kidney Damage

#### **Detection and surveillance**

Raised albumin excretion rate in Type 2 diabetes is often a sign of general vascular damage rather than specific renal damage. It is a useful arterial risk marker

Abnormal serum creatinine in Type 2 diabetes is often due to renal arterial disease and/or diuretic therapy for cardiac failure rather than to diabetic nephropathy

Detection and surveillance of specific kidney problems therefore depends on identifying progression of albumin excretion rate and serum creatinine, in the absence of other causes

#### *Check* for proteinuria yearly using reagent strips

Measure urinary albumin excretion yearly ( if not proteinuric ) using :

- > pre-breakfast albumin:creatinine ratio, or
- > pre-breakfast urinary albumin concentration
- If ratio >2.5 mg/mmol ( >30 mg/g ) in men or >3.5 mg/mmol ( >40 mg/g ) in women or concentration >20 mg/l :
  - repeat to confirm
  - monitor any progression of kidney damage by more frequent measurement

Check for infection and consider other renal disease if proteinuria positive

⇒ exclude infection with leucocyte/nitrate strips and microscopy / culture if positive

Measure serum creatinine yearly (more often if abnormal, or if rising and metformin-treated)

*Measure* blood pressure yearly for surveillance purposes (sitting, after 5 min rest, 1st/5th phase)

#### Management if raised albumin excretion rate

If serum creatinine normal :

- monitor albumin excretion rate yearly to detect progression suggestive of specific diabetic kidney damage
- intensify management of modifiable arterial risk factors (glucose, lipids, blood pressure)

If serum creatinine abnormal :

- review other possible causes of renal impairment (recurrent infection, renal arterial / hypertensive damage, loop diuretic therapy / cardiac failure, glomerulonephritis)
- monitor albumin excretion and serum creatinine more frequently to detect progression of renal damage

If specific diabetic kidney damage (diabetic nephropathy) suspected :

- $\Rightarrow$  treat blood pressure aggressively with a target of <130/80 mmHg
  - ⇒ reduce salt intake
  - ⇒ use ACE-inhibitors as first-line drug therapy
  - ⇒ add loop diuretics, other agents if necessary
- $\Rightarrow$  reduce protein intake with target of <0.8 g/kg
- ⇒ maintain good blood glucose control and tight arterial risk factor control ( see above )
- ⇒ treat urinary infections aggressively; consider papillary necrosis if recurrent
- $\Rightarrow$  arrange evaluation by a nephrologist before creatinine rises to 250 µmol/l ( 3.0 mg/dl )

## 17 Eye Damage

#### **Detection and surveillance**

Detection and surveillance of eye problems are a routine part of Annual Review

*Organize* a recall system to ensure it occurs regularly for every individual

Measure or assess yearly :

- visual acuity (glasses or pinhole)
- > the lens and vitreous (ophthalmoscopy)
- > the retina (dilated pupils, retinal photography or skilled ophthalmoscopy)
- related factors ( smoking / blood pressure )

Reassess after shorter interval (3-6 mo) if :

- > pregnant ( see section 20 )
- > new or progressive early or moderate non-proliferative retinopathy
- blood glucose control recently improved in people with retinopathy

#### Eye disease management

Refer to ophthalmologist if :

- severe non-proliferative retinopathy
- > proliferative retinopathy
- > macular oedema or exudative maculopathy
- visual disability from cataract
- unexplained deterioration of visual acuity
- > other eye disease of visual significance
- unrecognized eye lesions

#### Review and intensify management of :

- diabetic kidney disease
- blood pressure ( target <140/85 mmHg )</pre>
- blood glucose control
- blood lipid control ( if hard exudates )
- smoking

Attend to the psychological and social aspects of visual impairment where it develops

The primary management of diabetic eye disease is by careful attention to blood glucose control targets from the time of diagnosis

## **18 Foot Problems**

#### **Detection and surveillance**

Detection and surveillance of foot problems are a routine part of Annual Review

*Organize* a recall system to ensure it occurs regularly for every individual

#### Examine yearly :

- foot shape, deformity, joint rigidity, and shoes
- > foot skin condition (fragility, cracking, oedema, callus, ulceration)
- foot and ankle pulses
- sensitivity to monofilament or vibration, and pin prick

#### Assess yearly :

- history of foot problems since last review
- visual and mobility problems preventing self-care of feet
- > self-care behaviours and knowledge of foot care (including carer if appropriate)

#### Categorize as :

- ⇒ **Foot ulcer** : active foot ulceration
- or High risk : neuropathy or vascular disease or previous ulcer or Charcot foot
- or At risk : deformity or self-care problem or simple skin problem
- or Low current risk

*Monitor* related factors (blood glucose control, claudication, drug therapy, smoking)

#### Foot management - preventative

#### High risk foot

*Involve* a specialist in diabetes foot care *Provide* :

- regular foot assessment
- Iocal preventative attention to callus
- > relief of pressure using foam spacers, made-to-order shoes, customized insoles
- regular foot care education the commandments of foot care
- > vascular referral if symptoms or critical arterial supply

#### At risk foot

**Provide** :

- routine foot care according to need
- advice on appropriate footwear
- foot care education at routine visits
- advice to carers

#### Foot management – advanced disease

#### Established foot ulceration / infection

Involve your local diabetes foot team without delay

Use local measures including :

- debridement and trimming of callus
  foot casts to relieve pressure
- dressings to absorb exudate
- $\geq$ surgical drainage

Use systemic and proximal measures including :

- > intravenous or oral antibiotic therapy usually staphylococcal coverage, plus wider spectrum, anaerobes, or streptococcal as specifically indicated
- > vascular referral, investigation, and reconstruction / angioplasty if indicated

Reserve amputation for :

- uncontrolled pain (secondary to vascular disease)
- > debilitating, long-term, non-healing ulceration
- > a useless and disabling infected or Charcot foot

## 19 Nerve Damage

\* for *Foot problems* see previous section

#### **Detection and surveillance**

Detection and surveillance of nerve damage are a routine part of Annual Review

Enquire yearly for :

- > painful and other symptomatic neuropathy
- erectile impotence in men

Enquire for other manifestations of autonomic neuropathy if :

- > other complications (especially kidney)
- before anaesthesia
- erratic blood glucose control

#### Management of painful neuropathy

*Counsel* for the depressing and disabling nature of the condition *Consider* initially :

- ⇒ bed foot cradles for night-time problems
- ⇒ simple analgesia taken in advance of diurnal symptoms
- ⇒ contact dressings

Consider therapeutic trials of :

- ⇒ tricyclic drugs ( amitriptyline )
- ⇒ carbamazepine at high doses ( 600-1200 mg/day )

#### Management of autonomic neuropathy

#### Erectile impotence

- ⇒ sildenafil may be helpful if not contraindicated (beware of nitrate therapy)
- ⇒ intracavernosal / intraurethral alprostadil can be useful in some men
- ⇒ referral to professionals with specialist expertise can be useful for :
  - advice on vacuum devices, or mechanical or surgical prostheses
  - vascular investigation and reconstruction
  - psychological assistance

#### Gastroparesis

- ⇒ investigation using radiological or radioisotope methods may help in diagnosis
- investigation of cardiovascular autonomic neuropathy may help diagnosis
- ⇒ cisapride and domperidone are worth a trial

#### Diabetic nocturnal diarrhoea

- ⇒ investigation must exclude other causes of intestinal upset
- ⇒ may be helped by high doses of codeine, loperamide or diphenoxylate, or by erythromycin / tetracycline

#### **Gustatory sweating**

- ⇒ explanation and counselling are often required
- ⇒ try topical or oral anticholinergic agents

#### Pregnancy and Contraception in Women with Type 2 Diabetes 20

Women of child-bearing age with Type 2 diabetes are almost invariably overweight and have a high relative risk of arterial damage / thrombotic problems Women who develop diabetes in pregnancy and revert to normal after delivery (gestational diabetes) are at high risk of developing Type 2 diabetes in later life

#### Contraception / pre-pregnancy management

#### Enquire :

- as to need for contraceptive advice if pregnancy not intended  $\geq$
- as part of Annual Review as to pregnancy intentions  $\geq$

#### Advise :

- on barrier methods, or low-dose oral contraceptives if low arterial risk (see above)
- > not to discontinue contraception until adequate metabolic control achieved
- repeatedly the need for pregnancy planning
- on the intensity of diabetic pregnancy management, and the risks to the fetus

#### If pregnancy is intended :

- ⇒ start folic acid
- ⇒ stop oral glucose-lowering drugs ( consider insulin therapy )
- ⇒ stop statins
- ⇒ optimize blood glucose control :
  - self-monitoring targets : pre-prandial 3.5-5.5 mmol/l (65-100 mg/dl)
    - post-prandial 5.0-8.0 mmol/l (90-145 mg/dl)
- $\Rightarrow$  assess and normalize ( <130/80 mmHg ) blood pressure :
  - ⇒ replace ACE-inhibitors with methyldopa / nifedipine / labetalol
- ⇒ assess retina and treat as indicated
- ⇒ review education and repeat as needed
- ⇒ urge to stop smoking

#### **Diagnosis of diabetes in pregnancy**

If venous plasma glucose >6.0 mmol/l ( ≥110 mg/dl ) at any time :

- ⇒ perform 75 g oral glucose tolerance test
- $\Rightarrow$  manage as diabetes :
  - if fasting plasma glucose  $\geq$ 7.0 mmol/l (>125 mg/dl)
  - or 2-h plasma glucose  $\geq$ 7.8 mmol/l ( $\geq$ 140 mg/dl)

#### **Pregnancy care**

#### Organize joint obstetric care in a designated centre

include a diabetologist, a diabetes teaching nurse, a dietician, an obstetrician, a midwife, and a neonatologist

Provide support for continuing good blood glucose control :

- ⇒ frequent review (every 1-2 weeks)
- ⇒ appropriate educational support
- ⇒ regular self-monitoring of blood glucose with reliable system
- ⇒ target blood glucose as close to normal as possible, while avoiding hypoglycaemia
  - self-monitored blood glucose fasting : 3.5-5.5 mmol/l (65-100 mg/dl)
    - post-prandial : 5.0-7.5 mmol/l (90-135 mg/dl)
  - glycated haemoglobin close to the upper limit of normal
- ➡ food intake
  - weight controlling but adequate to maintain maternal and fetal nutrition
  - frequent small meals may facilitate improved blood glucose control
- ⇒ insulin therapy if blood glucose control remains above targets

#### Examine eyes each trimester

#### Provide regular obstetric care :

- ⇒ ultrasound examination early and repeated for dates and fetal malformation
- ⇒ fetal monitoring in later stages
- ⇒ frequent antenatal review

#### Provide a normal safe delivery :

- ⇒ deliver at term unless obstetric or diabetes risk
- ⇒ deliver vaginally unless obstetric or diabetes risk
- ⇒ provide optimal neonatal care :
  - access to specialized neonatal intensive care
  - neonatologists warned of expected delivery
- ⇒ good blood glucose control during / after labour
- IV infusion of glucose and insulin if necessary with frequent blood glucose measurement
- cessation of insulin therapy at delivery if started during pregnancy ( and no suspicion of Type 1 diabetes )

If diabetes before pregnancy provide advice for post-pregnancy blood glucose control

If diabetes diagnosed in pregnancy :

- ⇒ confirm remission at post-natal follow-up
- ⇒ advise patient / family doctor of need for regular arterial risk factor review for rest of life

#### Evaluate quality of care

- ⇒ monitor outcomes of pregnancy of women with diabetes
- ⇒ compare outcomes with other diabetes services
- $\Rightarrow$  review any need for improvements in pregnancy care

## 21 Management of Diabetes during Surgery

#### Organization

Prepare a local care protocol

Disseminate the protocol to relevant professionals

#### Management

Optimize blood glucose control pre-operatively (see section 8)

Delay major surgery if possible when :

- ➢ HbA<sub>1c</sub> >9.0 %, or
- > fasting blood glucose >10.0 mmol/l (>180 mg/dl ), or
- post-prandial >13.0 mmol/l ( >230 mg/dl )

Screen for complications which may affect surgery risk; alert the surgical team :

- heart or kidney problems
- > autonomic or peripheral nerve damage
- proliferative retinopathy

#### Manage blood glucose :

- ⇒ If diet / oral agents and good blood glucose control and minor surgery :
  - ⇒ omit therapy on morning of surgery
  - $\Rightarrow$  restart when eating normally (metformin only after renal function check )
  - ⇒ avoid glucose-containing IV infusions
- ⇒ If insulin therapy or unsatisfactory blood glucose control or major surgery :
  - ⇒ use IV glucose-insulin-potassium infusion (GIK)
  - ⇒ start at 0800 h and continue until eating normally
- ⇒ monitor blood glucose before, during, and after (1-4 hourly) surgery
  - use a quality-assured method
- $\Rightarrow$  aim for blood glucose levels of 6.0-10.0 mmol/l ( 110-180 mg/dl )

Encourage supervised self-management while in hospital

#### Surgical glucose-insulin-potassium (GIK) regimens

- $\Rightarrow$  Use 500 ml 10 % ( 100 g/l ) glucose ( dextrose ) containing :
  - unmodified ( soluble, regular ) human insulin 16 U
  - potassium chloride 10 mmol
  - Infuse at 80 ml/h from a volumetric pump
- ⇒ Consider higher dose ( 20 U ) if obese, or initial blood glucose high
- $\Rightarrow$  Consider lower dose (12 U) if very thin, or usual insulin dose low
- ⇒ Decrease dose by 4 U if glucose falling and normal or low
- ⇒ Increase dose by 4 U if glucose rising or high
- ⇒ Continue the GIK infusion until 30-60 min after first meal
- ⇒ Use higher strength glucose solutions if water volume a problem
- ⇒ Check for dilutional hyponatraemia daily

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#### **Statement of Duality of Interest**

A number of members of the Policy Group, personally or through their employers, hold research contracts with, or provide consultation to, governmental and commercial organizations (including the sponsors) with an interest in areas covered by these Guidelines.

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## Index

Albumin excretion rate 23,25 Annual Review 8,9 Arterial risk factors 15,16,23 Autonomic neuropathy 29 Blood glucose control: targets 15,16; therapy 19,20 Blood lipid control: targets 15,16; therapy 21 Blood pressure control: targets 15,16,25; therapy 22,25 Care delivery (organization) 7,9 Care team 7 Consultation 8,9 Contraception 30 Diagnosis of hyperglycaemic states 5,6 Diet 17 Driving licences 13 Education of patients 11,12,13 **Employment 13 Empowerment 11** Exercise 18 Eye damage (retinopathy) 26 Foot problems 27,28 Gestational diabetes 30,31 **GIK 32** Glycated haemoglobin (HbA<sub>1c</sub>) 6,16 Heart disease 23,24 Hypertension 16,22,25 Hypoglycaemia 12,19,20 Impaired fasting glycaemia (IFG) 5 Impaired glucose tolerance (IGT) 5 Impotence 29 Insulin therapy 20 Insurance 13 Ischaemic heart disease 24 Kidney damage (nephropathy) 25 Lipid lowering drugs 21 Lipids 16,21 Living with diabetes 13 Microalbuminuria (raised albumin excretion rate) 23,25 Nephropathy 25 Nerve damage (neuropathy) 29 Nutritional management 17 Oral glucose-lowering drugs 19,20 Pregnancy 30,31 Quality development 10 Retinopathy 26 Self-management 11,12,14 Self-monitoring of blood glucose control 14 Smoking 15 Surgical management 32 Targets for blood pressure control 15,16,25 Targets for glucose control 15,16 Targets for lipid control 15,16 Teams 7 Travel 13

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## **DIABETES TYPE 2 DESKTOP GUIDELINES**

**EUROPEAN DIABETES POLICY GROUP 1999**