

guideline development NICE IDF

Seoul

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Development of NICE and IDF diabetes guidelines

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NICE and IDF guideline development talk: *Background and duality of interest*

- The speaker was lead clinical advisor to the NICE-inherited type 2 diabetes guideline, the type 1 diabetes guideline, and the type 2 diabetes guidelines to 2008; he was also chair of the IDF Clinical Guidelines Task Force
- The speaker for himself or institutions with which he is associated accepts funding for his advisory, research, and lecturing activities from all major pharmaceutical companies active in diabetes care

NICE = National Institute for Clinical Excellence (UK)

- responsible for technology appraisals and clinical guidelines

IDF = International Diabetes Federation

- a federation of patient-led national diabetes associations

NICE and IDF guideline development talk:

Background and duality of interest

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This talk is about guideline development
It is not about guideline recommendations
A guideline is rather like a randomized
controlled trial:

- if you do not understand the methods,
you cannot assess the validity of the
output

- responsible for technology appraisals and clinical guidelines

IDF = International Diabetes Federation

- a federation of patient-led national diabetes associations

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“ There is no disease that has been so little improved in its history, theory, or cure, as the diabetes ”

Francis Home, Edinburgh, 1783

“ There is no disease that has so much improved in its theory or management, as the diabetes in the last 15-30 years ”

Philip Home, Melbourne, 2013

Dietary advice from the seventh century

Diabetes therapy

" . . . pot-herbs, endive, lettuce, rock-fishes, juices of knotgrass, elecampane in dark-coloured wine and decoctions of dates and myrtle . . . "

Paul of Aegina, ~600 AD



The NICE guidelines process: *the independence of NICE*

- *NICE is part of the UK National Health Service*
- *NICE is funded directly by the UK Department of Health, but its functions are independent of that*
- *NICE is independent of local health funders (Commissioning Groups) or health-care providers (primary/secondary/support)*

www.nice.org.uk

The NICE guidelines process

Department of Health / NICE

- Topic selection

- In practice national diabetes guidelines already existed
 - type 1 diabetes in adults and in children
 - type 2 diabetes
 - foot care
 - diabetes in pregnancy
- The issue then is should they be revised? Recurrently.
 - using updated and more rigorous process
 - more specifically what sections need updating?
- For this NICE commissions a Collaborating Centre responsible for the guidelines to prepare recommendations to the NICE executive
- NICE also registers (by self-application) stakeholders
 - will be consulted on scope of guideline, and draft versions

The NICE guidelines process

Department of Health / NICE

- Topic selection



NICE administration

- Register stakeholders
- Commission Collaborating Centre

The NICE guidelines process

Department of Health / NICE

- Topic selection



NICE administration

- Register stakeholders
- Commission Collaborating Centre



NICE Collaborating Centre – professional guideline developers

- Manage guideline development
- Develop the scope
- Appoint Guidelines Development Group
- Undertake systematic/economic reviews

The NICE guidelines process

Department of Health / NICE

- Topic selection



NICE administration

- Register stakeholders
- Commission Collaborating Centre



NICE Collaborating Centre – professional guideline developers

- Manage guideline development
- **Develop the scope**
- Appoint Guidelines Development Group
- Undertake systematic reviews

- The scope is what questions should be addressed
- Determines the budget
- Diabetes is a very big series of topics – limitations inevitable
- Is put out to consultation

The NICE guidelines process

Department of Health / NICE

- Topic selection



NICE administration

- Register stakeholders
- Commission Collaborating Centre



NICE Collaborating Centre – professional guideline developers

- Manage guideline development
- Develop the scope
- Appoint Guidelines Development Group
- **Undertake systematic/economic reviews**

- The Collaborating Centre may employ:
 - An operations manager and a clinical director
 - A project (guideline) manager
 - An information scientist – performs the evidence searches - RCTs
 - A systematic reviewer – organizes the identified evidence
 - A research fellow – draws together the evidence and other inputs
 - A health economist – performs health economic analysis

The NICE guidelines process

Department of Health / NICE

- Topic selection

NICE administration

- Register stakeholders
- Commission Collaborating Centre

NICE Collaborating Centre – professional guideline developers

- Manage guideline development
- Develop the scope
- Appoint Guidelines Development Group
- **Undertake systematic/economic reviews**

- The Collaborating Centre may employ:

- An **Aim: to ensure a high quality information feed**
- A professional guideline developer
- An information scientist – performs the evidence searches - RCTs
- A systematic reviewer – organizes the identified evidence
- A research fellow – draws together the evidence and other inputs
- A health economist – performs health economic analysis

The NICE guidelines process

Department of Health / NICE

- Topic selection

NICE administration

- Register stakeholders
- Commission Collaborating Centre

NICE Collaborating Centre – professional guideline developers

- Administer guideline development
- Develop the scope
- **Appoint Guidelines Development Group**
- Undertake systematic literature reviews

- Group members include health professionals, public health, and patient/carer representatives with relevant expertise and experience. The Chairman will not be a practising clinician in the field.
- Registered stakeholders are invited to nominate people to join the group.
- The Guideline Development Group (GDG) looks at the evidence available and considers comments made on draft versions of the guideline issued for consultation before making final recommendations.

The NICE guidelines process

Department of Health / NICE

- Topic selection

NICE administration

- Register stakeholders
- Commission Collaborating Centre

NICE Collaborating Centre – professional guideline developers

- Administer guideline development
- Develop the scope
- **Appoint Guidelines Development Group**
- Undertake systematic literature reviews

- Group members include health professionals, public health, and patient/carer representatives. The group will not be a primary author.
- Register stakeholders will not be a primary author.
- The Guideline Development Group (GDG) looks at the evidence available and considers comments made on draft versions of the guideline issued for consultation before making final recommendations.

Aim: to ensure a high quality translation of evidence into clinical recommendations

The NICE guidelines process

Department of Health / NICE

- Topic selection

NICE administration

- Register stakeholders
- Commission Collaborating Centre

NICE Collaborating Centre

- Administer guideline development
- Develop the scope
- Appoint Guidelines Development Group
- Undertake systematic/economic reviews

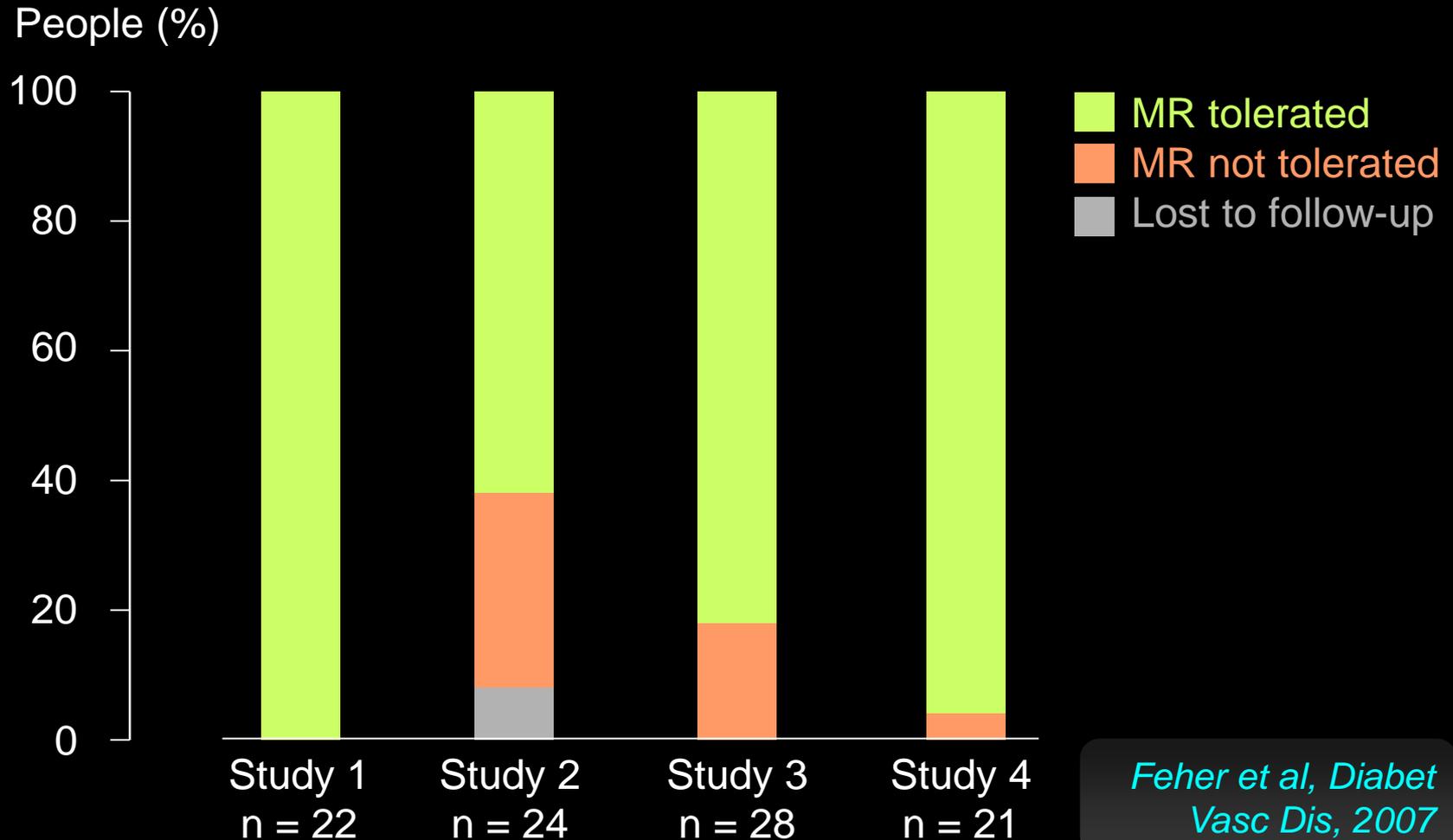
Guidelines Development Group

- Agree review questions
- Review evidence – assess quality
- Draw up recommendations

The problems of NICE (and derivative) guidelines

- The evidence base is generally weak
 - many randomized controlled trials are
 - short term
 - underpowered
 - in selected populations
 - RCTs often are not available; few are comparative
- The economic analyses are both sophisticated and primitive – complicated but with limited validity
- The technologies are evolving fast :
 - new evidence on old technologies
 - new technologies

Tolerance of metformin MR in people previously having gastrointestinal intolerance on metformin IR



UK national guideline
Nature of the evidence

2005

nature of evidence

ons

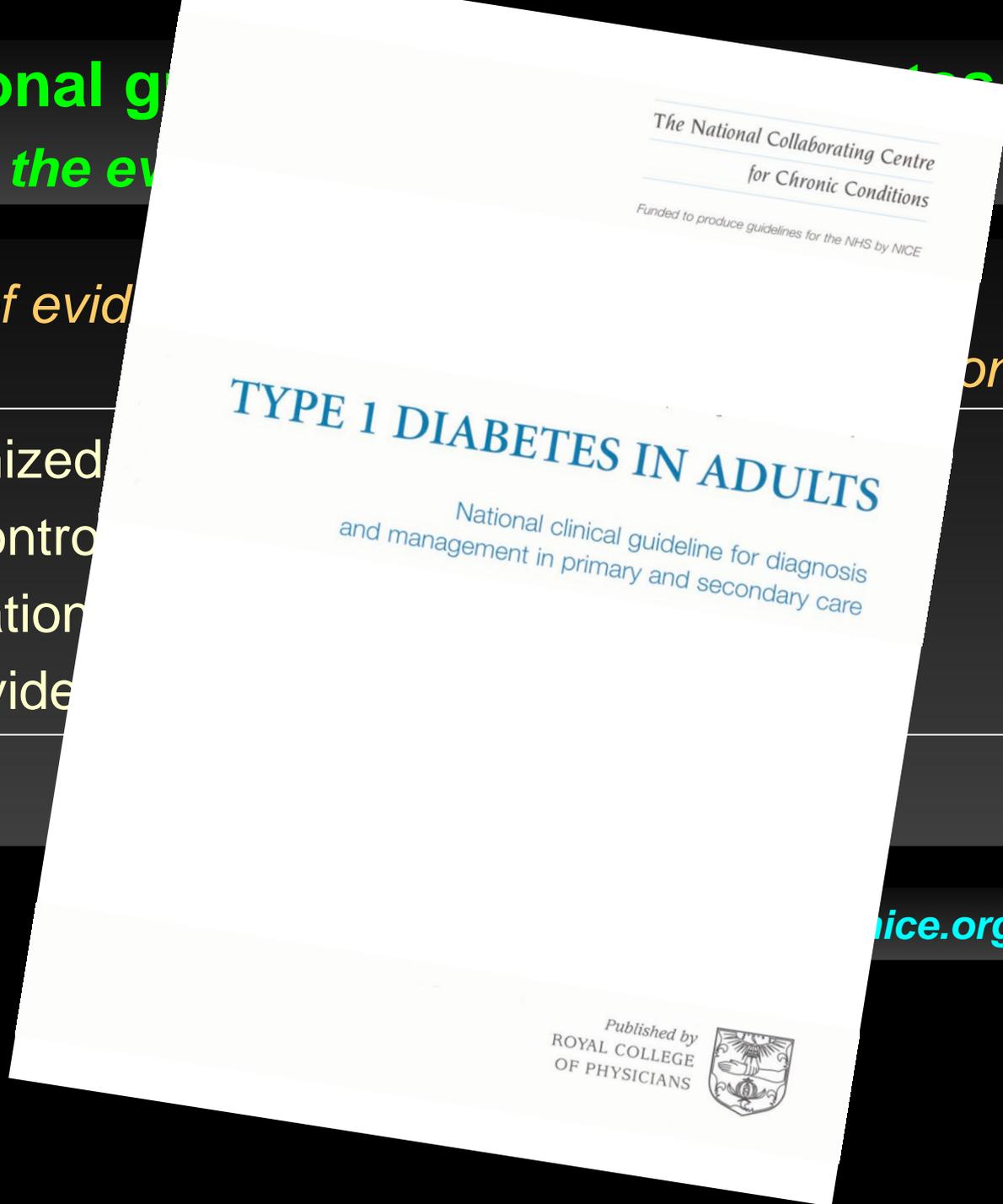
Randomized

Other controlled

Observational

Other evidence

all



nice.org.uk, 2005

UK national guideline for Type 1 diabetes, 2005

Nature of the evidence used

<i>nature of evidence</i>	<i>number of recommendations</i>
Randomized controlled trials	20
Other controlled trials	11
Observational studies	7
Other evidence	136
all	174

www.nice.org.uk, 2005

Published by
ROYAL COLLEGE
OF PHYSICIANS



The NICE guidelines process

Department of Health / NICE

- Topic selection

NICE administration

- Scoping of topic
- Register stakeholders
- Commission Collaborating Centre

NICE Collaborating Centre

- Administer guideline development
- Undertake systematic/economic reviews
- Appoint Guidelines Development Group

Guidelines Development Group

- Review evidence
- Draw up recommendations

NICE Collaborating Centre

- Consultation cycle and revision

Clinical guideline

The NICE guidelines process

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Meanwhile . . . what does NICE itself do?

- Guideline Development Group meetings are attended by NICE technical officers and NICE guideline executives
 - Due process is monitored carefully
- Wording of recommendations is agonised over
- Overlap issues are monitored
- Consultation is managed
- Structure of guideline outputs is determined

Guidelines Development Group

- Review evidence
- Draw up recommendations

NICE Collaborating Centre

- Consultation cycle and revision

Clinical guideline



*National Institute for
Health and Clinical Excellence*

Issue date: May 2008

Type 2 diabetes

The management of type 2 diabetes

**This is an update of
NICE clinical guidelines E, F, G and H**



*National Institute for
Health and Clinical Excellence*

Issue date: May 2009

Type 2 diabetes: newer agents

**Type 2 diabetes: newer agents for blood
glucose control in type 2 diabetes**

**This short clinical guideline partially
updates NICE clinical guideline 66. The
recommendations have been combined
with unchanged recommendations from
CG66 in NICE clinical guideline 87**

The NICE guidelines process

De *Meanwhile . . . what does NICE itself do?*

- Guideline Development Group meetings are attended by NICE technical officers and NICE guideline executives
 - Due process is monitored carefully
- Wording of recommendations is agonised over
- Overlap issues are monitored
- Consultation is managed
- **Structure of guideline outputs is determined:**
 - Full guideline (evidence, recommendations, economic analysis)
 - Recommendations
 - Quick access guideline
 - Summary for people with diabetes

• Consultation cycle and revision



Clinical guideline

Chapters Diabetes

Type 2

- 01 Screening
- 03 Education
- 05 Lifestyle
- 07 Clinical
- 09 Glucose
oral therapy
- 11 Blood pressure
- 13 Eye screening
- 15 Foot care
- 17 Pregnancy
- 19 In-patient

Global Guideline for Type 2 Diabetes



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control levels
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Chapters in the *Global Guideline for Type 2 Diabetes, 2005*

01 Screening and diagnosis

03 Education

05 Lifestyle management

07 Clinical monitoring

09 Glucose control:
oral therapy

11 Blood pressure control

13 Eye screening

15 Foot care

17 Pregnancy

19 In-patient care

02 Care delivery

04 Psychological care

06 Glucose control levels

08 Self-monitoring

10 Glucose control:
insulin therapy

12 Cardiovascular risk
protection

14 Kidney damage

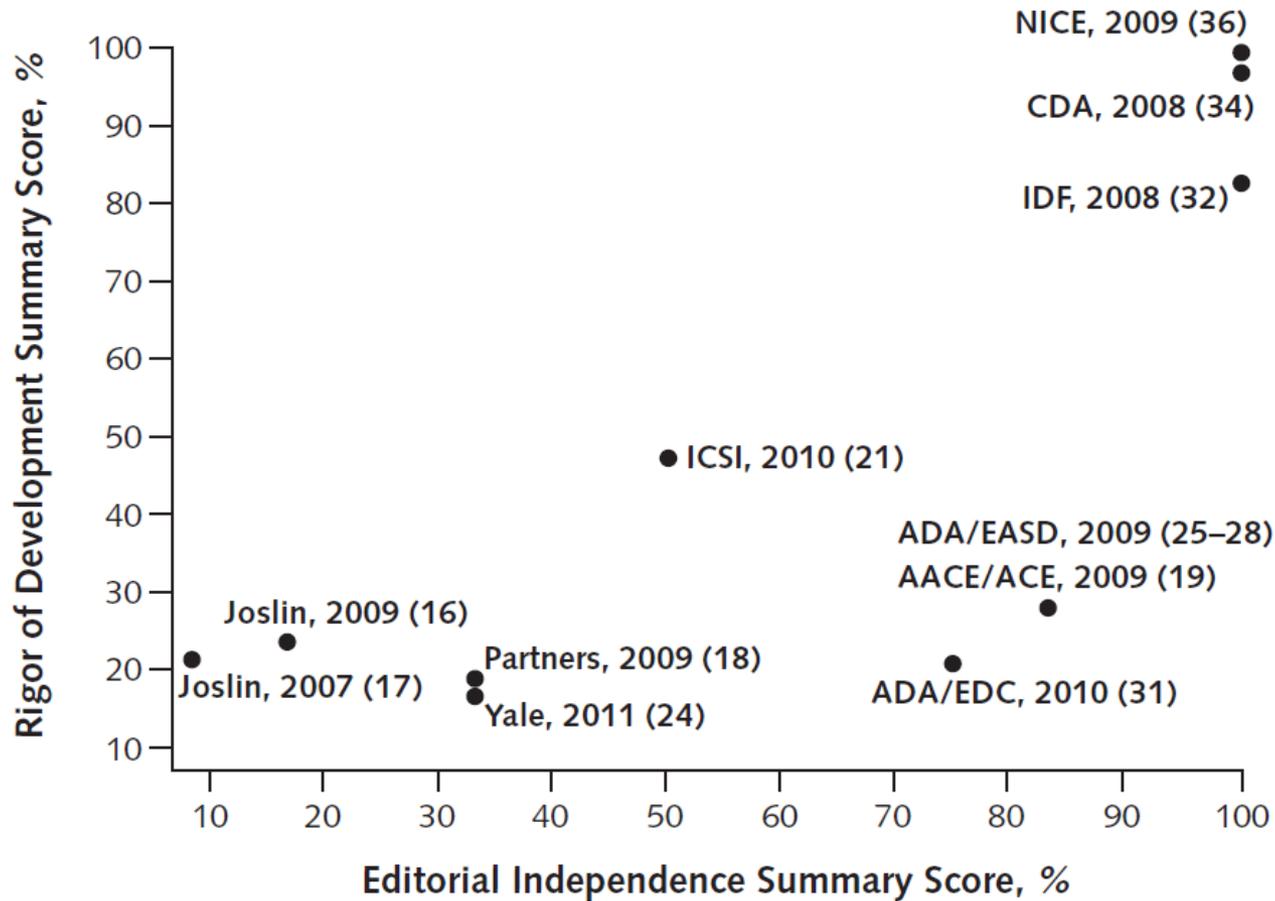
16 Nerve damage

18 Children

IDF Clinical Guideline for Type 2 Diabetes *Funding*

- IDF activities depend on attracting their own funding
- The Clinical Guideline was industry funded
- Independence was managed:
 - By having multiple and competing funders
 - By excluding funders from the development process
 - Allowing input only at the consultation stage with other stakeholders

Assessment of guideline quality



Bennett et al, Ann Int Med, 2012

IDF Clinical Guideline for Type 2 Diabetes

Development process

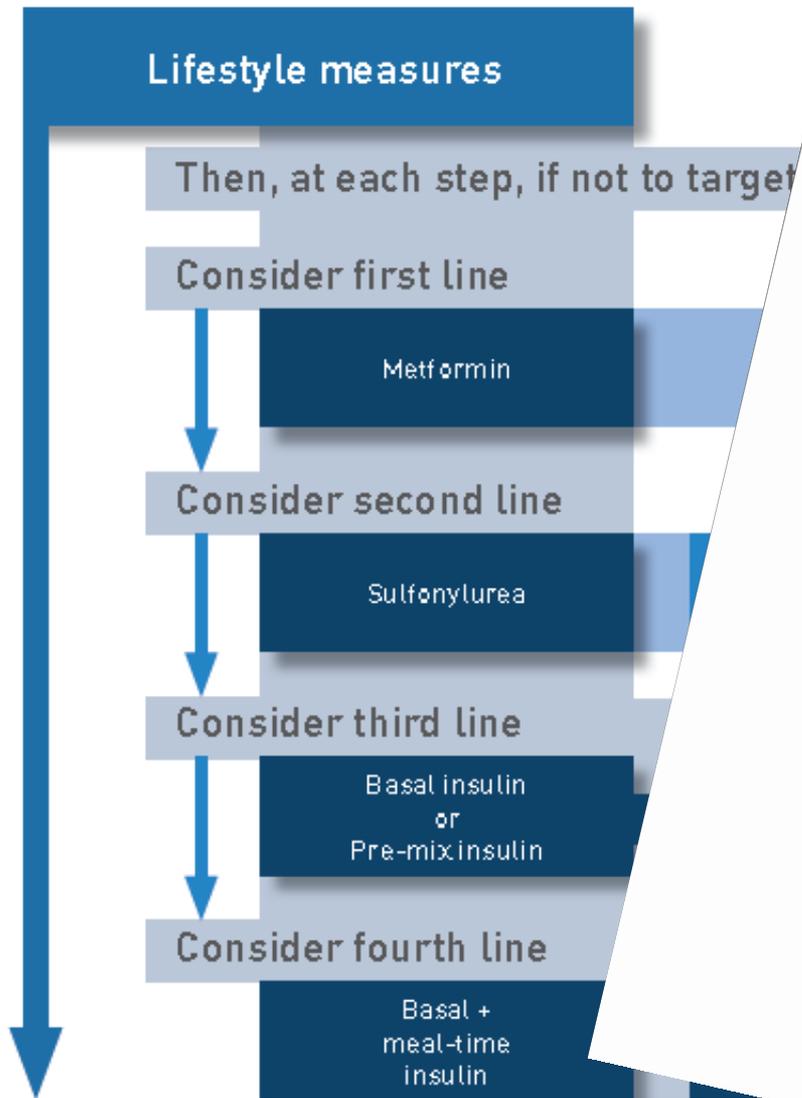
- No funding for information scientists, systematic reviewers, health economists
- Instead small groups on each topic reviewed published evidence-based assessments from other organizations
- A large Guidelines Development Group (GDG) met once to review and consider the findings of each small group, and distill them into recommendations
- A guidelines editor collated the material considered, the views of the small groups, and the comments of the GDG
- Draft recommendations were reviewed by all the GDG
- And then the draft reviewed by IDF association members and funders

IDF Clinical Guideline for Type 2 Diabetes

Coping with different levels of resources

- Globally IDF covers the span from lower income countries to high income countries
- And within many lower and middle income countries there is a huge variation in access to health-care funding
- Accordingly no single one economic perspective can be applied globally
- The IDF task force developed a three-layer system designed to address resource-limited, resource-controlled, and unrestricted-resource scenarios

IDF Treatment Algorithm for People with Type 2 Diabetes



NICE and IDF Clinical Guidelines *Revision*

- The diabetes evidence-base and technologies included have not stopped changing
 - new RCTs
 - new medication classes, new insulins, new support technologies
- Guideline developers are therefore forced into a 'race' to keep up
- Complete revision of guidelines is usually unnecessary
- But continued revision has resulted in some fragmentation and inconsistencies
- Guideline development is not a 'do and forget' process!

Thank you for your attention



