“Algoritmo AMD vs Algoritmo IDF"

Pro e Contro

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Biomèdiques
August Pi i Sunyer

“Algoritmo AMD vs Algoritmo IDF"

E’ necessario un algoritmo per la personalizzazione della terapia nel diabete?

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Metformina: 1ª scelta

- **Metformina:** farmaco preferito dalle linee-guida
  - efficacia sul compenso glicemico
  - tollerabilità
  - *safety* (ipoglicemie)
  - costi
  - effetti su altri fattori di rischio (PAO, BMI, lipidi, iperinsulinemia, fibrinolisi, aggregazione piastrinica)
  - effetti antitumorali?
  - efficacia su eventi e mortalità CV?
- Pochi studi, sottopotenziati e discordanti

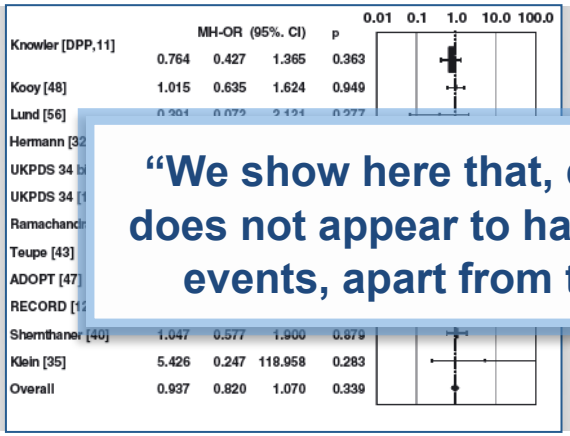
original article

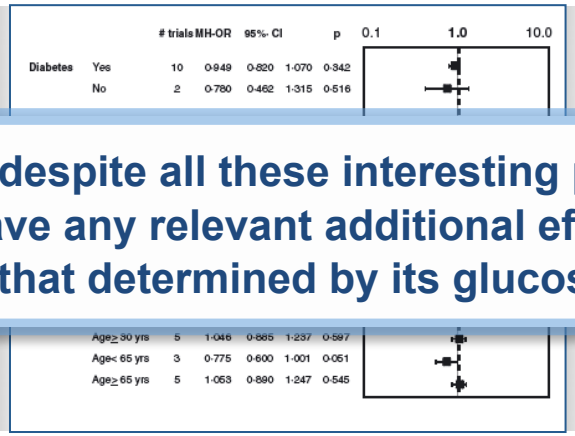
Diabetes, Obesity and Metabolism 13: 221–228, 2011.

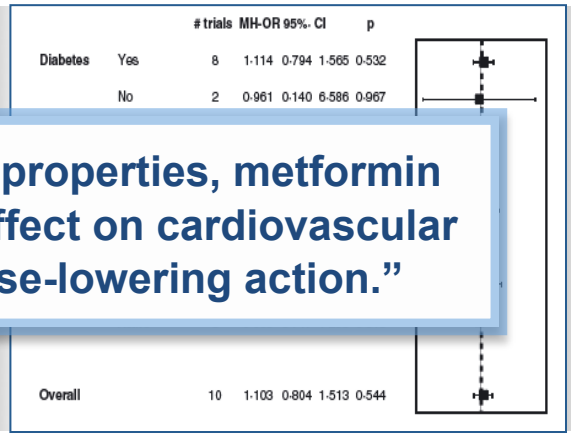
Effect of metformin on cardiovascular events and mortality: a meta-analysis of randomized clinical trials

C. Lamanna[1], M. Monami[2], N. Marchionni[2] & E. Mannucci[1]

- Metanalisi di 35 trial clinici (≥52 sett.) su metformina vs.
  - placebo
  - altri antidiabetici
  - nessuna terapia
- Complessivamente, nessun effetto
- Riduzione significativa eventi CV vs. placebo o nessuna terapia
  - trial più lunghi, con pz <30 anni, escludendo pz >65 anni







"We show here that, despite all these interesting properties, metformin does not appear to have any relevant additional effect on cardiovascular events, apart from that determined by its glucose-lowering action."

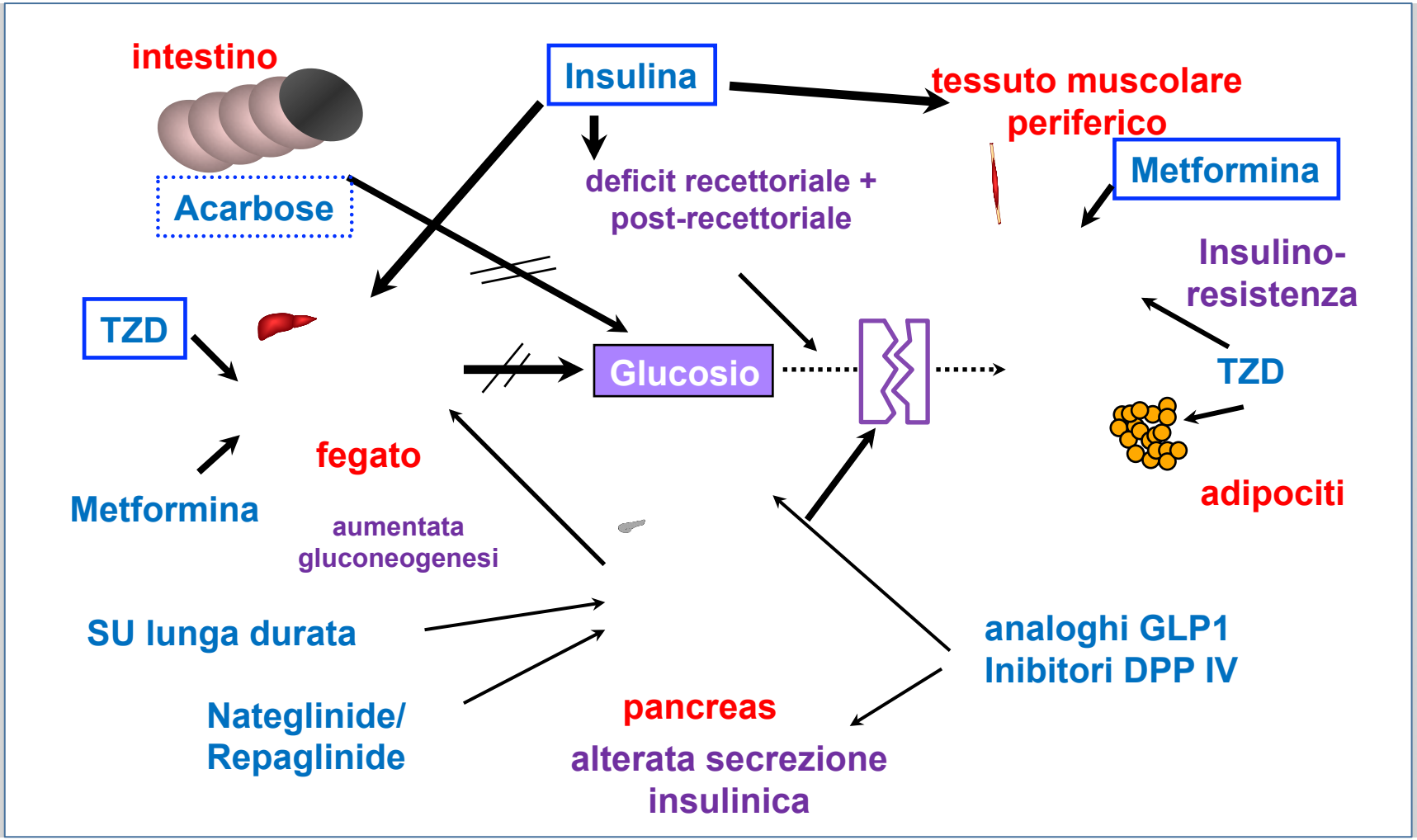
Includendo tutti gli RCT | **Eventi CV** | **Mortalità**

Insuccesso metformina da sola: quale antidiabetico associare?

- Ogni anno, ~5-10% dei pazienti in monoterapia con metformina va incontro a *secondary failure*
- Necessità aggiunta 2° farmaco, tenendo conto dei diversi aspetti contributivi alla patogenesi del DM

Brown JB. et al. , Diabetes Care 2010

Antidiabetici disponibili



AMD – SID 2009-2010

DIAGNOSI

Intervento su stile di vita

Metformina

Metformina + glitazone

Metformina + analogo GLP1

Metformina + gliptina

Metformina + sulfonilurea o glinide

Metformina + insulina basale

Metformina + sulfonilurea o glinide + glitazone

Metformina + sulfonilurea o glinide + analogo GLP1

Metformina + sulfonilurea + gliptina*

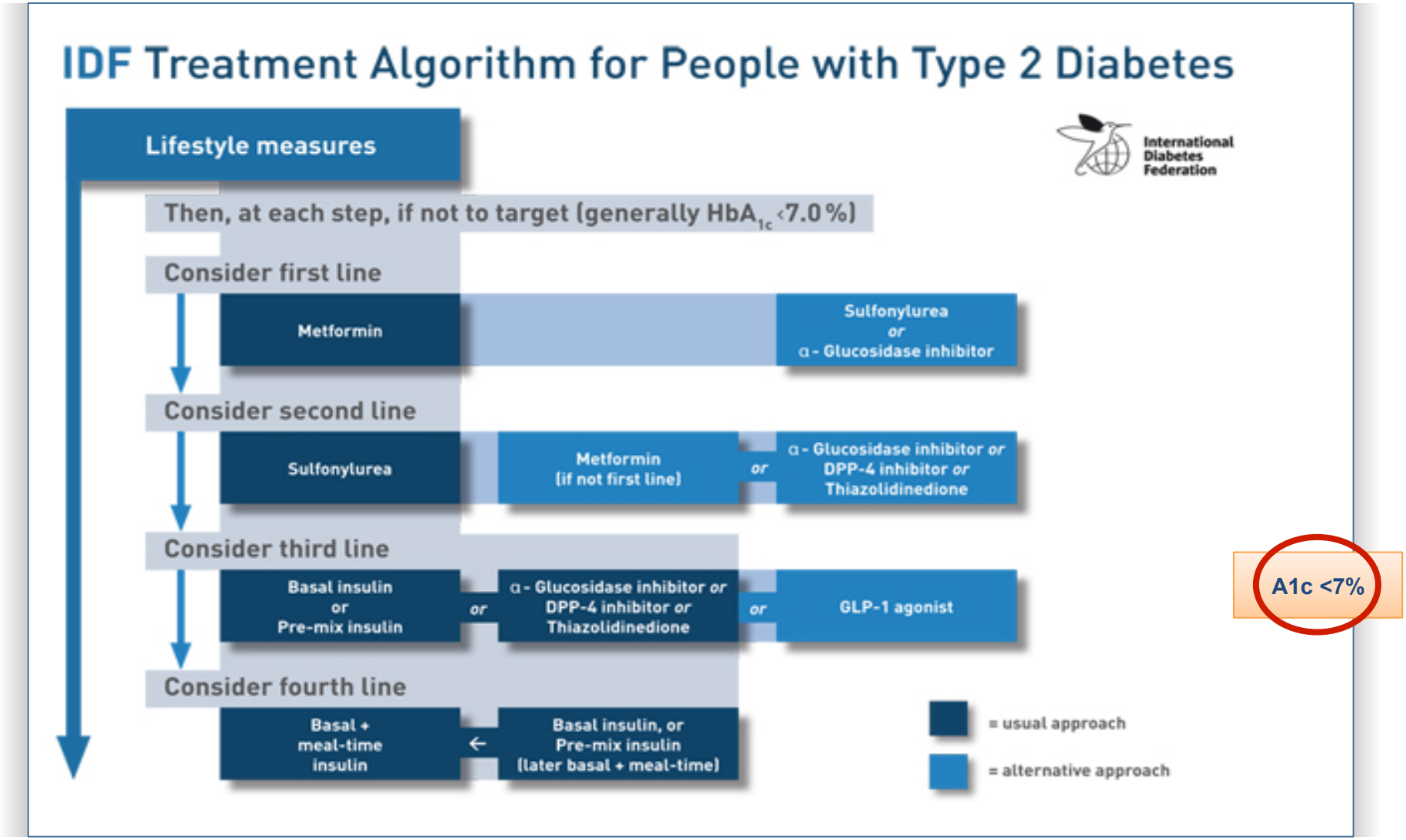
Metformina + insulina basale

Metformina + sulfonilurea o glinide + insulina basale

Metformina + insulina basal-bolus

A1c <7%

IDF 2010

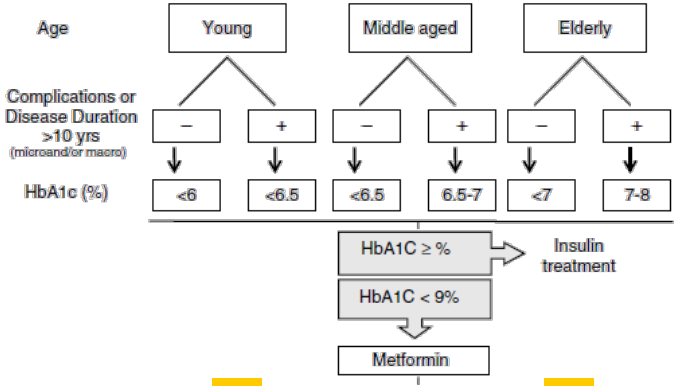

IDF Treatment Algorithm for People with Type 2 Diabetes
International Diabetes Federation
Lifestyle measures
Then, at each step, if not to target (generally HbA1c <7.0 %)
Consider first line
Metformin
Sulfonylurea or α - Glucosidase inhibitor
Consider second line
Sulfonylurea
Metformin (if not first line)
or
α - Glucosidase inhibitor or DPP-4 inhibitor or Thiazolidinedione
Consider third line
Basal insulin or Pre-mix insulin
or
α - Glucosidase inhibitor or DPP-4 inhibitor or Thiazolidinedione
or
GLP-1 agonist
Consider fourth line
Basal + meal-time insulin
←
Basal insulin, or Pre-mix insulin (later basal + meal-time)
= usual approach
= alternative approach
A1c <7%

The A1C and ABCD of glycaemia management in type 2 diabetes: a physician's personalized approach

Paolo Pozzilli[1,2†]
R. David Leslie[2,3*†]
Juliana Chan[4] Ralph De Fronzo[5]
Louis Monnier[6] Itamar Raz[7]
Stefano Del Prato[8]

Diabetes Metab Res Rev 2010

A



B **C**

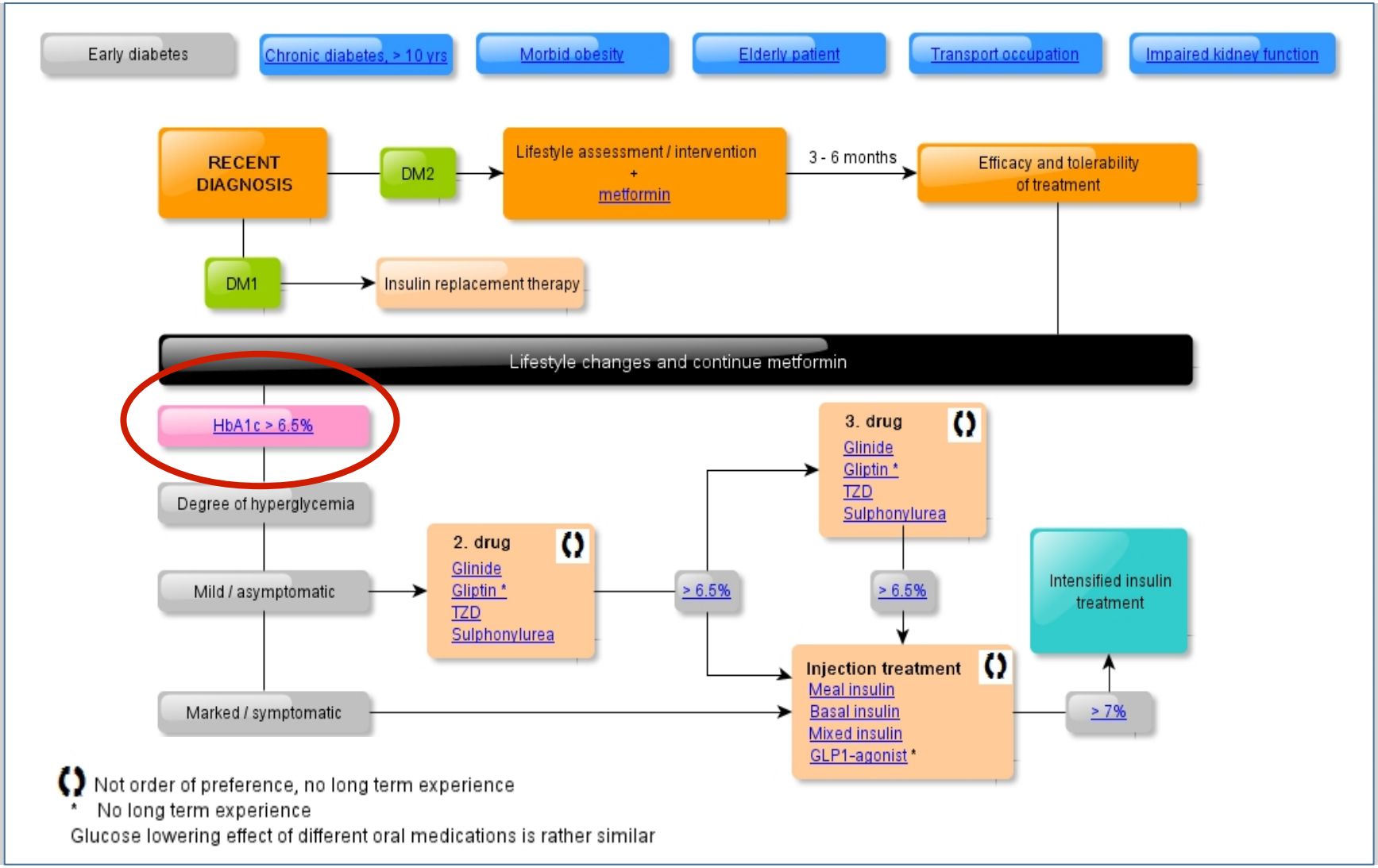
Class	Effect on Body Weight	Risk of Hypoglycaemia	Cardio-renal Complications: Contraindications
Physician should choose drug according to patient's risk of weight gain, hypoglycaemia, cardio-renal complications			
Metformin	Weight loss	Negligible as monotherapy	Moderate renal failure; Heart failure
GLP1 analogues	Weight loss	Negligibleas monotherapy	Severe renal failure
DPPIV inhibitors	Neutral	Negligible as monotherapy	Severe renal failure
Glucosidase inhibitors	Neutral	Negligible as monotherapy	Severe renal failure
Thiazolidinediones	Weight gain	Negligible as Monotherapy	Renal Failure; Heart failure (class III or IV)
Insulinanalogues: Rapid-acting analogues Long-acting analogues	Weight gain (rapid-acting> long-acting)	High risk Minimal risk	
Sulphonylureas	Weight gain	Minimal to significant (depending on agent)	Moderate renal failure
Glinides	Weight gain	Minimal/moderate	

			At presentation				Add-on therapy to metformin	
			Mild hyperglycaemia		Severe hyperglycaemia			
Strategy	Glycaemic goal	Time frame to reach glycaemic goal	Definition	Type of intervention	Definition	Type of intervention	Principles in selecting interventions	Drugs excluded
ABCD	Individualized <6–8%[a]	Individualized 3–12 months[a]	A1C <9%	Lifestyle + metformin	A1C ≥9%	Insulin	Age body weight; complications; diabetes duration	–

ABCD, age, body weight, complications and duration of disease.

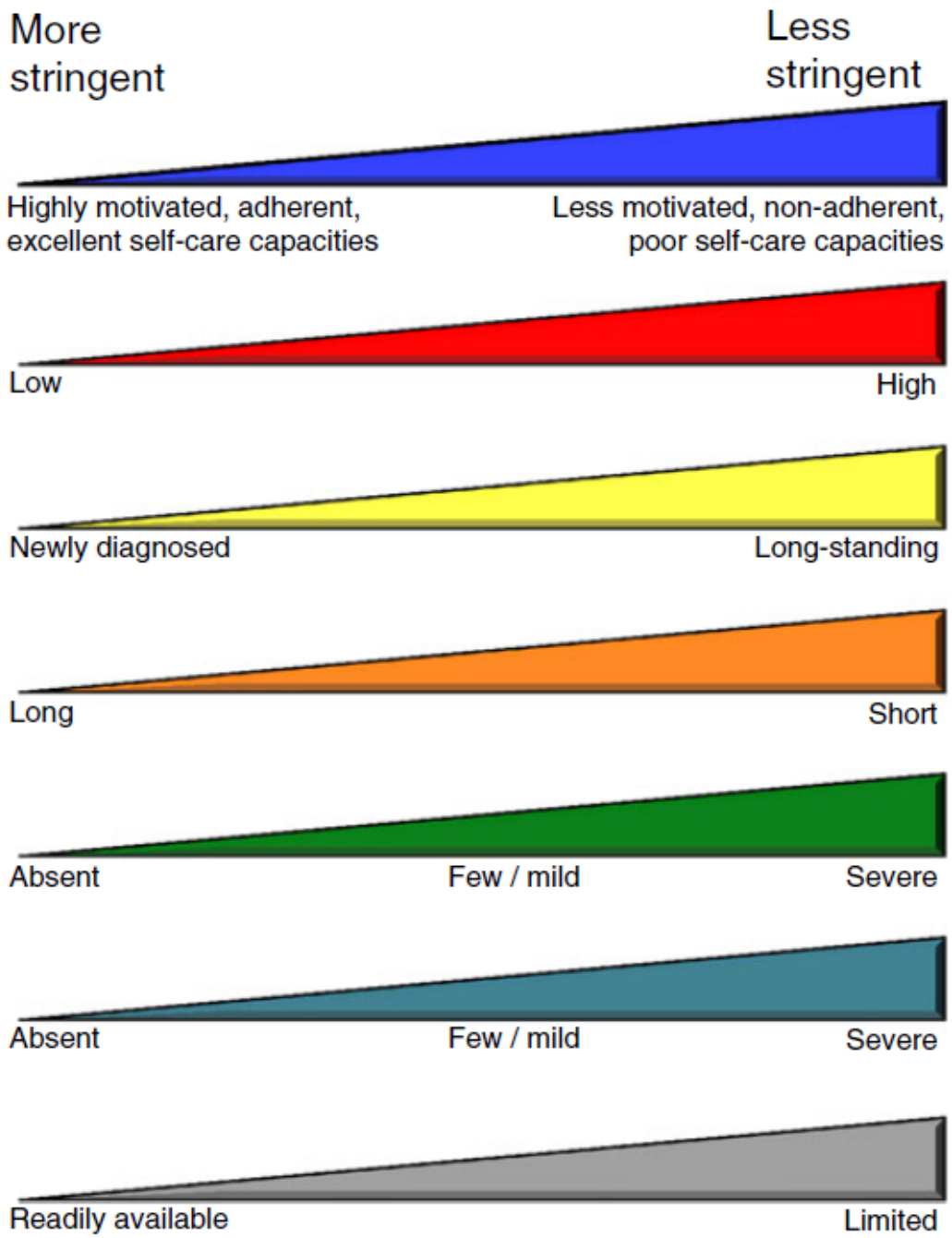
Diabetes treatment algorithm from the Diabetes Current Care Guideline. Working group set up by the Finnish Medical Society Duodecim and the Finnish Society of Internal Medicine.

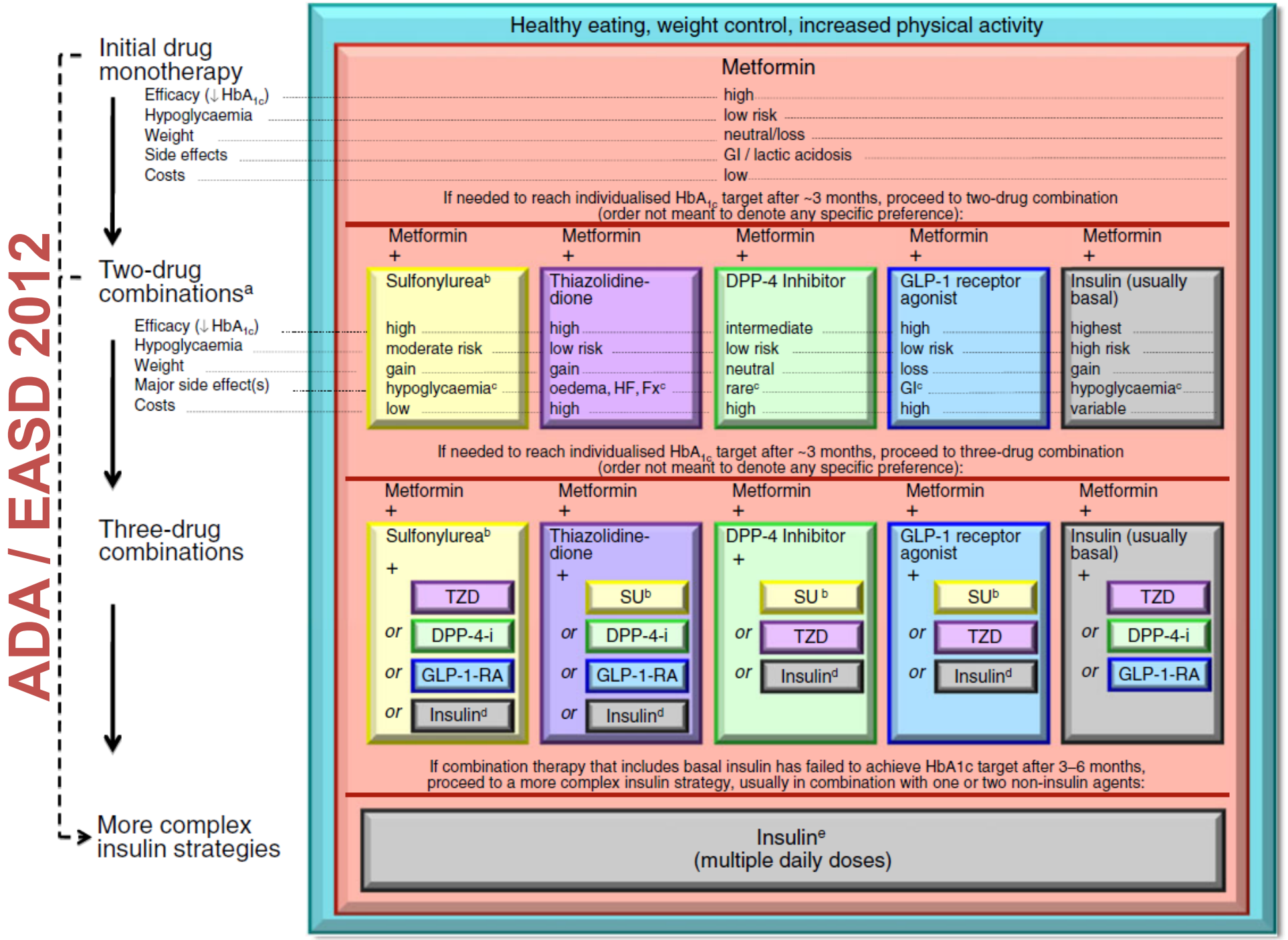
Available from: www.terveysportti.fi/xmedia/ccs/varhainen_diabetes_en.html



ADA / EASD 2012

Approach to management of hyperglycaemia:




ADA / EASD 2012
Initial drug monotherapy
Efficacy (↓HbA1c)
Hypoglycaemia
Weight
Side effects
Costs
Two-drug combinations[a]
Efficacy (↓HbA1c)
Hypoglycaemia
Weight
Major side effect(s)
Costs
Three-drug combinations
More complex insulin strategies
Healthy eating, weight control, increased physical activity
Metformin
high
low risk
neutral/loss
GI / lactic acidosis
low
If needed to reach individualised HbA1c target after ~3 months, proceed to two-drug combination (order not meant to denote any specific preference):
Metformin + Sulfonylurea[b]
high
moderate risk
gain
hypoglycaemia[c]
low
Metformin + Thiazolidine-dione
high
low risk
gain
oedema, HF, Fx[c]
high
Metformin + DPP-4 Inhibitor
intermediate
low risk
neutral
rare[c]
high
Metformin + GLP-1 receptor agonist
high
low risk
loss
GI[c]
high
Metformin + Insulin (usually basal)
highest
high risk
gain
hypoglycaemia[c]
variable
If needed to reach individualised HbA1c target after ~3 months, proceed to three-drug combination (order not meant to denote any specific preference):
Metformin + Sulfonylurea[b] + TZD or DPP-4-i or GLP-1-RA or Insulin[d]
Metformin + Thiazolidine-dione + SU[b] or DPP-4-i or GLP-1-RA or Insulin[d]
Metformin + DPP-4 Inhibitor + SU[b] or TZD or Insulin[d]
Metformin + GLP-1 receptor agonist + SU[b] or TZD or Insulin[d]
Metformin + Insulin (usually basal) + TZD or DPP-4-i or GLP-1-RA
If combination therapy that includes basal insulin has failed to achieve HbA1c target after 3–6 months, proceed to a more complex insulin strategy, usually in combination with one or two non-insulin agents:
Insulin[e] (multiple daily doses)

Diabetologia
DOI 10.1007/s00125-012-2642-x

LETTER

To what extent is the new position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) 'personalised'?

A. Ceriello · M. Gallo · S. Gentile · C. B. Giorda · A. De Micheli · on behalf of Associazione Medici Diabetologi (AMD)

Received: 14 June 2012 / Accepted: 18 June 2012

Keywords Algorithm · Fasting glycaemia · Personalised · Postprandial hyperglycaemia · Self blood glucose monitoring

Abbreviations
AMD Associazione Medici Diabetologi
SMBG Self-monitoring of blood glucose

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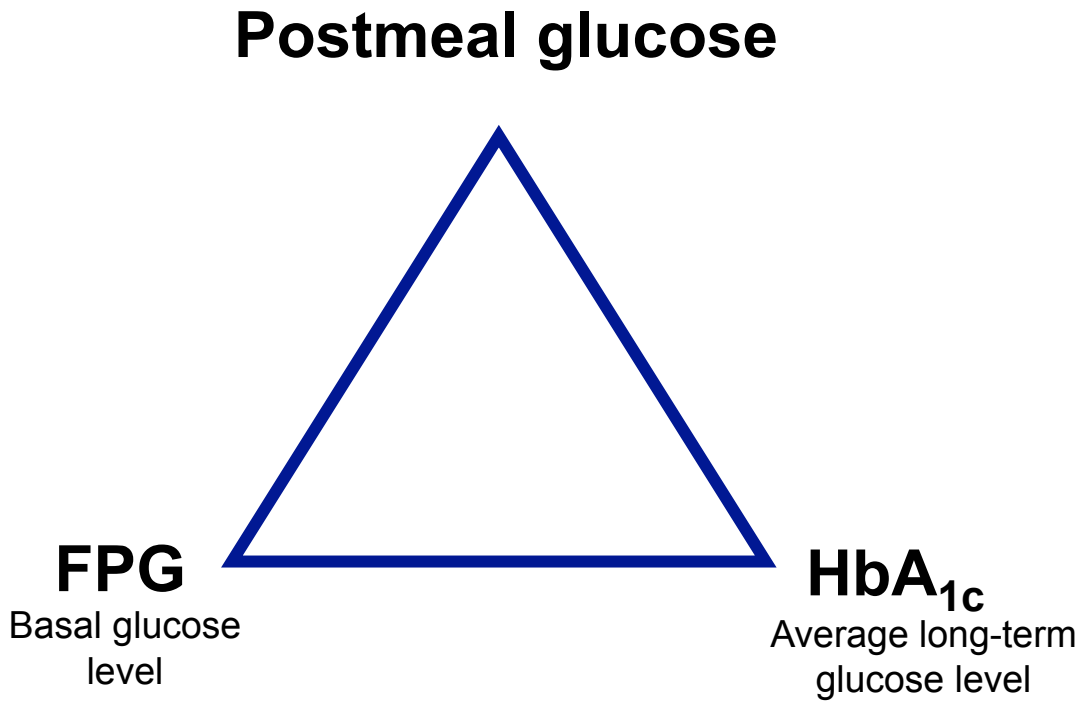
To the Editor: The joint position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) on the management of hyperglycaemia in type 2 diabetes [1] not only constitutes a revision of the previous algorithm [2], but also a paradigm shift in the concept of diabetes care: the aspect repeatedly emphasised in this document is 'patient-centred care'. The new ADA/EASD position statement is certainly innovative compared with its predecessor, because it includes many other therapeutic options based on patient-centred care with respect to sulfonylureas and basal insulin, when treatment with metformin alone has not achieved the therapeutic target [2]. The new algorithm takes into consideration the need for personalised treatment, and provides a series of recommendations about possible choices, highlighting the advantages and limitations of each therapeutic option. In this sense, the document appears to fail in its purpose, by focusing—as do all guidelines available to date—on a lengthy though highly detailed list of the possible therapeutic choices. Even though the authors define the new recommendations as being less prescriptive and not as 'algorithm-like' as its forerunners, it is still up to the physician to choose the most appropriate therapy for the patient. It seems likely that the authors thought of proposing different algorithms based on various aspects that vary over time (apart from those proposed to avoid weight gain, minimise cost and avoid hypoglycaemia), but realised that these would be highly complicated. An effective way of overcoming this problem would be to use an online interactive resource, as recently proposed with the algorithms relating to tailoring drug therapy for patients with type 2 diabetes issued by the Finnish Medical Society [3]. This computerised system allows people to quickly find subjects of interest according to their own particular clinical features, as well as to follow easy, step-by-step suggestions for additional therapeutic pathways.

Published online: 17 July 2012

‘Glucose triad’ of diabetes management



HbA_{1c} = glycated haemoglobin
FPG = fasting plasma glucose

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 14, Number 4, 2012

DOI: 10.1089/dia.2011.0233

Perspective

Personalizing Treatment in Type 2 Diabetes: A Self-Monitoring of Blood Glucose Inclusive Innovative Approach

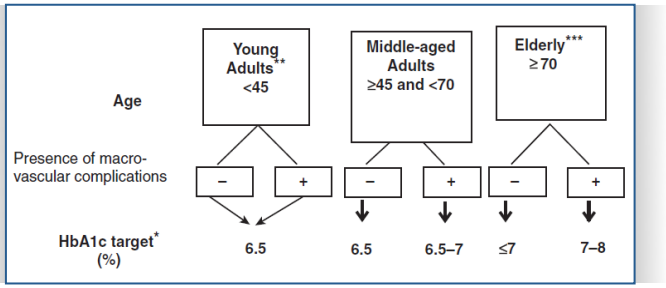
Antonio Ceriello, M.D., Ph.D.,[1,2] Marco Gallo, M.D.,[3] Vincenzo Armentano, M.D.,[4] Gabriele Perriello, M.D.,[5] Sandro Gentile, M.D., Ph.D.,[6] and Alberto De Micheli, M.D.,[7]
on behalf of the Associazione Medici Diabetologi

Documento di consenso GdL Terapia Personalizzata AMD *Il Giornale di AMD 2011;14:35-45*

La personalizzazione della terapia: innovazione nella gestione del paziente con diabete di tipo 2

Caratterizzazione del paziente:

- situazione clinica generale del paziente
- entità iperglicemia
- obesità
- rischio ipoglicemie
- insufficienza renale



Caratterizzazione delle iperglicemie:

- prevalentemente a digiuno/pre-prandiali
- prevalentemente post-prandiali
- pre- e post-prandiali

SMBG quale strumento guida per apportare correzioni più tempestive e ridurre i periodi di iperglicemia

Ceriello A., Armentano V., De Micheli A., Gallo M., Perriello G., Gentile S.

Note:
• I riquadri cliccabili consentono il passaggio al gradino terapeutico successivo qualora il target di HbA_{1c} non sia stato raggiunto. Intervallo/durata di trattamento fra i vari gradini terapeutici: 3-6 mesi con soggetto a target; 3 mesi non a target.

• HbA_{1c}: valore target da individualizzare in funzione delle caratteristiche del paziente

• Glicemia a digiuno* e pre-prandiale: **70-115 mg/dl**

• Glicemia post-prandiale**: **<160mg/dl**

Connotazione dell'iperglicemia: sulla base dell'analisi delle misurazioni effettuate con l'autocontrollo, vengono identificate le seguenti condizioni:

* **Iperglicemia prevalentemente a digiuno**: quando vi sia una proporzione di valori di iperglicemia misurati a digiuno in automonitoraggio, >60% sul totale delle misurazioni effettuate (ad es. 3 su 5 valori sono **>115 mg/dl**)
** **Iperglicemia prevalentemente post-prandiale**: quando vi sia una proporzione di valori di glicemia misurati a 1-2 ore dal pasto in automonitoraggio (secondo l'indicazione IDF) >60% sul totale delle misurazioni effettuate (ad es. 3 su 5 sono **>160 mg/dl)**

In tutte le flowchart di intervento che seguono, valgono le seguenti note di specifica:

1. I valori target di HbA_{1c} proposti, sono da intendersi come obiettivi da perseguire in sicurezza, limitando il rischio di ipoglicemia

2.In ogni passaggio di intervento è sempre possibile l'avvio della terapia insulinica ponendo particolare cautela in caso di rischio di ipoglicemie e dopo attenta valutazione costo/beneficio per BMI >30

3.L'intervallo/durata di trattamento suggerito nei vari passaggi, è variabile in funzione del conseguimento o meno dei valori target di buon controllo glicometabolico (i.e: 6 mesi se è a target; 3 mesi se non è target)

4.Le associazioni farmacologiche suggerite, nell'applicazione clinica, sono da intendersi come da indicazioni/autorizzazioni riportate nei singoli Riassunti delle Caratteristiche del Prodotto

ROSES: role of self-monitoring of blood glucose and intensive education in patients with Type 2 diabetes not receiving insulin. A pilot randomized clinical trial.

Monica Franciosi M et al.,

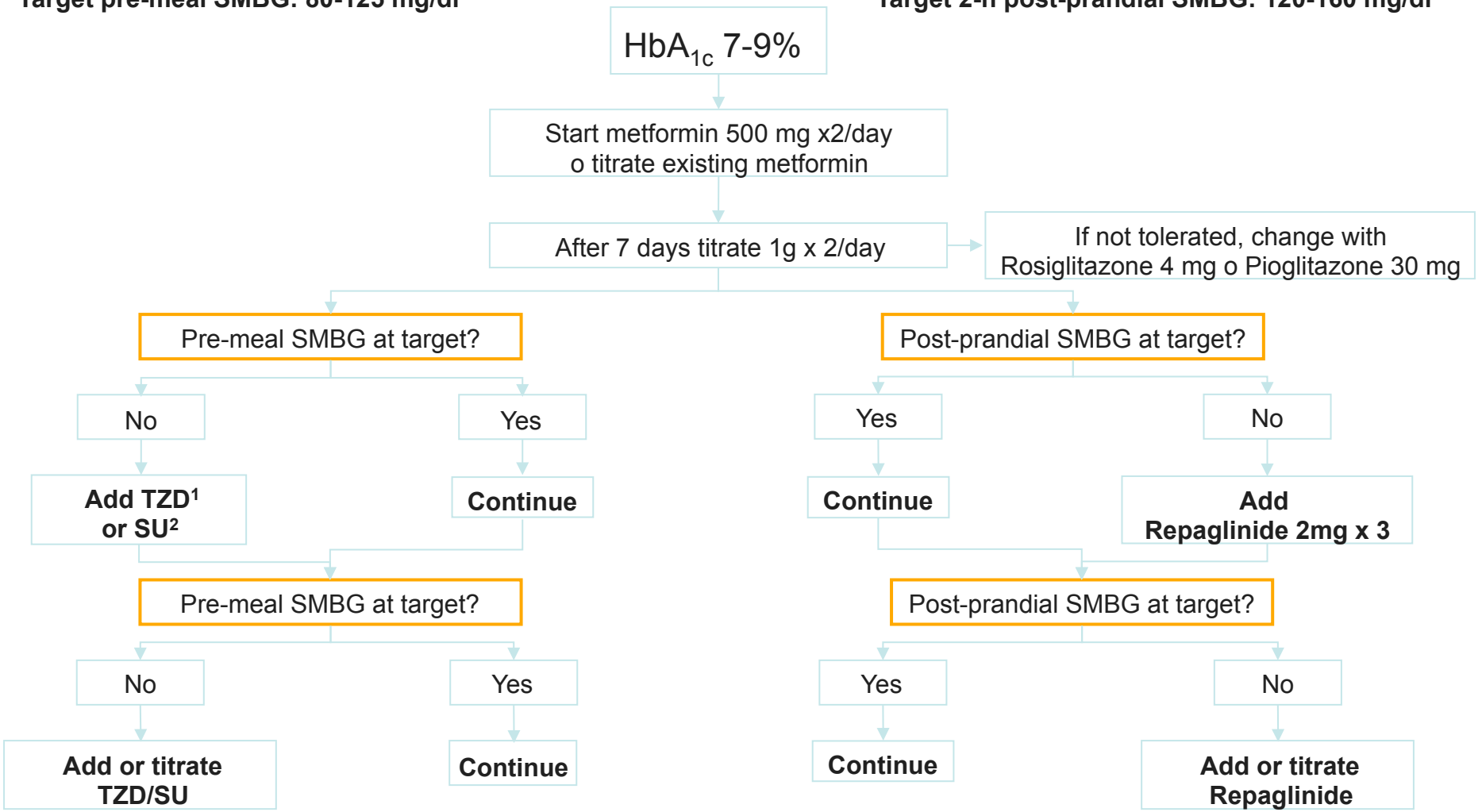
Diabet Med. 2011;28:789-796

AIMS

- **Aim of this pilot study was to evaluate the feasibility and the efficacy of an educational approach led by nurses, combined with SMBG, aimed at lifestyle modification and timely changes in therapy, as compared to usual care.**

Target pre-meal SMBG: 80-125 mg/dl

Target 2-h post-prandial SMBG: 120-160 mg/dl



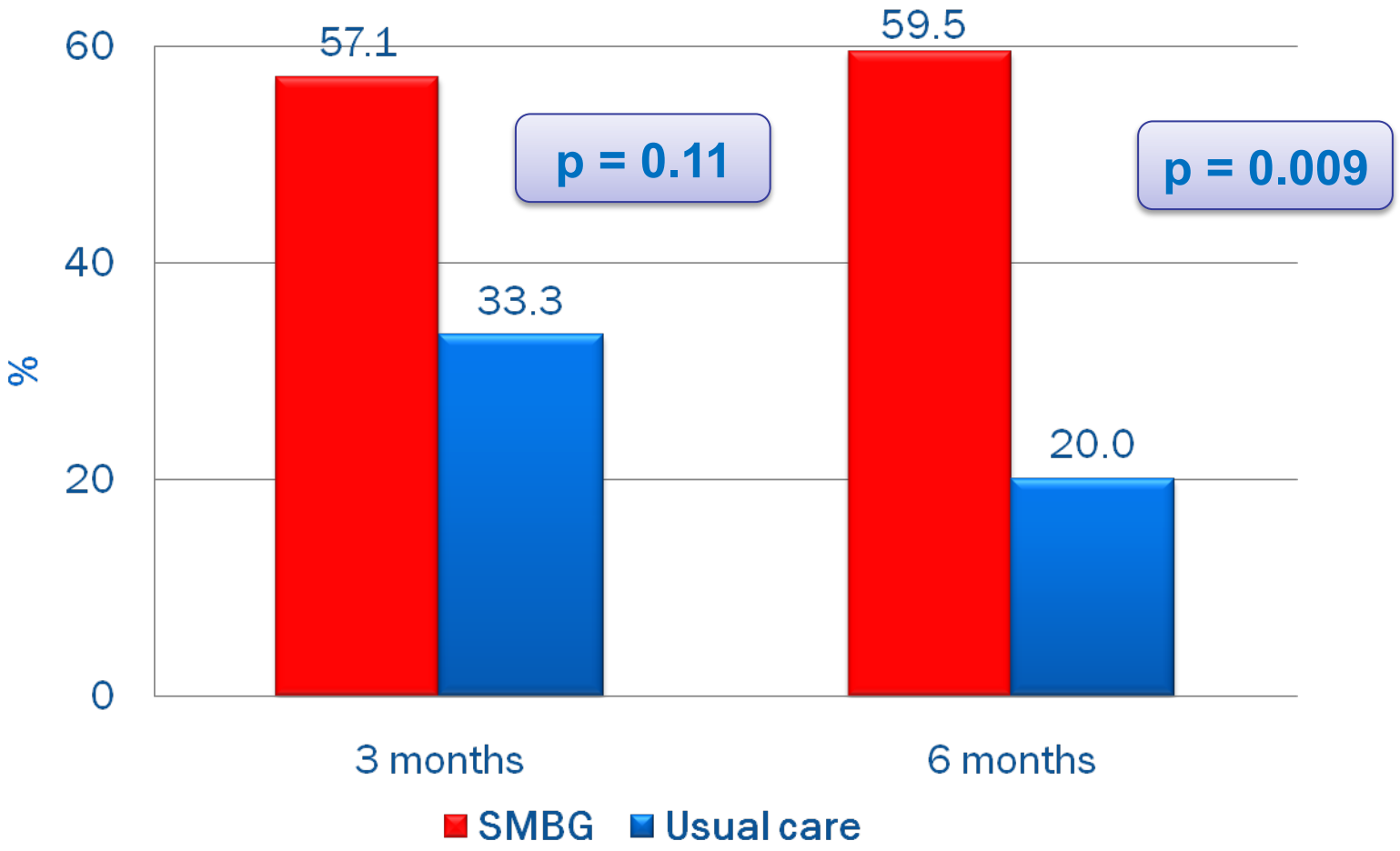
1 Rosiglitazone 4 mg/day o Pioglitazone 30 mg/day
2 Glimepiride 4 mg/day o Glicazide RM 30 mg/day

Maximum doses allowed:

Metformin 1gr x 2/day
Pioglitazone 45 mg/day
Glicazide RM 90 mg/day

Rosiglitazone 8 mg/day
Glimepiride 8 mg/day
Repaglinide 4 mgx3/day

RESULTS: PATIENTS WITH HbA_{1C}<7%



Diabetes Res Clin Pract. 2010 Oct 26. [Epub ahead of print]

Efficacy of occasional self-monitoring of postprandial blood glucose levels in type 2 diabetic patients without insulin therapy.

Shiraiwa T, Takahara M, Kaneto H, Miyatsuka T, Yamamoto K, Yoshiuchi K, Sakamoto K, Matsuoka TA, Matsuhisa M, Yamasaki Y, Shimomura I.

Medical Corporation, Shiraiwa Medical Clinic, 1-12-8 Hirano, Kashiwara, Osaka 582-0019, Japan; Department of Metabolic Medicine, Osaka University Graduate School of Medicine, 2-2 Yamadaoka, Suita, Osaka 565-0871, Japan.

PMID: 21030103 [PubMed - as supplied by publisher]

SMBG group: Measurement of postprandial glucose not more than 10 times per month

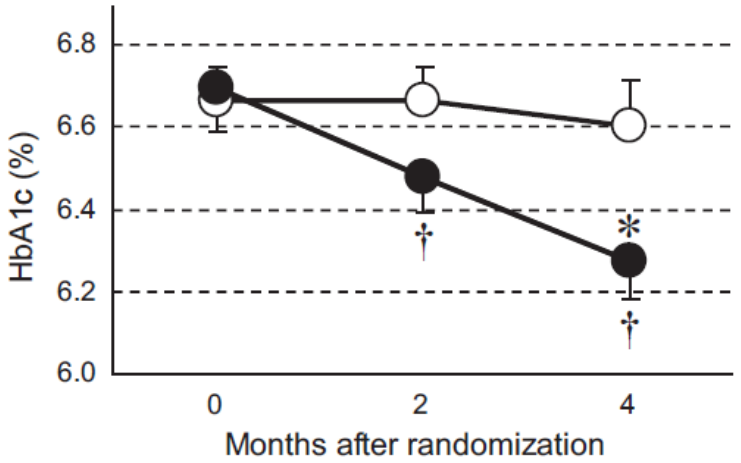
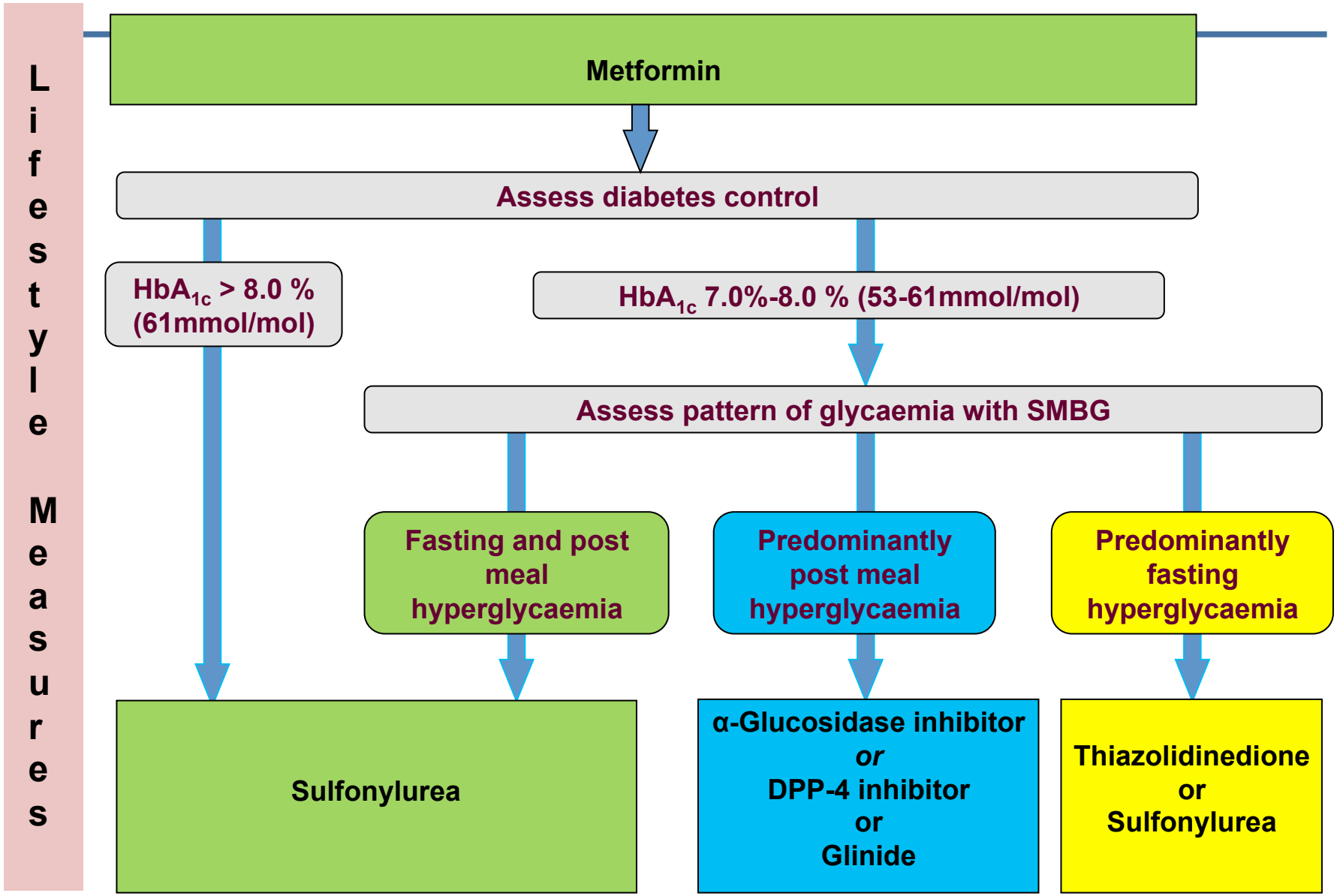


Fig. 1 – Change in glycaemic control during the study. Data are mean ± SE. *$p < 0.05$ vs. control group (unpaired t test). †$p < 0.05$ vs. baseline (paired t test). Filled circles, SMBG group; open circles, control group. HbA1c, haemoglobin A1c.

Fig 3

IDF Treatment Algorithm for Type 2 Diabetes Second Line – Personalized Usual Approach



IDF Algorithm for Personalized Treatment in Type 2 Diabetes
Membri del Gruppo di Sviluppo Linee Guida

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E’ necessario un algoritmo per la personalizzazione della terapia nel diabete?

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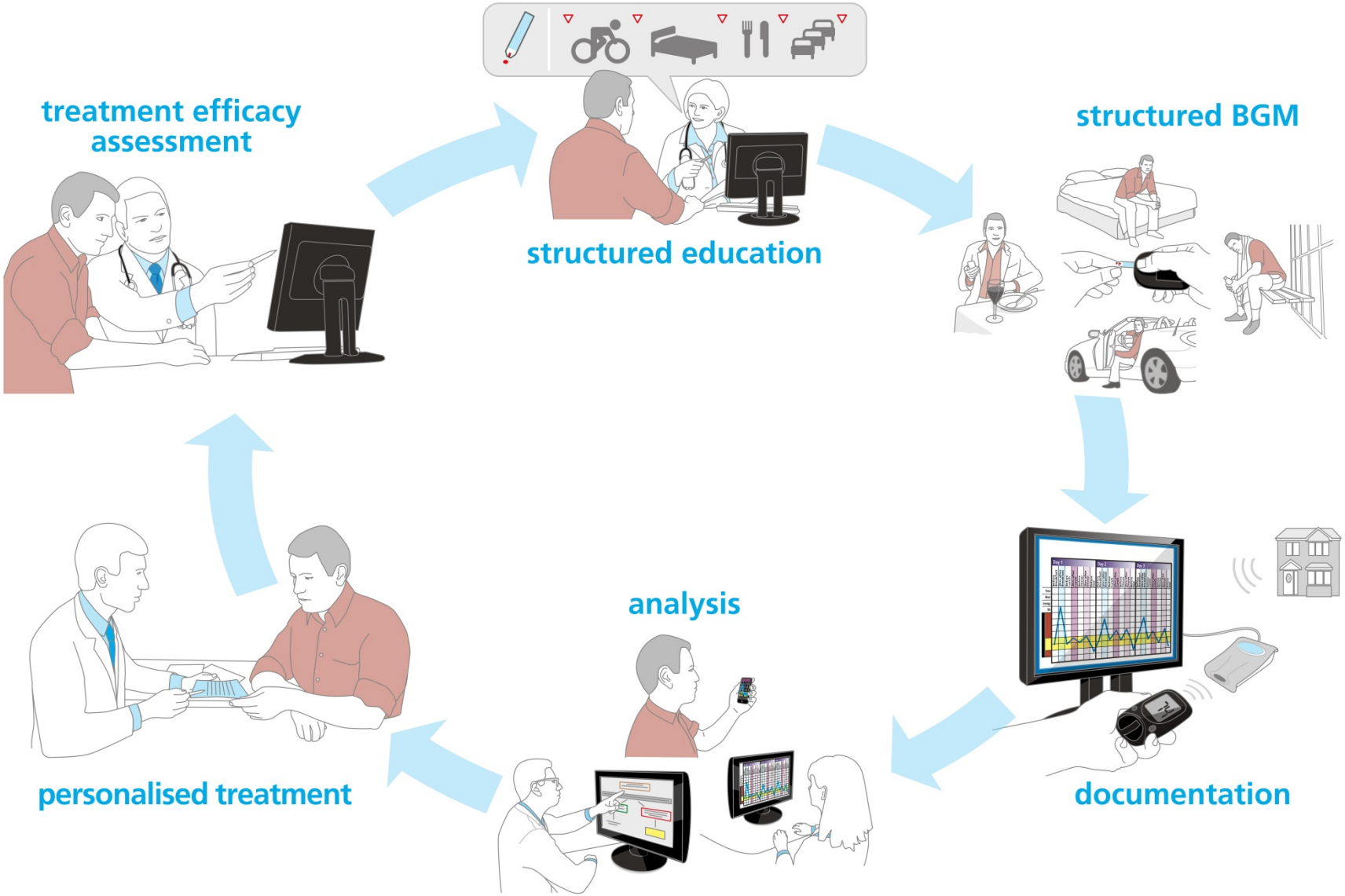
The Personalized Diabetes Management Cycle



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International Diabetes Federation

Review

Diabetes as a case study of chronic disease management with a personalized approach: The role of a structured feedback loop

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SMBG
Personalized

ABSTRACT

As non communicable or chronic diseases are a growing threat to human health and economic growth, political stakeholders are aiming to identify options for improved response to the challenges of prevention and management of non communicable diseases. This paper is intended to contribute ideas on personalized chronic disease management which are based on experience with one major chronic disease, namely diabetes mellitus.

Diabetes provides a pertinent case of chronic disease management with a particular focus on patient self management. Despite advances in diabetes therapy, many people with diabetes still fail to achieve treatment targets thus remaining at risk of complications. Personalizing the management of diabetes according to the patient's individual profile can help in improving therapy adherence and treatment outcomes. This paper suggests using a six step cycle for personalized diabetes (self) management and collaborative use of structured blood glucose data. E health solutions can be used to improve process efficiencies and allow remote access. Decision support tools and algorithms can help doctors in making

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E mail address: aceriell@clinic.ub.es (A. Ceriello).

http://dx.doi.org/10.1016/j.diabres.2012.07.005

Please cite this article in press as: Ceriello A, et al. Diabetes as a case study of chronic disease management with a personalized approach: The role of a structured feedback loop. Diabetes Res Clin Pract (2012), http://dx.doi.org/10.1016/j.diabres.2012.07.005

EU Environment

European Commission

27 Commissioners

Initiates legislation

Prepares policy

Follows implementation

EU Environment

Council of the European Union

EU Environment

European Parliament

754 Members of the EP

2 Seats

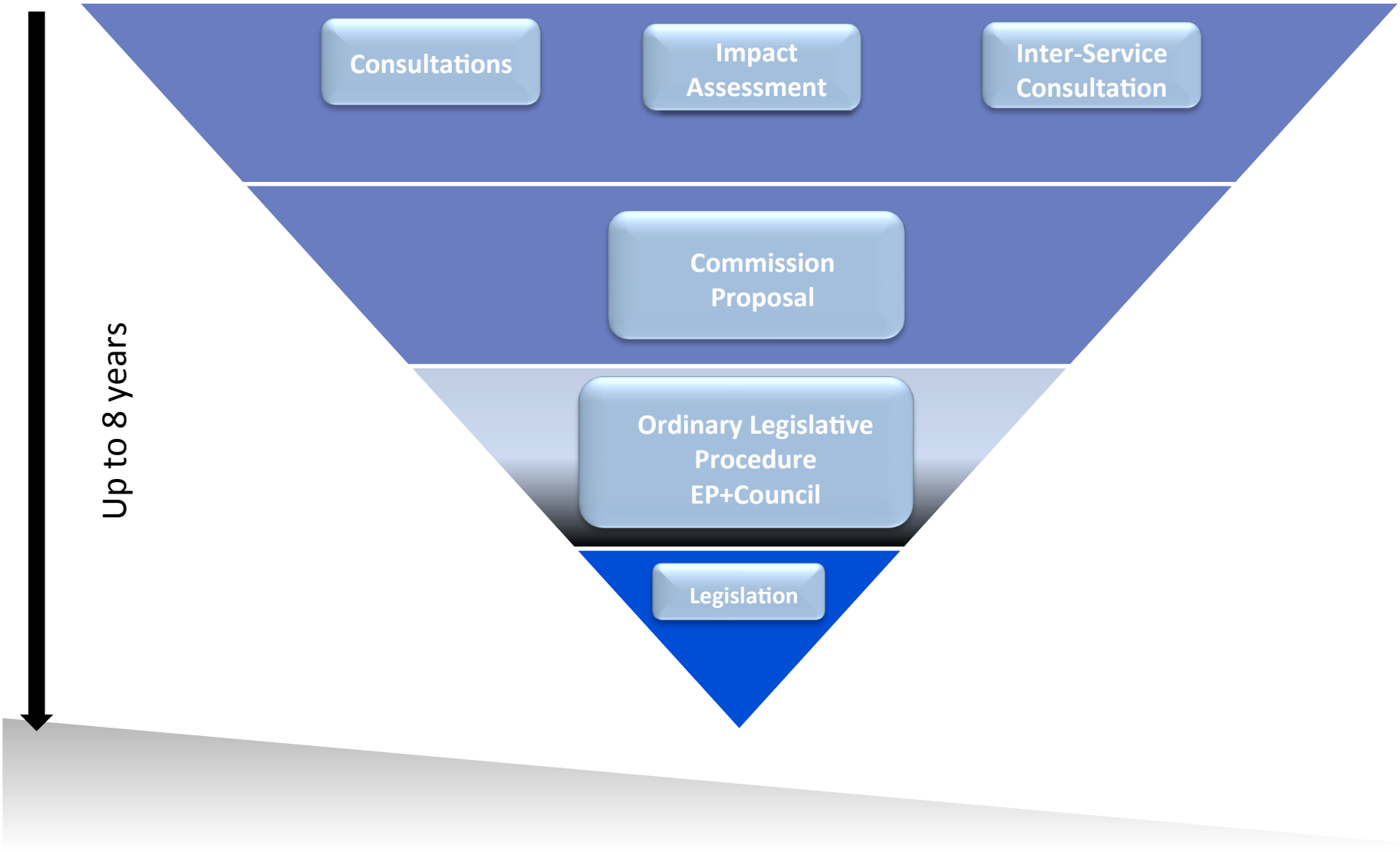
Co-legislates with the Council

Contributes to launching debate

Scrutiny power

EU Environment

Policy-Making Process for legislation



EU Reflection Process

Policy-Making Process – Directions

2010 – Council Conclusion on "Innovative approaches for chronic diseases in public health and healthcare systems"

- Adopted under the Belgian Presidency of the Council
- The EU endeavours to tackle cross-cutting issues
- The Council Conclusion calls for a Reflection Process to start in 2012

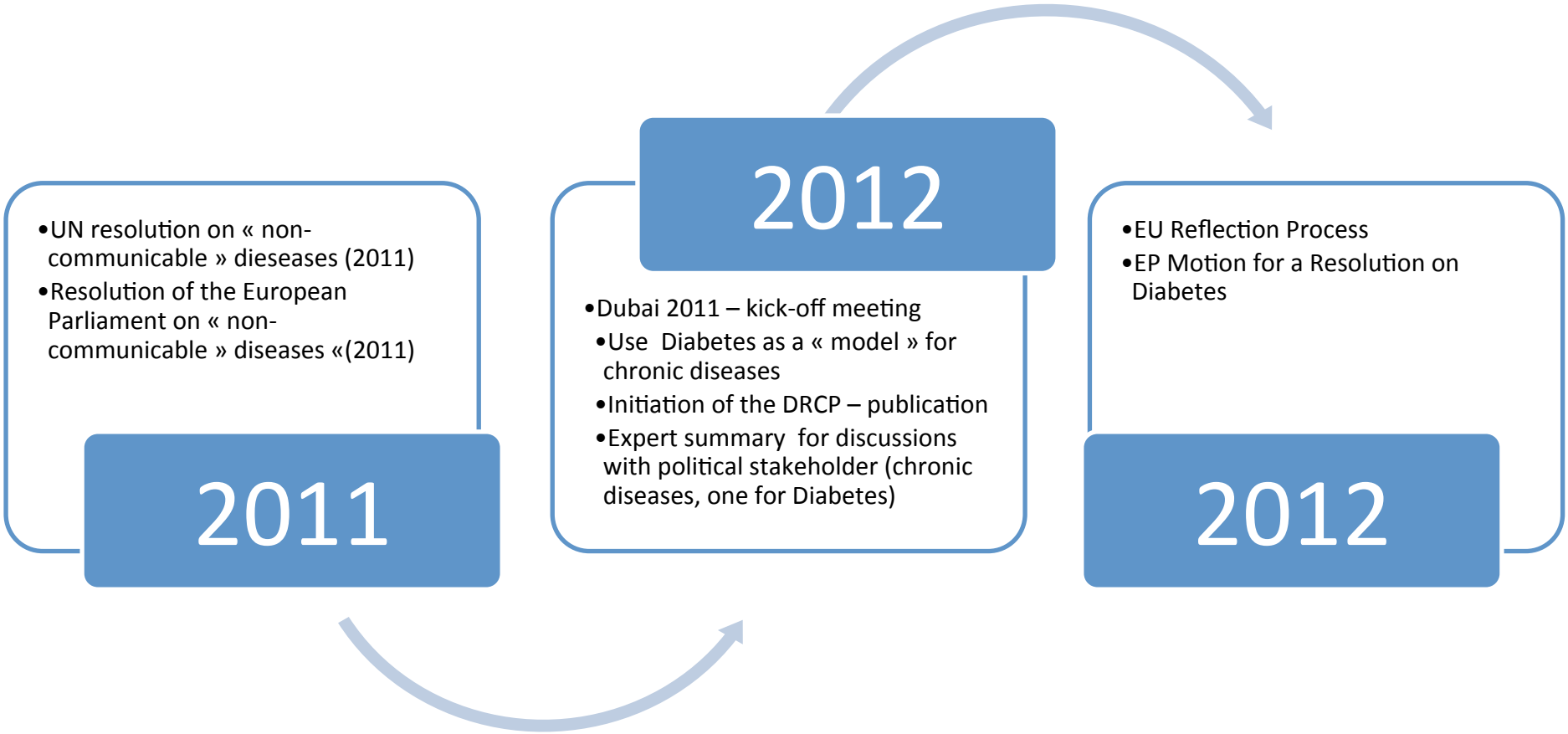
2012 – EU Reflection Process on Chronic Diseases

- In December 2011, the European Commission launched the Reflection Process by circulating a questionnaire to all Member States
- A drafting Group composed of Poland, Denmark, Cyprus, Ireland, Lithuania and Greece has been formed to draft a Council text

2013 – 2014 Expected Outcome

- The Council text is expected to focus on prevention and management of Chronic Diseases
- The implementation of national plans on Chronic Diseases is the expected outcome to this reflection process.
- The Commission is planning to publish an Action Plan in 2014 (tbd)

ACTIONS of the WORKING GROUP



DIABETES TECHNOLOGY & THERAPEUTICS
Volume 14, Number 4, 2012

DOI: 10.1089/dia.2011.0233

Perspective

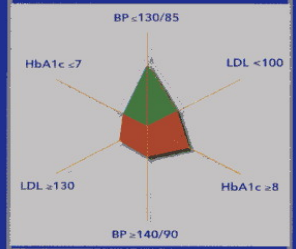
Personalizing Treatment in Type 2 Diabetes: A Self-Monitoring of Blood Glucose Inclusive Innovative Approach

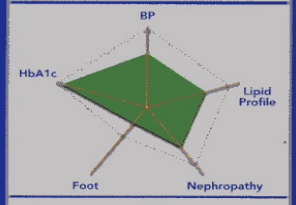
Antonio Ceriello, M.D., Ph.D.,[1,2] Marco Gallo, M.D.,[3] Vincenzo Armentano, M.D.,[4] Gabriele Perriello, M.D.,[5] Sandro Gentile, M.D., Ph.D.,[6] and Alberto De Micheli, M.D.,[7]
on behalf of the Associazione Medici Diabetologi

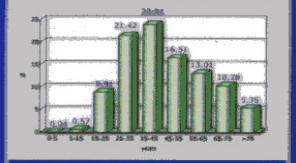
AMD

2006 Annals

AMD 2006 Annals







Quality Indicators in Diabetes Care in Italy

Antonino Cimino, Carlo Giorda,
Illidio Meloncelli, Antonio Nicolucci,
Fabio Pellegrini, Maria Chiara Rossi,
Giacomo Vespasiani

English version edited by Carlo Giorda

AMD
Associazione Medici Diabetologi

2006 Annals

Contact Programmes - 2012

DG SANCO

Innovation for Health Consumers

DG SANCO

Health Determinants

DG CONNECT

ICT for Health

S&D

Vittorio Prodi, IT

Loukas Georgiou

Kris Boers

Vincent Houdry

Antonis Lanaras and Dimitris Florinis

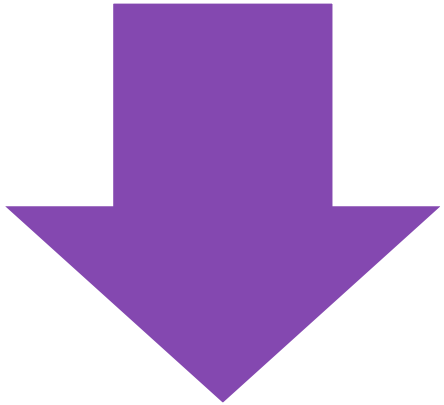
Eugene Lennon

Pierdavide Lecchini

……

What can be done at national level?

Top-Down and Bottom-Up Engagement

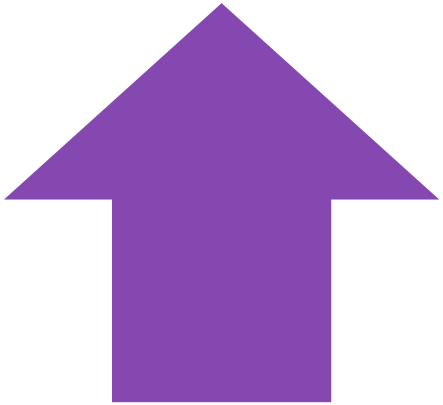


EU level – Current outcome of the interim report

"Taking well established good practices as starting point, e.g. for the empowerment of patients in the management of diabetes, and exploring whether these practices can be transferred to other chronic diseases."

National Stakeholders (Patients, HCPs, Academics)

- **Present the diabetes management to national governments and include it in the local diabetes/chronic disease plan**
- Champion the need for a holistic approach to be taken to HTA and health economic evaluation, thus including eHealth/ICT for Health options
- Advocate for national governments and insurers to reimburse ICT solutions and treatment option for diabetes



Gracias
Thank you
Grazie