International Perspectives on Treatment of the Diabetic Foot—A Walk Across the World

The Diabetic Foot in South America—The Brazilian Experience

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Disclosures:

- Board member: Sanofi Aventis
- Speaker’s bureau: Boeringher-Ingelheim, Eli-Lilly, Mantecorp, Merck, MSD, Sanofi-Aventis
- Research support: Sanofi-Aventis

Disclose no conflict of interest for this presentation
Map 4.5 Prevalence* (§) estimates of diabetes (20-79 years), 2015

29.6 mi – 2015
48.8 mi – 2040
60% increase
Honduras – 12.2% (prevalence)
Brazil 14.3 million
What about the diabetic foot?

Data in SACA developing countries

- Only regional data on amputations, ulcers, costs
- Hospital beds are taken by foot problems: socio-economical problem
- Health systems: coverage is incomplete for the total population

The Brazilian Experience

Where we were, in the “ninities” and early “2000’s”?
1990’s: Depressing situation in Brazil

- Low interest in diabetic foot problems
- Lack of national data on amputations, ulcers, costs
- Foot care: restricted to surgical interventions (vascular, orthopedist)
- NO foot clinic specialists
- Scarce foot material to exam and wound care
- NO podiatrists

Prof Andrew Boulton, International Consultant
1st visit to Brazil – 1991

Links initiated with:
- The Royal Infirmary, University of Manchester, UK
- The University of Texas, USA – Dr Lawrence Harkless
An approach to introduce DF care to the hospital endocrine team was started.

The beginning of the Save the Diabetic Foot Project: main targets

1. To train health professionals on to exam and care of DF
2. To set up a specialist foot clinic
3. To get the policymakers aware of cost x benefit of a standard care by a team

Spread of news in Brasília and Brazil

The diabetic foot in South America: progress with the Brazilian Save the Diabetic Foot Project

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¹Centro de Pé Diabético do Distrito Federal e Fundação de Ensino e Pesquisa em Ciências da Saúde, Secretaria de Estado de Saúde do Distrito Federal, Brasília, Brazil; ²Universidade Católica, Brasília, Brazil; ³Manchester Royal Infirmary, Manchester, UK
**First step: Opening of an outpatient clinic**

**“Team” in 1992:**
1. Diabetologist-endocrinologist
2. Nurse / Nurse aid (helper)
3. Social worker

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**Table III: The hospital teams in 1992 vs. 2002.**

<table>
<thead>
<tr>
<th></th>
<th>1992</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetologist</td>
<td>Diabetologists(^a)</td>
<td>Infectious disease specialist(^a)</td>
</tr>
<tr>
<td>Nurse and nurse aid (helpers)</td>
<td>Nurses and nurse aid (helpers)</td>
<td>Social worker(^a)</td>
</tr>
<tr>
<td>Social worker</td>
<td>Vascular surgeon(^b)</td>
<td>Physiotherapist(^b)</td>
</tr>
<tr>
<td></td>
<td>Orthotists(^d)</td>
<td>Orthopedist(^d)</td>
</tr>
<tr>
<td></td>
<td>Psychiatrist(^d)</td>
<td>Dermatologist(^e)</td>
</tr>
<tr>
<td></td>
<td>Plastic surgeon(^e)</td>
<td>Physiatrist(^e)</td>
</tr>
</tbody>
</table>

\(^a\)Daily, \(^b\)four times a week, \(^c\)twice a week, \(^d\)once a week, \(^e\)available at different units.
Orthesists and nurses at Sala Prof Andrew Boulton
Trends towards amputation reduction

Amputation reduction: 77.8%

Second step: Organization of care

- Set up: Reference and counter-reference system
- Integration with primary care

Pedrosa HC, Novaes C, Leme LAP, Boulton AJM. International Diabetes Monitor 16; 11-17, 2002.
Brazilian validated monofilament: a tool taken from the Leprosy Program

Monofilaments (Leprosy kit)

* Manufactured by SORRI®
  (non-profit organization in São Paulo)
  www.sorri-bauru.com.br

Orange color – 10 g Monofilament
  (Diabetes kit)

Carville link

IWGDF - Practical Guidelines: pilot screening implementation

$N = 302 / 367$

- **Set A**
  - Hospital = 57.7%
  - (60/104)

- **Set B**
  - Health centre = 10.3%
  - (10/106)

- **Set C**
  - Senate = 7.6%
  - (07/92)

IWGDF – Links with Prof Karel Bakker

Brazilian version of International Consensus*
Launched at 13th Congress of the Brazilian Diabetes Society (SBD), 10-14 Oct 2001
Rio de Janeiro

*4.000 issues

Support: Ministry of Health – Dr Laurenice Pereira Lima (in memoriam)
SBD - Brazilian Diabetes Society, IWGDF – Dr Nicolaas Schaper
Local academic and international links

2001 - 2004

- Medical Course – FEPECS (Brasília)
- Catholic University – Physiotherapy Course (Brasília)
- University of Texas – Dr David Armstrong
- Veterans Hospital – Dr Robert Frykberg
- ALAD (Latin American Diabetes Association, GLEPED* was founded in São Paulo, 2004)

*GLEPED – Grupo Latinoamericano de Pé Diabético
Medical students at the DF Centre

*discovery*: feet are important!

FEPECS – ESCS: Medical graduation course
Brasília, 2002-2004
Data emerge on the amputation and impact of DF clinics in the country
Data from Rio de Janeiro: 1st amputation level (most above knee)

Brazilian Save the Diabetic Foot Project

Full support of Ministry of Health to workshops:


60 DF outpatients clinics

Pedrosa HC, Novaes C, Leme LAP, Boulton AJM. International Diabetes Monitor 16; 11-17, 2002.
The Brazilian Project inspires the Step by Step Program and reaches IDF through Karel Bakker and IWGDF
Step by Step philosophy:

Minimal – Intermediate – Maximal (Excellence)

- “TIME TO ACT”, 2005
- IDF Document: www.idf.org
IDF | IWGDF - World Diabetes Day 2005
Global Conference in Brazil

- Congress of the Brazilian Diabetes Society (SBD), Salvador - 2005

  - Brazil’s mail: launches a seal and stamp to celebrate the WDD

  - Ministry of Health: delivers a “Portaria” (Ordinance) to set up a Diabetic Foot Task Force (only two meetings occurred...)
Seal and stamp: Celebrating 2005 WDD

Dr Rhys Williams (IDF)

More data on DF from national studies

- Registration of foot exam: PDN and PAD
- Costs

Support of SBD, Universities and CNPq*
CNPq* - National Research Council
## Type 2 DM patients in the target: Screening of diabetic complications*

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Foot exam*</td>
<td>58.2% (1.300)</td>
<td></td>
</tr>
<tr>
<td>Eye exam*</td>
<td>46.9% (1.047)</td>
<td></td>
</tr>
<tr>
<td>Microalbuminuria*</td>
<td>38.9% (869)</td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td>54.5% (1.216)</td>
<td></td>
</tr>
</tbody>
</table>

* Evaluation in the previous year – in 14 centres

Multicentric study: Type1DM complications

Mean incomplete data = 15%
DF exam: highest incomplete registration = 37%

* N = 3,180 patients, 28 Centers, 20 cities, Age = 22 ± 11.8 yrs, 56.3% F, 57.4% caucasians

<table>
<thead>
<tr>
<th>Prevalence Type2DM</th>
<th>7.12 million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ulcers</td>
<td>6.8% - 484.569</td>
</tr>
<tr>
<td>Hospital admission</td>
<td>35% - 169.569</td>
</tr>
<tr>
<td>Amputation</td>
<td></td>
</tr>
<tr>
<td>- Maior</td>
<td>44.2% - 35.751</td>
</tr>
<tr>
<td>- Minor</td>
<td>55.8% - 45.133</td>
</tr>
<tr>
<td>Death</td>
<td>12.8% - 21.705</td>
</tr>
</tbody>
</table>

# Diabetic foot costs in Brazil-SUS: based on 2015 DM IDF and cumulative inflation*

<table>
<thead>
<tr>
<th>Hospital admission for amputation (total estimated cost**)</th>
<th>US$ 175,958,000,00 million</th>
<th>R$ 707,453,964,00 million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital admission for diabetic foot ulcer (total estimated cost**)</td>
<td>US$ 370,476,000,00 million</td>
<td>R$ 1,489,530,000,00 billion</td>
</tr>
</tbody>
</table>

*Cumulative inflation 2006 – 2015 = 59%
Real vs US dollar = 28/may/2016

** Based on IDF estimates of diabetes in Brazil for 2015: 14,000,000 million people

Other achievements in the past 6 years
Screening provision material: donated by SBD (Brazilian Diabetes Society)

- 10g Monofilaments - 1,000 units
- Hand Pocket Foot Exam (ADA-SBD translation into Portuguese)* - 5,000 prints
- SISPED**: data collection system
- BrasPEDI*** files: clinical care organization
- Brazupa (study on PDN and DF)

*Thanks to Drs L. Lavery and D. Armstrong for the help

**SISPED – Save the Diabetic Foot System
***BrasPEDI – Brazilian Diabetic Foot Group
**CLASSIFICAÇÃO DE RISCO E REFERÊNCIA / SEGUIMENTO**

<table>
<thead>
<tr>
<th>Nível de risco</th>
<th>Definição</th>
<th>Recomendações de Tratamento</th>
<th>Recomendações de Seguimento</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Sem PSP, Sem DAP</td>
<td>Proporcionar educação para o paciente</td>
<td>Anualmente, por médico generalista ou especialista</td>
</tr>
<tr>
<td>1</td>
<td>PSP ≤ Deformidade</td>
<td>Considerar o uso de sapatos especiais</td>
<td>A cada 3 a 6 meses, por médico especialista</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Considerar cirurgia profilática se a deformidade não puder ser acomodada com segurança nos sapatos. Continuar a educação do paciente</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>DAP ≤ PSP</td>
<td>Considerar o uso de sapatos especiais</td>
<td>A cada 2 ou 3 meses, por médico especialista</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Considerar consulta com especialista vascular para seguimento conjunto se DAP estiver presente</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>História de úlcera ou amputação</td>
<td>Considerar o uso de sapatos especiais</td>
<td>A cada 1 ou 2 meses, por médico especialista</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Considerar consulta com especialista vascular para seguimento conjunto se DAP estiver presente</td>
<td></td>
</tr>
</tbody>
</table>

PSP = Porção de Sensibilidade Protetora  
DAP = Doença Arterial Periférica

**O EXAME DO PÉ DIABÉTICO**

1. **TESTE DE MONOFILAMENTO DE SEMMES-WEINSTEIN**
2. **CÁLCULO DO ÍNDICE TORNOLEZO-BRAÇO (ITB)**

**AVAILAÇÃO**

- História do paciente
  - Ulceração prévia nos pés
  - Amputação prévia
  - Diabetes > 10 anos
  - A1C ≥ 7%
  - Visão comprometida
  - Sintomas neuropáticos
  - Claudicação

- Exame dermatológico
  - Pele seca
  - Ausência de pelos
  - Unhas incravadas ou ponteagudas
  - Massuração interdigital
  - Ulceração

- Rastreamento para neuropatia
  - Monofilamento Semmes-Weinstein (10g)
  - Perda de percepção em um ou mais locais de teste
  - Limiar de percepção vibratória
  - Limite de percepção vibratória > 25 volts
  - Diapason (128 Hz)
  - Percepção vibratória anormal

- Avaliação vascular
  - Palpação dos pulsos podolso dorsal e tibial posterior
  - Pulsos ausentes
  - Índice tornozele-braço (ITB)
  - ITB < 0,30 é consistente com doença arterial periférica

- Avaliação biomecânica do pé
  - Flexão plantar ou dorsiflexão do tornozele e halux (bilateralmente)
  - Mobilidade articular diminuída
  - Observar a desamputação do paciente
  - Visão diminuída, marcha alterada, necessidade de órteses
  - Inspeção dos sapatos do paciente
  - Os sapatos ajustam-se mal aos pés do paciente
  - Inspeção das deformidades
  - Incapacidade do paciente de ver e alcançar os pés
  - Cravos, calosidades, halux valgus
  - Cabeças de metatarsos prominentes
  - Dedo em martelo, em jarra

**Educação do Paciente**

Instruir o paciente sobre os seguintes aspectos:
- Calçados apropriados e não andar descalço, mesmo dentro de casa
- Inspeção diária dos pés – observar o espaço entre os dedos e a planta dos pés
- Informar imediatamente a ocorrência de qualquer lesão, descoloração ou edema dos pés

© 2008 American Diabetes Association


Traduzido e adaptado pelos Drs. Augusto Pinto et al. (SP) e Hermínia Cordeiro Pedrosa (DF). Contribuição: Dr. Fábio Batista (SP), Chacarera para uso no Brasil da Sociedade Brasileira de Diabéticos, Departamento de Pé Diabético, Diretora Dra. Hermínia Cordeiro Pedrosa. 

Neuropathy and Diabetic Foot Outpatient Clinic Program Step by Step (Passo a Passo)
Hospital: Neuropathy and Diabetic Foot Outpatient Clinic

Program Step by Step (Passo a Passo)

SBD IWGDF
Basic Care Attention: Neuropathy and Diabetic Foot Outpatient Clinic

Program Step by Step (Passo a Passo)

SBD IWGDF
Emphasis: Education on self-exam and care

And from the Ministry of Health

- National multicentric study: 12 centres
  - Epitelial Growth Factor (*Heberprot®*) Study FioCRUZ-Manguinhos (requested from ANVISA*)
  - International consultants: Drs W. Jeffcoate and F. Game (UK)
  - Target: set up a standard foot care in all centres

*ANVISA: Agência Nacional de Vigilância Sanitária*
Guidelines on Diabetic Foot 2016*
An issue to avoid failure:

Guidelines **without training** will not be effective enough!
There has been a R3 Process: Reevaluation – Reflexion – Rescue*

Where are we going?

*IDF Congress, 2009 – Rescue Project did not progress
...towards the Step by Step (SbS) Program

**SACA** Spanish

**Paso a Paso**

**SACA** Brazil

**Passo a Passo**

BrasPEDI

*South America Central America
IDF Region*
Train the Foot Trainers Course*

Brasília-Brazil
6-9 / December / 2012

Support from IDF – until 2015
Faculty and SACA Delegates

1st TtFT Course

13 countries: Argentina, Bolivia, Brazil, Chile, Colombia, Cuba, Dominicana, Equator, Mexico, Panama, Paraguay, Peru and Uruguay (59 selected DF leaders in SACA). Only Venezuela did not attend.
BrasPEDI* 

Brazilian Diabetic Foot Group

* Launched at the Train the Foot Trainers Course, Brasília, 2012
BrasPEDI – Brazilian Diabetic Foot Group

Support: Departament of Diabetic Foot
Brazilian Society of Diabetes (SBD)

* Launched at the TtFT Course, 06-09 / Dec / 2012, Brasilia, Brazil. Logo: Darlan Rosa
Joinville: 1st city to hold Basic Course (2013), Curitiba: 1st City to hold Advanced Course (2014), Goiânia, Campina Grande and Fortaleza: only Basic Course. Rio de Janeiro, Macapá and Porto Alegre: no courses held. All others had both courses.

Campina Grande, Fortaleza e Goiânia: NO Advanced Course in 2015 – explain reduction of attendance

## Where we are now?

<table>
<thead>
<tr>
<th>Centres of excellence and intermediate model</th>
<th>Brasília, Espírito Santo, Paraná, Rio de Janeiro, São Paulo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal model foot clinics and screening* in primary care</td>
<td>Brasília*, Bahia*, Ceará, Goiás, Minas Gerais, Paraná and Santa Catarina</td>
</tr>
<tr>
<td>High technology: dressings, negative pressure, HOB, reconstructive surgery</td>
<td>Available</td>
</tr>
<tr>
<td>Podology course (short duration)</td>
<td>Available in São Paulo</td>
</tr>
<tr>
<td>Insole and footwear free provision</td>
<td>Brasília, Goiás, Minas Gerais, São Paulo, Rio Janeiro, Santa Catarina</td>
</tr>
<tr>
<td>Workshops for training and update (PND, PAD, DF)</td>
<td>In the oficial scientific program of SBD Congress (since 2001)</td>
</tr>
</tbody>
</table>
What about the DF clinics?

2016 estimate: 84

SbS and IOT (SP)

Underserved regions AM, NE, CW
Main point of concern:

- **Sustainability is mandatory** for programs to survive in developing countries!

*IDF – support to SbS ended in 2015*
Conclusions

- Organization of public health system in Brazil and most SACA countries have not (adequately) considered DF a priority yet

- The *Brazilian Save the DF Project* is under a *rescue strategy* through the SbS Program

- SBD support is important, but it is not enough to lead a national DF care policy

- Sadly, the SbS has not achieved an official commitment in Brazil yet
Acknowledgments:

Andrew JM Boulton

Karel Bakker

Kristien Van Acker

All 43 collaborators: Launched in 2013-2014 4,000 issues in Brazil
Diabetic Neuropathy and Diabetic Foot Team
Unit of Endocrinology – Research Centre
FEPECS – HRT SES-DF

Brasília-DF, May 31 - 2016
Representatives to the IWGDF (International Working Group on the Diabetic Foot)

Dr Hermelinda C. Pedrosa - DF-Brasília
Dr Luiz Clemente Rolim - SP-São Paulo

SbS Brazil National Facilitators

Dr Fernanda S. Tavares - DF-Brasília
Dr Rosangela Réa - PR-Curitiba
Dr Julia Apel - SC-Joinville
Dr Geísa Macedo - PE-Recife
Nurse Soraia Rizzo - SP-São Paulo
SbS - Brazil Regional Coordinators

- Dr Regina Calsolari, Nurse Mariana Morais Silva - MG-Belo Horizonte
- Dr Helena Maria Madeira, Nurse Leila S. Sales - DF-Brasília
- Dr Cícero Fidelis, Nurse Maria Graça Velanes - BA-Salvador
- Dr Rosangela Réa, Nurse Rosangela Maria S. Ataíde - PR-Curitiba
- Dr Angela Delmira, Nurse Maria Lindomar R.Mota - CE-Fortaleza
- Dr Judith Mesquita, Nurse Cristina Pereira - GO-Goiânia
- Dr Julia Apel, Nurse Dienne Cristine Diefenbach - SC-Joinville
- Dr Geísa Macedo, Nurse Maria Socorro Bernsmann - PE-Recife
- Dr Marta Barreto, Nurse Suanny B. da Silva - PB-Campina Grande
- Dr Maria Candida Parisi | Dr Luis Clemente Rolim, Nurse Soraia Rizzo-São Paulo - SP
Thank you ! Muito obrigada !

Brasília Metropolitan Cathedral
By Oscar Niemeyer

World Diabetes Day - 2011