

# IWGDF

GUIDANCE AND IMPLEMENTATION DAY

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## Development of an evidence-based global consensus The 2015 IWGDF Guidance documents **An Update**

Karel Bakker MD, PhD, Immediate past-chair IWGDF - IDF CS

on behalf of

J. Apelqvist; B. A. Lipsky; J. J. van Netten; N. C. Schaper; K. Bakker

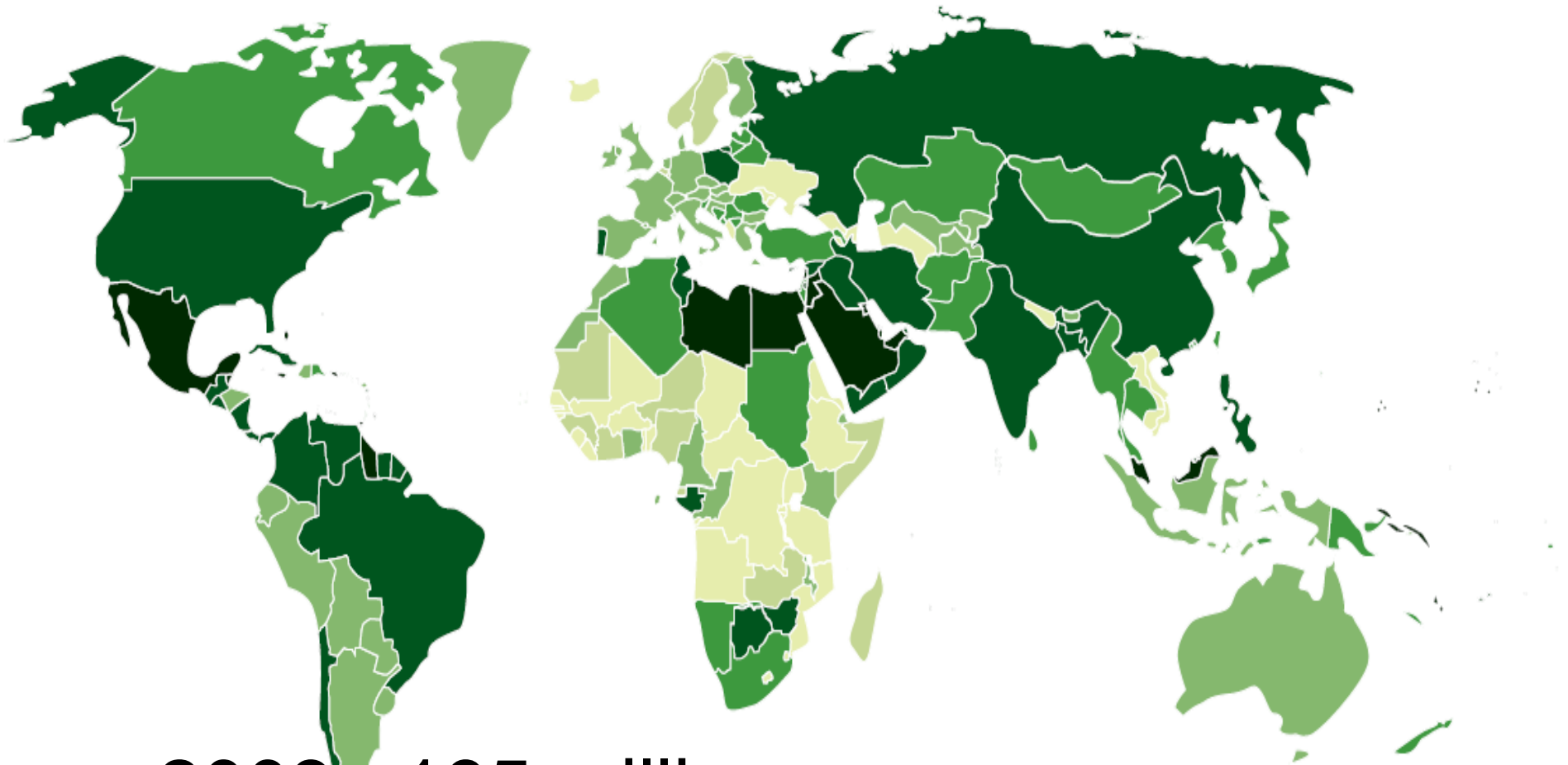
WCS, Utrecht, 24 november 2015

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Disclosure belangen spreker:

Geen belangenverstrengeling

# Prevalence of diabetes (20-79 y)

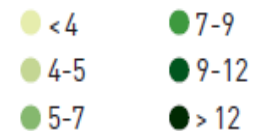


2003: 195 million

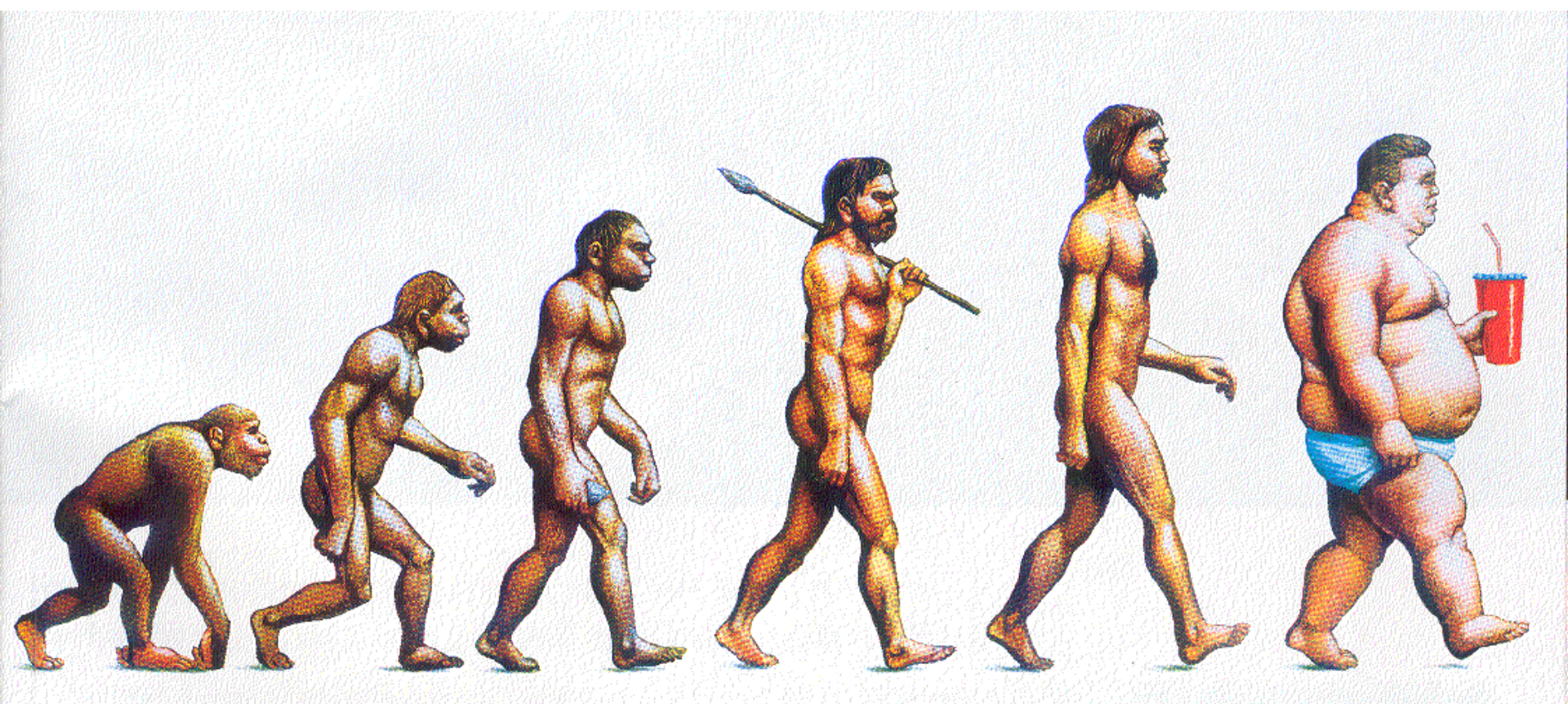
2014 : 387 million

2035 : 592 million

Turkey: prevalence > 10 %



\*comparative prevalence





387 million:  
80%  
in  
Low-and  
middle-income  
countries

IDF Atlas 2014



# Metabolic Syndrome

## Type 2 Diabetes







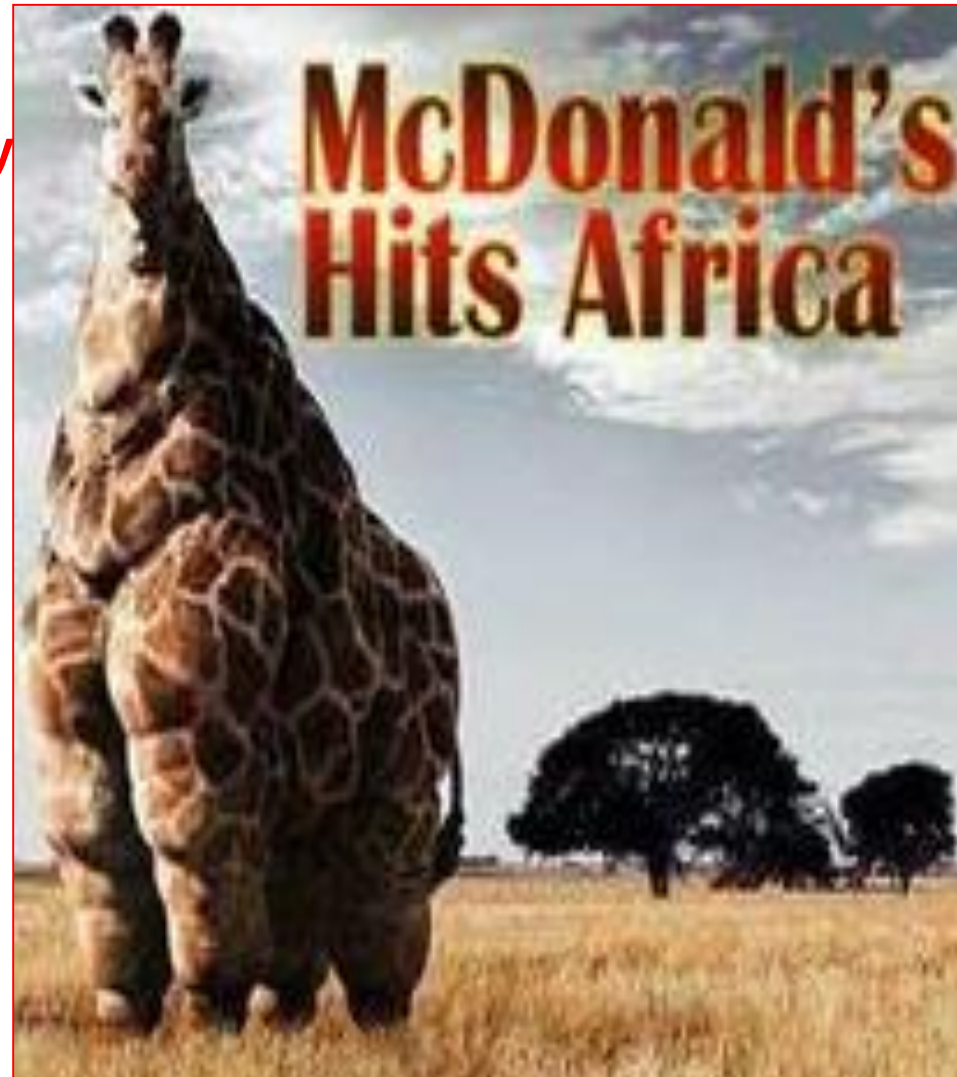
China....



# **Patients want to be listened to if we are going to achieve “Motivational and Therapeutic Lifestyle Changes”**

**Reducing 5-7% Body Weight greatly  
reduces DM risk in every  
Race/Ethnicity**

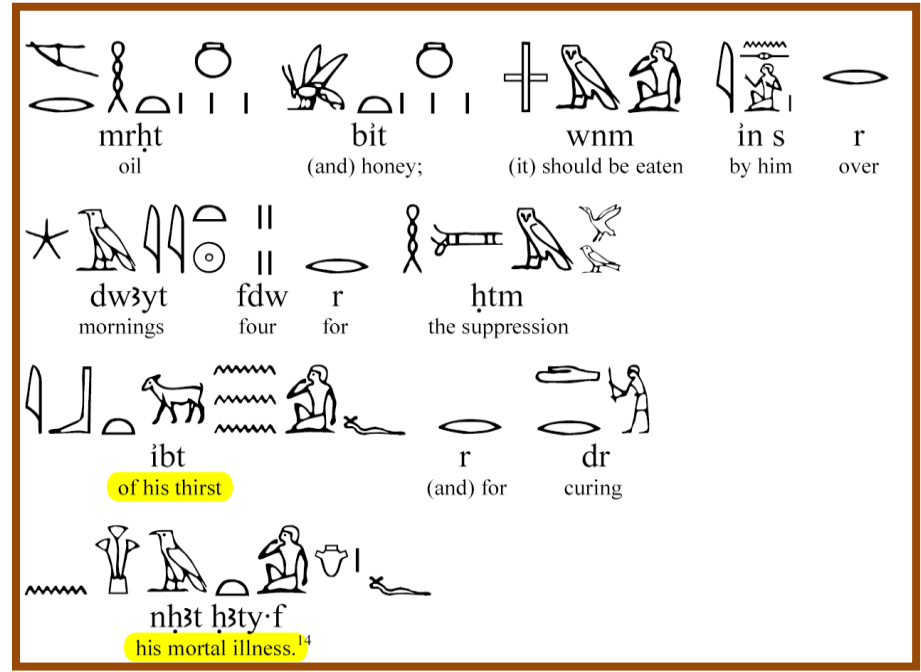
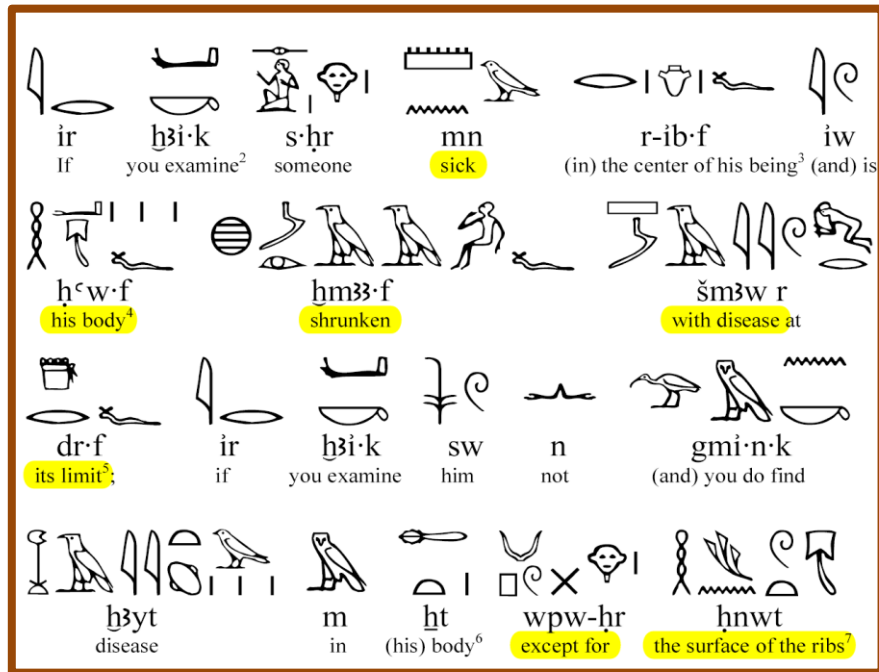
**Lessons learned through time:  
“Diet and Exercise Are Essential”**







# Ebers Papyrus the 1<sup>st</sup> reference for Diabetes 1550 BC



If you examine someone mortally ill (and) his body is shrunk with disease *in extremis*; if you examine him (and) you do not find disease in his body except for the surface of the ribs, the members of which protrude like pills; **you should then recite** (a spell against) this disease in your house; **you should (also) then prepare for him ingredients for treating it**: blood stone of Elephantine, ground; red grain; carob; cook in oil (and) honey; it should be eaten by him over four mornings for the suppression of his thirst and for curing his mortal illness.



Ebers Papyrus the 1<sup>st</sup> reference for Diabetes 1550 BC



# Foot facts

- People with diabetes are 25 times more likely to lose a leg than people without the condition
- Throughout the world, up to **70% of all leg** amputations happen to people with diabetes

# Foot facts

- In developed countries one in every six people with diabetes will have an ulcer during their lifetime
- In developing countries, foot problems related to diabetes are thought to be even more common



# THE LANCET

Volume 366 Number 9498 Pages 1673-750 November 12-18, 2005

[www.thelancet.com](http://www.thelancet.com)

"Every 30 seconds a lower limb  
is lost somewhere in the world  
as a consequence of diabetes."

See [Review](#) page 1719

Every 20 seconds...?

## Articles

SIDESTEP: ertapenem for  
diabetic foot infections  
See page 1696

## Articles

Wound therapy after diabetic  
foot amputation  
See page 1704

## Articles

Skin microcirculation and  
muscle metabolism of  
diabetic foot  
See page 1711

## Review

Treatment of diabetic  
foot ulcers  
See page 1725

## Review

Wound healing in  
diabetic foot  
See page 1736

£5.00 Registered as a newspaper. ISSN 0140-6736  
Founded 1823. Published weekly







IWGDF Steering Committee 1997



## IWGDF Editorial Board 1997





# International Consensus on the Diabetic Foot

*by the International Working Group on the Diabetic Foot*

1999



100.000

Copies

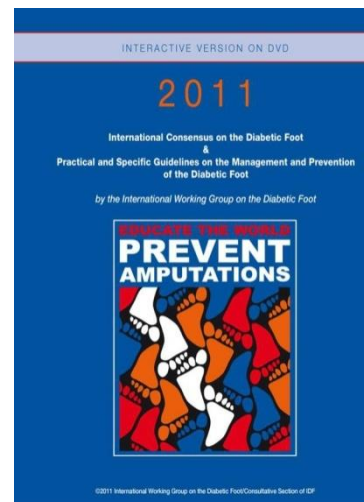
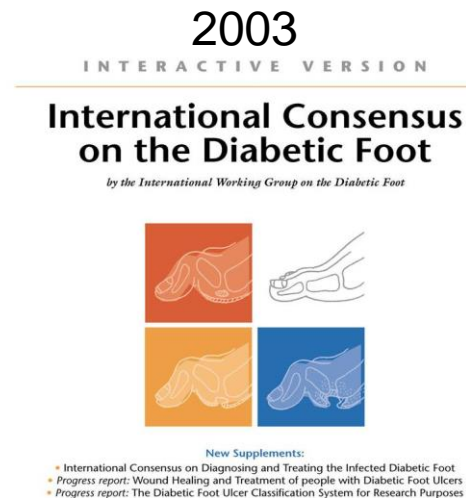
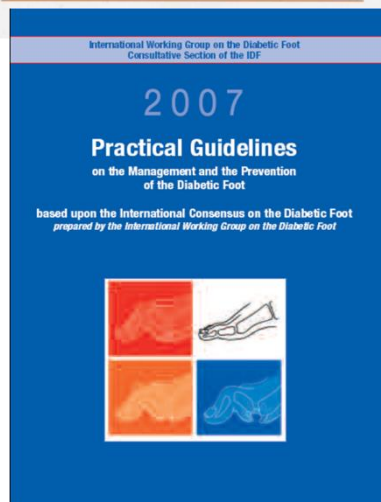
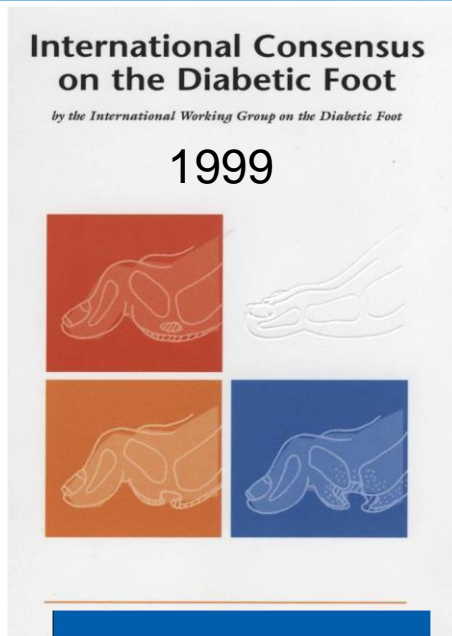


## 26 Translations



# IWGDF Guidelines 1999-2011

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**7th International  
symposium on the  
diabetic foot**

**Save the date!**  
**May 20 – 23, 2015**

**World Forum - The Hague - The Netherlands**

Come and join this large International scientific meeting on lower extremity problems in diabetes. Meet your colleagues from all over the world and let renowned experts bring you up to date with the latest developments and innovations.

The former  
"Noordwijkerhout"  
symposium



[www.diabeticfoot.nl](http://www.diabeticfoot.nl)



IWGDF

# Stakeholders meeting Amsterdam 1-2 November 2013

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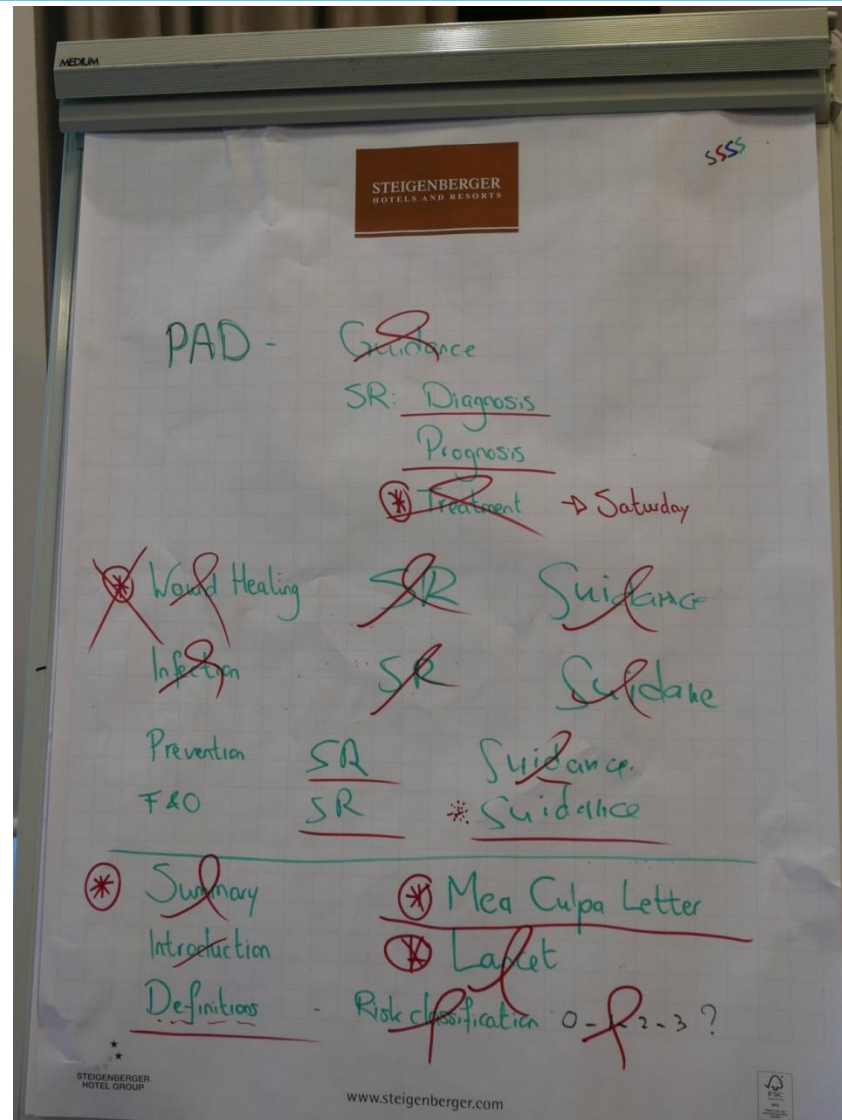
# Editorial Board 2015

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# Struggling

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IWGDF

# IWGDF Guidance 2015 development

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- 5 IWGDF working groups
  - 49 specialists in the field
  - corresponding members
  - from US, South America, Asia, Australia and Europe
  - 15 meetings in 18 months
-

- Methods
    - From Practical Guidelines to Guidance
    - 2007 and 2011:
      - based on systematic reviews and expert opinion
    - 2015:
      - all systematic reviews updated
      - new addition: recommendations formulated based on the GRADE system
-



- Seven systematic reviews
    - Clear search strategy
    - Titles, abstracts and full text articles screened by two independent reviewers
    - Inclusion based on pre-defined criteria
      - People with diabetes
      - No case reports or expert opinion
    - Included articles
      - Assessed by two independent reviewers
      - Authors were not involved in discussion of their own articles
      - Assessed for level of evidence, quality, risk of bias, and outcomes
-

- Seven systematic reviews
  - Assessment of quality of the evidence
  - Grading of Recommendations Assessment and Development and Evaluation (GRADE)
    - Strength of Recommendation
    - Quality of Evidence
-

## IWGDF Systematic Reviews

ID IMPLEMENTATION DAY

Identification

Prevention: n=9051  
Footwear and offloading: n=10127  
PAD: n=41543  
Infection: n=13365  
Wound healing: n=5632

Screening

Total publications screened:  
**79718**

Eligibility

Total full text publications assessed for  
eligibility:  
**1809**

Included

Total publications included for qualitative  
analysis:  
**429**

Publications included for quantitative  
analysis: n=0

- **Development** of an evidence-based global guidance
  - **Prevention** of foot ulcers in at-risk patients with diabetes
  - **Footwear and offloading** to prevent and heal foot ulcers in diabetes
  - Diagnosis, prognosis and management of **peripheral artery disease (PAD)** in patients with foot ulcers in diabetes
  - Diagnosis and management of **foot infections** in persons with diabetes
  - Interventions to **enhance healing** of chronic ulcers of the foot in diabetes
  - **Summary guidance for daily practice**
-



- GRADE
    - Strength of recommendation (strong – weak)
      - Quality of evidence
      - Balance between benefits and harms
      - Patient values and preferences
      - Resource utilization
    - Quality of Evidence (high – moderate – low)
      - Risk of bias of included studies (*i.e.: results from systematic reviews*)
      - Effect size
      - Expert opinion
-

**May 20 – 23, 2015**

**World Forum - The Hague - The Netherlands**



[www.diabeticfoot.nl](http://www.diabeticfoot.nl)



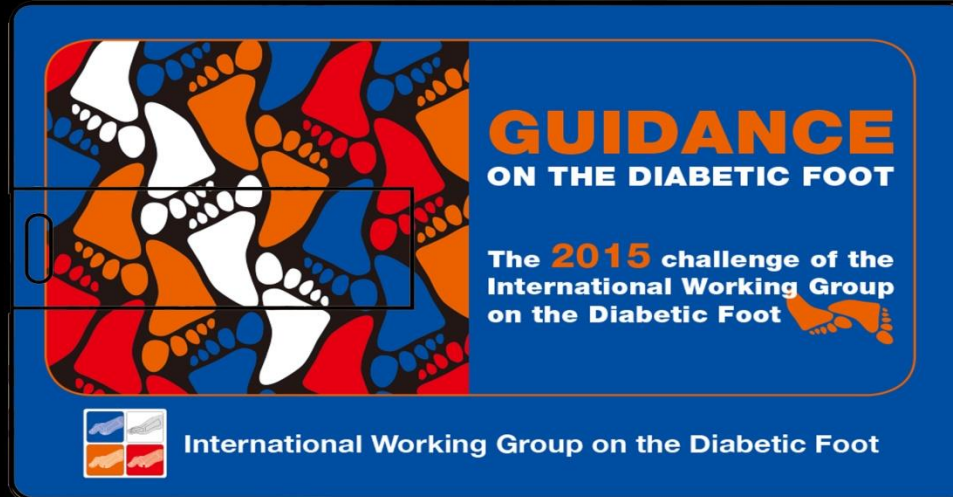


Guidance-Implementation Day  
19 May 2015, The Hague, The Netherlands

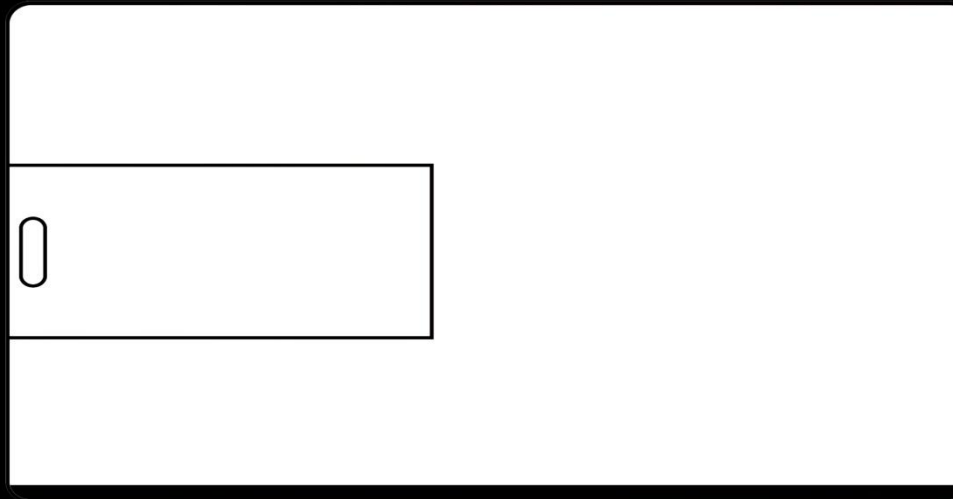
# Guidance 2015

GUIDANCE AND IMPLEMENTATION DAY

Front



Back







## Prevention and Management of Foot Problems in Diabetes Guidance Documents and Recommendations

Summary for  
Daily Practice

Guidance Documents

Definitions  
and Criteria



### **GUIDANCE** ON THE DIABETIC FOOT

The **2015** challenge of the  
International Working Group  
on the Diabetic Foot 

An interactive program on the **International Consensus on the Diabetic Foot 2015**  
Including **Summary for Daily Practice**  
a **Series of Guidance Documents** and **Definitions and Criteria**



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## Prevention and Management of Foot Problems in Diabetes Guidance Documents and Recommendations

Development of  
Guidance Documents

Summary for  
Daily Practice

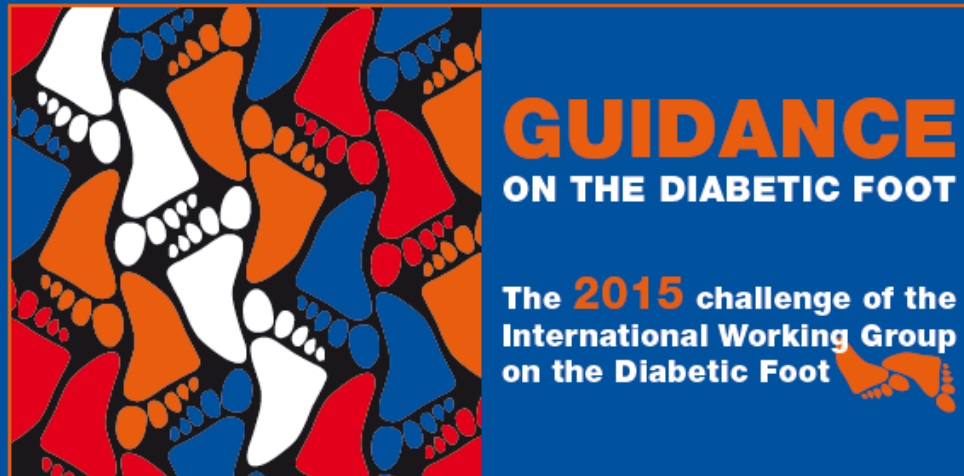
Guidance  
Prevention

Guidance  
Footwear and  
Offloading

Guidance  
Peripheral Artery  
Disease

Guidance  
Infection

Guidance  
Wound Healing



This information is linked with the International Consensus on the Diabetic Foot 2015 on the website [www.iwgdf.org](http://www.iwgdf.org). This is an interactive programme. You can choose how to access and read this information: front to back, topic by topic, on screen and on paper.



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## 13 recommendations

- Screening
- Treatment of pre-ulcers
- Prevention via footwear, education, surgery, home monitoring, integrated care

## 6 key controversies

- Evidence for screening, cost-effectiveness
  - Adherence
-



## 13 recommendations

- Casting, footwear, surgery

## 8 key controversies

- Measuring offloading, cost-effectiveness
  - Adherence
-

## 16 recommendations

- Diagnosis, prognosis, revascularisation, surgery, cardiovascular risk management

## 3 key controversies

- Endovascular vs bypass, angiosomes, when not to revascularize
-

## 26 recommendations

- Diagnosis, osteomyelitis, assessment, microbiology, surgery, antimicrobial treatment

## 7 key controversies

- Duration of antibiotic treatment, medical vs. surgical
-



## IWGDF Guidance on the diagnosis and management of foot infections in persons with diabetes

Prepared by the IWGDF Working Group on Foot Infections

### Recommendations

### Introduction

### Pathophysiology

### Diagnosis and Classification

### Soft tissue infection

### Osteomyelitis

### Assessing severity

### Microbiological considerations

### Treatment

### Key Controversies

### References

### Systematic review

**Figure 1:** Technique of percutaneous bone biopsy of the foot



Divide specimen for:  
- Microbiology  
- Histopathology

**Note:** May be done at bedside, in a radiology suite or in the operating theatre. If needed, can use fluoroscopic or computed tomographic guidance. If bone core obtained, send to microbiology for aseptic division with one piece for culture and the other sent to histopathology.

(Photographs courtesy of Dr E. Beltrand, Orthopedic Surgery Department, Dron Hospital, Tourcoing France)

Ideally, the bone specimen should be processed for both culture and histopathology. Infected bone usually has inflammatory cells (granulocytes early and mononuclear cells later), while the histomorphology of uninfected bone is normal in diabetic patients, including those with neuropathy or peripheral arterial disease (112,113). Work by one group has suggested that histopathology examination may help to define three types of DFO: (1) acute, defined by necrosis and infiltration of polymorphonuclear granulocytes in cortical and medullary sites, usually associated with congestion or thrombosis of small vessels; (2) chronic, characterized by destroyed bone and infiltration of lymphocytes, histiocytes or plasma cells; and, (3) acute exacerbation of chronic osteomyelitis, with a background of chronic osteomyelitis with infiltration of polymorphonuclear granulocytes (114). However, we need further evaluation of these findings from other groups. The concordance among several pathologists in diagnosing DFO in bone samples was found to be low in one study, but this may have been related to a lack of







IWGDF Working Group  
Woundhealing

Our opinion, based on 7 systematic reviews and GRADE-ing the evidence:

- Good quality care by trained and dedicated professionals is more important than wound healing products
-

## Key unresolved issues

- Low evidence
- What is the outcome measure of choice?
- Very few data on effectiveness and cost-effectiveness

## Other aspects

- For wound products to target the market, they need to be safe, not effective; this creates an “overdose” of products, rather than superior products

## Conclusion

- We do not know what wound healing products work, despite other messages
-

## 9 recommendations

- Clean ulcers regularly with clean water or saline, debride them when possible in order to remove debris from the wound surface and dress them with a sterile, inert dressing in order to control excessive exudate and maintain a warm, moist environment in order to promote healing. (Strong; Low)
  - In general remove slough, necrotic tissue and surrounding callus with sharp debridement in preference to other methods, taking relative contra-indications such as severe ischemia into account. (Strong; Low)
  - Select dressings principally on the basis of exudate control, comfort and cost. (Strong; Low)
  - Do not use antimicrobial dressings with the goal of improving wound healing or preventing secondary infection. (Strong; Moderate)
  - Consider the use of systemic hyperbaric oxygen therapy, even though further blinded and randomised trials are required to confirm its cost-effectiveness, as well as to identify the population most likely to benefit from its use. (Weak; Moderate)
-



- Topical negative pressure wound therapy may be considered in post-operative wounds even though the effectiveness and cost-effectiveness of the approach remains to be established. (Weak; Moderate)
  - Do not select agents reported to improve wound healing by altering the biology of the wound, including growth factors, bioengineered skin products and gases, in preference to accepted standards of good quality care. (Strong; Low)
  - Do not select agents reported to have an impact on wound healing through alteration of the physical environment, including through the use of electricity, magnetism, ultrasound and shockwaves, in preference to accepted standards of good quality care. (Strong; Low)
  - Do not select systemic treatments reported to improve wound healing, including drugs and herbal therapies, in preference to accepted standards of good quality care. (Strong; Low)
-

A summary with the most important aspects of diabetic foot care, based on the five guidance documents

- 5 cornerstones of prevention
- Description of standardized assessment
- 5 principles of treatment
- 3 levels of multidisciplinary care

To be used as a “quick guide to the diabetic foot”

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## Prevention and management of foot problems in diabetes: a Summary Guidance for daily practice 2015, based on the IWGDF Guidance documents

Introduction

Foot problems in diabetes

Pathophysiology

Cornerstones of prevention

Foot ulcers

Ulcer treatment

Principles of ulcer treatment

Organization

References

Addendum

*Figure 2: Areas at risk for foot ulceration*



### 2. Regular inspection and examination

All people with diabetes should have their feet examined at least once a year to identify those at risk for foot ulceration. Patients found to have a risk factor should be examined more often, based on their IWGDF risk category (Table 1).

The absence of symptoms in a person with diabetes does not exclude foot disorders; they may have asymptomatic neuropathy, peripheral artery disease, pre-ulcerative signs or even an ulcer. The clinician should examine the feet with the patient both lying down and standing up, and should also inspect their shoes and socks. Inspection and examination should minimally consist of:

#### History and foot examination:

- History: Previous ulcer/amputation, end stage renal disease, previous foot education, social isolation, poor access to healthcare, bare-foot walking
- Vascular status: History of claudication, rest pain, palpation of pedal pulses
- Skin: Callus, colour, temperature, oedema
- Bone/joint: Deformities (e.g., claw toes, hammer toes) or bony prominences, limited joint mobility
- Footwear/socks (worn when at home and when outside): Assessment of both their inside and outside



Definitions and criteria		
Vascular	Rest pain:	Severe and persistent pain localized to the foot due to peripheral artery disease, that can, at least partially, be relieved by putting the foot in a dependent position.
	Angioplasty:	The technique to re-establish the patency of an artery by percutaneous transluminal or subintimal procedures.
Ulcer	Superficial ulcer:	Full thickness lesion of the skin not penetrating any structure deeper than the dermis.
	Deep ulcer:	Full thickness lesion of the skin penetrating below the dermis to subcutaneous structures, such as fascia, muscle, tendon or bone.
Infection	Infection:	A pathological state caused by invasion and multiplication of microorganisms in tissues accompanied by tissue destruction or a host inflammatory response.
	Superficial infection:	An infection of the skin not extending to any structure below the dermis.
	Deep infection:	An infection that extends deeper than the dermis, that may include evidence of abscess, septic arthritis, osteomyelitis, septic tenosynovitis or necrotizing fasciitis.
	Cellulitis:	An infection of the skin manifested by one or more of the following signs and symptoms: induration, erythema, warmth, pain or tenderness.
	Osteitis: Osteomyelitis:	Infection of the bone cortex without involvement of bone marrow. Infection of the bone, with involvement of the bone marrow.
Amputation	Amputation:	Resection of a segment of a limb through a bone.
	Disarticulation:	Resection of a limb through a joint.
	Major amputation/ disarticulation:	Any resection proximal of the ankle.







Launch of the Guidance 2015 to Dr Kristien van Acker  
World Forum, The Hague 23 May 2015

# IWGDF website

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## International Working Group on the Diabetic Foot

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### Home



*Photo by Jesper Westley*

It is estimated that in 2013 approximately 382 million people have diabetes – 8.3% of the world's population. Around 80% of these people live in developing countries. By 2030, the global estimate is expected to rise to over 552 million – 9.9 % of the adult population. Every 20 seconds a lower limb is lost to diabetes somewhere in the world.

#### Links

- [Frequently asked questions](#)
- [Copyright & Disclaimer](#)
- [Future meetings](#)
- [Foot notes](#)

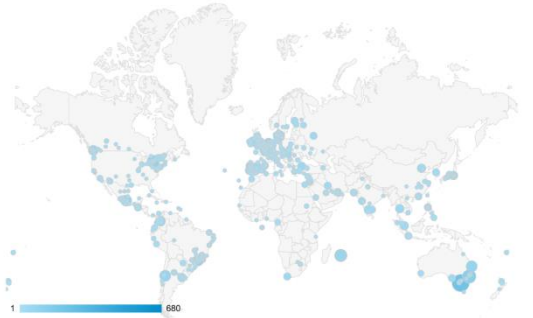
#### Latest news

- [Newsletter November 2014](#)
- [Newsletter June 2014](#)
- [Newsletter March 2014](#)
- [Newsletter November 2013](#)
- [Newsletter July 2013](#)

#### Receive our newsletter

Email address:

Since we started analyzing the data in November 2013, 10.629 readers have visited the website until October 2014. Even more interesting is the fact that every visitor, on average, reads almost four pages. This makes for a total page view count of almost 40.000. On average, each IWGDF.org visitor spends nearly four and a half minutes on the website, of which we are very proud.









Thank you  
very much