The research commercialisation office of the University of Oxford, previously called **Isis Innovation**, has been renamed **Oxford University Innovation**

All documents and other materials will be updated accordingly. In the meantime the remaining content of this Isis Innovation document is still valid.

URLs beginning www.isis-innovation.com/... are automatically redirected to our new domain, www.innovation.ox.ac.uk/...

Phone numbers and email addresses for individual members of staff are unchanged

Email : enquiries@innovation.ox.ac.uk

Beyond Blood Glucose/HbA1c:
Measuring the Patient's Perspective of the Benefits of Diabetes Interventions

Dr. Keith Meadows – DHP Author, Founder – DHP
February 4th, 2016

Mapi
Insight for solutions
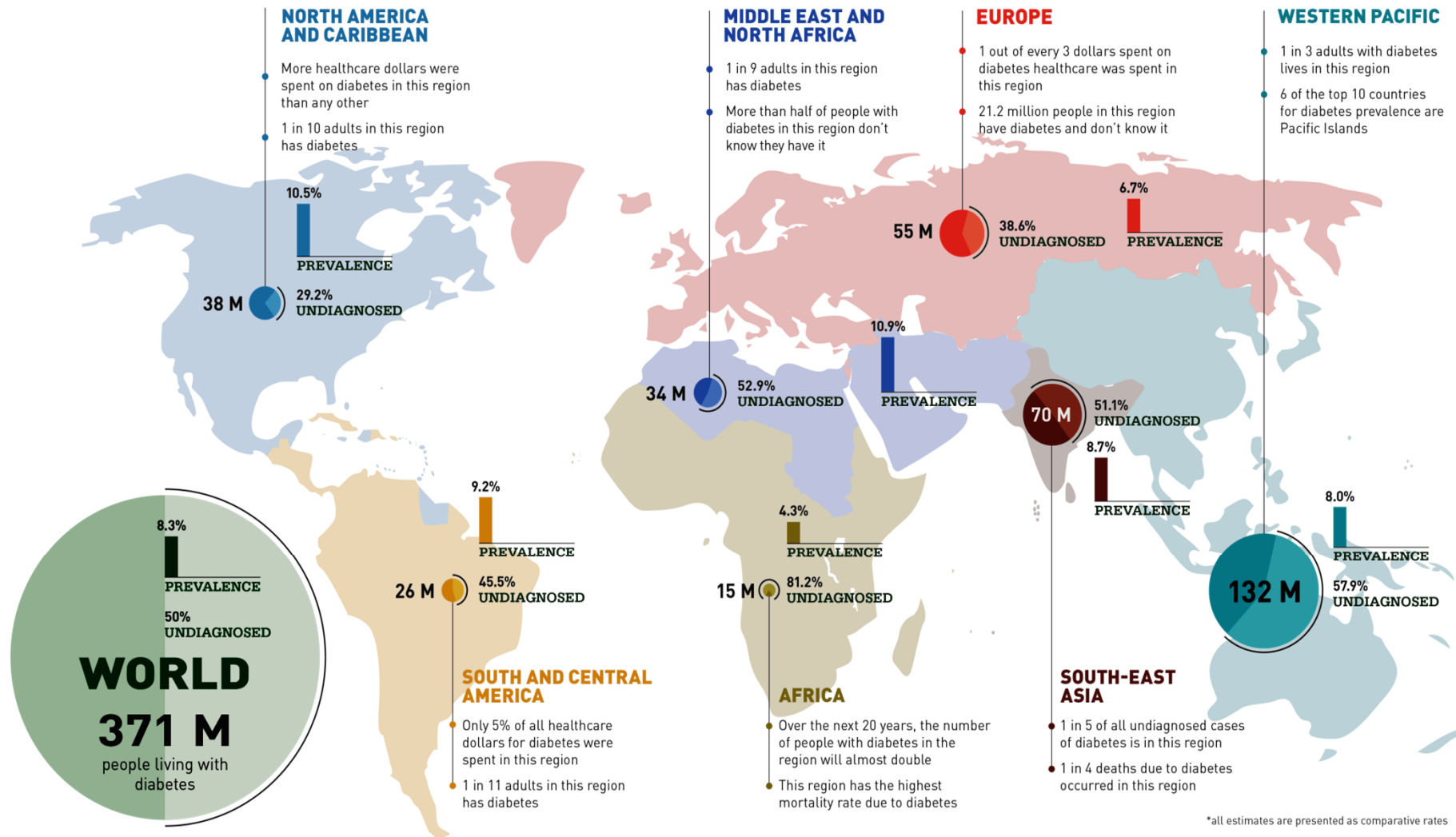
dhpresearch
Outcomes with insight

Today's Webinar Host

Dr. Keith Meadows,
BA (Hons), PhD, CMRS

Founder/Director -
DHP Research & Consultancy Ltd.

DHP Screening Tool Author -
The Diabetes Health Profile (DHP)

POST-EVENT QUESTIONS FOR THE HOST?
Email: kmeadows@dhpresearch.com

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Global Diabetes Impact – Infographic

NORTH AMERICA AND CARIBBEAN
- More healthcare dollars were spent on diabetes in this region than any other
- 1 in 10 adults in this region has diabetes

10.5%
PREVALENCE

38 M
29.2% UNDIAGNOSED

MIDDLE EAST AND NORTH AFRICA
- 1 in 9 adults in this region has diabetes
- More than half of people with diabetes in this region don't know they have it

34 M
52.9% UNDIAGNOSED
10.9% PREVALENCE

EUROPE
- 1 out of every 3 dollars spent on diabetes healthcare was spent in this region
- 21.2 million people in this region have diabetes and don't know it

55 M
38.6% UNDIAGNOSED
6.7% PREVALENCE

WESTERN PACIFIC
- 1 in 3 adults with diabetes lives in this region
- 6 of the top 10 countries for diabetes prevalence are Pacific Islands

8.0% PREVALENCE
132 M
57.9% UNDIAGNOSED

70 M
51.1% UNDIAGNOSED
8.7% PREVALENCE

8.3% PREVALENCE
50% UNDIAGNOSED
WORLD
371 M
people living with diabetes

9.2% PREVALENCE
26 M
45.5% UNDIAGNOSED

SOUTH AND CENTRAL AMERICA
- Only 5% of all healthcare dollars for diabetes were spent in this region
- 1 in 11 adults in this region has diabetes

4.3% PREVALENCE
15 M
81.2% UNDIAGNOSED

AFRICA
- Over the next 20 years, the number of people with diabetes in the region will almost double
- This region has the highest mortality rate due to diabetes

SOUTH-EAST ASIA
- 1 in 5 of all undiagnosed cases of diabetes is in this region
- 1 in 4 deaths due to diabetes occurred in this region

*all estimates are presented as comparative rates

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Diabetes in the U.K.

UK Diagnosed

2.9 million diagnosed with diabetes by 2011

Diabetes type

10% of people with diabetes have Type 1

90% of people with diabetes have Type 2

Financial costs

£192 million a week spent by the NHS

By the time you've finished boiling an egg, one more person in Britain would have been diagnosed with Diabetes.

The impact

52% Deaths due to cardiovascular disease

21% Type 1 Deaths due to kidney disease

70% Of people die within 5 years of an amputation

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Diabetes in the U.K.

The number of people in Britain suffering from Diabetes without knowing it would fill the 2012 Olympic stadium over...

6 times

In 2011, one in every 400 to 600 children were diagnosed with diabetes...

The Psychological Impact of Living with Diabetes

The facts

10% of the population in Britain have depression at any one time

However,

according to Diabetes UK, people with diabetes are **twice** as likely to experience depression...

...and the risk is higher for women than for man

"Yet there is little routine psychological support for people with diabetes."

Diabetes UK

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ANXIETY

aggression

Denial

Treatment non-adherence

Eating problems

POOR QUALITY OF LIFE

disruption to social and professional life

Diabetes-specific PROs in a Real World Setting

- Efficacy of treatment

- Need for real world data driven by changing regulatory environment, drug safety and efficacy

- Identification of factors leading to treatment non-adherence and drug ineffectiveness

- Enables clinicians to tailor treatment regimens based on patient needs

- Increase treatment adherence as part of patient support programmes

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The Diabetes Health Profile (DHP), a multidimensional, diabetes-specific (T1 and T2), patient self-report outcome measure of the psychological and behavioural impact of patients living with diabetes.

diabetesprofile
Patient research

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Provisional development of the DHP

- A review of the literature.

- In-depth interviews with 45 diabetes patients analysed using a thematic approach.

- Examination of existing instruments of psychosocial functioning.

- Discussions with health care professionals (diabetologists), Diabetes Specialist Nurse (DSN) and dieticians.

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The Conceptual Model

DHP-1 Conceptual framework

Psychological distress
- Depressed due to diabetes
- Lose temper/shout due to diabetes
- Wished dead
- Feels like crying due to diabetes
- Lose temper over small things
- Wished never born
- Touchy about diabetes
- Arguments at home
- Wish diabetes would go away
- Throw things when upset
- Lose temper over diet/testing
- Hurt self when upset
- Tension headaches
- Look forward to the future

Barriers to activity
- Days tied to meal times
- Plan days around injections
- Difficult staying out late
- Nagging fear of hypos
- Food controls life
- Edgy when out
- Worry about diabetic coma
- Avoid going too far incase of hypo
- Worry about going into hypo
- Avoid going out if sugars on low side
- Worry about colds and flu
- Difficult doing things due to diabetes
- Frightened busy/crowded shops

Disinhibited eating
- Not easy to stop eating
- Hard saying no to food
- Eat to cheer self up
- Eat extra when bored/fed up
- Wished not so many nice things to eat

DHP-18 Conceptual framework

Psychological distress
- Depressed due to diabetes
- Lose temper/shout due to diabetes
- Lose temper over small things
- Moody due to diabetes
- Lose temper over testing
- More arguements at home

Barriers to activity
- Days tied to meal times
- Food controls life
- Difficult staying out late
- Worry about colds and flu
- Get edgy when nowhere to eat
- Avoid going out when sugars are low
- Worry about going into busy shops

Disinhibited eating
- Eat to cheer self up
- Hard saying no to food
- Easy to stop eating
- Eat extra when bored/fed up
- Wish not so many nice things to eat

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The Diabetes Health Profile

	DHP-1	DHP-18
Administer	Type 1 Diabetes Individuals 16 years and older	Type 1 Diabetes Individuals 16 years and older
Reading Level	6th grade	6th grade
Scales (No of items)	Psychological distress (14) Barriers to activity (13) Disinhibited eating (5)	Psychological distress (6) Barriers to activity (7) Disinhibited eating (5)
Response options	Four-point adjectival scales	Four-point adjectival scales
Formats	Paper-and-pencil, interview	Paper-and-pencil interview, electronic hand held, tablet, IVR, web
Scoring	Items scores 0-3 in each dimension summed & transformed to produce score 0 (no dysfunction to 100)	Items scores 0-3 in each dimension summed & transformed to produce score 0 (no dysfunction to 100)
Completion time	9–12 minutes	5–6 minutes
Research & Resources	DHP manual, research support, training and workshops*	DHP manual, research support, training and workshops**
FAQs	Yes (see below)	Yes (see below)

Development of the Diabetes Health Profile

Appraisal component	DHP-1	DHP-18
Reproducibility	★	★
Internal consistency	★★	★★★
Content validity	★★★	★★★
Construct validity	★★★	★★★
Responsiveness	★	★
Interpretability	★	★
MID	0	★
Floor/ceiling effects	★★★	★★★
Acceptability	★★	★★
Feasibility	0	0
Cost utility analysis	0	★

0 Not reported   ★ Some limited evidence   ★★ Some good evidence in favour   ★★★ Good evidence in favour

Previous and Current Users of the DHP

MORE THAN
12,000
TYPE 1 & TYPE 2 RESPONDENTS
HAVE COMPLETED
THE DHP-1/DHP-18

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Typical Applications of the DHP

- Measure improvement or decline in the psychological and behavioural functioning of patients

- Screen for unmet need

- Demonstrate drug efficacy (perceived value)

- Assess treatment effectiveness

- Assess intervention programmes

- Enhance treatment adherence by improving communication between you and your patients

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Translations

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- Dutch (Belgium)
- English (Canada)
- English (USA)
- Finish
- French
- French (Belgium)
- French (Canada)
- French (Swiss)
- German

- German (Austria)
- German (Swiss)
- Hungarian
- Italian
- Italian (Swiss)
- Mandarin
- Norwegian
- Polish
- Romanian
- Turkish (German)
- Slovak
- Slovenian
- Spanish
- Spanish (USA)
- Swedish
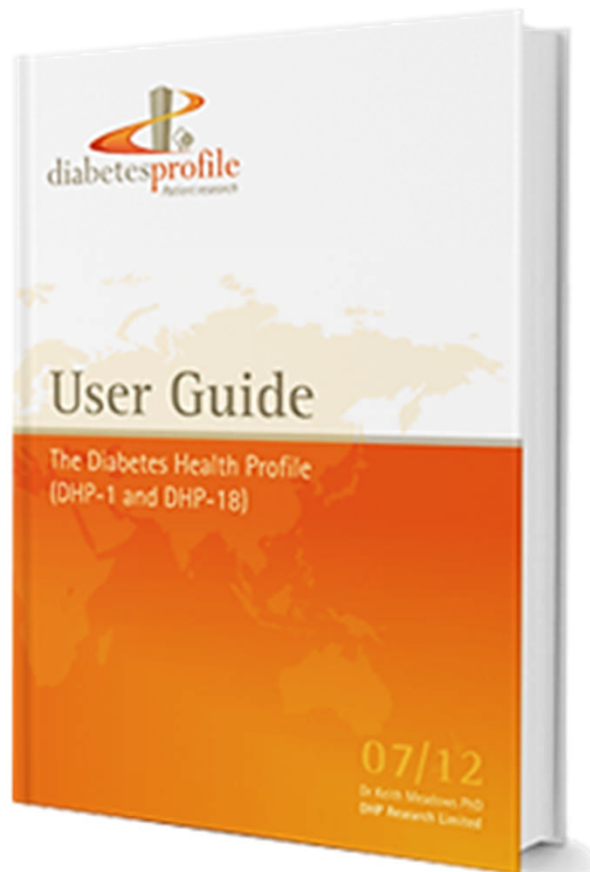
Modes of Administration
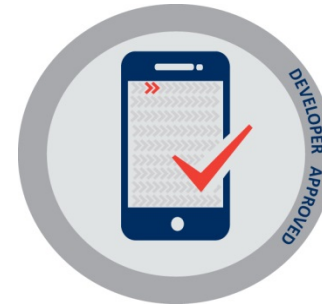
Pilot study of patient reported outcome measures (PROMs) in primary care

UK Department of Health

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DHP-18 % Response Rates

33 General practices   1121 Questionnaires (Baseline)
424 Questionnaires (Follow-up)
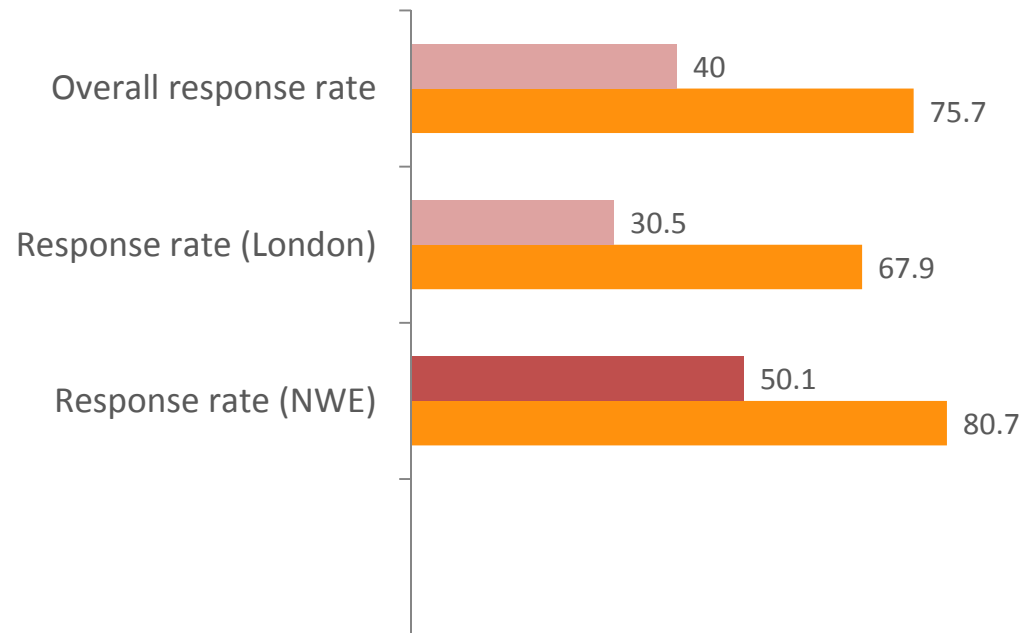
Overall response rate
- 40
- 75.7

Response rate (London)
- 30.5
- 67.9

Response rate (NWE)
- 50.1
- 80.7

Pilot study of patient reported outcome measures (PROMs) in primary care. *Report to the Department of Health.*
Michele Peters Department of Public Health University of Oxford 2013.

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Response rates by LTC

Heart failure(520) (234): Baseline 50, Follow-up 66.2
COPD(567)(262): Baseline 49.2, Follow-up 71.4
Diabetes (1121)(424): Baseline 40, Follow-up 75.7
Stroke(418)(137): Baseline 36.4, Follow-up 74.5
Epilepsy(525)(166): Baseline 34, Follow-up 74.5
Asthma (1334)(366): Baseline 30, Follow-up 73

Baseline
Follow-up

Pilot study of patient reported outcome measures (PROMs) in primary care. *Report to the Department of Health.* Michele Peters Department of Public Health University of Oxford 2013.

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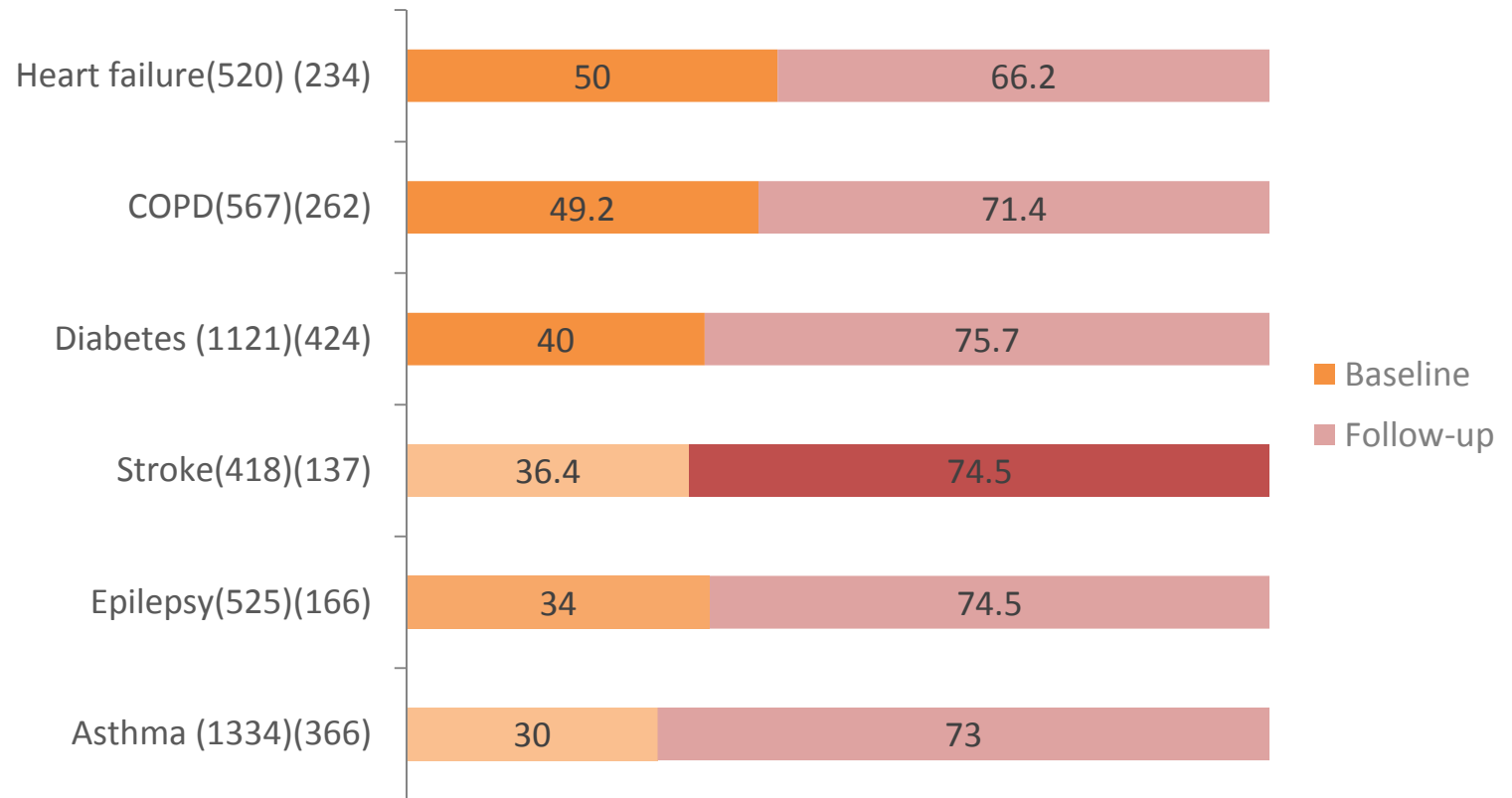
% of missing data for the EQ5D and DHP
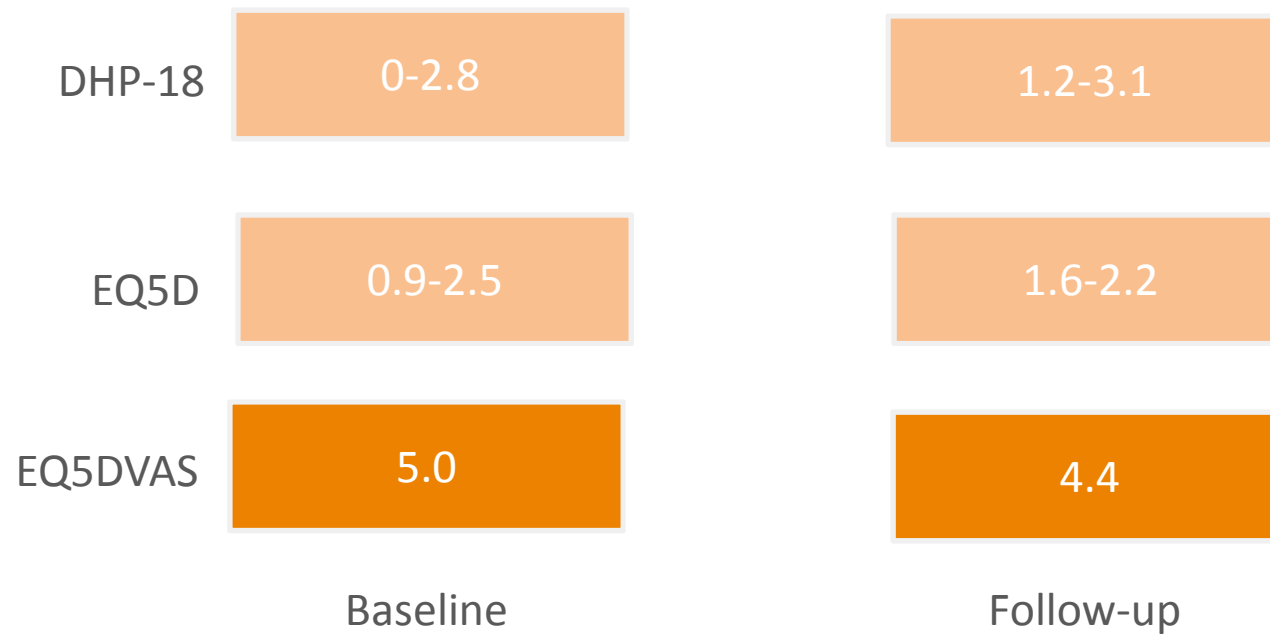
	Baseline	Follow-up
DHP-18	0-2.8	1.2-3.1
EQ5D	0.9-2.5	1.6-2.2
EQ5DVAS	5.0	4.4

Pilot study of patient reported outcome measures (PROMs) in primary care. *Report to the Department of Health.* Michele Peters Department of Public Health University of Oxford 2013.

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**What does the
Diabetes Health Profile
tell us about living with diabetes?**

Dr Keith Meadows

DHP-18 Domain scores by comorbidity

N=1802 (45% RR) TI & T2 diabetes general practice patients

DHP Score %

40

0

- Disinhibited eating
- Barriers to activity
- Psychological distress

No additional health problems — Co-morbidity — Related health problems — Related health problems & co-morbidity

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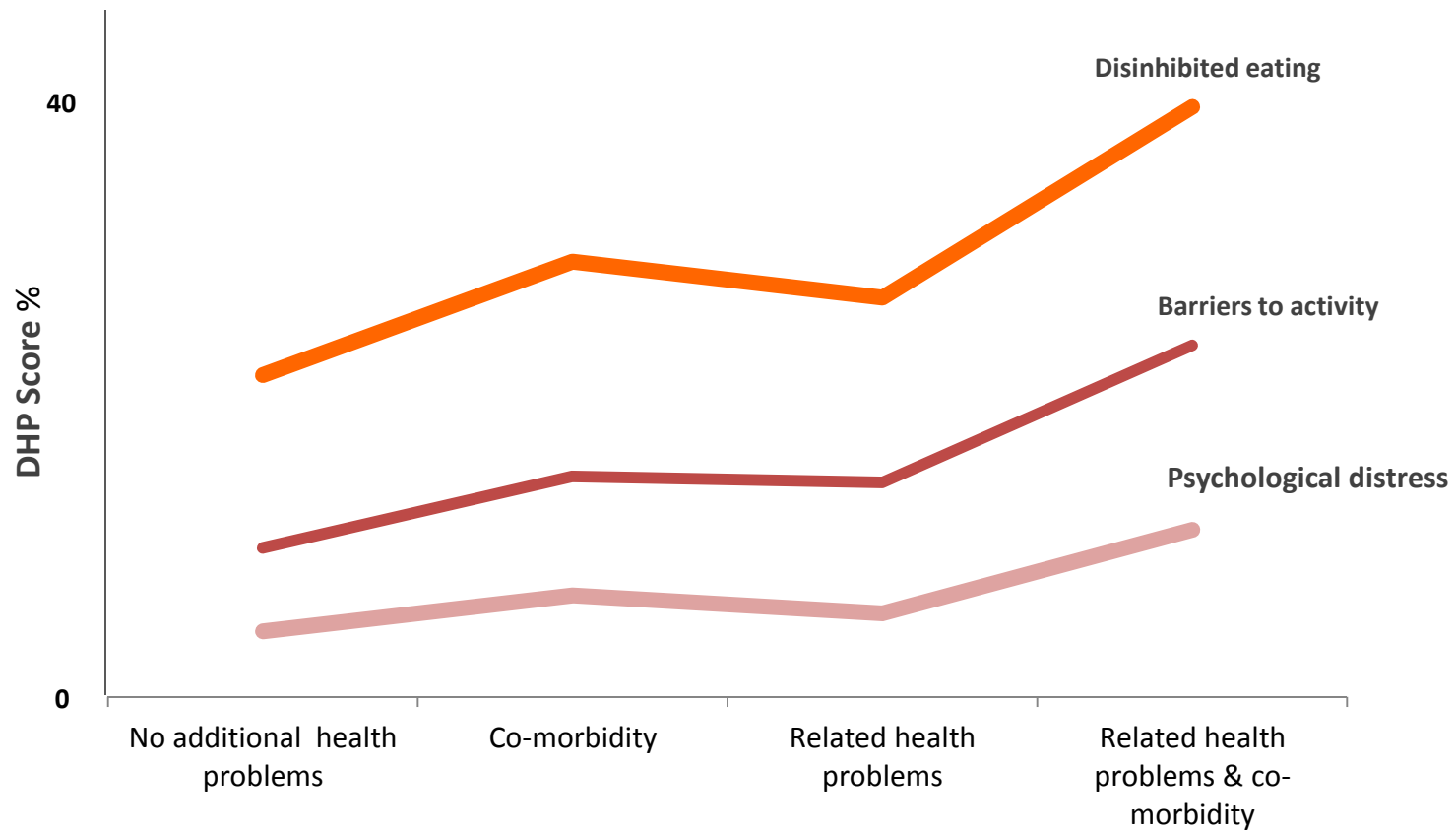
Living with diabetes:
Interpreting the Diabetes Health Profile

3173

91% Type 2 and 9% Type 1 patients completed the questionnaire.

M 55% F 45%

Mean age

63.9 years

DHP domain scores by treatment modality

- Disinhibeted eating
- Psycholigical distress
- Barriers to activity

Insulin

Oral

40 — 45 — 50 — 55 — 60

Score 0=No dysfunctioning $p < 0.05$
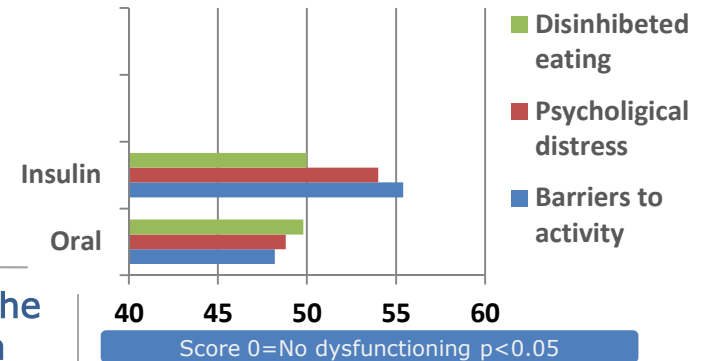
77%
Of patients experiencing three severe hypoglycaemic episodes reported their days are tied to meal times.

59%
Of patients experiencing one severe hypoglycaemic episode reported their days are tied to meal times.

Patients (mean) scores on the Disinhibited eating domain by BMI

BMI <25 → 47.8

BMI 25-34 → 49.2

BMI >35 → 52.4

Score 0=No dysfunctioning $p < 0.05$

Barriers to activity domain scores

100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%

Patients reporting severe hypoglycaemic episodes

35-44   45-54   55-64   65-74   >75
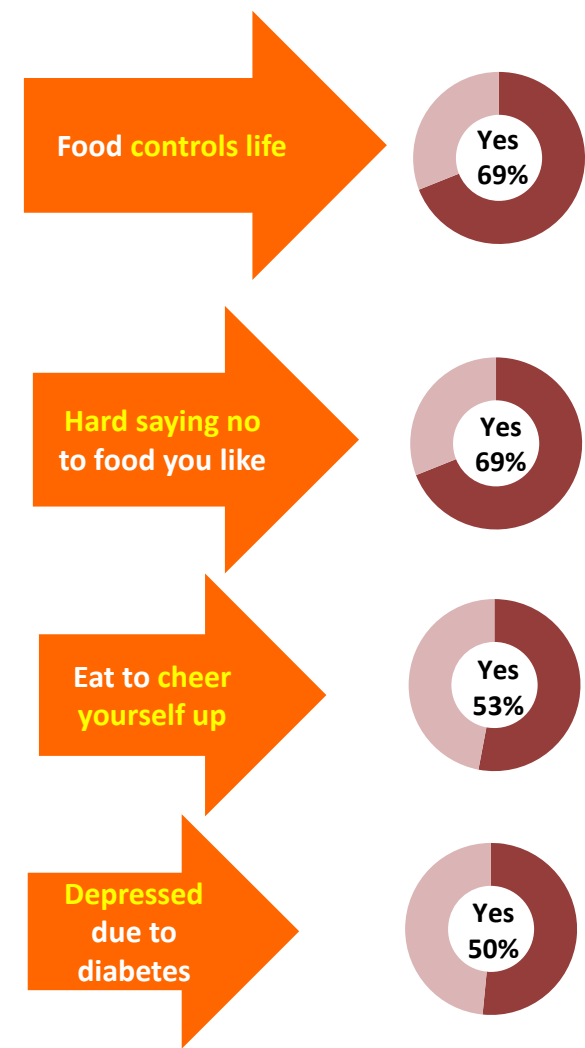
Score 0=No dysfunctioning
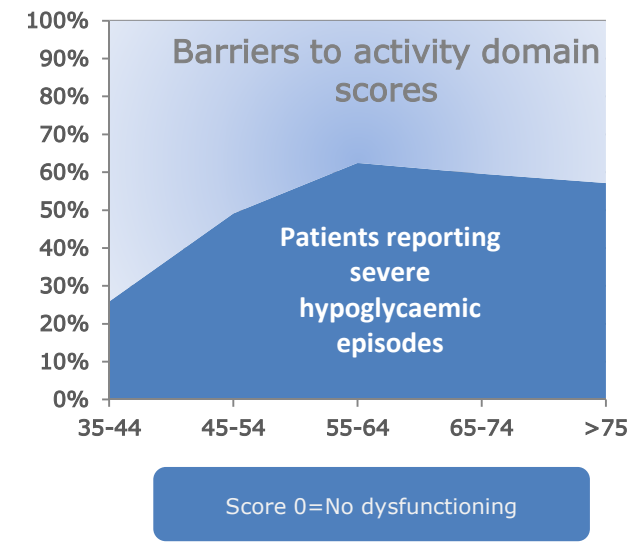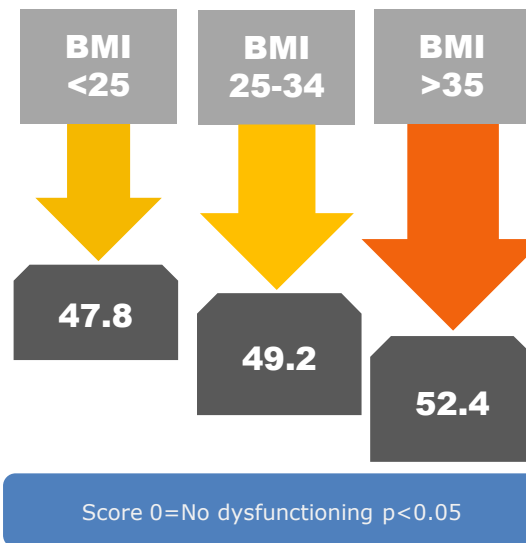
Factors associated with psychological and behavioural functioning in people with type 2 diabetes living in France. Stephanie Boini, Marie-Line Erpelding et al. Health Quality of Life Outcomes 2010, 8:124

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Getting an In-Depth Look at Diabetes with the DHP-18

Psychological distress

MOST AT RISK

- Comorbidity
- Severe hypoglycaemia
- Female
- > Age
- Visit to the psychiatrist

Barriers to activity

MOST AT RISK

- Severe hypoglycaemia
- Other health issues
- Visit to the psychiatrist

Disinhibited eating

MOST AT RISK

- Younger women
- Forgetting to take insulin
- Unaware of HbA1 level
- Visit to the psychiatrist
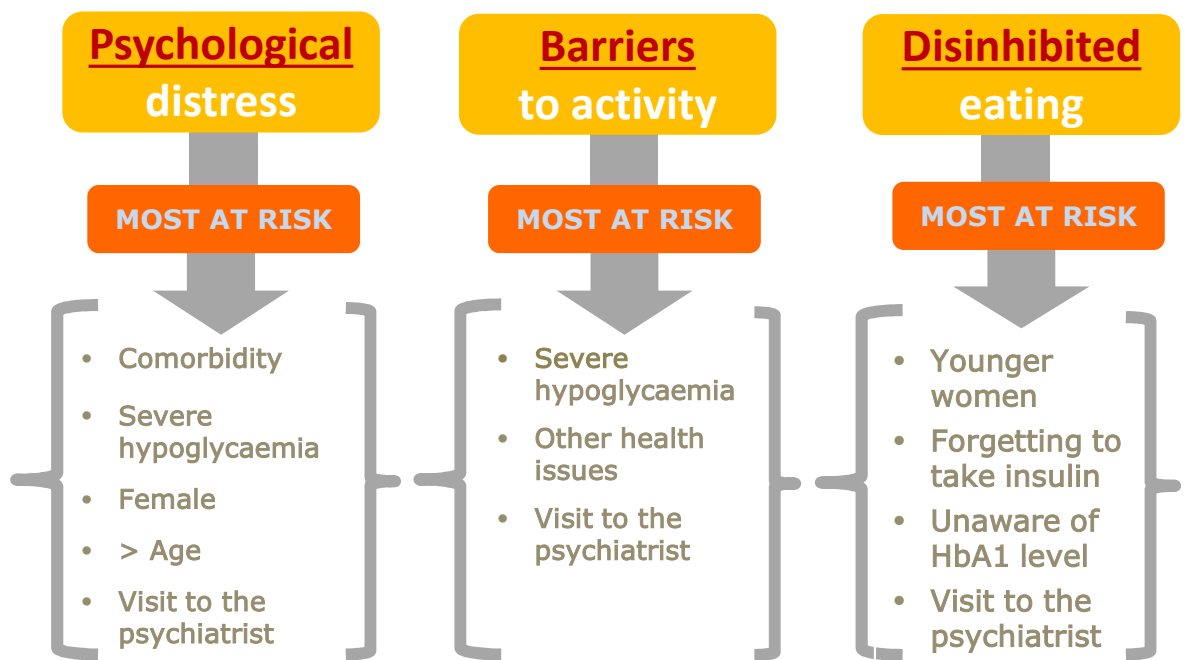
Represents high scores

PD — Frequent and or substantial emotional stress including: dysphoric mood, irritability and externally directed hostility.

BA — Very significant levels of anxiety restricting behaviour and perceived limitations in social/role activities

DE — Substantial and or frequent levels of eating in response to food cues and emotional arousal.

Food controls life — Yes 69%

Hard saying no to food you like — Yes 69%

Eat to cheer yourself up — Yes 53%

Depressed due to diabetes — Yes 50%

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Recent Developments

**The minimally important difference (MID)** is the smallest score difference on the **Diabetes Health Profile** that represents the minimal clinically significant difference.

Investigating the minimally important difference of the Diabetes Health Profile (DHP-18) and the EQ-5D and SF-6D in a UK diabetes mellitus population. Mulhern B and Meadows K. Health 5: 1045-1054,2013

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Interpreting the Diabetes Health Profile

A longitudinal dataset from a UK community-based postal survey carried out in one health authority area

- 1092 respondents with a reported diagnosis of Type 1
- Type 2 (n = 999) diabetes…

who fully completed the EQ-5D, SF-6D and DHP-18 at both baseline and 1-year follow-up.

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Interpreting the Diabetes Health Profile

The required MID change in score for the DHP-18 domains

Psychological distress	**7 - 11**
Barriers to activity	**6.5 - 9.9**
Disinhibited eating	**7.5 - 11.4**

Investigating the minimally important difference of the Diabetes Health Profile (DHP-18) and the EQ-5D and SF-6D in a UK diabetes mellitus population. Mulhern B and Meadows K. Health 5: 1045-1054,2013

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Patient research

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Development of an e-version of the DHP
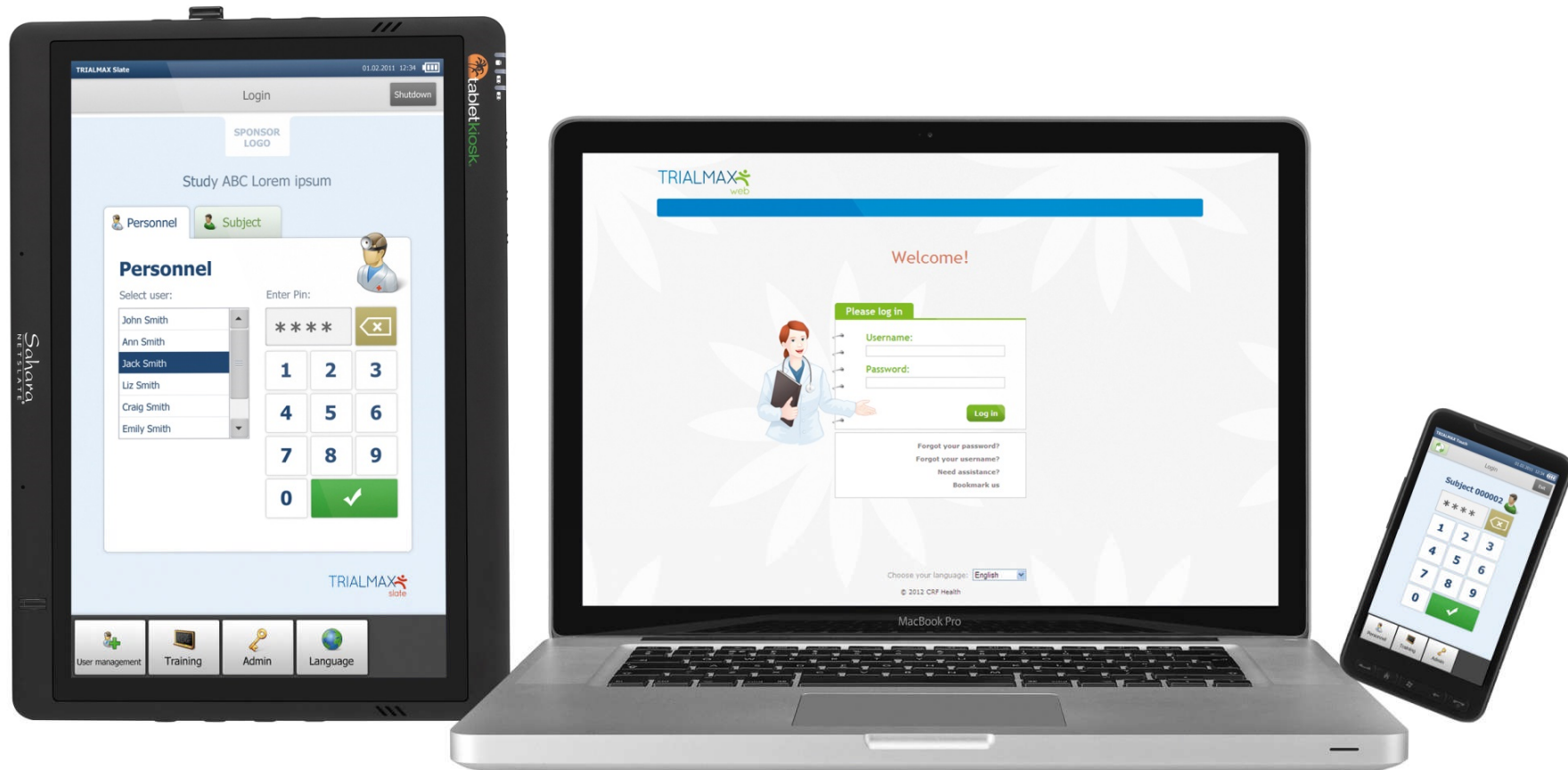
What is an Author Pre-Approved eCOA?

"An *Author pre-approved instrument qualifies the migrated instrument to the author's level of quality* and expectation. **- Elan Josielewski (Mapi Group)**

Having followed *good practices in instrument migration*, it is considered that an *Author pre-approved instrument would*, with reasonable testing (in line with industry guidelines), *demonstrate equivalence*".

- David Churchman (iOutcomes)

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Advantages of an eDHP

- Facility to apply computerised adaptive scoring

- Preference-based scoring using three-item DHP currently being derived from the DHP-18

- Collection of symptom events etc. on the same electronic platform

- Real-time DHP-18 scores benchmarked against age, gender, diabetes type, acute complications e.g. hypoglycaemic episodes

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Integration of the DHP-18 into holistic assessment of needs programme for Type 1 and Type 2 patients.
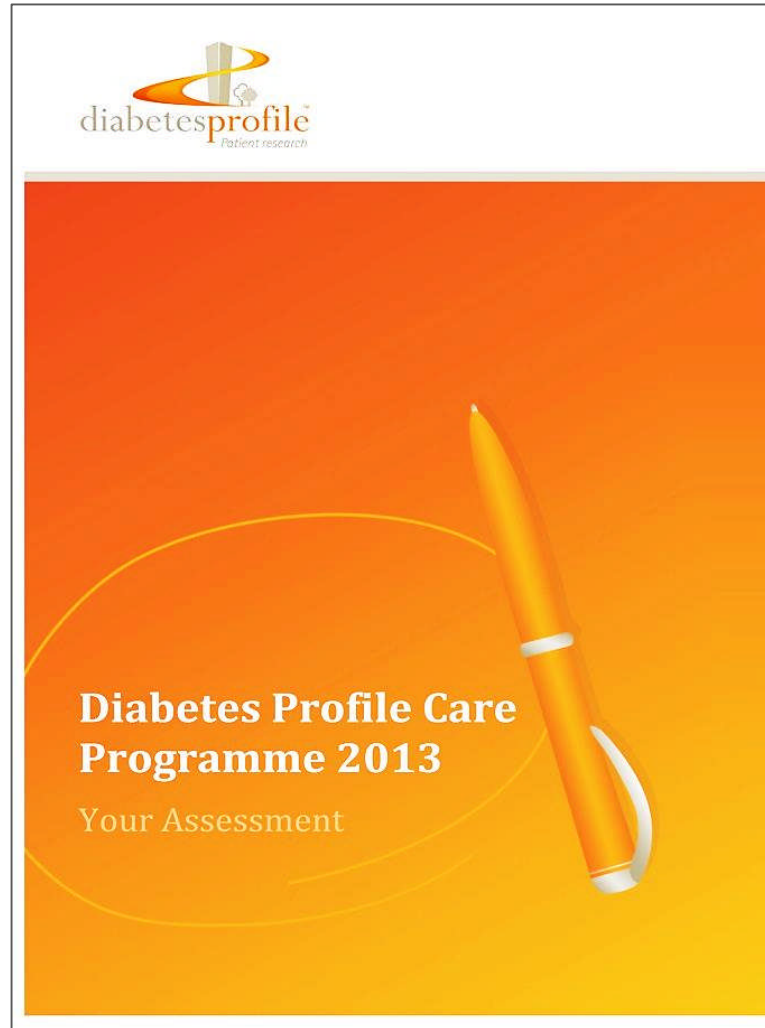
DHP preference-based measure

- **DHP-3 & DHP5** will be able to estimate QALYs for the assessment of diabetes specific interventions in existing datasets or in future trials that include the DHP-18 or DHP-1

- **The DHP-5D** be able to estimate QALYs in data or trials where the DHP-1 and SF-36 are included

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KEY ATTRIBUTES:
The Diabetes Health Profile

- **Developed** with significant patient input
- **A clearly defined conceptual framewor**k of the measurement model which conforms to the FDA Final guidance for Industry
- **The measurement of dysfunctional eating behaviour** – which despite its importance in the management of diabetes is absent in other scales

- **Content** No hypothetical questions relates to real life experiences which respondents identify and engage with
- **Suitable** for use in range of research settings including population surveys, phase III and real world data collection
- **Minimum Important Difference (MID)** Values available
- **Now available** as an eDHP Author approved

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Thank You for Attending!

For more information, email us or visit our website:
- info@dhpresearch.com
- www.diabetesprofile.com

For licensing enquiries, email or call the following:
- healthoutcomes@innovation.ox.ac.uk
- T: +44 (0)1865 614417