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Challenges of managing diabetes in primary care: Clinical, organisational and personal

Dr Sarah Jarvis

GP and medical broadcaster

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Job number: PHGB/VOK/0315/0020 Date of preparation: March 2015

Declaration of interests

- Dr Sarah Jarvis has received honoraria for speaking and sitting on advisory boards for Abbott, AZ, Janssen, MSD and Takeda

Topics covered in this presentation

- Burden of diabetes in the UK
- Clinical outcomes in type 2 diabetes in the UK
  - What are we doing well?
  - What are the opportunities for improvement?
- Identifying local priorities in the management of diabetes
  - What tools are available?
- Challenges and barriers
  - What do we need to overcome when seeking to improve clinical outcomes?

The burden of diabetes: Figures from Diabetes UK

- **Every 3 minutes** someone in the UK learns that they have diabetes
- There are about **3.2 million** people in England living with the condition
  - >2,700,000 diagnosed (90% with type 2 diabetes)
  - Approximately 500,000 people have undiagnosed type 2 diabetes
- A 38% increase in diagnosed diabetes was seen between 2001 and 2013
- Another 9.8 million people could be at high risk of developing type 2 diabetes
- If current trends continue:
  - **By 2025**: 4 million people in the UK will have diabetes
  - **By 2030**: diabetes prevalence could be 14% in some areas

Diabetes UK (2014) *State of the Nation: challenges for 2015 and beyond.* Available at: http://www.diabetes.org.uk/Documents/About%20Us/What%20we%20say/State%20of%20the%20nation%202014.pdf accessed 04.03.2015

Goals in the management of type 2 diabetes: What are we trying to achieve?

- Preventing people from dying prematurely
- Enhancing quality of life
- Helping people recover from episodes of ill health
- Ensuring people have a positive experience of care
- Treating and caring for people in a safe environment and protecting them from avoidable harm

Based upon the domains of the NHS Outcomes Framework

Department of Health (2013) *NHS Outcomes Framework 2014/15 – at a glance.* Available at: http://bit.ly/18Hc8vs (accessed 19.03.2014)

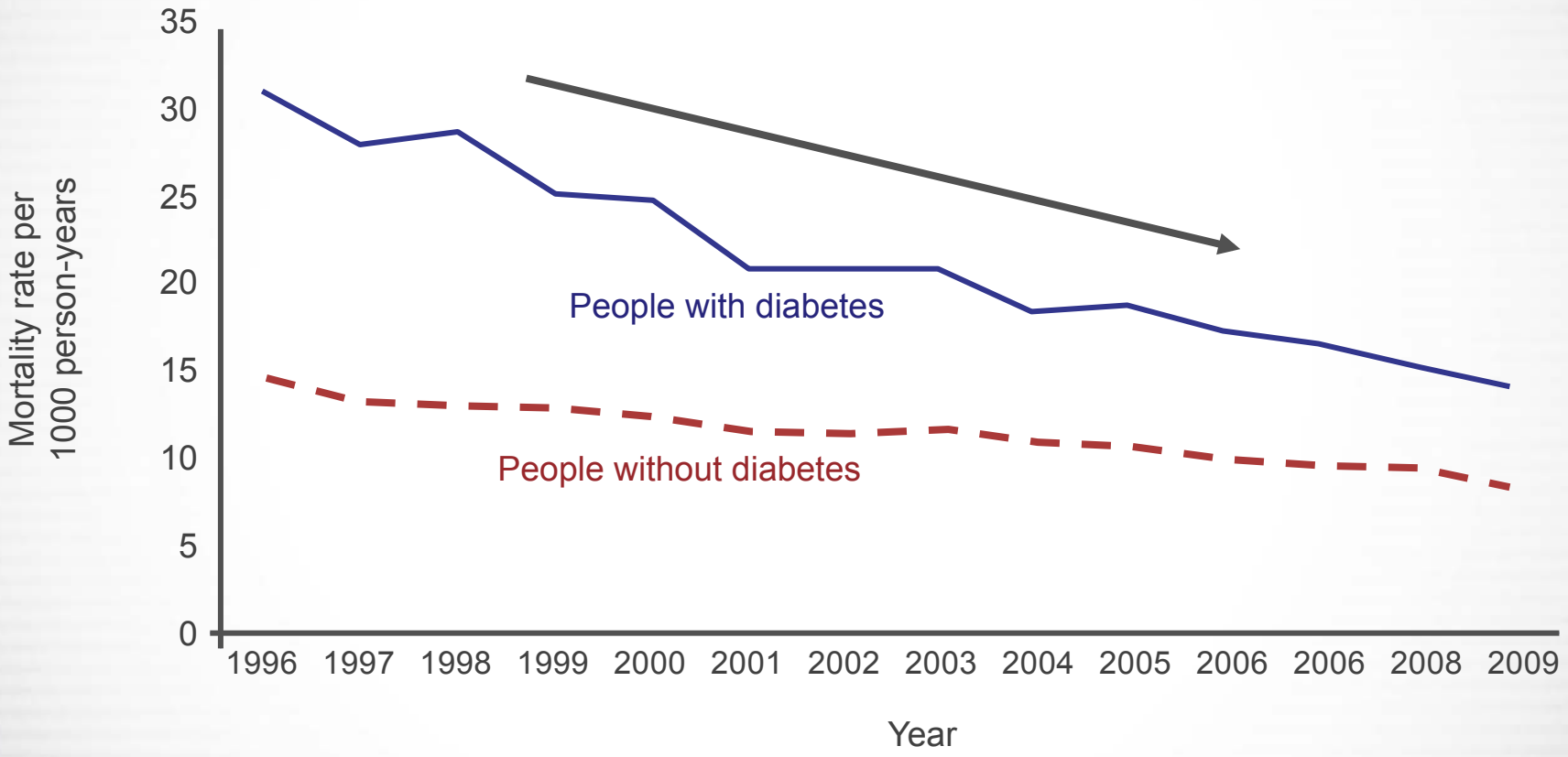
Clinical outcomes in type 2 diabetes in the UK

What are we doing well?

Mortality rates

Are we seeing a decline in the UK population with diabetes?

Adjusted absolute rates of mortality for people with and without diabetes in the UK THIN database



THIN=The Health Improvement Network.

Lind M et al (2013) *Diabetologia* **56**: 2601–8

Admissions rates for cardiovascular complications

Is there a downward trend developing in the UK population with diabetes?

Admission rates for major cardiovascular events and procedures are declining in people with diabetes

Angina	Acute myocardial infarction	CABG	Stroke	PCI
• ↓ 5% per year	• ↓ 5% per year	• ↓ 3% per year	• No change	• ↑ 1% per year

Study authors:

- "…individuals with diabetes experienced similar proportional changes in all CVD outcomes as people without diabetes"
- "…despite significant declines, people with diabetes still are at an ~3.5- to 5-fold risk of CVD events compared with those without diabetes"

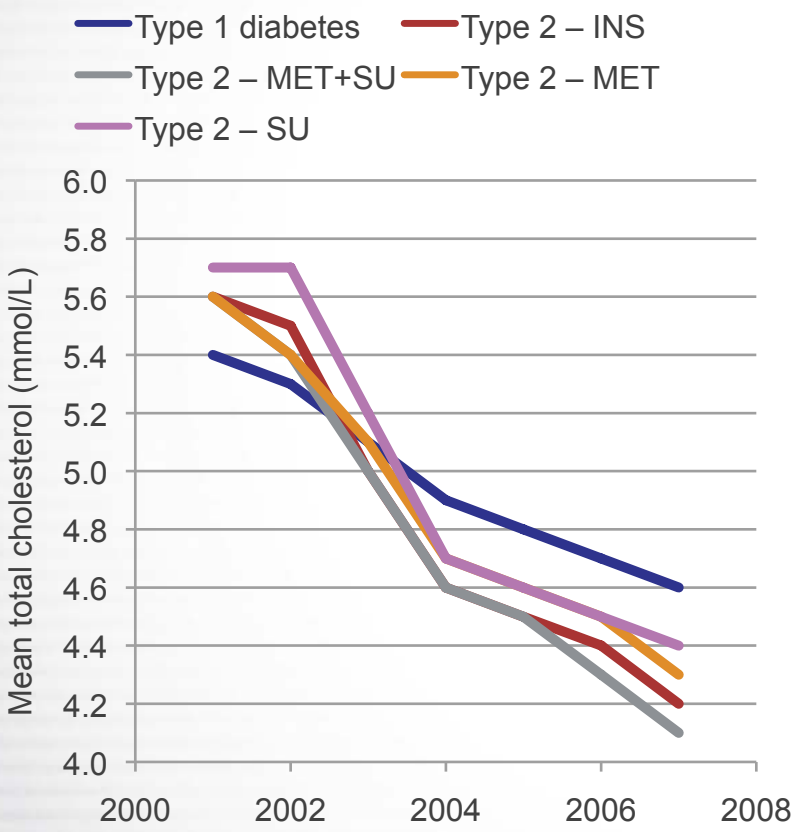
Rates based on Poisson regression analyses adjusted for age, sex and year. Data extracted from Hospital Episode Statistics database for financial years 2004–5 and 2009–10 for all NHS hospital trusts in England.

CABG=coronary artery bypass graft; PCI=percutaneous coronary intervention

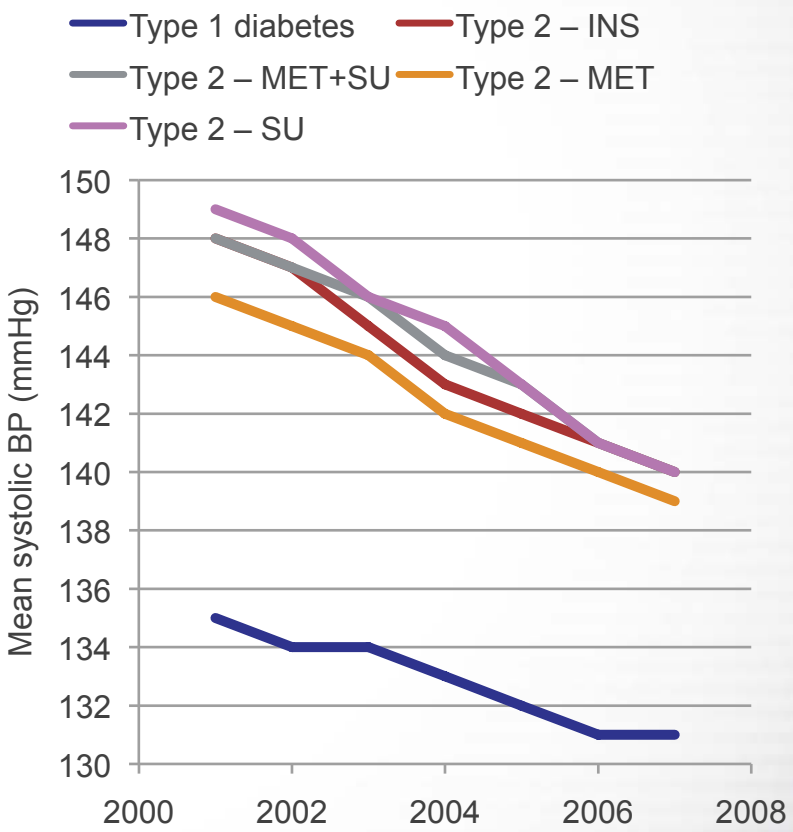
Vamos EP et al (2012) *Diabetes Care* **35**: 265–72

Risk factor trends over time in people with type 2 diabetes managed in primary care

Change in mean total cholesterol levels



Change in mean systolic BP levels



BP=blood pressure; INS=insulin; MET=metformin; SU=sulphonylurea

Adapted from: Currie CJ et al (2010) *Diabet Med* **27**: 938–48

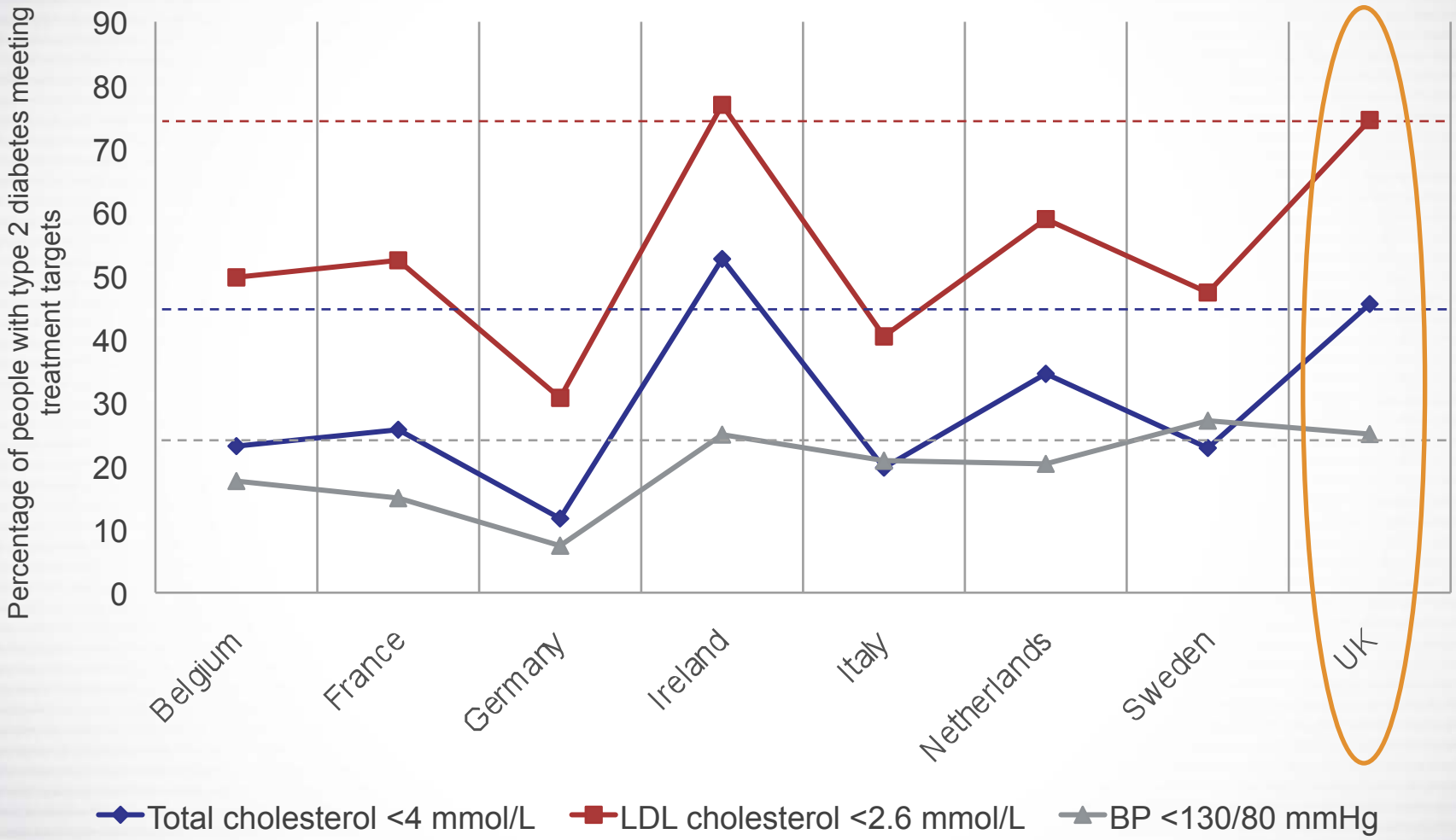
The State of the Nation says

- 92% of those with T2DM had a cholesterol check in the previous year
- 75% achieved total cholesterol under 5mmol/l total
- 40% achieved total cholesterol under 4mmol/l

- 95% had BP check in previous year
- 69% had BP under 140/80
- Up from 62% in 2010-11
- But those with type 2 diabetes were less likely to meet blood pressure targets than those with type 1 diabetes

Diabetes UK (2014) *State of the Nation: challenges for 2015 and beyond.* Available at: http://www.diabetes.org.uk/Documents/About%20Us/What%20we%20say/State%20of%20the%20nation%202014.pdf accessed 04.03.2015

Target attainment for BP and cholesterol appears to be higher in the UK than in several other EU countries



Dashed lines denote proportions meeting corresponding target in the UK. Data from the GUIDANCE (Guideline Adherence to Enhance Care) Study of 7597 people with type 2 diabetes. For consistency in comparing countries, targets were derived from internationally recognised American Diabetes Association guidelines rather than national guidelines for each country. BP=blood pressure. Stone MA et al (2013) *Diabetes Care* **36**: 2628–38

What role do you think QOF has had in driving achievement of these targets?

- It is the main driver behind the trend
- It has had some impact
- I'm not sure
- It has had a detrimental impact
- Something else

QOF=Quality and Outcomes Framework.

Summary so far

- The UK appears to be doing well compared with other countries in areas such as blood pressure and cholesterol target attainment, and minimising premature mortality
- Within the UK, there are trends towards declines in admissions for cardiovascular events and mortality in people with diabetes
- But where are the opportunities for improvement?

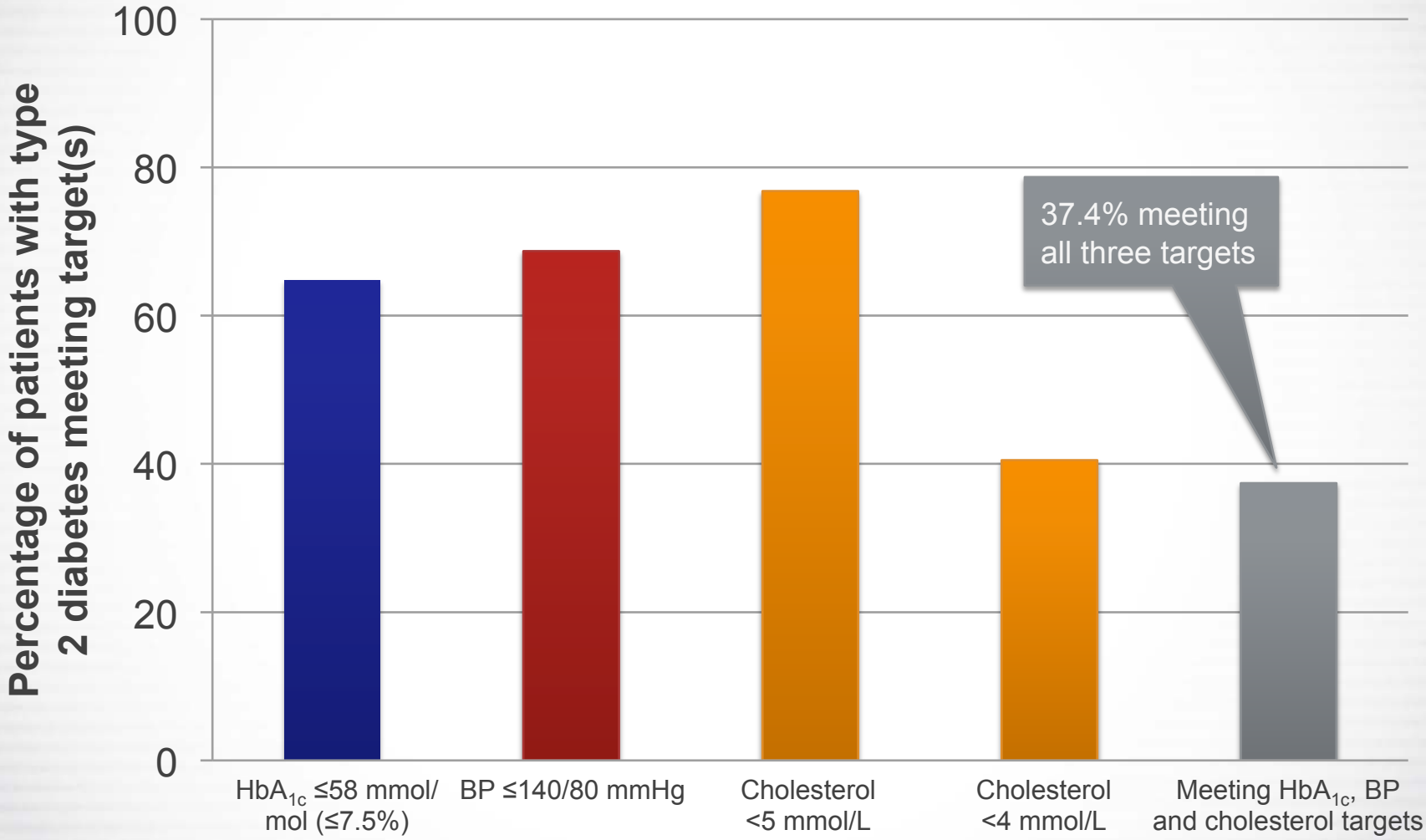
Clinical outcomes in type 2 diabetes in the UK

What are the opportunities for improvement?

Completing care processes and attaining targets

More to do?

A minority of people with type 2 diabetes are achieving multiple treatment targets



Data for 2012–2013 for England and Wales, from the National Diabetes Audit. BP=blood pressure

Health and Social Care Information Centre (2014) *National Diabetes Audit 2012–2013. Report 1: Care Processes and Treatment Targets.* Available at: http://bit.ly/ZuxniQ (accessed 02.10.2014)

Importance of multiple target attainment in type 2 diabetes: Reductions in absolute risk in Steno-2

- Randomisation to intensified, target-driven therapy for a median of 7.8 years yielded the following benefits compared with conventional multifactorial treatment when patients were observed after a further 5.5 years:

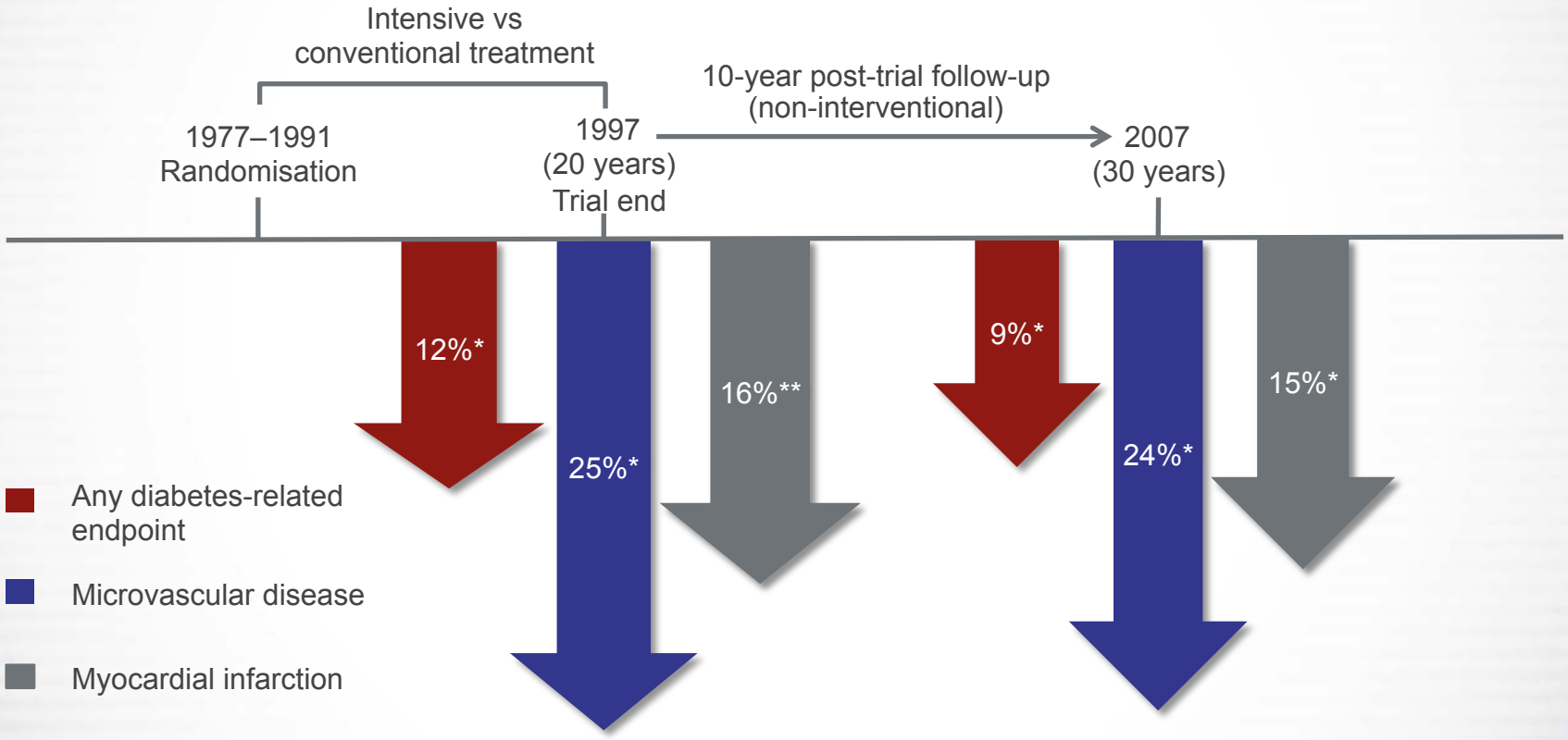
Mortality rate: **20% absolute risk reduction** (50% vs. 30%; *P*=0.02)	**Cardiovascular event rate:** **29% absolute risk reduction** (60% vs. 31%; *P*<0.001)

- Participants (n=160) had type 2 diabetes and persistent microalbuminuria
- Intensive treatment included the following targets:
  - HbA_{1c} <48 mmol/mol (<6.5%)
  - Total cholesterol <4.5 mmol/L
  - Triglycerides <1.7 mmol/L
  - Systolic BP <130 mmHg
  - Diastolic BP <80 mmHg

Gaede P et al (2008) *N Engl J Med* **358**: 580–91

UK Prospective Diabetes Study: Importance of early tight glycaemic control of HbA_{1c} in type 2 diabetes

Reduction in endpoints on intensive treatment (with sulphonylurea or insulin) versus conventional treatment (diet)



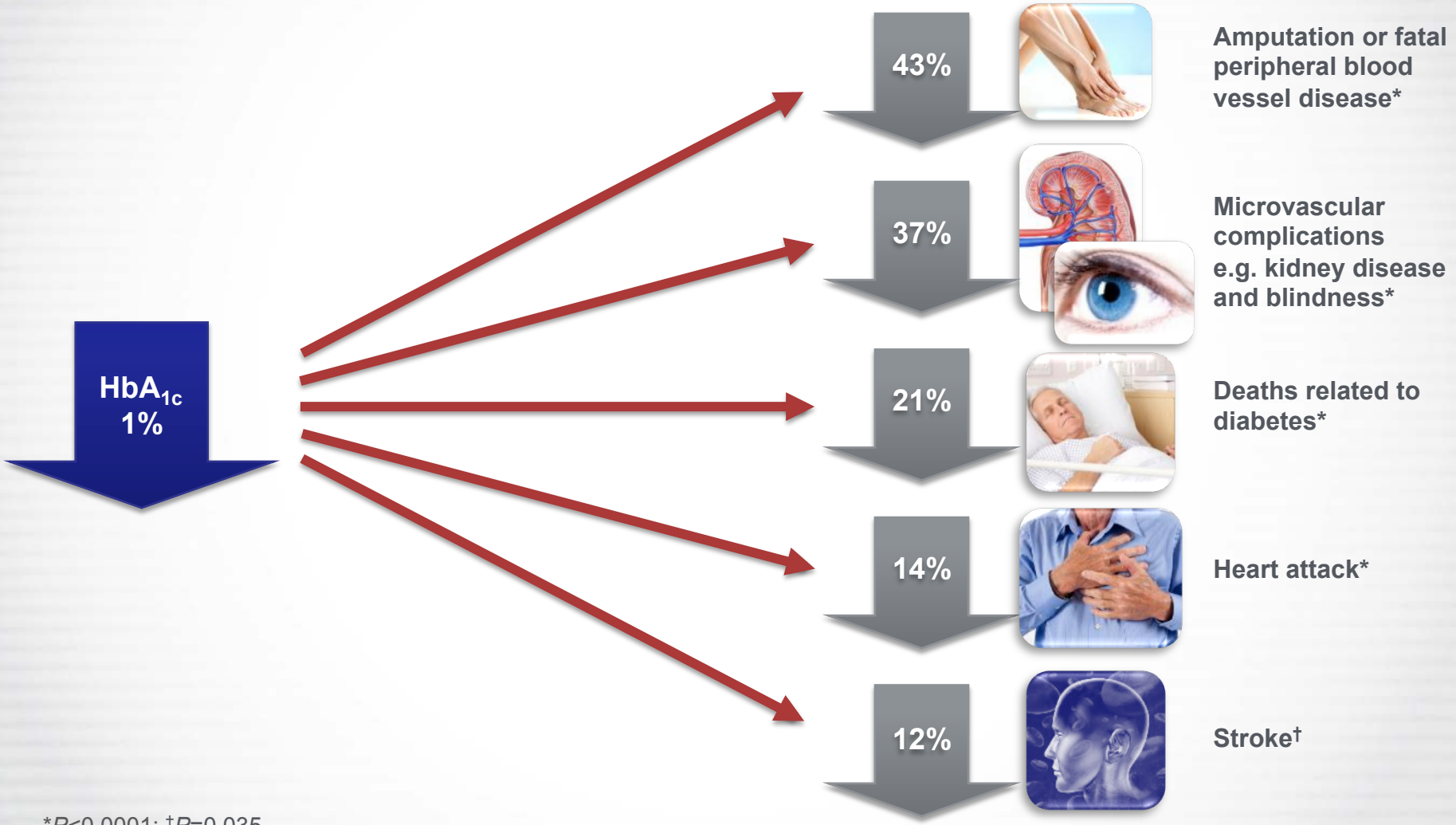
Median HbA_{1c} over 10 years: *Intensive treatment* **53 mmol/mol (7.0%)**, *conventional treatment* **63 mmol/mol (7.9%)**

*P<0.05; **P=0.052 (for comparison of intensive and conventional treatment of glycaemia)

UKPDS Group (1998) *Lancet* **352**: 837–53

Holman RR et al (2008) *N Engl J Med* **359**: 1577–89

UKPDS analysis: A 1% (11 mmol/mol) decrease in HbA_{1c} is associated with a lower relative risk of complications

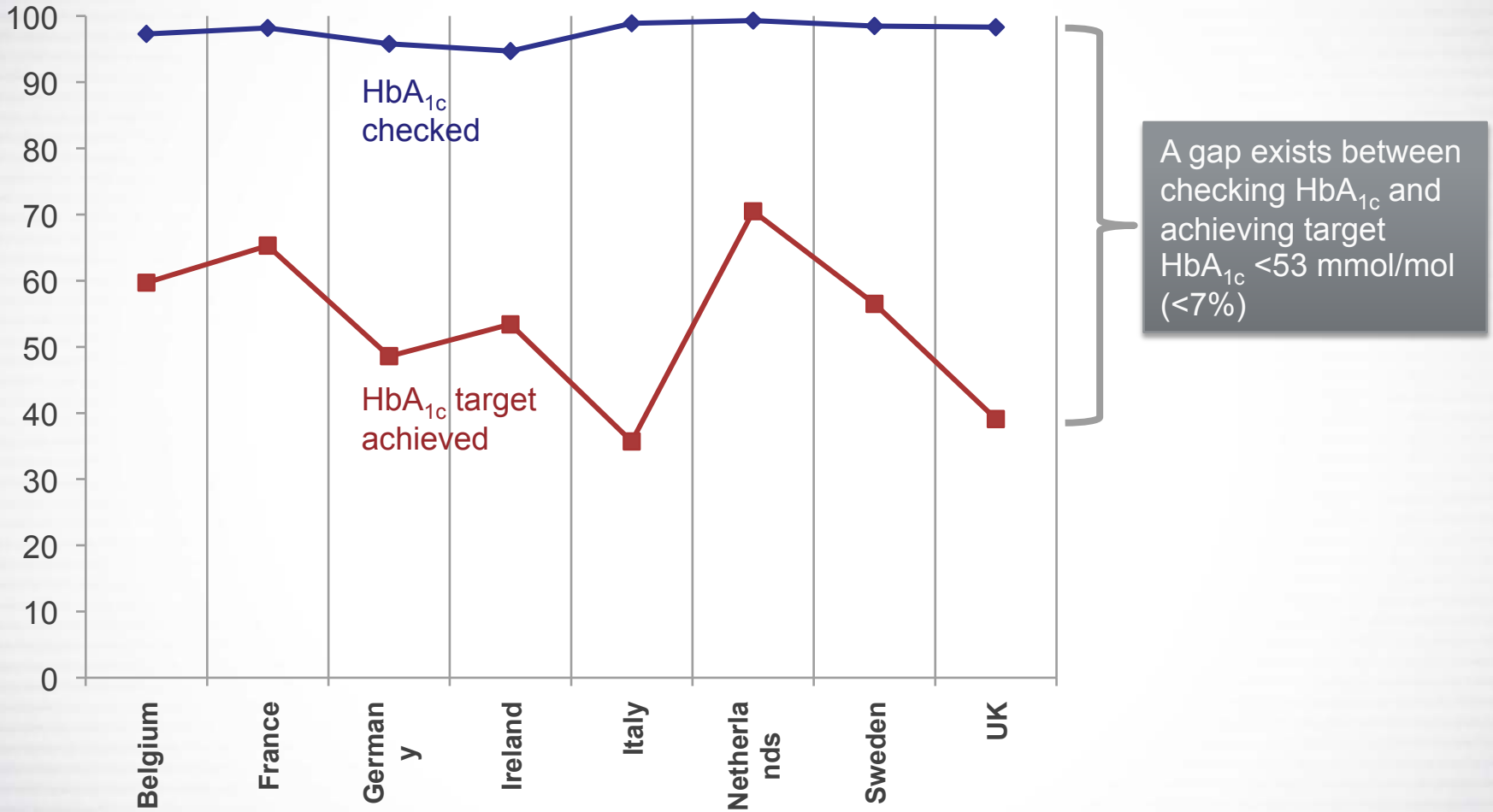


*P<0.0001; †P=0.035.

UKPDS=UK Prospective Diabetes Study.

Stratton IM et al (2000) *BMJ* **321**: 405–12

UK appears to compare poorly with other EU countries in terms of HbA_{1c} target attainment



Data from the GUIDANCE (Guideline Adherence to Enhance Care) Study of 7597 people with type 2 diabetes. For consistency in comparing countries, targets were derived from internationally recognised American Diabetes Association guidelines rather than national guidelines for each country

Stone MA et al (2013) *Diabetes Care* **36**: 2628–38

The State of the Nation says

- 94% of patients with T2DM have had HbA1c checked within the last year BUT
- 35% have HbA1c over 58mmol/mol (7.5%)
- 7% have HbA1c over 86mmol/mol (10%)
- 30% variation between best and worst performing CCGs

Diabetes UK (2014) *State of the Nation: challenges for 2015 and beyond.* Available at: http://www.diabetes.org.uk/Documents/About%20Us/What%20we%20say/State%20of%20the%20nation%202014.pdf accessed 04.03.2015

Why aren't more people with type 2 diabetes achieving their HbA_{1c} target, in your view?

- Non-adherence to treatment or lifestyle intervention
- Lack of knowledge about diabetes
- Clinical inertia – lack of treatment titration
- Clinical inertia – delay in treatment intensification
- Limitations of current antihyperglycaemic therapies
- Something else

Structured education and care planning

A need for improved provision and uptake?

Limited offering and uptake of structured education in the UK population with diabetes

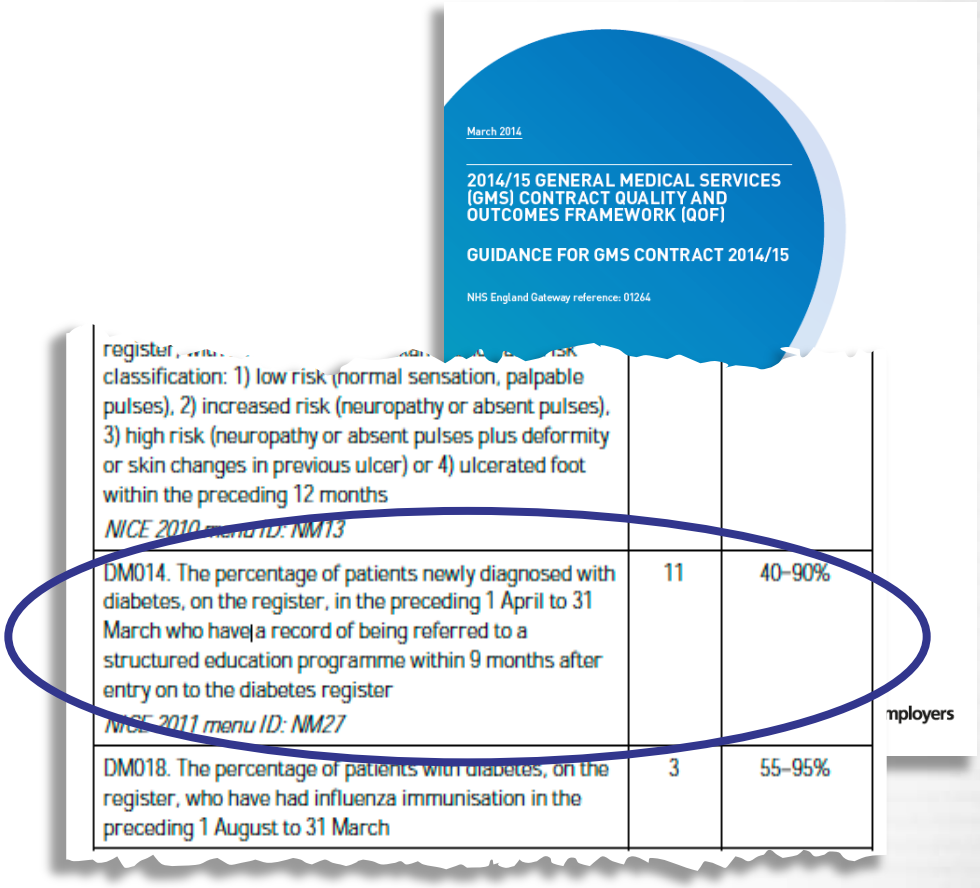
	Offered structured education (%)	Attended structured education (%)
Newly diagnosed with type 2 diabetes	16.7	3.6
All people with type 2 diabetes	6.0	1.6

Data on for England and Wales, as recorded in the National Diabetes Audit 2011/12

Health and Social Care Information Centre (2014) *National Diabetes Audit 2012–2013. Report 1: Care Processes and Treatment Targets.* Available at: http://bit.ly/ZuxniQ (accessed 02.10.2014)

Structured education and QOF in 2014/15

- Structured education referral introduced into QOF in 2013/14 and retained for 2014/15
- Carries 11 points
- 40–90% threshold for payment
- Programmes should meet criteria from Diabetes UK and the Department for Health
  - Evidence-based, suited to needs of individual
  - Structured curriculum
  - Delivered by trained educators
  - Quality assured and reviewed by trained independent assessors
  - Outcomes regularly audited



QOF=Quality and Outcomes Framework.

British Medical Association et al (2014) *Guidance for GMS contract 2014/15.* Available at: http://bit.ly/1fH7lcb (accessed 19.03.2014)

Diabetes UK: “Lack of care planning failing people with diabetes”

- Annual survey of 1609 people with diabetes revealed that **64.9% reported not having a care plan in place**

- “Personalised care planning is not about a person having a sheet on the file at their GP surgery that says ‘personal care plan’. To be effective it must not be a tick box exercise. It is about giving the person with diabetes the opportunity to work together with their healthcare team to be more informed, more vocal and play a bigger role in their care.”

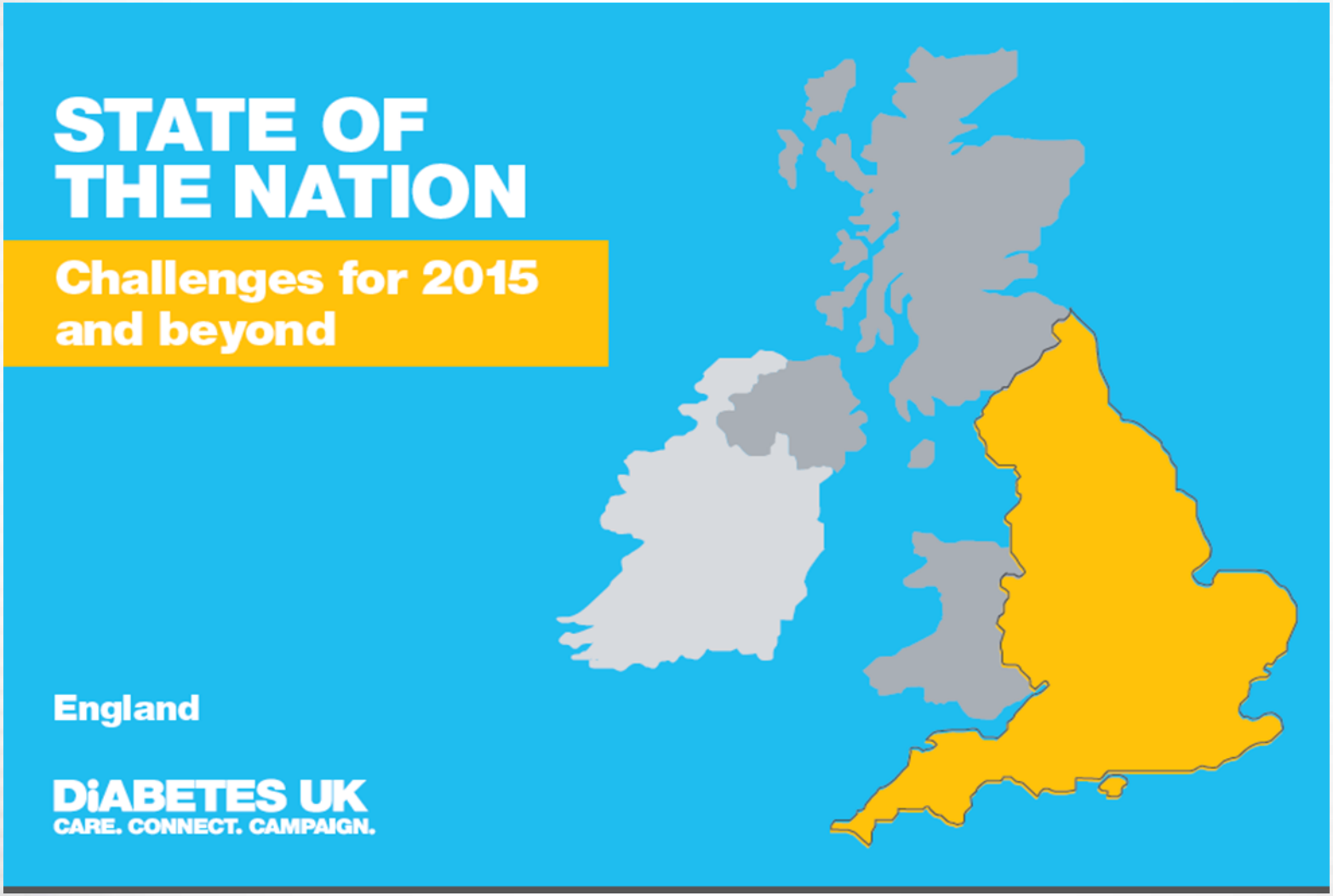
  Barbara Young, Chief Executive of Diabetes UK

Diabetes UK (2014) *Lack of care planning failing people with diabetes*. Available at: http://bit.ly/1fH4kZf (accessed 19.03.2014)

Identifying local priorities in the management of diabetes

Tools to help us improve in improving clinical outcomes

Geographic variation in diabetes care is a significant concern

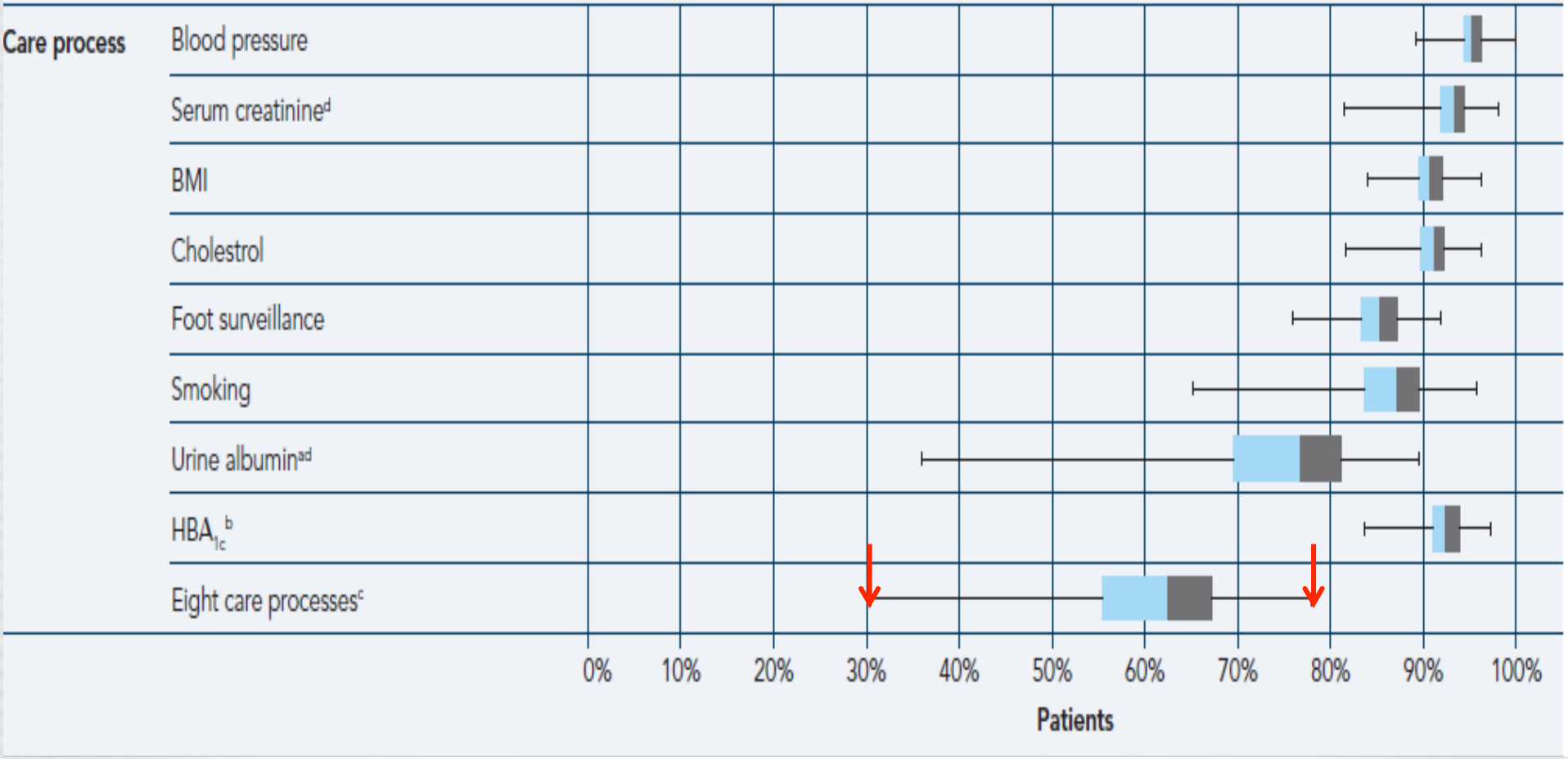


Diabetes UK (2014) *State of the Nation: challenges for 2015 and beyond.* Available at: http://www.diabetes.org.uk/Documents/About%20Us/What%20we%20say/State%20of%20the%20nation%202014.pdf accessed 04.03.2015

- For Blood pressure targets
- >30% difference between best and worst CCGs
- For retinopathy screening
- Rates varied between CCGs from <70% to >90%
- For smoking status
- Check rates varied between CCGs from 65% to >95%
- For foot checks
- Rates varied between CCGs from 75% to 90%

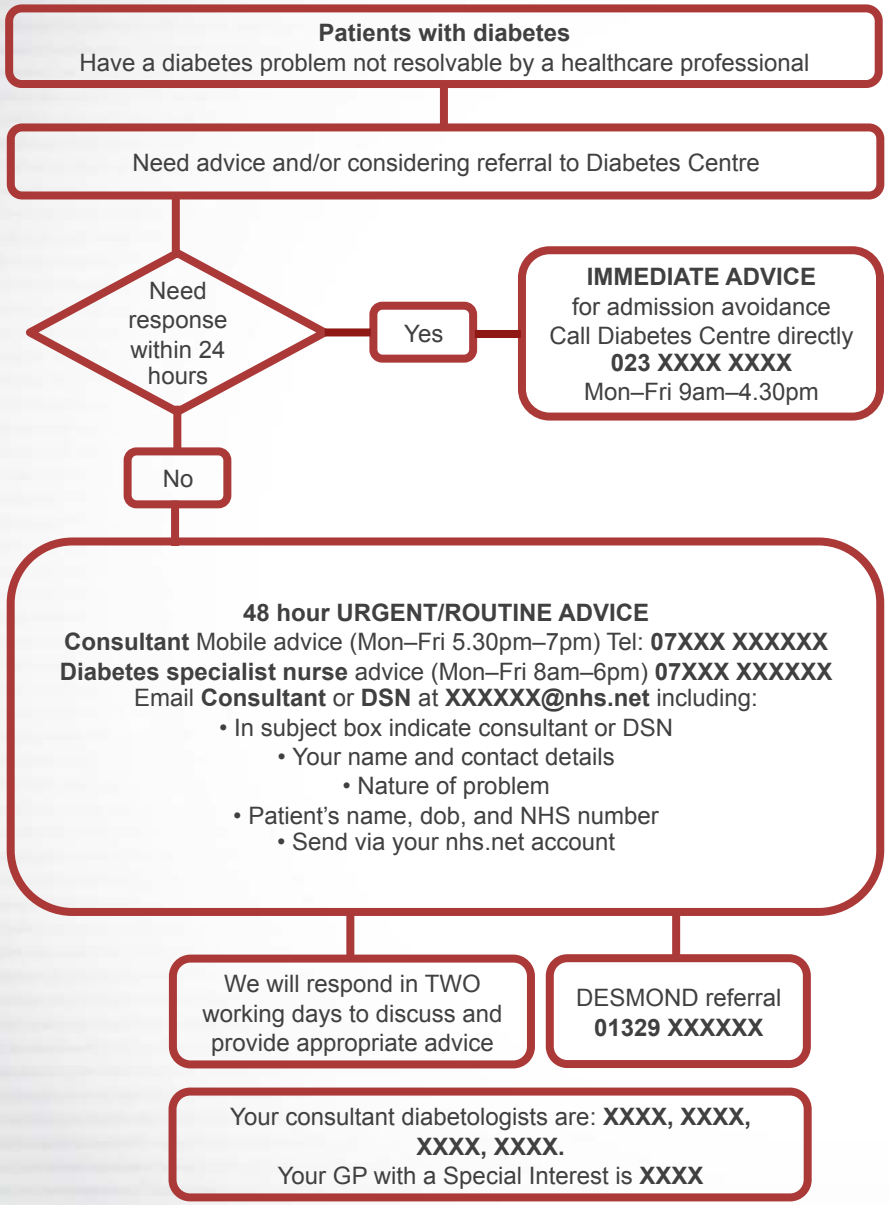
Diabetes UK (2014) *State of the Nation: challenges for 2015 and beyond.* Available at: http://www.diabetes.org.uk/Documents/About%20Us/What%20we%20say/State%20of%20the%20nation%202014.pdf accessed 04.03.2015

Figure 6
The range of CCG/LHB care process completion in England and Wales, 2012-2013



Health and Social Care Information Centre (2014) *National Diabetes Audit 2012–2013. Report 1: Care Processes and Treatment Targets.* Available at: http://bit.ly/ZuxniQ (accessed 02.10.2014)

Models of integrated diabetes care: Portsmouth



Community Diabetes Team (CDT)

Please discuss all potential referrals with the Community Diabetes Team. Any inappropriate referrals will be returned. Only refer to the Diabetes Centre for the following specialist clinics:

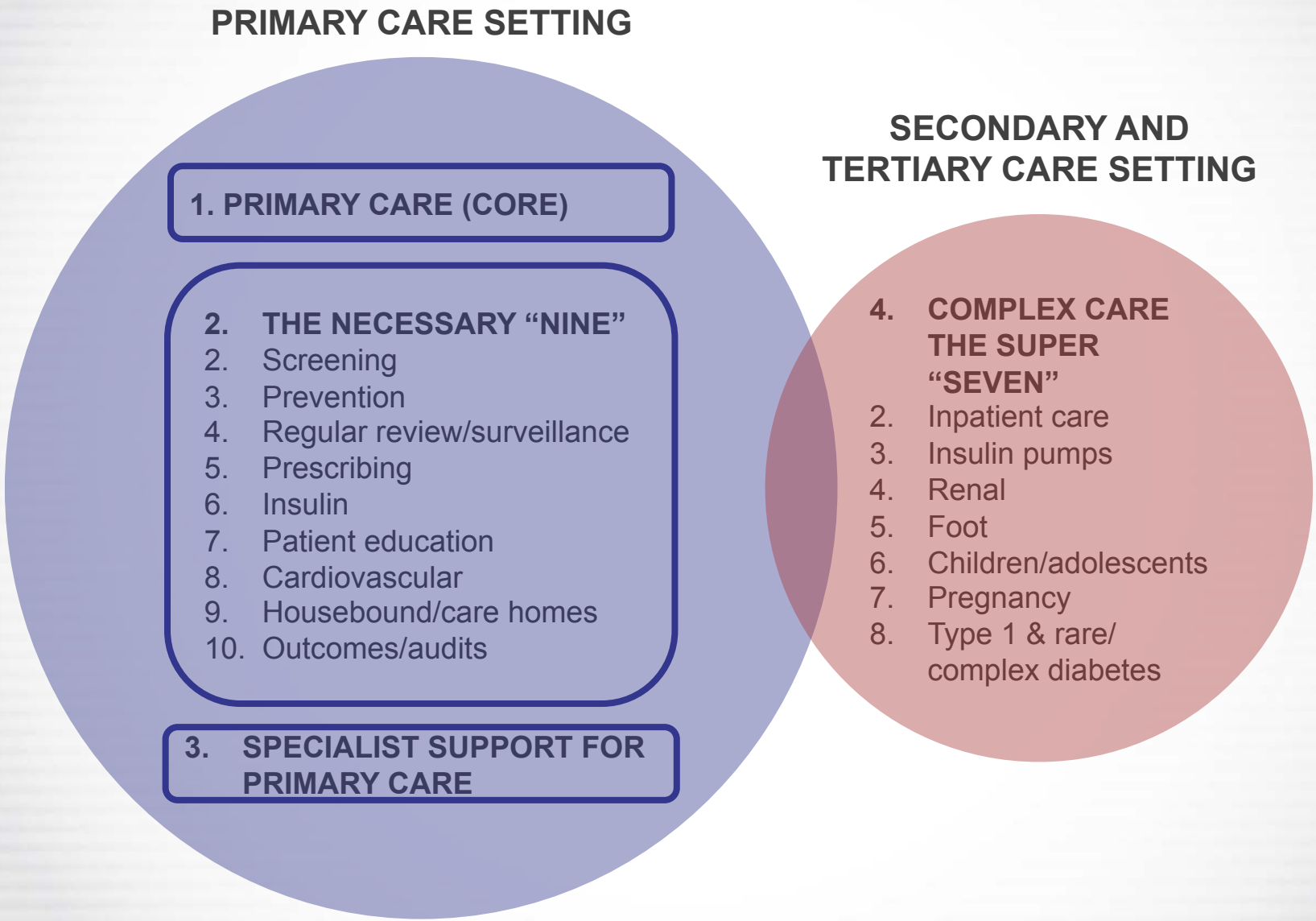
- Pregnancy and pre-pregnancy
- Acute type 1 diabetes
- Structured education for type 1 diabetes
- Patients suitable for and/or using continuous subcutaneous insulin infusion (CSII)
- Adolescent (non paediatric) diabetes
- Patients with diabetes and in CKD stage 3 or lower should be discussed with CDT consultant prior to referral to specialist clinic
- Patients on dialysis

Refer to Foot MDT all patients with:

- Non-healing foot ulcer
- Acute hot swollen neuropathic foot
- Sudden change to foot shape

CKD=chronic kidney disease; MDT=multidisciplinary team. Adapted from Kar P et al (2013) *Diabetes & Primary Care* **15**: 211–5

Models of integrated diabetes care: Leicester



Farooqi A, Stribling B (2014) Presentation at *Diabetes UK 2014 Annual Professional Conference*. Liverpool, UK, 5–7 March

Are there any other effective models for diabetes care in use locally?

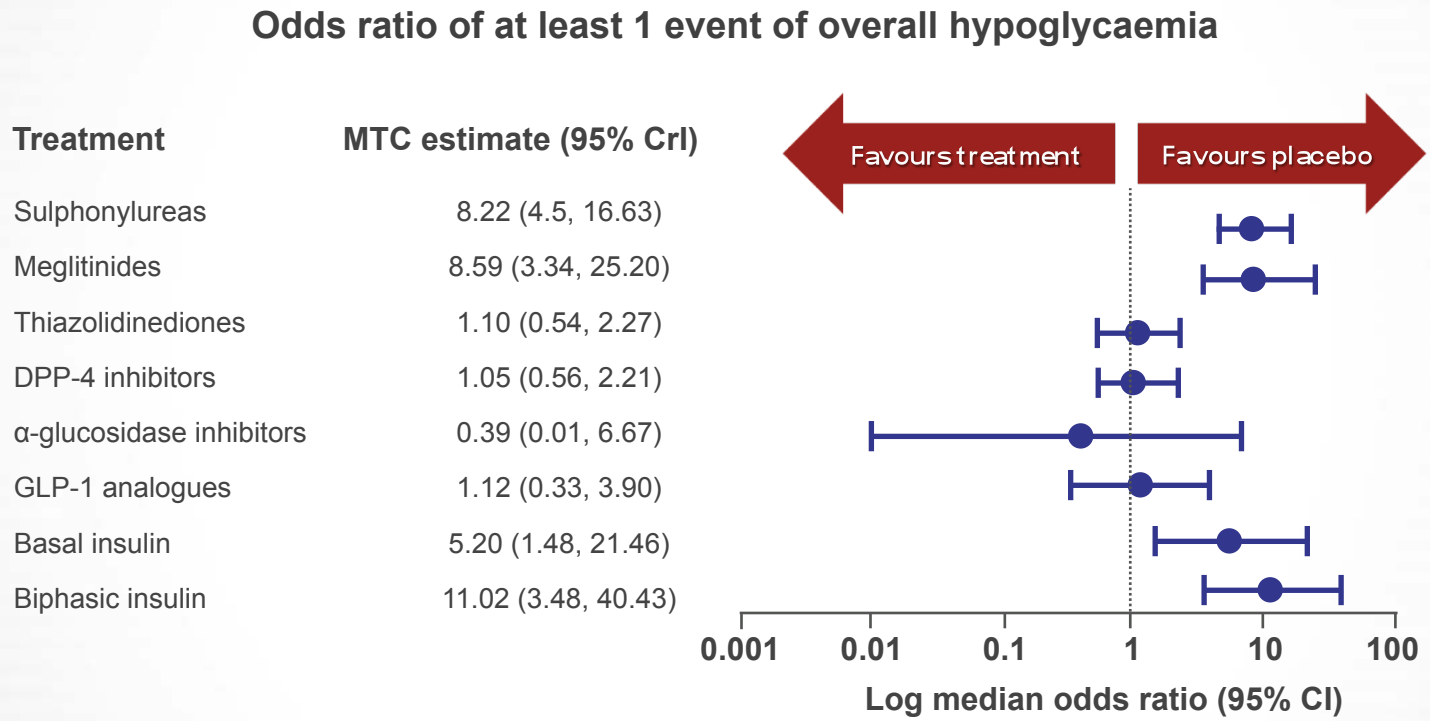
Challenges and barriers

What do we need to overcome when seeking to improve clinical outcomes?

Adverse effects of therapy

Hypoglycaemia, weight gain

Hypoglycaemia when adding on to metformin: Meta-analysis of antihyperglycaemic therapies

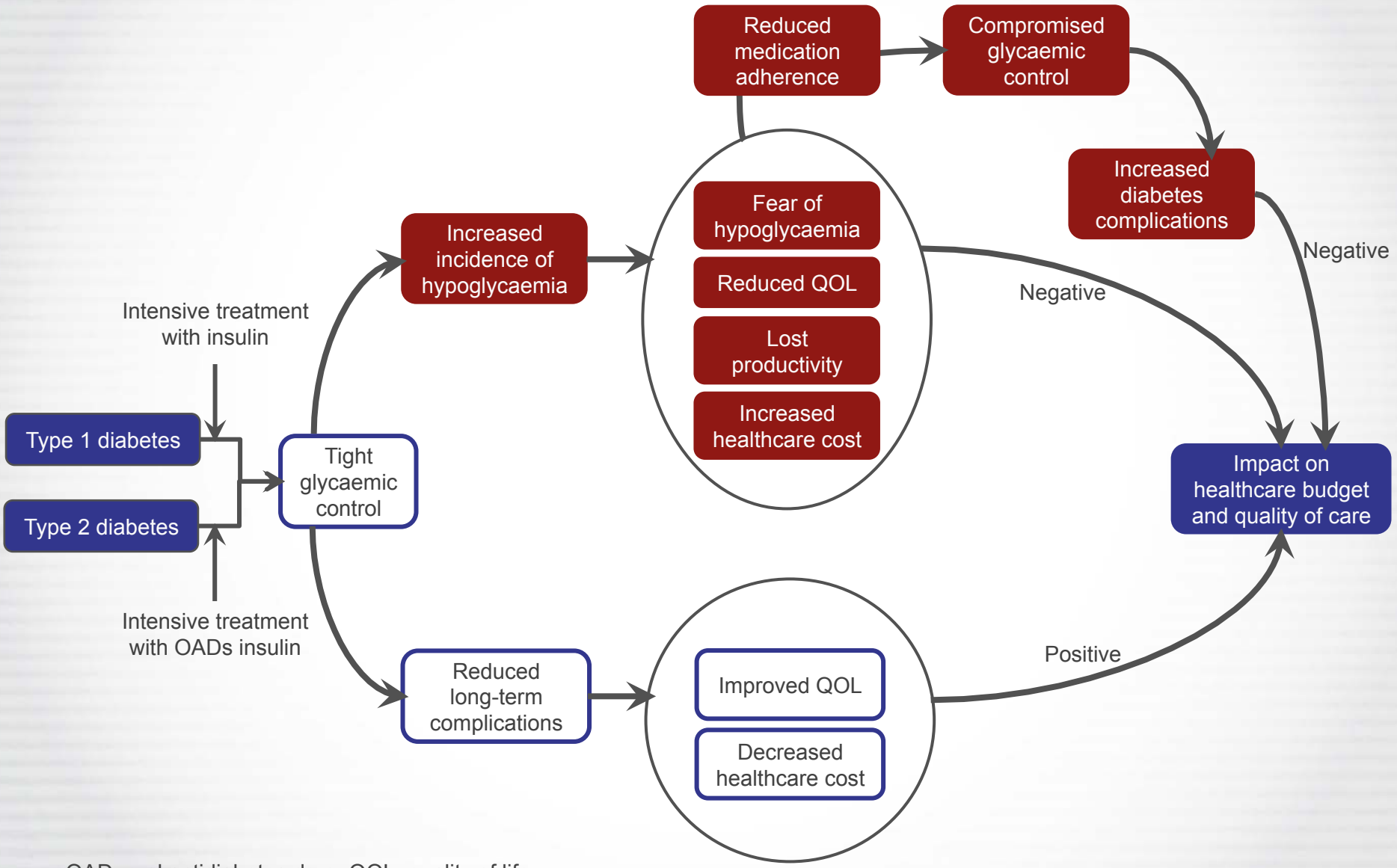


Mixed-treatment comparison (MTC) results showing the effect of adding second-line agents versus placebo in adults taking metformin on odds of at least 1 event of overall hypoglycaemia. MTC analysis based on 34 randomised controlled trials (n=16,704). Most trials were 6–12 months long. Overall, meta-regression and sensitivity analyses yielded minimal differences from the reference case.

CrI=credible interval; DPP-4=dipeptidyl peptidase-4; GLP-1=glucagon-like peptide-1.

McIntosh B et al (2011) *Open Med* **5**: e35-48

Impact of hypoglycaemia for people with diabetes and for the NHS



OAD=oral antidiabetes drug; QOL=quality of life

Adapted from Fidler C et al (2011) *J Med Econ* **14**: 646–55

Hypoglycaemia and driving: When does the DVLA need to be notified?[1,2]

Diabetes treatment	Group 1 (car, motorcycle)	Group 2 (LGV, PCV)
Managed by diet alone	No	No
Tablets not included below which have a low risk of causing hypos, e.g. metformin used alone	No	Yes
Non insulin injections, unless you are also taking one of the tablets below	No	Yes
Tablets that carry a risk of hypos. This includes sulphonylureas, such as gliclazide, and glinides (repaglinide, nateglinide)	No	Yes
Insulin	Yes	Yes
Temporary insulin (following a heart attack or during gestational diabetes)	No	Yes

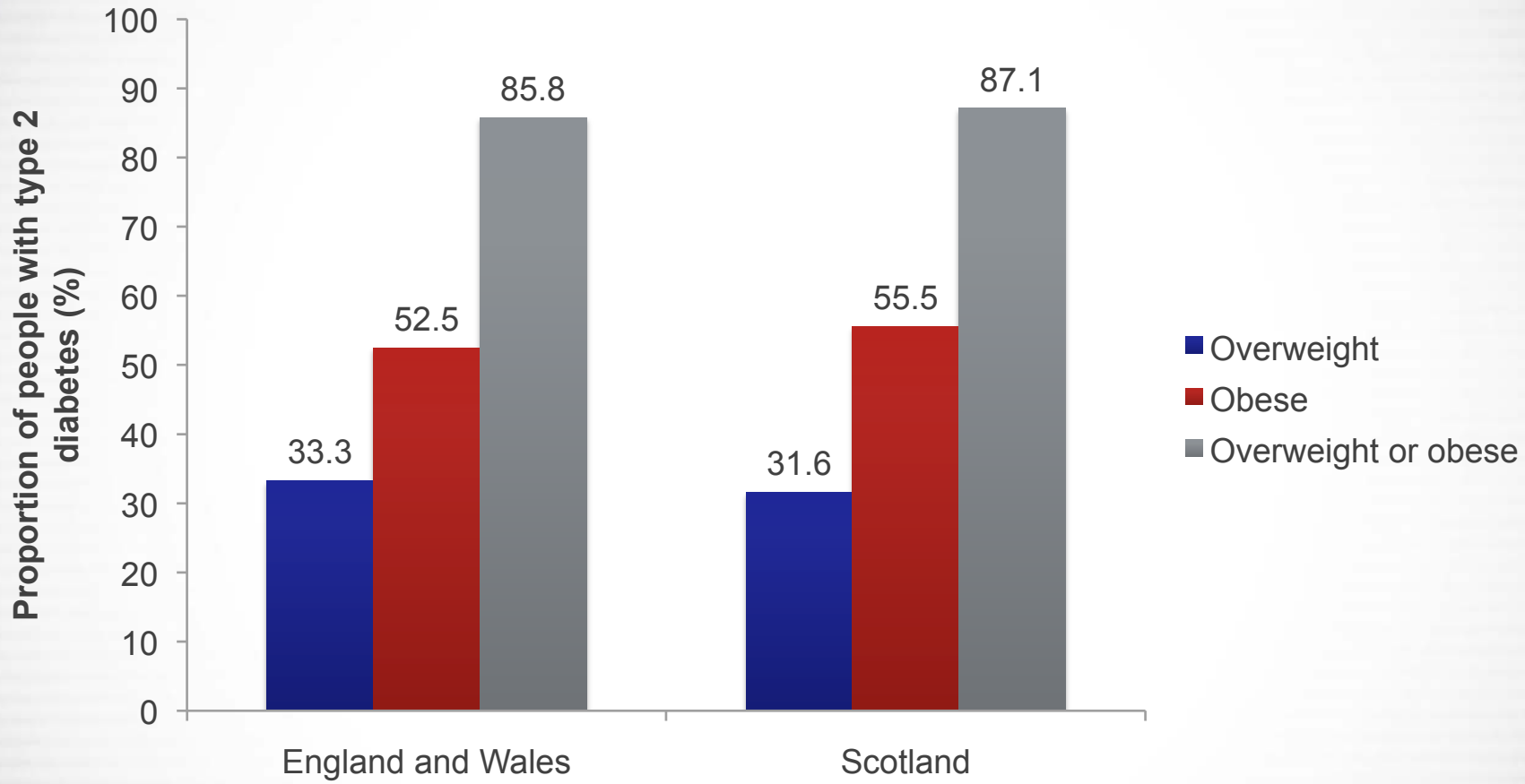
DVLA=Driver and Vehicle Licensing Agency; LGV=large goods vehicle; PCV=passenger carrying vehicle.
Adapted from: TREND-UK (2012) *Diabetes: Safe driving and the DVLA.* Available at: http://bit.ly/1ikUmOk (accessed 24.04.2014)

Medical consequences of overweight and obesity

- Coronary heart disease
- Stroke
- Type 2 diabetes
- Dyslipidaemia
- Hypertension
- Osteoarthritis
- Sleep apnoea
- Liver and gallbladder disease
- Gynaecological problems
- Cancers

Centers for Disease Control and Prevention (2013) *The health effects of overweight and obesity.* Available at: http://1.usa.gov/1tH9eA3 (accessed 24.04.2014)

Prevalence of overweight and obesity in people with type 2 diabetes



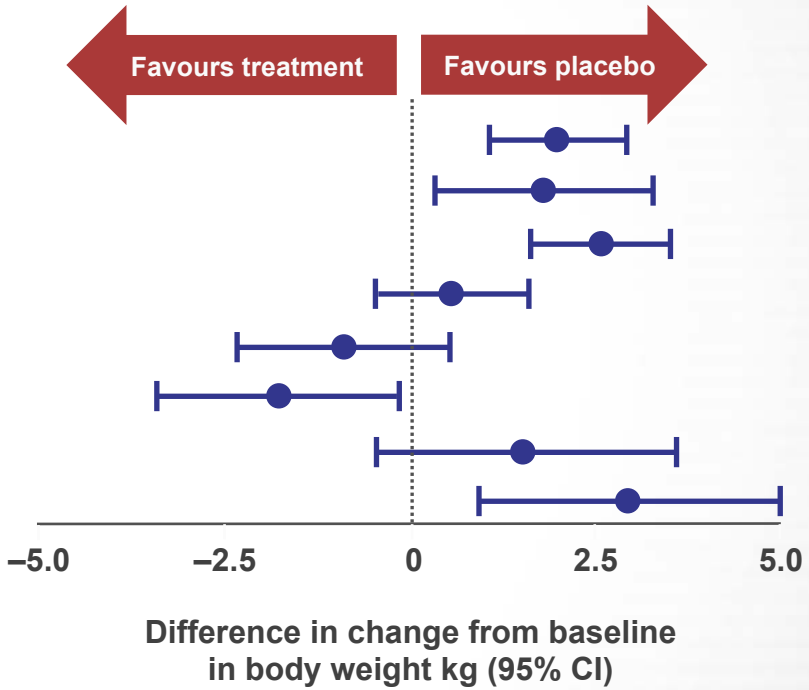
Overweight refers to BMI 25–29.9 kg/m^2; obese refers to BMI ≥30 kg/m^2

1. Health and Social Care Information Centre (2014) *National Diabetes Audit 2012–2013. Report 1: Care Processes and Treatment Targets.* Available at: http://bit.ly/ZuxniQ (accessed 02.10.2014)

2. Scottish Diabetes Survey Monitoring Group (2012) *Scottish Diabetes Survey 2012.* Available at: http://bit.ly/1gdzGGV (accessed 12.03.2014)

Weight changes when adding on to metformin: Meta-analysis of antihyperglycaemic therapies

Treatment	MTC estimate (95% CrI)
Sulphonylureas	2.01 (1.09, 2.94)
Meglitinides	1.80 (0.35, 3.29)
Thiazolidinediones	2.59 (1.66, 3.51)
DPP-4 inhibitors	0.57 (–0.45, 1.60)
Alpha-glucosidase inhibitors	–0.92 (–2.35, 0.51)
GLP-1 analogues	–1.79 (–3.43, –0.14)
Basal insulin	1.56 (–0.46, 3.63)
Biphasic insulin	2.96 (0.96, 5.00)

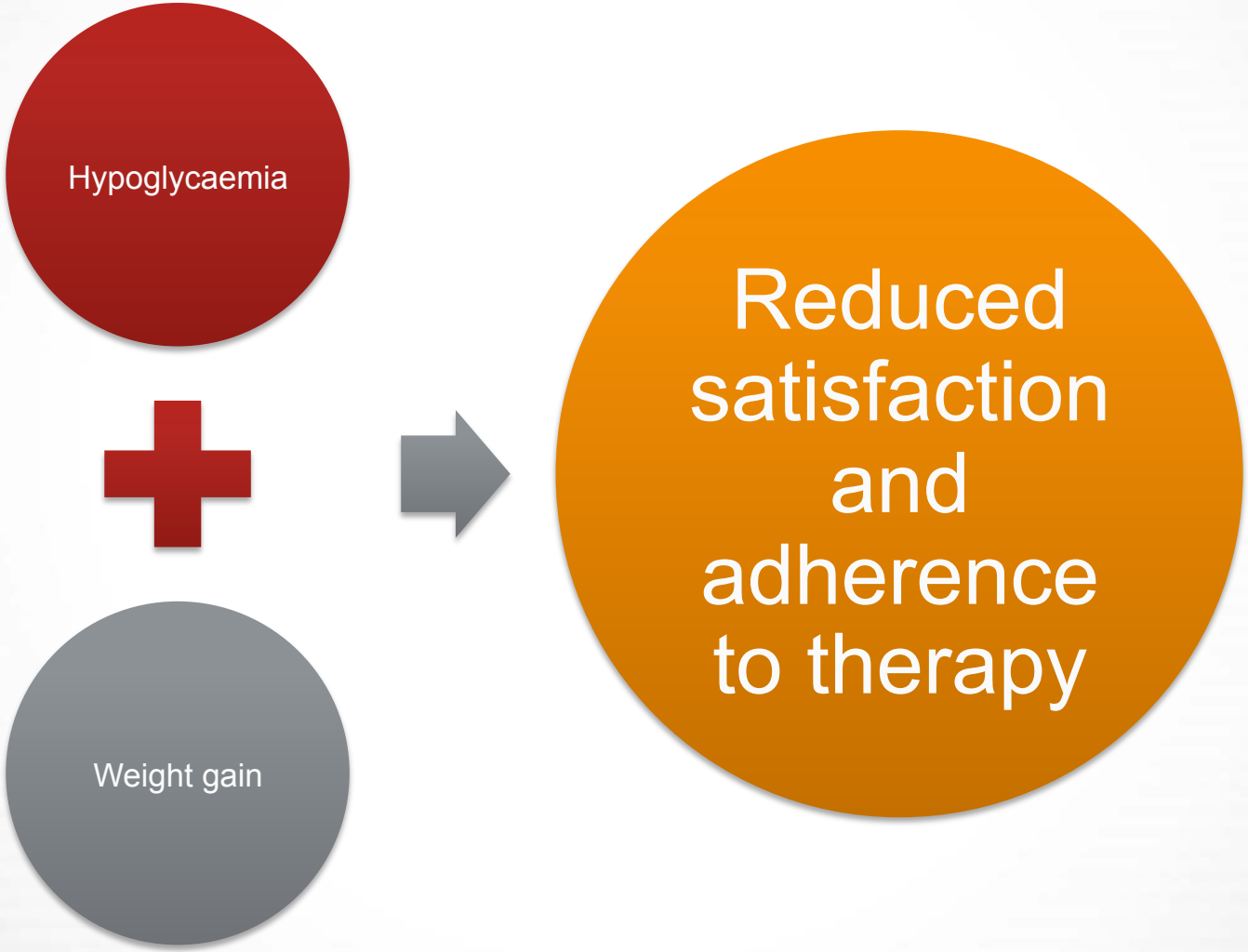


Mixed-treatment comparison (MTC) results showing the effect of adding second-line agents versus placebo in adults taking metformin on change from baseline in bodyweight (kg). MTC analysis based on 30 randomised controlled trials (n=15,265). Most trials were 6–12 months long. Overall, meta-regression and sensitivity analyses yielded minimal differences from the reference case.

CrI=credible interval; DPP-4=dipeptidyl peptidase-4; GLP-1=glucagon-like peptide-1.

McIntosh B et al (2011) *Open Med* **5**: e35-48

Weight gain and hypoglycaemia influence adherence to therapy

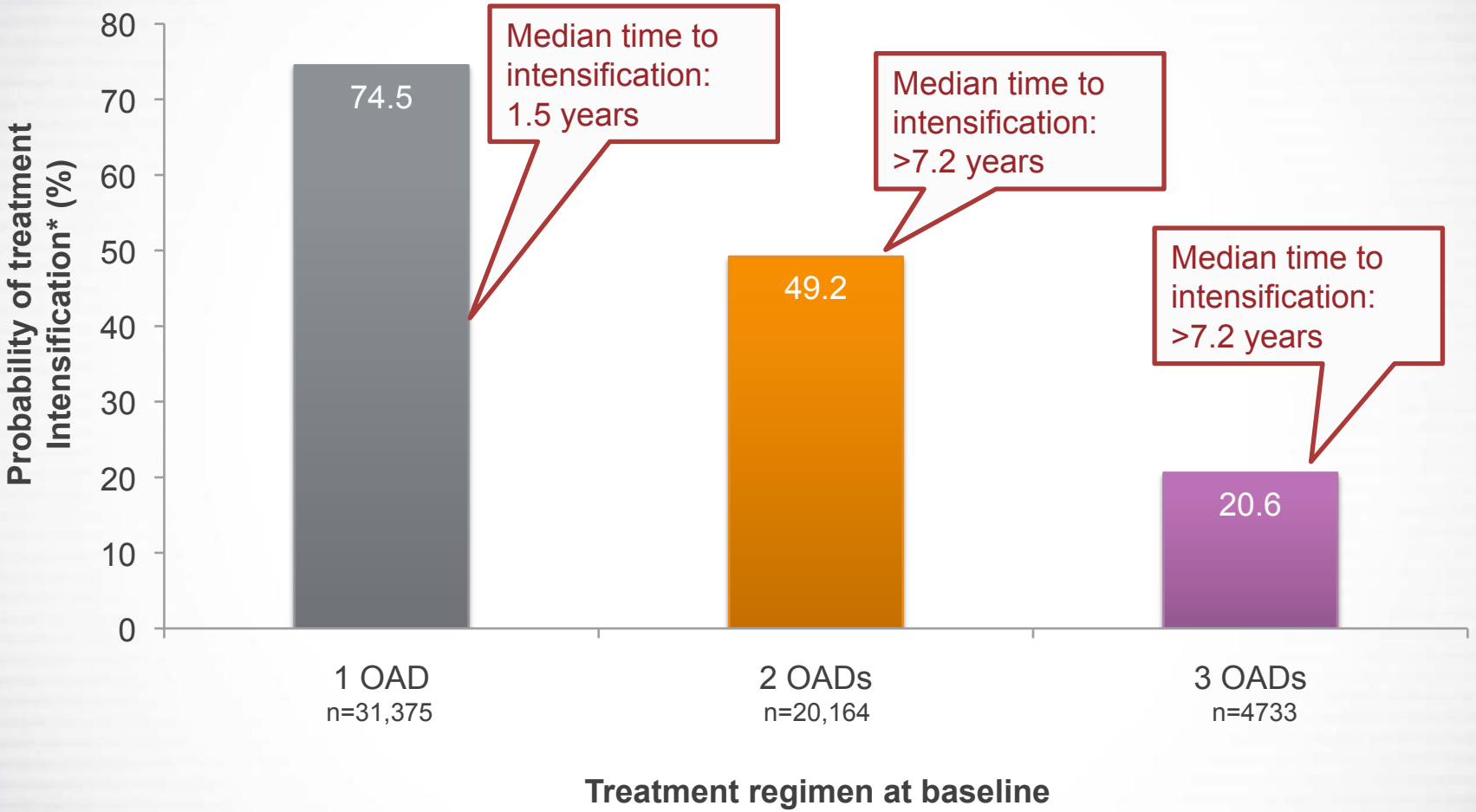


Nau DP (2012) *Am J Manag Care* **18**(3 Suppl): S49–54

Clinical inertia

How big an issue in type 2 diabetes?

Clinical inertia in type 2 diabetes: Probability of intensification when HbA_{1c} >58 mmol/mol (>7.5%)



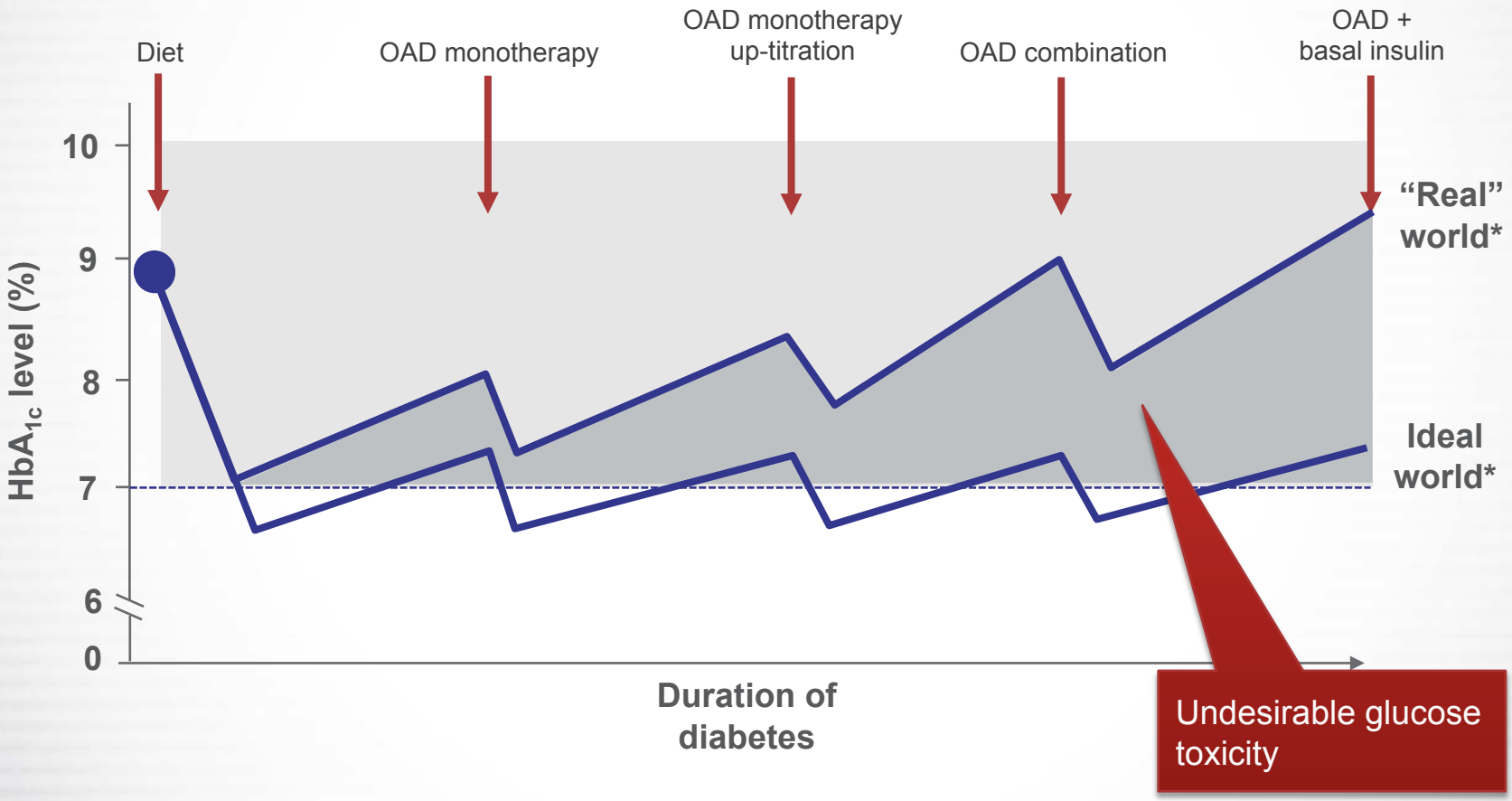
Data from a retrospective cohort study of more than 80,000 people with type 2 diabetes

*Refers to intensification with additional OAD or insulin .

OAD=oral antihyperglycaemic drug.

Khunti K et al (2013) *Diabetes Care* **36**: 3411–7

Implications of clinical inertia: “Ideal” vs “typical” patterns of glycaemic control



*Real and ideal world depictions from Khunti K (personal communication)

Diagram for illustrative purposes only, adapted from Del Prato S et al (2005) *Int J Clin Pract* **59**: 1345–55

Conclusions

Take home points (1)

- We can be proud that improvements have been made in the quality of diabetes care in the UK– debate remains as to what role QOF has had
- We may be seeing a downward trend in mortality and cardiovascular events, but a “gap” still remains between the populations with and without diabetes – we need to continue our good work
- Compared with other countries, the UK appears to be faring well in terms of target attainment for cholesterol and blood pressure – but there is still more to do

Take home points (2)

- The UK is doing less well in terms of glycaemic control compared with other countries
  - We need to consider the detrimental impact this is having on people with type 2 diabetes and their long-term outcomes
- Few people with diabetes are achieving multiple treatment targets, attending structured education or have care plans in place
- Tools are available to help us shape local priorities for diabetes management
- In seeking to improve clinical outcomes, we need therapies for type 2 diabetes that:
  - Help us overcome barriers such as high body weight and hypoglycaemia
  - Help us attain multiple treatment targets

What will you do differently as a result of what you've heard?

Job number: PHGB/VOK/0315/0020 Date of preparation: March 2015

PRESCRIBING INFORMATION

INVOKANA® ▼ film-coated tablets PRESCRIBING INFORMATION
ACTIVE INGREDIENT(S): Canagliflozin hemihydrate, equivalent to 100 mg or 300 mg canagliflozin. Please refer to Summary of Product Characteristics (SmPC) before prescribing. **INDICATION(S):** In adults with type 2 diabetes mellitus to improve glycaemic control as: monotherapy when diet and exercise alone do not provide adequate glycaemic control and use of metformin considered inappropriate; add-on therapy with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control. **DOSAGE & ADMINISTRATION: Adults:** recommended starting dose: 100 mg once daily. In patients tolerating this dose and with eGFR ≥ 60 mL/min/1.73 m2 needing tighter glycaemic control, dose can be increased to 300 mg once daily. Caution increasing dose in patients ≥ 75 years old, with known cardiovascular disease or for whom initial canagliflozin-induced diuresis is a risk. Correct volume depletion prior to initiation. When add-on, consider lower dose of insulin or insulin secretagogue to reduce risk of hypoglycaemia. **Children:** no data available. **Elderly:** consider renal function and risk of volume depletion. **Renal impairment:** not to be initiated with eGFR < 60 mL/min/1.73 m2. If eGFR falls below this value during treatment, adjust or maintain dose at 100 mg once daily. Discontinue if eGFR persistently < 45 mL/min/1.73 m2. Not for use in end stage renal disease or patients on dialysis. **Hepatic impairment:** mild or moderate hepatic impairment: no dose adjustment. **Severe hepatic impairment:** not studied, not recommended. **CONTRAINDICATIONS:** Hypersensitivity to active substance or any excipient. **SPECIAL WARNINGS & PRECAUTIONS:** Not studied in patients with type 1 diabetes. Not to be used for treatment of diabetic ketoacidosis. **Renal impairment:** eGFR < 60 mL/min/1.73 m2: higher incidence of ADRs associated with volume depletion particularly with 300 mg dose; more events of elevated potassium; greater increases in serum creatinine and BUN; limit dose to 100 mg once daily and discontinue when eGFR < 45 mL/min/1.73 m2. Not studied in severe renal impairment. Monitor renal function prior to initiation and at least annually. **Volume depletion:** caution in patients for whom a canagliflozin-induced drop in blood pressure is a risk (eg, known cardiovascular disease, eGFR < 60 mL/min/1.73 m2, anti-hypertensive therapy with history of hypotension, on diuretics or elderly people). Not recommended with loop diuretics or volume depleted patients. Monitor volume status and serum electrolytes. **Elevated haematocrit:** caution. **Genital mycotic infections:** risk in male and female patients, particularly in those with a history of GMI. **Urine laboratory assessment:** glucose in urine due to mechanism of action. **Lactose intolerance:** do not use in patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. **SIDE EFFECTS: Very common:** hypoglycaemia in combination with insulin or sulphonylurea, vulvovaginal candidiasis. **Common:** constipation, thirst, nausea, polyuria or pollakiuria, urinary tract infection, balanitis or balanoposthitis, dyslipidemia, hematocrit increased. **Uncommon:** dehydration, postural dizziness, syncope, hypotension, orthostatic hypotension, rash, urticaria, bone fracture, blood creatinine increased, blood urea increased, blood potassium increased, blood phosphate increased. **Refer to SmPC for other side effects. PREGNANCY:** No human data. Not recommended. **LACTATION:** Unknown if excreted in human milk. Should not be used during breast-feeding. **INTERACTIONS: Diuretics:** may increase risk of dehydration and hypotension. **Insulin and insulin secretagogues:** risk of hypoglycaemia; consider lower dose of insulin or insulin secretagogue. **Effects of other medicines on Invokana:** Enzyme inducers (eg, St. John's wort, rifampicin, barbiturates, phenytoin, carbamazepine, ritonavir, efavirenz) may decrease exposure of canagliflozin; monitor glycaemic control. Consider dose increase to 300 mg if administered with UGT enzyme inducer. Cholestyramine may reduce canagliflozin exposure; take canagliflozin at least 1 hour before or 4-6 hours after a bile acid sequestrant. **Effects of Invokana on other medicines:** Monitor patients on digoxin, other cardiac glycosides, dabigatran. Inhibition of Breast Cancer Resistance Protein cannot be excluded; possible increased exposure of drugs transported by BCRP (eg, rosuvastatin and some anti-cancer agents). **Refer to SmPC for full details of interactions. LEGAL CATEGORY:** POM **PRESENTATIONS, PACK SIZES, MARKETING AUTHORISATION NUMBER(S) & BASIC NHS COSTS** Invokana 100 mg film-coated tablets, EU/1/13/884/002, pack of 30 tablets: £39.20. Invokana 300 mg film-coated tablets, EU/1/13/884/006, pack of 30 tablets: £49.99. **MARKETING AUTHORISATION HOLDER:** Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium. **FURTHER INFORMATION IS AVAILABLE FROM:** Janssen-Cilag Ltd, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG UK.
Prescribing information last revised: April 2014.

Adverse events should be reported. This medicinal product is subject to additional monitoring and it is therefore important to report any suspected adverse events related to this medicinal product. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Janssen-Cilag Ltd on 01494 567447.