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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INDICATOR DEVELOPMENT PROGRAMME

Consultation report on indicators

Indicator area: Diabetes

Consultation period: 1 February – 29 February 2016

Potential output: NICE menu indicators

Contents

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Indicators included in the consultation

ID	Indicator	Evidence source
QOF4: **QOF5** (NM141[1])	The percentage of patients with diabetes in whom the last IFCC-HbA1c is 53 mmol/mol or less in the preceding 12 months. The percentage of patients with diabetes in whom the last IFCC-HbA1c is 58 mmol/mol or less in the preceding 12 months.	Indicators are supported by recommendation 1.6.7 from the NICE guideline on type 2 diabetes in adults and recommendation 1.6.9 from the NICE guideline on type 1 diabetes in adults
QOF6 (NM142[2])	Of the patients with type 1 diabetes who meet the following criteria: aged over 40 years and who have either had diabetes for more than 10 years, or who have established nephropathy or other CVD risk factors; the percentage currently treated with a statin.	This indicator is supported by recommendation 1.3.24 from the NICE guideline on lipid modification.
CCG3: **CCG4**:	The proportion of pregnant women with pre-existing diabetes who have a joint diabetes and antenatal care team review within 1 week of referral. The proportion of pregnant women diagnosed with gestational diabetes that have a joint diabetes and antenatal care team review within 1 week of diagnosis.	Indicators are supported by recommendation 1.2.9 from the NICE guideline on diabetes in pregnancy. NICE QS109 – diabetes in pregnancy – statements 2 and 5
GP3:	The proportion of women with a history of gestational diabetes who have had an HbA1c recorded in the preceding 12 months.	This indicator is supported by recommendation 1.6.14 from the NICE guideline on diabetes in pregnancy. NICE QS109 – diabetes in pregnancy – statement 7
CCG5:	Admission rates due to complications associated with diabetes	Outcome measure not attributable to a single guideline.
CCG6:	Proportion of children and young people who receive the following individual care processes: • Glycated Haemoglobin A1c (HbA1c) monitoring • Body Mass Index (BMI) • Blood pressure • Urinary Albumin • Cholesterol • Eye screening • Foot examination • Smoking • Screening for thyroid and coeliac disease • Psychological assessment	This indicator is supported by recommendations 1.3.20, 1.3.50, 1.2.12, from the NICE guideline on diabetes (type 1 and type 2) in children and young people.

[1] This indicator has been added to the NICE Indicator menu in August 2016 under the ID NM141
[2] This indicator has been added to the NICE indicator menu in August 2016 under the ID NM142

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HbA1c targets for people with diabetes (QOF4 and QOF5)

QOF4 The percentage of patients with diabetes in whom the last IFCC-HbA1c is 53 mmol/mol or less in the preceding 12 months.

QOF5 The percentage of patients with diabetes in whom the last IFCC-HbA1c is 58 mmol/mol or less in the preceding 12 months.

Background

The following indicators are live in the 2016/17 QOF in England:

- *DM007 The percentage of patients with diabetes in whom the last IFCC-HbA1c is 59 mmol/mol or less in the preceding 12 months.*
- *DM008 The percentage of patients with diabetes in whom the last IFCC-HbA1c is 64 mmol/mol or less in the preceding 12 months.*
- *DM009 The percentage of patients with diabetes in whom the last IFCC-HbA1c is 75 mmol/mol or less in the preceding 12 months.*

Poor blood glucose control is associated with increased risk of vascular complications. Therefore one of the main objectives of care for people with both type 1 and type 2 diabetes is to minimise the risk of these complications through optimised glycaemic control.

- For type 1 diabetes, updated NICE guidance recommends that diabetes services document the proportion of adults who achieve an HbA1c of 53 mmol/mol (7%) or lower.

- The updated guideline recommended management strategy for type 2 diabetes is to intensify drug treatment if HbA1c levels rise to 58 mmol/mol (7.5%) with a target of 53 mmol/mol (7.0%) to achieve glycaemic control.

What are we trying to achieve?

Evidence shows that rising levels of HbA1c increase the risk of mortality and developing macrovascular complications (heart attacks, ischaemic heart disease and strokes) and microvascular complications (damage to the eyes and kidneys). Lower HbA1c targets may reduce these complications.

Conversely, low targets may be associated with an increase of hypoglycaemia, which may also impact on quality of life.

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Comments

Mixed comments were received for the 2 indicators. Stakeholders including the Association of British Clinical Diabetologists and Public Health England welcome the inclusion, and others highlight that evidence suggests that long term control is a better predictor of outcomes in diabetes and question their usefulness.

Stakeholders including Public Health England and NHS England support aligning the indicators to NICE guidance but comment it should not compromise individualised care. Further comments suggest the indicators could lead to 'over medicalisation'. Comments also highlight the difference of cardiovascular risk for Type 1 and Type 2 diabetes and thus there should be differentiation of HbA1c measurements for the two groups to improve the quality of care.

Stakeholders noted that the latest NICE guidance for people with type 1 (NG17) and type 2 (NG28) diabetes recommends adults should be involved in decisions about their individual HbA1c targets, supporting the introduction of individualised targets. It was suggested that the introduction of further targets for inclusion in the QOF is counter to the principle of individualisation of therapy.

Stakeholders comment that HbA1c measurements are evidenced to be higher in older populations and therefore the inclusion of these indicators may imply more aggressive management in this group with an increased risk of hypoglycaemia, increases in falls and an increase in disability. Further comments highlight that these indicators are implementing the guideline recommendations without a patient centred approach and, incentivising the targets might lead to some people with diabetes being put at unacceptable risk of hypoglycaemia for little gain.

Comments also suggest the 2 indicator will reduce HbA1c in patients with the lowest risk and instead should focus on patients at higher risk, i.e. patients under 65 with HbA1c levels over 70mmol/mol.

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Considerations for the Advisory Committee

- The possible tension between setting targets for measurement / incentives and NICE guidance supporting individual HbA1c targets
- If the inclusion of QOF4 (53 mmol/mol) has the potential to inadvertently increase disability, adverse events and over treatment particularly in the elderly?
- If separate HbA1c indicators are required for people with Type 1 and Type 2 diabetes?
- The current QOF indicator DM009 (NM97) uses a target of 75 mmol/mol. Is this still a target that should be included in a QOF indicator?

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Statins for people with type 1 diabetes (QOF6)

Of the patients with type 1 diabetes who meet the following criteria: aged over 40 years and who have either had diabetes for more than 10 years, or who have established nephropathy or other CVD risk factors; the percentage currently treated with a statin.

Background

Statin therapy is associated with a reduction of fatal and non-fatal myocardial infarction (MI) and the composite outcome coronary heart disease death or non-fatal MI, fatal and nonfatal stroke and revascularisation. When assessed against the critical outcomes all-cause mortality, cardiovascular mortality, non-fatal MI and quality of life, high and medium intensity statin therapy have a beneficial effect on non-fatal MI.

What are we trying to achieve?

The purpose of this indicator is to increase the proportion of people with type 1 diabetes who are treated with statins, and reduce cardiovascular morbidity and mortality.

Comments

Stakeholders comment that patients are often reluctant to have statin treatment and of those who do, statin treatment induces poor diabetic control. Stakeholders also comment that this indicator is not patient centred and does not encourage informed patient choice. It was suggested that implementing this indicator will remove informed patient choice and lead to over-medicalisation.

It was noted that atorvastatin is contraindicated in women able to have children and not using reliable contraception, pregnant women and women that are breastfeeding.

Further comments highlight that a significant number of people with type 1 diabetes are managed in secondary care rather than general practice.

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Considerations for the Advisory Committee

- If the implementation of this indicator will result in 'over medicalisation'?
- If the implementation of this indicator is suitable for general practice?

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Diabetes in pregnancy (CCG3 and CCG4)

CCG3 The proportion of pregnant women with pre-existing diabetes who have a joint diabetes and antenatal care team review within 1 week of referral.

CCG4 The proportion of pregnant women diagnosed with gestational diabetes that have a joint diabetes and antenatal care team review within 1 week of diagnosis.

Background

Women with diabetes who become pregnant need extra care in addition to routine antenatal care. Members of the joint diabetes and antenatal care team are able to ensure that specialist care is delivered to minimise adverse pregnancy outcomes. Immediate access to the joint diabetes and antenatal care team within 1 week of pregnancy being confirmed or 1 week of diagnosis of gestational diabetes will help to ensure that a woman's diabetes is controlled during early pregnancy, when there in an increased risk of fetal loss and anomalies.

What are we trying to achieve?

The purpose of the 2 indicators is to increase immediate access to joint care teams for pregnant women with diabetes.

Comments

Stakeholders including Diabetes UK and NHS England welcome the inclusion of both indicators and comment that it will encourage the optimal management of diabetes in pregnancy and encourage a multidisciplinary review of diabetes management.

Stakeholders comment that given the current pathways, achieving this indicator would be difficult, moreover comments highlight that capacity and resources in diabetic and antenatal clinics may be a barrier to access. Stakeholders also comment that a 1-week target is too short as referrals usually take much longer, making this indicator unfeasible.

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Considerations for the Advisory Committee

- The committee are asked to consider the results of feasibility testing undertaken by the HSCIC.

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Women with a history of gestational diabetes (GP3)

The proportion of women with a history of gestational diabetes who have had an HbA1c recorded in the preceding 12 months.

Background

Women who have had gestational diabetes are at increased risk of developing type 2 diabetes either in the immediate postnatal period or in the future. Early detection of type 2 diabetes through annual HbA1c testing in primary care can delay disease progression and reduce the risk of complications

What are we trying to achieve?

The purpose of this indicator is to ensure routine testing for HbA1c in order to monitor and manage women who had gestational diabetes to identify early type 2 diabetes.

Comments

Stakeholders including Liverpool LA public health team support this indicator and comment that it will lead to the early identification and diagnosis of diabetes but also comment that the implementation of this indicator will increase the workload in primary care.

Stakeholders highlight that HbA1c measurements are not beneficial when conducted on their own. Comments suggest an annual check of all care processes and lifestyle advice is required to prevent complications.

The resource implications involved in implementing this indicator were noted by a number of stakeholders, it was highlighted that whilst important and useful the resource implications may be significant.

Stakeholders highlight that this is effectively a screening indicator and is not recommended by the National Screening Committee (NSC). Stakeholders also comment that it is unclear for how many years after the pregnancy the monitoring should continue and highlight the potential for unintended consequences when implementing this indicator.

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Considerations for the Advisory Committee

- The potential resource implications of recording HbA1c for all women with a history of gestational diabetes on an ongoing annual basis
- Would HbA1c measurements for women with a history of gestational diabetes be more valuable as part of an annual health check or the national type 2 diabetes prevention programme?

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Admissions due to complications associated with diabetes (CCG5)

Admission rates due to complications associated with diabetes

Background

There are an estimated 2.7 million people diagnosed with diabetes in England, about 10% of those diagnosed currently have Type 1 diabetes.

Diabetes is estimated to have cost the UK £9.8 billion in direct costs in 2010/2011, this equates to approximately 10% of the total health resource expenditure. It is estimated that 80% of these costs are incurred in treating potentially avoidable complications.

What are we trying to achieve?

The purpose of this indicator is to monitor admission rates to address, treat and reduce complications associated with diabetes. It is intended to be CCG level measure of the potentially avoidable complications.

Comments

Stakeholders support the inclusion of this indicator and comment that implementation will promote local data analysis improvement in care.

Stakeholders comment that it will be difficult to attribute causality for admission and data could easily be skewed due to coding errors or if the admission is linked to problems from smoking, hypertension or other factors. Further comments suggest that this indicator requires a more specific definition of 'complications from diabetes'.

Stakeholders also comment on the lack of knowledge of diabetes related complications in some populations groups and that often act as a barrier to implementation. Addressing these issues would help achieve this indicator. Stakeholders further highlight the lack of awareness among black and Asian minority groups and people with learning difficulties.

Considerations for the Advisory Committee

- The committee is asked to consider the HSCIC's report on which complications can be measured at CCG level.
- The merit of reporting on individual complications as opposed to the current composite CCG OIS indicator

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Care processes for children and young people (CCG6)

Proportion of children and young people who receive the following individual care processes:

- *Glycated Haemoglobin A1c (HbA1c) monitoring*
- *Body Mass Index (BMI)*
- *Blood pressure*
- *Urinary Albumin*
- *Cholesterol*
- *Eye screening*
- *Foot examination*
- *Smoking*
- *Screening for thyroid and coeliac disease*
- *Psychological assessment*

Background

The risk of complications associated with diabetes in children and young people can be reduced by monitoring care through carrying out a number of care processes. The nine care processes included in this indicator are recommended by NICE for children and young people with diabetes.

The National Paediatric Diabetes Audit (2014/15) highlights variation in the care received by children and young people. The audit highlights that three quarters of young people aged 12 years of age and above did not receive all seven recommended care processes on an annual basis as previously recommended by NICE at time of audit – the updated NICE guideline will be reflected in the 2015/16 audit.

What are we trying to achieve?

The purpose of this indicator is to increase the proportion of children and young people with diabetes that receive the NICE recommended care processes.

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Comments

Stakeholders support this indicator as it will promote local analysis and improvements in care for children and young people.

Stakeholders comment that care for children and young people with diabetes is usually provided in secondary care and for the successful implementation of this indicator, communication between services will be required. Stakeholders also highlight that teenagers can become disengaged with care and are sometimes lost to follow up.

Specific issue for consideration during consultation

- If the data are available should this indicator be broken down into age bands of perhaps 5 years – i.e., 0 – 5 years, 5 – 10 years, and 10 – 15 years etc?

Stakeholders comment that optimal management of different age groups is difficult so breaking down into age bands could be valuable and useful for young people transitioning into adult services.

Considerations for the Advisory Committee

- If splitting the population into age groups will improve the quality of care for children and young people?
- Should the indicator have a lower age cut-off?

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Appendix A: Consultation comments

Indicator no.	Proforma question no.	Stakeholder organisation	Comment
Question 8.1: Do you think there are any barriers to implementing the care described by these indicators?			
QOF 4 & QOF 5	8.1	Association for the study of obesity	No
QOF 4 & QOF 5	8.1	Association of British Clinical Diabetologists	No
QOF 4 & QOF 5	8.1	Association of British Clinical Diabetologists	Yes. See 8.4 [We welcome the motivation behind this suggested tightening of the HbA1c criteria in the QOF. For people without significant co-morbidities living independently, and who have good awareness of hypoglycaemia (where this is a potential consequence of their treatment), the more stringent targets are desirable.]
QOF 4 & QOF 5	8.1	British Holistic Medical Association	This would be yet another distraction from engaging with the human being.
QOF 4 & QOF 5	8.1	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	Unsure about usefulness - feasibility
QOF 4 & QOF 5	8.1	Individual comment	These indicators appear muddled
QOF 4 & QOF 5	8.1	Individual comment	Not all patients will have had an HbA1c done – although most will have. This indicator will establish this and the rest can be targeted.
QOF 4 & QOF 5	8.1	Individual comment	For older patients with multimorbidity, the danger of hypoglycaemia and sife-effectos of polypharmacy.needs to be balanced with tight HbA1C

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			control.
QOF 4 & QOF 5	8.1	Individual comment	patients don't want to engage in education sometimes. Primary care teams have finite resources to spend on this
QOF 4 & QOF 5	8.1	Individual comment	not an appropriate level of hba1c for all diabetes eps elderly those with co-morbidities
QOF 4 & QOF 5	8.1	Individual comment	no
QOF 4 & QOF 5	8.1	Individual comment	is epidemiology , see 6.4 [Talk to the GP system providers and let them adjust the computer systers so that these kind of epidemiology data can be found automatically]
QOF 4 & QOF 5	8.1	Individual comment	Yes it is statistically and scientifically invalid to combine type 1 and type 2 diabetes into one indicator
QOF 4 & QOF 5	8.1	Juvenile Diabetes Research Foundation (JDRF)	The Diabetes Control and Complications Trial (DCCT) established intensive insulin therapy as standard treatment in type 1 diabetes and identified severe hypoglycaemia as the chief adverse event associated with intensive insulin therapy. The DCCT demonstrated that intensive insulin therapy results in a threefold risk of hypoglycaemia. The risk and fear of hypoglycaemia is a barrier to the treatment of type 1 diabetes, and as a result a barrier to achieving recommended HbA1c indicators. While recent updates to NICE guidelines for the management of diabetes in both the child and adult populations provide access to newer tools that facilitate safe diabetes management and glucose control, criteria focus on specific subpopulations. Without broader access to these tools achieving indicators would be extremely difficult.
QOF 4 & QOF 5	8.1	Liverpool LA public health team	Unsure about usefulness - feasibility
QOF 4 & QOF 5	8.1	London Borough of Redbridge	No

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QOF 4 & QOF 5	8.1	London Diabetes Strategic Clinical Network	Not all patients will have had an HbA1c done – although most will have. This indicator will establish this and the rest can be targeted.
QOF 4 & QOF 5	8.1	Medtronic Limited	Lack of understanding of the health complications that can arise as a result of diabetes often acts as a barrier to effective adoption of steps which would help to achieve this indicator. An is needed improvement in education for patients and healthcare professionals working in primary and community care, on diabetes related complications
QOF 4 & QOF 5	8.1	NHS Employers	Patient choice as it's very difficult to achieve good control in a number of patient.
QOF 4 & QOF 5	8.1	NHS Sheffield Clinical Commissioning Group	This is a population target but NICE NG28 1.6.9. indicates that it may not be suitable for all patients and there should be consideration to relax the target on a case by case basis. Patients may not wish to increase their therapy or may not comply with additional therapies.
QOF 4 & QOF 5	8.1	Nightingale Valley Surgery.	This would be helpful but we will not have the resources to arrange all these additional blood tests.
QOF 4 & QOF 5	8.1	Primary Care Diabetes Society	NICE suggests intensification should be considered at 58mmol/mol . For practitioners who follow NICE guidance , this target may cause confusion . Perhaps by qualifying it by stating those patients on diet and monotherapy would be more reflective of the guideline.
QOF 4 & QOF 5	8.1	RCGP	The RCGP feels that the following could be barriers to implementing the care in these indicators: 1. HbA1c targets can often be more useful if individualised to the patient: an HbA1c target of 53 may not be appropriate for example in a

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			frail elderly person who has frequent hypoglycemia and falls and it maybe reasonable to set the target higher. This should be considered in implementing this standard. (commentator 1, 2) 2. Poor patient compliance with the medication doses/quantity/administration would make it difficult to achieve this target. (Commentator 3) 3. Patient involvement, commitment, lifestyle and an effective diabetic team. For older patients with multimorbidity, the danger of hypoglycaemia and side-effects of polypharmacy needs to be balanced with tight HbA1C control. (Commentator 4) 4. The lack of encouragement to prescribe newer diabetic drugs. Insulin is the cheapest choice, but not acceptable for many. This may be placing too much emphasis on blood sugar rather than blood pressure control. (Commentator 5) 5. Overtreatment of patients in a misguided attempt to reach targets goes against NICE guidelines. For example, the patient with an HbA1c of 56 mmol/mol could be treated with more drugs in an attempt to reach the 53 mmol/mol target even though the NICE guidelines only recommend intensification of therapy if the HbA1c rises above 58 mmol/mol. This is giving GPs financial incentives to go against NICE's own guidance. We are not aware of any evidence that confirms that tightening of diabetic control from 56 to 53mmol/mol will improve patient-meaningful outcomes. It will certainly increase the risk of harm. (RCGP

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			Overdiagnosis Group)
QOF 4 & QOF 5	8.1	Somerset CCG	This is a very non-person centred approach. This does not fit with quality evidence-based medicine (consider the EBM triad).
QOF 4 & QOF 5	8.1	South Eastern Hants CCG and NICE MPP Associate	My understanding of the NICE guidance are that the 2 fugures quoted here are not targets for sugar control in all diabetics but level at which intensification of a regime should be considered and in an ideal world achieved. However a major part of the NICE guidance is around agreeing an appropriate level of sugar control with the patient which may well be above these levels- especially in drivers on drugs hypoglycemic potential.
Question 8.2: Do you think there are potential unintended consequences to implementing / using these indicators?			
QOF 4 & QOF 5	8.2	Association for the study of obesity	No
QOF 4 & QOF 5	8.2	Association of British Clinical Diabetologists	Yes. We welcome the motivation behind this suggested tightening of the HbA1c criteria in the QOF. For people without significant co-morbidities living independently, and who have good awareness of hypoglycaemia (where this is a potential consequence of their treatment), the more stringent targets are desirable. For type 1 diabetes recommendation 1.6.9 must be read in the context of the previous recommendations: 1.6.7 Agree an individualised HbA1c target with each adult with type 1 diabetes, taking into account factors such as the person's daily activities, aspirations, likelihood of complications, comorbidities, occupation and history of hypoglycaemia. [new 2015] 1.6.8 Ensure that aiming for an HbA1c target is not accompanied by problematic hypoglycaemia in adults with type 1 diabetes. Failure to achieve the target where it is desirable should lead to referral to a specialist diabetes service with experience in and access to NICE-

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			approved technologies of proven benefit. For type 2 diabetes an indicator based on the recommendations 1.6.7, 1.6.8 and 1.6.9 would be a better indicator of the quality and safety of individualised care. It should be possible to extract this data based on type of diabetes, type of diabetes treatment (whether it contains agents that confer a risk of hypoglycaemia) and the presence of frailty, dementia, and other significant co-morbidities. Incentivising the targets as set out in the document might lead to some people with diabetes being put at unacceptable risk of hypoglycaemia for little gain, while others with little or no risk of hypoglycaemia may not be challenged to consider achieving even better glycaemic control, particularly those who have been diagnosed recently and who are not taking hypoglycaemic agents. It is also possible that more patients with multiple co-morbidities will be excepted, if this draft indicator is adopted without modification.
QOF 4 & QOF 5	8.2	British Holistic Medical Association	Yet another little step towards a clinical practice dictated by numbers and tests.
QOF 4 & QOF 5	8.2	British Medical Association	There are some groups, particularly the elderly or frail, who do not benefit and can be harmed by pharmacologically-achieved low blood glucose measures.
QOF 4 & QOF 5	8.2	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	May increase prevalence of hypoglycaemia and related consequences
QOF 4 & QOF 5	8.2	Diabetes UK	Such binary cut-offs have the potential to compromise individualised care
QOF 4 & QOF 5	8.2	Individual comment	Yes. This proposed indicator focuses in driving down the HbA1c of

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			patients in the lowest risk groups. We should be focussing on those in the high risk groups – those under 65 with HbA1c levels over 70mmol/mol. The evidence for medication reducing morbidity and mortality in diabetes is very weak. There is no evidence for the newer drugs, a tiny reduction after 20 years for sulphonylureas (UKPDS data) and even the small benefit from metformin was questioned in a recent BMJ article. We need to concentrate on motivating diabetics to focus on lifestyle and not adding in more and more pills and injections.
QOF 4 & QOF 5	8.2	Individual comment	of course; see 8.1 [patients don't want to engage in education sometimes]
QOF 4 & QOF 5	8.2	Individual comment	Overtreatment is very likely. The clinical benefit of very tight glucose control is very controversial to say the least. Patients end up on too many drugs.
QOF 4 & QOF 5	8.2	Individual comment	The consultation document quotes the guidelines for Type two diabetes as aiming for less than 58mmol/mol. The threshold of 53mmol/mol in this indicator is for Type one diabetes. However this distinction has not been made. There is potential harm to patients with type two diabetes of over intensive treatment.
QOF 4 & QOF 5	8.2	Individual comment	Once GP is more aware of elevated HbA1c result, they are more likely to refer patient onto community services or hospital services. Impact could be felt there, although these patients may need to be seen there anyway if competency and capacity lacking in GP surgery.
QOF 4 & QOF 5	8.2	Individual comment	They will contribute enormously to problems of polypharmacy
QOF 4 & QOF 5	8.2	Individual comment	I don’t like QOF4 as a concept and fear that we may over-medicate and increase the number of hypoglycaemic episodes. This also strikes me

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			as being too “glucocentric” and that we should be addressing getting BP and lipids better managed and reinforcing lifestyle messages about exercise especially in those with elevated HbA1c.
QOF 4 & QOF 5	8.2	Individual comment	no
QOF 4 & QOF 5	8.2	Individual comment	no
QOF 4 & QOF 5	8.2	Individual comment	excess treatment of the elderly causing falls, and illness. Ie should be outs for age, frailty, other illness.
QOF 4 & QOF 5	8.2	Individual comment	Yes since it is totally invalid to combine type 1 and type 2 HbA1c figures. The two types of diabetes need to be separated to have any valid indicator. The National Diabetes Audit got a shock in their 2011-12 report when they looked at the two results separately and found that the problems with type 1 diabetes were far more severe than they had realised. In the 2013-14 and 2014-15 reports they do not even combine these HbA1c figures as they have now realised that it is invalid for two key reasons: It is statistically invalid since the data for type 1 and type 2 HbA1c values do not even overlap, even at the level of the whiskers on the boxplot that represent the upper adjacent values. Type 1 and type 2 are different diseases with different treatments, even if they both involve problems with the pancreas. I could insert boxplots here to visually show this but if I just give the upper and lower quartile values you can see that there is no overlap whatsoever (data from 2014-15 NDA): Type 1 for <7.5% HbA1c (58 mmol/mol) 27.3 – 34.1 Type 2 for <7.5% HbA1c (58 mmol/mol) 64.6 – 69.3

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			Type 1 for <6.5% HbA1c (48 mmol/mol) 7.2 – 10.4 Type 2 for <6.5% HbA1c (48 mmol/mol) 26.4 – 33.3 So type 1 results are statistically very different to type 1 results and so any statistician will say that THEY SHOULD NEVER BE COMBINED. Type 1 represent some 10% of the total population but their complication rates are some four times higher as measured by the NDA and so costs to the NHS are some 40:60 split between the two types.
QOF 4 & QOF 5	8.2	JDRF	HbA1c is a biomarker that allows patients and clinicians to get an overall picture of what average blood glucose levels have been over a period of weeks/months. For people with diabetes, measures of blood glucose, such as HbA1c, are important, because as blood glucose increases so does the risk of developing diabetes-related complications. It has been established in scientific research that for people with type 1 and type 2 diabetes lowering blood glucose, and in turn lowering HbA1c, can cut the risk of microvascular complications by 25 percent. It is for this reason that it is correct for HbA1c to be used as an indicator of blood glucose control and as a target indicator for clinicians. However, there are concerns that using HbA1c as the sole indicator of good glucose control for reduced risk of long term complications could side-line other important indicators of safe glucose control. While a good indicator, HbA1c is not perfect. Evidence shows that some patients are given overwhelmingly positive feedback from their clinicians about their diabetes control because their HbA1c levels meet targets, even if their overall blood glucose levels are dangerously variable such that they experience significant hypoglycaemia and

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			hyperglycaemia. Moreover, HbA1c can be influenced by a number of factors including red blood cell count, non-diabetic medications, antioxidant agents, and genetic variants. Because HbA1c is imperfect, other indicators of glucose control, including time in normal glycaemic range, are emerging and there is increasing evidence that this indicator could in fact be a better measure of the risk of long term complications. Hypoglycaemia, including severe hypoglycaemia, is also an important diabetes indicator and often is a barrier to achieving treatment goals. If HbA1c is prioritised as a key indicator without explicit reference to these other indicators then it is possible there could be unintended consequences – clinical blind spots could be created as targets are geared towards achieving ideal median HbA1c levels at the expense of other indicators.
QOF 4 & QOF 5	8.2	Liverpool LA public health team	May increase prevalence of hypoglycaemia and related consequences
QOF 4 & QOF 5	8.2	London Borough of Redbridge	No
QOF 4 & QOF 5	8.2	London Diabetes Strategic Clinical Network	Once GP is more aware of elevated HbA1c result, they are more likely to refer patient onto community services or hospital services. Impact could be felt there, although these patients may need to be seen there anyway if competency and capacity lacking in GP surgery.
QOF 4 & QOF 5	8.2	Medtronic Limited	The Cardiovascular risks are different for Type 1 and Type 2 diabetes and so there should be differentiation of HbA1c levels for Type 1 and Type 2 diabetic patients for improved quality of care
QOF 4 & QOF 5	8.2	NHS Employers	Dual payment of achievement if this is in addition to existing indicators esp DM007 which is 59 m/mol or less.

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QOF 4 & QOF 5	8.2	NHS England	There are of course risks with over treatment but that is common to other conditions that require drug therapy and managing that balance is essential primary care. Care will be required not to cause hypoglycaemia in certain groups - especially elderly with pre-existing CHD, in whom there is a risk of contributing to higher mortality if glycaemic control is too tight
QOF 4 & QOF 5	8.2	NHS Sheffield Clinical Commissioning Group	As above, there may be an incentive to intensify blood glucose treatments when this is less appropriate or the patient has poor compliance with current treatments. The targets do not reflect the medicines optimisation agenda. A high percentage of exceptions may be recorded particularly for T2.
QOF 4 & QOF 5	8.2	NICE	Imposition of the guideline recommendations without a patient-centred approach
QOF 4 & QOF 5	8.2	Primary Care CVD Leadership Forum	There are of course risks with over treatment but that is common to other conditions that require drug therapy and managing that balance is essential primary care. However, there is some concern that the 53 target will increase risk of adverse effects especially in older people and is counter to the principle of individualisation of therapy.
QOF 4 & QOF 5	8.2	Primary Care Diabetes Society	This may cause confusion regarding NICE guideline . It may also encourage more aggressive and inappropriate intensification .The risks in achieving targets in elderly or those with longer duration of diabetes should be considered (VADT, ADVANCE & ACCORD studies)
QOF 4 & QOF 5	8.2	Public Health England	There are of course risks with over treatment but that is common to other conditions that require drug therapy and managing that balance is

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			essential primary care.
QOF 4 & QOF 5	8.2	RCGP	The RCGP has identified the following potential consequences to implementing these indicators: 1. *'Therefore one of the main objectives of care for people with both type 1 and type 2 diabetes is to minimise the risk of these complications through optimised glycaemic control.'* There is continuing disagreement about the benefit of conventional drug treatment (especially with newer drugs, where they have not been in use for long enough for to know their long-term risks & benefits) to reduce HBA1c to levels below 60mmol. This may lead to overdiagnosing diabetes, providing vigorous treatment to those with mild degrees of diabetes, and the potential of ignoring the needs of those with more serious degrees of diabetes. (DJ) 2. Providing such tight control in inappropriate patients may increase the risk of hypoglycemia and falls (RM), particularly in the elderly and frail, (CH) and is counter to the principle of individualisation of therapy. (MK) (RCGP Overdiagnosis Group) 3. It may lead to an increase in diabetic expenditure as newer drugs are marketed and tried. (JA) It will drive up costs with more patients needing insulin and the newer diabetic drugs when there is no evidence that these reduce morbidity and mortality in diabetes. (RCGP Overdiagnosis Group) 4. Is this the most recent A1c rate or any below 53 in the preceding year? There is a risk of a patient in April having a result of 52 and then the practice choosing not to repeat the test until the next indicator year. (TB)

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			5. The RCGP thinks GPs should be focussing on having discussions with diabetic patients around what their priorities are rather than focussing on targets. GPs would like to see a move towards having a dialogue with patients about the pros and cons of intensifying treatment and letting them decide what is best for them. (RCGP Overdiagnosis Group)
QOF 4 & QOF 5	8.2	Somerset CCG	Overmedicalisation. Adverse drug reactions. Cost with no real person benefit. Distracting from quality care. This SMART target is probably not smart. There is an anchoring bias. There is the danger of causing depersonalisation of the patient by the clinician.
QOF 4 & QOF 5	8.2	South Eastern Hants CCG and NICE MPP Associate	These targets might encourage clinical staff to aim for too low levels of HBA1c in patients and increase risk of hypoglycemic episodes with marginal gains in complication risk development. The evidence for intensive control over normal control, being beneficial is quote in the guidance and is mostly non significant statistically whilst the risk of hypoglycaemia significantly increased. In real life practice many patients have no change of getting near these targets and with both targets being quite low there is a risk that people with higher levels with be disincentivised to achieve these levels. The end result is likely to be multiple exclusions from the target in Qof making it ineffective as an incentive Multiple intensification of drug regimes increase costs massively with v

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			high QALYs well above £30,000 rate used as a guide for NICE decisions
QOF 4 & QOF 5	8.2	University of Surrey	Yes. We think this could lead to over treatment of elderly people with the stricter targets in place.
Question 8.3: Do you think there is potential for differential impact (in respect of age, disability, gender and gender reassignment, pregnancy and maternity, race, religion or belief, and sexual orientation)? If so, please state whether this is adverse or positive and for which group.			
QOF 4 & QOF 5	8.3	Lancaster University	Yes, people with learning disabilities (adverse)
QOF 4 & QOF 5	8.3	Primary Care Diabetes Society	It has been shown that HbA1c is higher in the elderly for the same glycaemic control as the young . Therefore this will imply a more aggressive management in the older population with increased risk of hypoglycaemia . A safer option would be evidence of documentation that a discussion has taken place for an individualised target.
QOF 4 & QOF 5	8.3	Association for the study of obesity	No
QOF 4 & QOF 5	8.3	Association of British Clinical Diabetologists	No
QOF 4 & QOF 5	8.3	British Holistic Medical Association	see 1.3 [This looks like political correctness. What matters is for the clinician to have respect for people because of their difference, not because it is PC to enquire.]
QOF 4 & QOF 5	8.3	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	Less useful for older people and those with frequent hypoglycaemic episodes.

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QOF 4 & QOF 5	8.3	Individual comment	AGE - Some patients, particularly young Type 1 patients may get “lost” to follow-up as at university etc elsewhere
QOF 4 & QOF 5	8.3	Individual comment	Older people/people with multimorbidity
QOF 4 & QOF 5	8.3	Individual comment	of course; age is all important; arguably treating to target in the very elderly will cause unnecessary deaths
QOF 4 & QOF 5	8.3	Individual comment	no
QOF 4 & QOF 5	8.3	Individual comment	dont know
QOF 4 & QOF 5	8.3	Individual comment	Will increase disability in elderly
QOF 4 & QOF 5	8.3	Liverpool LA public health team	Less useful for older people and those with frequent hypoglycaemic episodes.
QOF 4 & QOF 5	8.3	London Borough of Redbridge	No
QOF 4 & QOF 5	8.3	London Diabetes Strategic Clinical Network	AGE - Some patients, particularly young Type 1 patients may get “lost” to follow-up as at university etc elsewhere
QOF 4 & QOF 5	8.3	Medtronic Limited	Applies to all patient groups
QOF 4 & QOF 5	8.3	NHS England	Higher risk of adverse effects in older people when pursuing the HbA1c of 53
QOF 4 & QOF 5	8.3	NHS Sheffield Clinical Commissioning Group	NG28 1.6.9 includes a consideration of relaxing the targets for people who are older or frail. These patients may not tolerate intensification of blood glucose management. Other listed groups are unlikely to be affected.
QOF 4 & QOF 5	8.3	Primary Care CVD Leadership Forum	Higher risk of adverse effects in older people when pursuing the HbA1c of 53

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QOF 4 & QOF 5	8.3	Public Health England	Higher risk of adverse effects in older people when pursuing the HbA1c of 53
QOF 4 & QOF 5	8.3	RCGP	The RCGP feels that there would be negative impact on frail, elderly patients (commentator 1, 2), particularly those with multimorbidity (commentator 3) as well as those in different ethnic communities who have complex reasons contributing to their poor diabetic control (well exemplified in Martin Marshall's article in this month's BJGP). (commentator 5)
QOF 4 & QOF 5	8.3	Somerset CCG	Yes. There is significant variation with age in the health and wellbeing benefits and risks of lowering HbA1c with medication.
QOF 4 & QOF 5	8.3	University of Surrey	Yes. Afro Caribbean people may be discriminated against in view of their higher HbA1c (0.4% higher than white European origin with equivalent glycaemia). Practices with a higher proportion of black people may find this difficult.
Question 8.4: Do you have any general comments on these indicators?			
QOF 4 & QOF 5	8.4	Primary Care Diabetes Society	What percentage of patients are expected to reach these targets? There should be allowance for coding as NICE states that targets should be individualised and with patient contribution.
QOF 4 & QOF 5	8.4	Association for the study of obesity	Useful to clarify patients who differ in their level of control by HbA1c. BMI measures would be useful to support this and identify whether weight management information is required by those who diabetes is identified as being poorly controlled.
QOF 4 & QOF 5	8.4	Association of British Clinical Diabetologists	We welcome the motivation behind this suggested tightening of the HbA1c criteria in the QOF. For people without significant co-morbidities living independently, and who have good awareness of hypoglycaemia (where this is a potential consequence of their treatment), the more stringent targets are desirable.

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			For type 1 diabetes recommendation 1.6.9 must be read in the context of the previous recommendations: *1.6.7 Agree an individualised HbA1c target with each adult with type 1 diabetes, taking into account factors such as the person's daily activities, aspirations, likelihood of complications, comorbidities, occupation and history of hypoglycaemia. [new 2015]* *1.6.8 Ensure that aiming for an HbA1c target is not accompanied by problematic hypoglycaemia in adults with type 1 diabetes.* Failure to achieve the target where it is desirable should lead to referral to a specialist diabetes service with experience in and access to NICE-approved technologies of proven benefit. For type 2 diabetes an indicator based on the recommendations 1.6.7, 1.6.8 and 1.6.9 would be a better indicator of the quality and safety of individualised care. It should be possible to extract this data based on type of diabetes, type of diabetes treatment (whether it contains agents that confer a risk of hypoglycaemia) and the presence of frailty, dementia, and other significant co-morbidities. Incentivising the targets as set out in the document might lead to some people with diabetes being put at unacceptable risk of hypoglycaemia for little gain, while others with little or no risk of hypoglycaemia may not be challenged to consider achieving even better glycaemic control, particularly those who have been diagnosed recently and who are not taking hypoglycaemic agents. It is also possible that more patients with multiple co-morbidities will be excepted, if this draft indicator is adopted without modification.
QOF 4 & QOF 5	8.4	British Holistic Medical	slippery slope.

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		Association	
	8.4	British Medical Association	Previously low HbA1c's were removed from QOF as they caused harm and this could do the same. IND QOF4 is not a suitable indicator. NICE guidance itself is clear that HbA1c goals should be set in conjunction with the patient taking into account individual circumstances. To link payment to this places the GP in a conflict of interest situation. There are so many patients who will choose not to take medication to meet this target, or who will have adverse effects from the medication required, that exception reporting will be high. The total percentage will then be meaningless, as it will not inform as to whether those who are meeting the target are the patients who will benefit from it.
QOF 4 & QOF 5	8.4	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	Unsure about clinical usefulness, especially using target 53 mmol/mol.
QOF 4 & QOF 5	8.4	Diabetes UK	Diabetes UK support the importance being placed on good HbA1c control. This should not compromise the need for individualised care, as there are still some people with diabetes for whom these cut-offs may not be appropriate.
QOF 4 & QOF 5	8.4	Individual comment	I would suggest that QOF4 is amended to refer only to patients with type one diabetes.
QOF 4 & QOF 5	8.4	Individual comment	There is still some lack of understanding / useage of the "new" units for HbA1c. May be worth using old numbers – which are still colloquially used, in brackets?

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QOF 4 & QOF 5	8.4	Individual comment	There is now a large body of research showing very little benefit from trying to achieve low HbA1c targets in most patients with Type 2 diabetes. These indicators will not just perpetuate but also drive a style of medicine that treats laboratory results rather than seeks to achieve better patient outcomes. It is really disappointing to see NICE not recognise this.
QOF 4 & QOF 5	8.4	Individual comment	Not my field of experience.
QOF 4 & QOF 5	8.4	Individual comment	We need to focus on those at highest risk, not drive down HbA1c levels in those in the lowest risk group. The diabetic drug spend is huge and rapidly increasing but the evidence of benefit is just not there. Time to concentrate on diet and exercise
QOF 4 & QOF 5	8.4	Individual comment	are these to replace the current three ranges? I think you need to keep the higher ranges as they permit a practice to focus on those with worst control
QOF 4 & QOF 5	8.4	Individual comment	Talk to the GP system providers and let them adjust the computer systems so that these kind of epidemiology data can be found automatically
QOF 4 & QOF 5	8.4	Individual comment	My comment is that these combined indicators are invalid as stated above and I would just repeat my opening comments: See my submission to the Parliamentary Accounts Committee which was used in their recent critical report about the diabetes service - http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/public-accounts-committee/diabetes-followup/written/25329.html

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			One key point I will make is that QOF for 2014/15 shows that GP's earn 89.2% of their specialist diabetes points and yet the recent National Diabetes Audit shows no improvement in performance over the last 6 years with a success rate of around 17% for type 1 in meeting all three key NICE clinical targets, whilst type 2 it is 38%. So there is a big mismatch between 89.2% and the achieved results of 17% and 38%. This ought to raise some serious concerns. The latest QOF publication states: "The objective of the QOF is to improve the quality of care patients are given by rewarding practices for the quality of care they provide to their patients." For diabetes this is not achieved.
QOF 4 & QOF 5	8.4	Liverpool LA public health team	Unsure about clinical usefulness, especially using target 53 mmol/mol.
QOF 4 & QOF 5	8.4	London Borough of Redbridge	We welcome this indicator of lowering the IFCC-HbA1C from 58mmol/mol to 53 mmol/mol.
QOF 4 & QOF 5	8.4	London Diabetes Strategic Clinical Network	There is still some lack of understanding / useage of the "new" units for HbA1c. May be worth using old numbers – which are still colloquially used, in brackets?
QOF 4 & QOF 5	8.4	Medtronic Limited	As the Cardiovascular risks are different for Type 1 and Type 2 diabetes there needs to be separate indicators for HcA1c levels. For Type 1 Diabetes It is important to highlight in the QOF Indicators the target level recommended by NICE in NG17 for HbA1c is 48 mmol/mol " Support adults with type 1 diabetes to aim for a target HbA1c level of 48 mmol/mol (6.5%) or lower, to minimise the risk of long-term vascular

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			complications. **[new 2015]".** Currently this is not referenced in the QOF indicators and so we recommend including to aim for this target to minimise the risk of long-term vascular complications for patients with Type 1 diabetes
QOF 4 & QOF 5	8.4	NHS Employers	It needs to be clear if these are in addition to or replacing existing indicators and the rationale for the change.
QOF 4 & QOF 5	8.4	NHS England	NHS England supports aligning the indicators with the NICE recommendations so that they reflect the evidence of what impacts on outcomes. The national Diabetes Audit shows that there is significant variation between practices in achievement of treatment targets in diabetes and therefore significant potential for improvement. QOF4-This aligns to the new NICE guidelines and so is entirely appropriate. QOF5-This appears to replace a value of 59 so it is assumed that this will tidy up alignment with the new NICE guidelines, although a change from 59 to 58 will have little clinical impact.
QOF 4 & QOF 5	8.4	NHS Sheffield Clinical Commissioning Group	The tightening of the targets of the QoF indicator appears to be in contradiction to the emphasis in NG28 on patient centred care and individualisation of the target HbA1c. Whilst NG28 1.6.8 is cited under evidence, 1.6.9 does not appear to have been taken into account. There is a lack of patient orientated outcomes with intensification for patients with T2 diabetes.
QOF 4 & QOF 5	8.4	NICE Medicines and	These targets ignore recommendations 1.6.7 in the guidance on type 1

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		Prescribing Programme team	diabetes: ‘Agree an individualised HbA1c target with each adult with type 1 diabetes, taking into account factors such as the person's daily activities, aspirations, likelihood of complications, comorbidities, occupation and history of hypoglycaemia’ and recommendations 1.6.5 and 1.6.9 in the guidance on type 2 diabetes: ‘Involve adults with type 2 diabetes in decisions about their individual HbA1c target. Encourage them to achieve the target and maintain it unless any resulting adverse effects (including hypoglycaemia), or their efforts to achieve their target, impair their quality of life.’ ‘Consider relaxing the target HbA1c level (see recommendations 1.6.7 and 1.6.8) on a case-by-case basis, with particular consideration for people who are older or frail, for adults with type 2 diabetes: who are unlikely to achieve longer-term risk-reduction benefits, for example, people with a reduced life expectancy for whom tight blood glucose control poses a high risk of the consequences of hypoglycaemia, for example, people who are at risk of falling, people who have impaired awareness of hypoglycaemia, and people who drive or operate machinery as part of their job for whom intensive management would not be appropriate, for example, people with significant comorbidities. NICE has produced a patient decision aid that specifically supports

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			individualised decision-making regarding HbA1c targets in people with type 2 diabetes. The benefits of intensive glucose control are established in type 1 diabetes but not in type 2 diabetes. The type 2 diabetes guideline included a review question: 'Should intensive or conventional target values be used to control blood glucose levels in people with type 2 diabetes?'. The evidence review found no statistically significant benefit from intensive glycaemic control on mortality or any specific macrovascular or specific microvascular outcome it examined. Recommendation 1.1.1 states: Adopt an individualised approach to diabetes care that is tailored to the needs and circumstances of adults with type 2 diabetes, taking into account their personal preferences, comorbidities, risks from polypharmacy, and their ability to benefit from long‑term interventions because of reduced life expectancy. Such an approach is especially important in the context of multimorbidity. Reassess the person's needs and circumstances at each review and think about whether to stop any medicines that are not effective Thus incentivising target-chasing is inappropriate. A more patient-centred indicator would be The percentage of patients with diabetes [but see below] who have had [*or* have been have been offered the opportunity of] a documented, informed discussion of their individualised HbA1c target that takes account of their circumstances, needs, preferences and values, in the preceding 12 months

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			Furthermore, it is important to distinguish between people with type 1 and type 2 diabetes, since the diabetes care of the former group may be done exclusively by specialist services in some areas. It is also necessary to exclude women with gestational diabetes from this indicator.
QOF 4 & QOF 5	8.4	Primary Care CVD Leadership Forum	Yes we support aligning the indicators with the NICE recommendations so that they reflect the evidence of what impacts on outcomes. The national Diabetes Audit shows that there is significant variation between practices in achievement of treatment targets in diabetes and therefore significant potential for improvement.
QOF 4 & QOF 5	8.4	Public Health England	Yes we support aligning the indicators with the NICE recommendations so that they reflect the evidence of what impacts on outcomes. The national Diabetes Audit shows that there is significant variation between practices in achievement of treatment targets in diabetes and therefore significant potential for improvement. Whilst this indicator is supported by recommendations in NICE guidelines, the NICE guidelines also refer to adopting an individualised approach to diabetes care for adults with type 2 diabetes (recommendations 1.1.1, 1.6.5 and 1.6.9 from type 2 diabetes in adults), and to jointly agree individual care plans for adults with type 1 diabetes (recommendations 1.1.7 and 1.6.7 from type 1 diabetes in adults). There needs to be an indicator that ensures the denominator is as up to date as possible. Is there another indicator which says that all people diagnosed with diabetes must be recorded on the GP system within a defined period?

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			Would be improved by including a requirement 'to notify the Diabetic Eye Screening Programme' as there is currently no specific requirement to do so. Would also like to see something that requires them to participate in regular validation of the list.
QOF 4 & QOF 5	8.4	RCGP	The RCGP feels that a target of under 58 is reasonable but under 53 may encourage inappropriate prescribing in an effort to achieve a target that may not be appropriate for many patients. (Commentator 1) It would be helpful if the target was re-written to alert clinicians to the groups for whom this would be inappropriate. (Commentator 2) This target appeared in QOF some years ago, and was dropped in the face of informed and principled opposition and we are not aware that a lot of evidence has appeared to refute the previous arguments. (commentator 3) The RCGP highlights that GPs should be focussing their efforts on diabetics at highest risk – the youngest cohort of patients (eg those <65) with very high HbA1cs. This is the group that are most likely to benefit from interventions. (RCGP Overdiagnosis Group)
QOF 4 & QOF 5	8.4	Roche Diagnostics Ltd	We welcome the reduction in HbA1c targets to figures more in keeping with international guidelines. However, the proposed wording focuses on the last HbA1c reading within the preceding 12 months, whereas evidence suggests that long-term control is a better predictor of outcomes in diabetes. Therefore frequency of blood testing combined with a target goal would be an improvement on the current proposal. We suggest measuring "the percentage of patients with diabetes in whom the last two IFCC-HbA1c results at least 3 months apart, were 53 mmol/mol (or 58 mmol/mol for QOF5) or less in the preceding 12 months".

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			However, crucially, we feel this indicator set still misses an opportunity to pick up a growing at-risk group. Like AF, many type 2 diabetes patients are asymptomatic and are picked up in general practice opportunistically, when they present with associated medical problems. As the diabetes indicators are well established and progressively reducing acceptable HbA1c targets in general practice, this would be an opportune moment to pick-up the at-risk and undiagnosed group by assessing the proportion of patients without a diabetes diagnosis, who have high HbA1c (suggestive pre-diabetes or diabetes proper). Suggested wording would be "Of those patients registered at the practice aged 40 years and over and who have had at least one consultation in the preceding 12 months: the proportion that have had a HbA1c > 42 mmol/mol on at least one occasion."
QOF 4 & QOF 5	8.4	Somerset CCG	Absolutely the wrong incentivised target in a health system where the clinician has a wish to maximise an individual's health and wellbeing.
QOF 4 & QOF 5	8.4	University of Surrey	They should be age (and possibly ethnicity) adjusted.

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Question 9.1: Do you think there are any barriers to implementing the care described by this indicator?			
QOF6	9.1	Association for the study of obesity	No
QOF6	9.1	Association of British Clinical Diabetologists	No
QOF6	9.1	British Holistic Medical Association	This is another step towards overtreatment
QOF6	9.1	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	no
QOF6	9.1	Individual comment	I am not aware of any statins that have a license in children. If a patient is diagnosed at age three or four they could hit the ten year mark aged 13 or 14. I would suggest limiting this to patients over 18 years of age.
QOF6	9.1	Individual comment	Patients sometimes indicate reluctance to have statin treatment. (Should we be assessing quality of dietary intake more in Type 1??)
QOF6	9.1	Individual comment	patient choice
QOF6	9.1	Individual comment	YES. Recent national newspaper headlines picking up on research studies demonstrating a two-fold increase in the risk of Diabetes in those taking statins is very un-timely and as such I believe until further data is published to back or refute these claims there should be no further push towards using statins more frequently than we currently do.
QOF6	9.1	Individual comment	no

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QOF6	9.1	Individual comment	is epidemiology see comment 6.4 [Talk to the GP system providers and let them adjust the computer systers so that these kind of epidemiology data can be found automatically]
QOF6	9.1	Liverpool LA public health team	no
QOF6	9.1	London Borough of Redbridge	No
QOF6	9.1	London Diabetes Strategic Clinical Network	Patients sometimes indicate reluctance to have statin treatment. (Should we be assessing quality of dietary intake more in Type 1??)
QOF6	9.1	Nightingale Valley Surgery.	I think this is good and important.
QOF6	9.1	Primary Care CVD Leadership Forum	Significant numbers of people with type 1 diabetes are managed in secondary care – recall in primary care may be less well established.
QOF6	9.1	Public Health England	Significant numbers of people with type 1 diabetes are managed in secondary care – in some places recall in primary care may be less well established.
QOF6	9.1	RCGP	The RCGP has identified several barriers to implementing the care described by this indicator, primarily that significant numbers of people with type 1 diabetes are managed in secondary care by hospital diabetologists, so this may be unsuitable as a QOF indicator. (Commentator 1, 2) We also feel that the current bad press for statins may be a barrier to implementation (Commentator 3) but suggest this can be accommodated in QOF by means of exception reporting (ie where

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			patients cannot tolerate statins)(Commentator 4). The wording “who are currently treated with a statin” is extremely unhelpful. It does not take into consideration patient choice and shared decision making. The RCGP would much prefer to use the wording “offered a statin” in line with other indicators, and including a supplementary measure of “statin OTC or statin contraindicated” (Commentator 5) which allows a discussion to take place and gives the patient full autonomy to choose what is right for them. It is much more patient-centred. (RCGP Overdiagnosis Group) (Commentator 6) The indicator would benefit from including patient choice and pregnancy (Commentator 7).
QOF6	9.1	Somerset CCG	Individual (patient) preferences. Difficulty in communicating risk in a way that is meaningful to the clinician or the person. Difficulty in interpreting what this risk means to the individual and their life time health and wellbeing.
Question 9.2: Do you think there are potential unintended consequences to implementing / using this indicator?			
QOF6	9.2	Primary Care Diabetes Society	Poorer diabetic control due to elevation in HbA1c when statin therapy is introduced
QOF6	9.2	Association for the study of obesity	No
QOF6	9.2	Association of British Clinical Diabetologists	No
QOF6	9.2	Cheshire and Merseyside Directors of Public Health, Champs Public Health	no

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		Collaborative	
QOF6	9.2	Individual comment	Cost.
QOF6	9.2	Individual comment	High level of anecdotal and informal suggestion of frequent statin side effects – exhaustion and joint/muscle aches – which make people discontinue use. But seemingly no research on this – perhaps because it goes against “policy”?
QOF6	9.2	Individual comment	lots of side effects on statins
QOF6	9.2	Individual comment	no
QOF6	9.2	Individual comment	stress due to more targets
QOF6	9.2	Liverpool LA public health team	no
QOF6	9.2	London Borough of Redbridge	No
QOF6	9.2	London Diabetes Strategic Clinical Network	Cost.
QOF6	9.2	NHS Employers	Why is there a 40 years age limit it patients can have T1 DM from birth?
QOF6	9.2	NHS England	Significant numbers of people with type 1 diabetes are managed in secondary care – recall in primary care may be less well established.
QOF6	9.2	NICE – Medicines and Prescribing programme team	Imposition of the guideline recommendations without a patient-centred approach

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QOF6	9.2	RCGP	The RCGP feels that statin prescription should be the patient's choice on doctor's recommendation, not the doctor's enforcement, (commentator 1) harming the doctor-patient relationship. (RCGP Overdiagnosis Group) This indicator will also increase the number of bloods test (LFTs done a couple of months after starting). (Commentator 2)
QOF6	9.2	Somerset CCG	Overmedicalisation.
Question 9.3: Do you think there is potential for differential impact (in respect of age, disability, gender and gender reassignment, pregnancy and maternity, race, religion or belief, and sexual orientation)? If so, please state whether this is adverse or positive and for which group.			
QOF6	9.3	Association for the study of obesity	No
QOF6	9.3	Association of British Clinical Diabetologists	Continuing statin treatment in people with diabetes who are at the end of life is unlikely to be of benefit.
QOF6	9.3	British Holistic Medical Association	This looks like political correctness. What matters is for the clinician to have respect for people because of their difference, not because it is PC to enquire.
QOF6	9.3	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	no
QOF6	9.3	Individual comment	There is a cohort of patients who indicate reluctance to have statin treatment.

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			They tend to be better educated individuals, who are well-read and don't trust the literature on statins.
QOF6	9.3	Individual comment	no
QOF6	9.3	Individual comment	don't know
QOF6	9.3	Liverpool LA public health team	no
QOF6	9.3	London Borough of Redbridge	No
QOF6	9.3	London Diabetes Strategic Clinical Network Individual	There is a cohort of patients who indicate reluctance to have statin treatment. They tend to be better educated individuals, who are well-read and don't trust the literature on statins.
QOF6	9.3	NHS England	The initiation of statins in females should be after completion of family.
QOF6	9.3	RCGP	The RCGP notes that statins are contra-indicated in pregnancy and breast-feeding (Commentator 1) and this indicator will therefore exclude those who fall into these categories.
QOF6	9.3	Somerset CCG	No
Question 9.4: Do you have any general comments on this indicator?			
QOF6	9.4	Association for the study of obesity	No
QOF6	9.4	Association of British Clinical Diabetologists	**IND QOF6** The draft wording does not faithfully reproduce the NICE recommendation 1.3.24. appended below. By substituting 'or' by 'and' it will exclude a cohort of people with type 1 diabetes diagnosed in their

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			thirties being offered statin treatment at age 40 years. Subject to this change of wording ABCD would support the indicator, but believe it could be improved to give valuable insight into the reasons for under utilisation of statins. The recommendation is for a statin to be 'offered', and if this is recorded and audited to determine the proportion of people who decline, and the proportion of people who stop taking statins it would be a valuable indicator. ***1.3.24 Offer statin treatment for the primary prevention of CVD to adults with type 1 diabetes who:*** *are older than 40 years* ***or*** *have had diabetes for more than 10 years or* *have established nephropathy or* *have other CVD risk factors.* Subject to t There is an opportunity to test adherence to the recommendation to use a high intensity statin. 1.3.25 Start treatment for adults with type 1 diabetes with atorvastatin 20 mg.
QOF6	9.4	British Holistic Medical Association	This is another step towards overtreatment
QOF6	9.4	British Medical Association	This indicator seems unnecessarily complex. There may also be issues about the correct historic coding for onset of diabetes. The decision to take a treatment which reduces the chance of future events should always rest with the patient after a discussion of the risks or benefits of intervention. It would be better to have a measure of discussions taking place regarding the risks and benefits, possibly supported by a patient decision making aid if one can be produced with

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			a good evidence base for its helpfulness.
QOF6	9.4	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	It appears to be a good idea.
QOF6	9.4	Individual comment	Yes. How about awarding QOF points for having a discussion about statins instead? It should be about patients making an informed decision, not telling people what they should be doing. The implication in this indicator is that patients should take statins and are wrong if they choose not to. That's not patient-centred!! Those that choose not to take statins have made an informed decision – please accept that patient autonomy really matters.
QOF6	9.4	Individual comment	There is a cohort of patients who indicate reluctance to have statin treatment.
QOF6	9.4	Individual comment	Not my field of experience
QOF6	9.4	Individual comment	good
QOF6	9.4	Individual comment	is epidemiology Talk to the GP system providers and let them adjust the computer systers so that these kind of epidemiology data can be found automatically [stress due to more targets]
QOF6	9.4	Liverpool LA public health team	It appears to be a good idea.
QOF6	9.4	London Borough of Redbridge	No

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QOF6	9.4	London Diabetes Strategic Clinical Network	As above.
QOF6	9.4	NHS Employers	How will the other risk factors be defined either clinically or in a coding sense in order to produce the eligible patients?
QOF6	9.4	NHS England	NHS England supports this indicator. The national Diabetes Audit shows achievement of treatment targets and delivery of key care processes is less good in type 1 diabetes. This indicator would be helpful in terms of promoting a focus on type 1 diabetes.
QOF6	9.4	NICE – Medicines and Prescribing Programme team	The NICE guideline on lipid modification (CG181), which gives guidance on statin therapy in people with type 1 diabetes, states in recommendation 1.3.12 The decision whether to start statin therapy should be made after an informed discussion between the clinician and the person about the risks and benefits of statin treatment, taking into account additional factors such as potential benefits from lifestyle modifications, informed patient preference, comorbidities, polypharmacy, general frailty and life expectancy. And in recommendation 1.3.29 Provide annual medication reviews for people taking statins.

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			Use these reviews to discuss medicines adherence and lifestyle modification and address CVD risk factors. Consider an annual non-fasting blood test for non-HDL cholesterol to inform the discussion. [new 2014] Thus the indicator should reflect a patient-centred approach and state 'Of the patients with type 1 diabetes who meet the following criteria: aged over 40 years and who have either had diabetes for more than 10 years, or who have established nephropathy or other CVD risk factors; the percentage of people who have had [*or* have been have been offered the opportunity of] a documented, informed discussion of the risks and benefits of statin therapy that considers their circumstances, needs, preferences and values, in the preceding 12 months.'
QOF6	9.4	Primary Care CVD Leadership Forum	Yes we support this indicator. The national Diabetes Audit shows achievement of treatment targets and delivery of key care processes is less good in type 1 diabetes.
QOF6	9.4	Public Health England	This indicator is useful as the national Diabetes Audit shows achievement of treatment targets and delivery of key care processes is less good in type 1 diabetes. In addition, it has the potential to reduce Abdominal Aortic Aneurysms as well. Is there sufficient evidence to back up this indicator?
QOF6	9.4	RCGP	The RCGP notes there is no evidence or estimate that this group of patients is not already being offered statin treatment (Commentator 1), and the indicator should include the ability of a patient to make an informed decision not to take a statin. (Commentator 2)

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QOF6	9.4	Somerset CCG	At a population level would seem sensible, but perhaps not at an individual level. Risk/benefit discussions tools need significant improvement.
QOF6	9.4	The British Heart Foundation	Supports the implementation of NICE evidence based practice, where we know there is currently significant variation in implementation. We note the indicator diverges from the JBS 3 recommendations in a number of details – e.g. 10 year duration, over 40 years of age (JBS 3 suggests 5yrs duration). See below: QOF6All people with type 1 diabetes should receive professional lifestyle advice. Statins should be offered in type 1 diabetes for the following categories: All patients with type 1 diabetes aged ≥50 years. The majority aged 40–50 years, unless short duration of diabetes (<5 years) and absence of other CVD risk factors. Those aged 30–40 years with any of the following features: long duration of diabetes (20 years) and poor control (HbA1c >9% (75 mmol/mol), persistent albuminuria (>30 mg/day) or estimated glomerular filtration rate (eGFR) <60 mL/min, proliferative retinopathy, treated hypertension, current smoking, autonomic neuropathy, TC >5 mL/min with reduced HDL-c (<1 mmol/L for males and <1.2 mmol/L for females), or central obesity, or with a family history of premature CVD (<50 years). Those aged 18–30 years should receive statins if persistent albuminuria is detected, with caution exercised in women of childbearing potential.

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Question 10.1: Do you think there are any barriers to implementing the care described by this indicator?			
CCG3	10.1	Association for the study of obesity	Uncertain
CCG3	10.1	Association of British Clinical Diabetologists	No. This is an achievable standard.
CCG3	10.1	British Holistic Medical Association	It should be a decision based on the balance of pressures on clinical time, not about financial reward.
CCG3	10.1	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	Uncertainty about resources and implementation feasibility.
CCG3	10.1	Individual	appointment times, staff, etc
CCG3	10.1	Individual comment	Knowledge amongst patients GPs, Practice Nurses, wider diabetes community team including dieticians and podiatrists etc of need for this timescale within the pathway. Education issue. Capacity within antenatal and diabetes clinics.
CCG3	10.1	Individual comment	This can only be achieved by the commissioners establishing a contract w providers. A week seems really tight.
CCG3	10.1	Individual comment	logistics
CCG3	10.1	Individual comment	workforce numbers may not be able to deliver this. If going to have this

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			marker then it should count that a referral has been sent within the week of receiving the result. Secondary care and attached staff availability shouldn't be in the equation for a marker for General Practice whereby payment can be affected
CCG3	10.1	Liverpool LA public health team	Uncertainty about resources and implementation feasibility.
CCG3	10.1	London Borough of Redbridge	No
CCG3	10.1	London Diabetes Strategic Clinical Network	Knowledge amongst patients GPs, Practice Nurses, wider diabetes community team including dieticians and podiatrists etc of need for this timescale within the pathway. Education issue. Capacity within antenatal and diabetes clinics.
CCG3	10.1	Medtronic Limited	We support this indicator
CCG3	10.1	Nightingale Valley Surgery.	Again a good idea whether or not secondary care have the resource's to manage is another matter.
CCG3	10.1	Primary Care Diabetes Society	This is a secondary care issue and not reflective of Primary Care. Primary care can initiate the referral but do not have an influence on secondary acre antenatal clinic infrastructure. Primary care can have an influence on pre-pregnancy advice and early referral but not on hospital care. Therefore this is an inappropriate QOF indicator

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CCG3	10.1	RCGP	The RCGP would recommend a longer timeline than 1 week to implement this indicator (commentator 1, 2): the referral process usually takes much longer than this (Commentator 3) and the availability of joint specialist clinics in smaller hospitals may be a barrier.(RM) It can only be achieved by the commissioners establishing a contract with providers. (commentator 4) We would also recommend altering the wording to clarify whether it means when the referral was received or when it was sent. (commentator 5)
Question 10.2: Do you think there are potential unintended consequences to implementing / using this indicator?			
CCG3	10.2	Association for the study of obesity	No
CCG3	10.2	Association of British Clinical Diabetologists	No
CCG3	10.2	British Holistic Medical Association	no comment
CCG3	10.2	British Medical Association	This would drive the numbers of patients referred as emergencies to A+E in order to hit the very tight target
CCG3	10.2	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	no
CCG3	10.2	Individual comment	This is obviously dependent on the attendance of the mother to be. Perhaps it would be better to say that an appointment is offered in the

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			first week after referral.
CCG3	10.2	Individual comment	Capacity within antenatal and diabetes clinics.
CCG3	10.2	Individual comment	stress
CCG3	10.2	Liverpool LA public health team	no
CCG3	10.2	London Borough of Redbridge	No
CCG3	10.2	London Diabetes Strategic Clinical Network	Capacity within antenatal and diabetes clinics.
CCG3	10.2	Medtronic Limited	none
CCG3	10.2	RCGP	The RCGP feels the one week turnaround time is unfeasible (Commentator 1), particularly as it would require accessible diabetic/antenatal clinics once or twice a week, which would be unrealistic. (Commentator 2)
Question 10.3: Do you think there is potential for differential impact (in respect of age, disability, gender and gender reassignment, pregnancy and maternity, race, religion or belief, and sexual orientation)? If so, please state whether this is adverse or positive and for which group.			
CCG3	10.3	Association for the study of obesity	No
CCG3	10.3	Association of British Clinical Diabetologists	No

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CCG3	10.3	British Holistic Medical Association	This looks like political correctness. What matters is for the clinician to have respect for people because of their difference, not because it is PC to enquire.
CCG3	10.3	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	no
CCG3	10.3	Individual comment	Patient knowledge is key to the patient seeking advice from GP/ Practice nurse and being referred – this varies amongst diabetes cohorts depending on the factors described.
CCG3	10.3	Individual comment	Women with already poor control.
CCG3	10.3	Individual comment	don't know
CCG3	10.3	Liverpool LA public health team	no
CCG3	10.3	London Borough of Redbridge	No
CCG3	10.3	London Diabetes Strategic Clinical Network	Patient knowledge is key to the patient seeking advice from GP/ Practice nurse and being referred – this varies amongst diabetes cohorts depending on the factors described.
CCG3	10.3	Medtronic Limited	Applies to all patient groups
CCG3	10.3	RCGP	The RCGP feels that women with already poor control (Commentator 1) and non-English speaking patients would have adverse impact from this indicator. (Commentator 2)

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C Do you have any general comments on this indicator?			
CCG3	10.4	Association for the study of obesity	Be useful to record current BMI also, to highlight the risks to the pregnancy of elevated body weight, and encourage it to be considered in any management strategies
CCG3	10.4	Association of British Clinical Diabetologists	ABCD supports this indicator, but the draft wording is different from QS 109, 'Women with pre-existing diabetes are seen by members of the joint diabetes and antenatal care team within 1 week of *their pregnancy being confirmed*.' We would advise keeping the wording of the QS as this will require the referral to be made with appropriate urgency.
CCG3	10.4	British Holistic Medical Association	no comment
CCG3	10.4	British Medical Association	Patients with type 1 diabetes will be known about and are often stable, so a target of 1 week is probably unnecessary, being seen within two weeks would be more practical.
CCG3	10.4	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	This is a good idea to allow multidisciplinary review of diabetes management. Uncertain whether feasible to implement. Unclear the rationale for an appointment within a week. The important issue is that these women are given appropriate care, advice and support that this may not necessarily be in a shared clinic. There are women with range of long term conditions such as hypertension, epilepsy who could benefit from prompt antenatal shared care. You may wish to consider to expand this indicator.
CCG3	10.4	Diabetes UK	Diabetes UK support the inclusion of this indicator to place emphasis on the need for pregnant women with diabetes to have urgent joint review. However, given the proportion of unplanned pregnancies, it would be important to also focus one of the indicators on the proportion of women

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			with pre-existing diabetes who have received preconception advice prior to conceiving. We believe this would make more of an impact in minimising adverse pregnancy outcomes.
CCG3	10.4	Individual comment	If patient waits to discuss this with staff later in pregnancy, the impact of this quick referral may be less.
CCG3	10.4	Individual comment	Unachievable given current care pathways.
CCG3	10.4	Individual comment	Not my field of experience
CCG3	10.4	Individual comment	what is the evidence to bring this in?
CCG3	10.4	Liverpool LA public health team	This is a good idea to allow multidisciplinary review of diabetes management. Uncertain whether feasible to implement. Unclear the rationale for an appointment within a week. The important issue is that these women are given appropriate care, advice and support that this may not necessarily be in a shared clinic. There are women with range of long term conditions such as hypertension, epilepsy who could benefit from prompt antenatal shared care. You may wish to consider to expand this indicator.
CCG3	10.4	London Borough of Redbridge	No
CCG3	10.4	London Diabetes Strategic Clinical Network	If patient waits to discuss this with staff later in pregnancy, the impact of this quick referral may be less.
CCG3	10.4	NHS England	NHS England supports this indicator to encourage optimal management of diabetes in pregnancy Whilst the indicator is welcome, it more relates to the high risk of complications during pregnancy than to the management of the

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			diabetes. The Pregnancy in Diabetes Audit module of the National Diabetes Audit has also highlighted the deficiencies in pre-pregnancy planning, particularly for those with pre-existing Type 2 diabetes who tend to be looked after in primary care, rather than by specialist clinics (many with Type 1 diabetes are under specialist clinics). An indicator around pre pregnancy planning, as assessed by not being on ACE Inhibitors or statins at conception, and being on folic acid at conception, would be particularly useful.
CCG3	10.4	Primary Care CVD Leadership Forum	Yes we support this indicator to encourage optimal management of diabetes in pregnancy
CCG3	10.4.	Public Health England	Yes we support this indicator to encourage optimal management of diabetes in pregnancy. Pre-pregnancy care is the key to optimising outcomes. Suggestion to incentivise attendance at a joint clinic could be around attendance as early to conception as possible (very early appointments indicating already in place before the woman knew she was pregnant). This data is already collected by the National Pregnancy in Diabetes (NPID) audit. Would be improved by the addition of a requirement for 'timely notification of pregnant woman with pre-existing diabetes to local diabetic eye screening programmes'. Need further definition around "antenatal care team". There needs to be a link between IND CCG3 IND CCG4 and IND

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			CCG1.
CCG3	10.4	RCGP	The RCGP feels this indicator is unachievable given the current pathways (Commentator 1) and implementing it is usually out of the GP's control (commentator 2). We also recommend taking into account previous pregnancies or preconceptual advice, where the need for very tight control could have been discussed, as well as the women's own record of how well they control their diabetes. These factors might mean that for some women there would be no need for such urgent referral. (Commentator 3)
CCG3	10.4	University of Surrey	We think that a 1 week target may not always be appropriate. For example, well controlled type 2 diabetes when presented very early in pregnancy.

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Question 11.1: Do you think there are any barriers to implementing the care described by this indicator?			
CCG4	11.1	Primary Care Diabetes Society	This is a secondary care issue and not reflective of Primary Care. Primary care can initiate the referral but do not have an influence on secondary acre antenatal clinic infrastructure. Primary care can have an influence on pre-pregnancy advice and early referral but not on hospital care. Therefore this is an inappropriate QOF indicator
CCG4	11.1	Association for the study of obesity	No
CCG4	11.1	Association of British Clinical Diabetologists	No
CCG4	11.1	British Holistic Medical Association	See remarks under 10.1 [No. This is an achievable standard.]
CCG4	11.1	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	Uncertainty about resources and implementation feasibility.
CCG4	11.1	Individual comment	workforce numbers may not be able to deliver this. If going to have this marker then it should count that a referral has been sent within the week of receiving the result. Secondary care and attached staff availability shouldn't be in the equation for a marker for General Practice whereby payment can be affected
CCG4	11.1	Individual comment	Knowledge amongst the primary, community and secondary services of this indicator, and testing for GDM is variable.

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			The coding – and therefore baseline number of women with GDM varies by practice. Identifying these patients clearly is also needed. Women with a previous history of GDM need to be assessed annually and prior to any planned pregnancy – this varies in practice.
CCG4	11.1	Individual comment	logistics
CCG4	11.1	Individual comment	availability of every one involved and reception time
CCG4	11.1	Individual comment	Assumes that the Hospitals have the resources and will to make the changes Assumes the referral process does not include a referral pathway from the Midwife, who is not employed by the GP. Ie this is work that should be undertaken at CCG level.
CCG4	11.1	Liverpool LA public health team	Uncertainty about resources and implementation feasibility.
CCG4	11.1	London Borough of Redbridge	There might be potential capacity issues to have a joint review within 1 week of diagnosis however, on diagnosis woman should be given appropriate advice on managing their condition prior to the joint review.
CCG4	11.1	London Diabetes Strategic Clinical Network	Knowledge amongst the primary, community and secondary services of this indicator, and testing for GDM is variable. The coding – and therefore baseline number of women with GDM varies by practice. Identifying these patients clearly is also needed. Women with a

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			previous history of GDM need to be assessed annually and prior to any planned pregnancy – this varies in practice.
CCG4	11.1	Medtronic Limited	We support this indicator
CCG4	11.1	RCGP	The RCGP would recommend a longer timeline than 1 week to implement this indicator (commentator 1, 2): the referral process usually takes much longer than this (commentator 3) and the availability of joint specialist clinics in smaller hospitals maybe a barrier to this. (commentator 4)
Question 11.2: Do you think there are potential unintended consequences to implementing / using this indicator?			
Question 11.3: Do you think there is potential for differential impact (in respect of age, disability, gender and gender reassignment, pregnancy and maternity, race, religion or belief, and sexual orientation)? If so, please state whether this is adverse or positive and for which group.			
CCG4	11.2	Association for the study of obesity	No
CCG4	11.3	Association for the study of obesity	No
CCG4	11.2	Association of British Clinical Diabetologists	No
CCG4	11.3	Association of British Clinical Diabetologists	No
CCG4	11.2	British Medical Association	This would drive the numbers of patients referred as emergencies to A+E in order to hit the very tight target
CCG4	11.2	Cheshire and Merseyside Directors of Public Health,	no

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		Champs Public Health Collaborative	
CCG4	11.3	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	no
CCG4	11.2	Individual comment	Capacity within GP practices, antenatal and diabetes clinics to see so soon.
CCG4	11.2	Individual comment	This is obviously dependent on the attendance of the mother to be. Perhaps it would be better to say that an appointment is offered in the first week after referral.
CCG4	11.2	Individual comment	stress
CCG4	11.3	Individual comment	Patient knowledge is key to the patient seeking advice from GP/ Practice nurse and being referred – this varies amongst diabetes cohorts depending on the factors described.
CCG4	11.3	Individual comment	don't know
CCG4	11.2	Liverpool LA public health team	no
CCG4	11.3	Liverpool LA public health team	no
CCG4	11.2	London Borough of Redbridge	No
CCG4	11.3	London Borough of Redbridge	No

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CCG4	11.2	London Diabetes Strategic Clinical Network	Capacity within GP practices, antenatal and diabetes clinics to see so soon.
CCG4	11.3	London Diabetes Strategic Clinical Network	Patient knowledge is key to the patient seeking advice from GP/ Practice nurse and being referred – this varies amongst diabetes cohorts depending on the factors described.
CCG4	11.3	Medtronic Limited	Applies to all patient groups
CCG4	11.2	RCGP	The RCGP has not identified any potential unintended consequences to implementing / using this indicator.
CCG4	11.3	RCGP	The RCGP feels that it may prove difficult for a service to be available within 1 week for non-English speaking women in order to implement this indicator. (Commentator 1)
Question 11.4: Do you have any general comments on this indicator?			
CCG4	11.4	Association for the study of obesity	BMI measurement would be of value at this review
CCG4	11.4	Association of British Clinical Diabetologists	ABCD supports this indicator. The draft rationale has attempted to combine those for QS 109 statements 2 and 5, but the rationale is different for each and are best kept separate.
CCG4	11.4	British Medical Association	Women diagnosed with gestational diabetes do need seeing ASAP, but those with diabetes as opposed to mildly impaired glucose tolerance, because it is unknown whether they are undiagnosed type 2 or gestational diabetics until afterwards and therefore the foetus may have been expose to high sugars for a considerable (and unknown) time.
CCG4	11.4	Cheshire and	This is a good idea to allow multidisciplinary review of diabetes

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		Merseyside Directors of Public Health, Champs Public Health Collaborative	management. Uncertain whether feasible to implement. Unclear the rationale for an appointment within a week. The important issue is that these women are given appropriate care, advice and support that this may not necessarily be in a shared clinic.
CCG4	11.4	Diabetes UK	Diabetes UK supports
CCG4	11.4	Individual comment	Not my field of experience
CCG4	11.4	Individual comment	what is the evidence to bring this in?
CCG4	11.4	Liverpool LA public health team	This is a good idea to allow multidisciplinary review of diabetes management. Uncertain whether feasible to implement. Unclear the rationale for an appointment within a week. The important issue is that these women are given appropriate care, advice and support that this may not necessarily be in a shared clinic.
CCG4	11.4	NHS England	NHS England supports this indicator to encourage optimal management of diabetes in pregnancy.
CCG4	11.4	Primary Care CVD Leadership Forum	Yes we support this indicator to encourage optimal management of diabetes in pregnancy.
CCG4	11.4	Public Health England	Yes we support this indicator to encourage optimal management of diabetes in pregnancy. Would be improved by the addition of a requirement for 'timely notification of pregnant woman with pre-existing diabetes to local diabetic eye screening programmes'. Need further definition of "antenatal care team".

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			There needs to be a link between IND CCG3 IND CCG4 and IND CCG1.
CCG4	11.4	RCGP	The RCGP has no further comments on this indicator.

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Question 12.1: Do you think there are any barriers to implementing the care described by this indicator?			
GP3	12.1	Individual comment	No
GP3	12.1	Individual comment	There remains poor coding of this in some GP practices. Processes to systematically assess these patients, differs greatly from practice to practice.
GP3	12.1	Individual comment	Increased workload for practices. HbA1C on it's own is not valuable - needs to be accompanied by relevant life-style advice/behaviour change advice.
GP3	12.1	London Diabetes Strategic Clinical Network	There remains poor coding of this in some GP practices. Processes to systematically assess these patients, differs greatly from practice to practice.
GP3	12.1	London Borough of Redbridge	Call / recall of women with history of gestational diabetes since it is unlikely that these women will be accessing GP services on a regular basis.
GP3	12.1	Individual comment	patients don't see the need
GP3	12.1	Individual comment	This is a good marker but not a priority for limited resources
GP3	12.1	Individual comment	no
GP3	12.1	Individual comment	staff and patient time
GP3	12.1	Individual comment	Need to have a lead in register for a couple of years to give time to troll through notes. Assumes that yearly HBA1c for rest of life is cost effective (has any one worked out the total costs and compared it with testing when symptoms

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			or next pregnant.)
GP3	12.1	Primary Care CVD Leadership Forum	No, it will be a valuable incentive to identify diabetes in a high risk group
GP3	12.1	Association of British Clinical Diabetologists	No
GP3	12.1	Liverpool LA public health team	Monitoring for diabetes is only one aspect of care. We need to consider impaired glucose regulation (IGR) pathway for lifestyle advice and education as well as annual follow up.
GP3	12.1	NHS Employers	It may be difficult to get these women in annually for a blood test.
GP3	12.1	Public Health England	No, it will be a valuable incentive to identify diabetes in a high risk group
GP3	12.1	Association for the study of obesity	Uncertain
GP3	12.1	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	Monitoring for diabetes is only one aspect of care. We need to consider impaired glucose regulation (IGR) pathway for lifestyle advice and education as well as annual follow up.
GP3	12.1	Somerset CCG	Yes. An HbA1c check in the year following delivery could be seen as feasible. Calling all (well) women in every 12 months for a HbA1c review is not person-centred or an efficient/effective use of resources.
GP3	12.1	NHS England	No, it will be a valuable incentive to identify diabetes in a high risk group.
GP3	12.1	British Holistic Medical Association	No comments

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GP3	12.1	RCGP	The RCGP notes that this indicator does not clarify for how many years after the pregnancy this should continue (Commentator 1) and that gathering data on this would be limited by the practice's information system and whether the patient stays with the practice (Commentator 2). We also feel that implementing this indicator would create an increased workload for practices. HbA1C on its own is not valuable – it needs to be accompanied by relevant life-style advice/behaviour change advice. (Commentator 3)
Question 12.2: Do you think there are potential unintended consequences to implementing / using this indicator?			
GP3	12.2	Individual comment	No
GP3	12.2	Individual comment	Capacity within GP Practices, antenatal and diabetes clinics.
GP3	12.2	London Diabetes Strategic Clinical Network	Capacity within GP Practices, antenatal and diabetes clinics.
GP3	12.2	London Borough of Redbridge	No
GP3	12.2	Individual comment	Yes. I think that it will waste GP and nurse time
GP3	12.2	Individual comment	no
GP3	12.2	Individual comment	labelling patients, uncertainty
GP3	12.2	Individual comment	Steals resources from elsewhere. The Salami can be sliced no thinner.
GP3	12.2	Association of British Clinical Diabetologists	No

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GP3	12.2	Liverpool LA public health team	no
GP3	12.2	Association for the study of obesity	No
GP3	12.2	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	no
GP3	12.2	Somerset CCG	Overmedicalisation. Distraction from other needs in healthcare.
GP3	12.2	RCGP	The RCGP feels that a potential unintended consequence to implementing this indicator will be that practices who are not copied in with electronic test results may end up taking duplicate blood samples driven by this metric. This will cause problems for the women involved but also means an unwise use of resources. (Commentator 1) The RCGP identifies as a consequence the waste of resources, especially time that will be diverted away from areas of higher priority. It can cause frustration to these women, with young families, to have to attend annual blood tests for the rest of their lives. We worry that this indicator will label women who have had gestational diabetes as having an illness when what they actually have is a risk factor for diabetes. (RCGP Overdiagnosis Group)

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Question 12.3: Do you think there is potential for differential impact (in respect of age, disability, gender and gender reassignment, pregnancy and maternity, race, religion or belief, and sexual orientation)? If so, please state whether this is adverse or positive and for which group.			
GP3	12.3	Individual comment	No
GP3	12.3	Individual comment	Women who are already 'difficult to engage'.
GP3	12.3	London Diabetes Strategic Clinical Network	No
GP3	12.3	Medtronic Limited	Applies to all patient groups
GP3	12.3	London Borough of Redbridge	No
GP3	12.3	Individual comment	no
GP3	12.3	Individual comment	don't know
GP3	12.3	Association of British Clinical Diabetologists	No
GP3	12.3	Liverpool LA public health team	no
GP3	12.3	British Medical Association	This is a screening procedure and as such is excluded from provision under essential services as defined in the GMS contract. This can only be considered as a quality indicator in specific areas where this screening service is commissioned from GPs. Screening procedures should only take place within the NHS if they have been approved by the NSC and resources have been provided.
GP3	12.3	Association for the study of obesity	No

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GP3	12.3	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	no
GP3	12.3	Somerset CCG	No
GP3	12.3	RCGP	The RCGP has not identified any potential for differential impact for this indicator.
Question 12.4: Do you have any general comments on this indicator?			
GP3	12.4	Individual comment	Should these women have more than an HbA1c test – why don't they have all care processes annually to prevent complications?
GP3	12.4	?	I am not aware of any benefit of this type of follow up.
GP3	12.4	London Diabetes Strategic Clinical Network	Should these women have more than an HbA1c test – why don't they have all care processes annually to prevent complications?
GP3	12.4	Primary Care Diabetes Society	Agree use of annual hba1c. Consider number of diabetic women of fertile age who are given both pre conceptual advice & a medication review as an indicator
GP3	12.4	London Borough of Redbridge	Although the indicator is welcome calling / recalling women have a history of gestational diabetes for HbA1C testing might have an impact on the already overstretched practices.
GP3	12.4	Individual comment	We all agree that gestational diabetes increases the risk of diabetes but where is the evidence that screening women in this way will improve outcomes? If there is no evidence we should not be doing it until there

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			is.
GP3	12.4	Individual comment	labelling women for their whole lifetime nad anxieties this would cause; historical labelling of gestational diabetes likely to be incomplete and/or inaccurate
GP3	12.4	Primary Care CVD Leadership Forum	Yes we support this indicator as this is an important group with long-term increased risk of developing type 2 diabetes. The newly commissioned national Diabetes Prevention Programme will provide practices with an evidence based service to offer women who develop non diabetic hyperglycaemia. HbA1c is not an appropriate measure in some people eg those with anaemia, haemoglobinopathy – fasting plasma glucose more appropriate here.
GP3	12.4	Association of British Clinical Diabetologists	ABCD supports this indicator, but would expand it to include the proportion of those screened with abnormally high results, and evidence that these were acted upon.
GP3	12.4	Liverpool LA public health team	This appears to be a good idea, as will potentially lead to early diagnosis of diabetes, but even better as part of CVD risk assessment or diabetes prevention programme.
GP3	12.4	NHS Employers	Will this be a rolling 12 month period or 12 months from a set point?
GP3	12.4	Public Health England	Yes we support this indicator as this is an important group with long-term increased risk of developing type 2 diabetes. The newly commissioned national Diabetes Prevention Programme will provide practices with an evidence based service to offer women who develop non diabetic hyperglycaemia. HbA1c is not an appropriate measure in some people eg those with

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			anaemia, haemoglobinopathy – fasting plasma glucose more appropriate here.
GP3	12.4	Diabetes UK	Diabetes UK support the inclusion of this indicator to emphasise the importance of annual HbA1c test for women with history of generational diabetes.
GP3	12.4	Association for the study of obesity	BMI measurements would be of value in order to make certain those who are either overweight or obese are highlighted at this time
GP3	12.4	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	This appears to be a good idea, as will potentially lead to early diagnosis of diabetes, but even better as part of CVD risk assessment or diabetes prevention programme.
GP3	12.4	Somerset CCG	Education of those that have gestational diabetes (during pregnancy) on reducing their risk of future diabetes would be sensible. Perhaps with guidance of when to seek attention in the future.
GP3	12.4	NHS England	NHS England supports this indicator as this is an important group with long-term increased risk of developing type 2 diabetes. The newly commissioned national Diabetes Prevention Programme will provide practices with an evidence based service to offer women who develop non diabetic hyperglycaemia. HbA1c is not an appropriate measure in some people eg those with anaemia, haemoglobinopathy – fasting plasma glucose more appropriate here.
GP3	12.4	University of Surrey	We strongly support the addition of this indicator.
GP3	12.4	RCGP	The RCGP feels that annual testing may be excessive and would

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			welcome statistics for how many women go on to develop diabetes. (Commentator 1) The RCGP highlights that this is a screening test for diabetes and is not recommended by the UK National Screening Committee. (RCGP Overdiagnosis Group)

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Question 13.1: Do you think there are any barriers to implementing the care that would impact on this indicator?			
CCG5	13.1	Individual comment	Knowledge amongst the primary, community and secondary services of this indicator, and processes within hospitals to get these patients to diabetes care if they go in a surgical or emergency route rather than medical –coding remains an ever present issue.
CCG5	13.1	?	It will be difficult to attribute causality – is the admission linked to problems from diabetes, or smoking, or hypertension, or other factors
CCG5	13.1	Individual comment	Difficult to assess whether an admission is solely due to complication of diabetes – who will make that decision?
CCG5	13.1	London Diabetes Strategic Clinical Network	Knowledge amongst the primary, community and secondary services of this indicator, and processes within hospitals to get these patients to diabetes care if they go in a surgical or emergency route rather than medical –coding remains an ever present issue.
CCG5	13.1	Primary Care Diabetes Society	This is too loose and complications of diabetes needs more explanation . Is this a measure of poor glycaemia (admissions with hypoglycaemia , hyperglycaemia , DKA) all of which may be unpredictable and due to other reasons that are out of the control of a normal practitioner. Or , is this longterm complications such as retinopathy , Renal disease , peripheral vascular disease , stroke , MI or infection.
CCG5	13.1	Medtronic Limited	Lack of understanding of the health complications that can arise as a result of diabetes often acts as a barrier to effective adoption of steps which would help to achieve this indicator. An improvement in education for patients and healthcare professionals working in primary and community care, on diabetes related complications
CCG5	13.1	London Borough of Redbridge	Patient education and awareness especially within certain BAME communities. Potential coding issues.

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CCG5	13.1	Individual comment	so many variables in developing DKA both medical and social out of the control of the medical carers to include this as a marker.
CCG5	13.1	Nightingale Valley Surgery.	This would be massively labour intensive and difficulty to isolate in pt. as admissions are often multifactorial.
CCG5	13.1	Association of British Clinical Diabetologists	No
CCG5	13.1	Liverpool LA public health team	Difficult to implement as issues with hospital admissions coding. One in ten people in hospital have diabetes whether it is a contributing factor, causal or incidental.
CCG5	13.1	Boehringer Ingelheim	CV complications are not front of mind for many clinicians.
CCG5	13.1	Association for the study of obesity	No
CCG5	13.1	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	Difficult to implement as issues with hospital admissions coding. One in ten people in hospital have diabetes whether it is a contributing factor, causal or incidental.
CCG5	13.1	All Party Parliamentary Group on Vascular Disease	Lack of understanding of the health complications that can arise as a result of diabetes often acts as a barrier to effective adoption of steps which would help to achieve this indicator. In particular, diseases such as Peripheral Arterial Disease and Critical Limb Ischaemia are not widely understood by patients or healthcare professionals alike. This results in symptoms often not being identified early, such as foot ulcers which can develop into Critical Limb Ischaemia if not identified and dealt with correctly. More needs to be done to educate patients and healthcare

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			professionals, in particular GPs and others working in primary and community care, on diabetes related complications, such as Peripheral Arterial Disease. Moreover, more should be done to encourage CCGs to adopt and promote effective pathways on footcare. The Stop Unnecessary Amputations (STAMP) pathway, for example, adopted across Greater Manchester, is a good example of a pathway which supports the care aimed for under this indicator.
CCG5	13.1	University of Surrey	It will be very difficult to attribute causation for a whole range of morbidities that may occur in the presence of diabetes.
CCG5	13.1	British Holistic Medical Association	This will not help the individual patient and should not be part of QOF
CCG5	13.1	RCGP	The RCGP feels that the main barrier to implementing the care that impacts on this indicator is how this would be measured and what would count as a complication of diabetes. Every condition is complicated by diabetes and diabetes contributes to it. (Commentator 1) It would also be difficult to assess whether an admission is solely due to complication of diabetes – who will make that decision? (Commentator 2)
Question 13.2: Do you think there are potential unintended consequences to implementing / using this indicator?			
CCG5	13.2	Individual comment	Once figures are clearer, the true impact of diabetes will be even more evident and hopefully the push to prevent complications will be stronger made and better funded to reduce morbidity.
CCG5	13.2	?	Admission rates are often a function of the set up of out of hours care; how an acute Trust defines admission as opposed to attendance will vary, distorting any indicators

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CCG5	13.2	London Diabetes Strategic Clinical Network	Once figures are clearer, the true impact of diabetes will be even more evident and hopefully the push to prevent complications will be stronger made and better funded to reduce morbidity.
CCG5	13.2	Primary Care Diabetes Society	This could potentially result in patients not being admitted early enough and result in admission with patients in crisis.
CCG5	13.2	London Borough of Redbridge	No
CCG5	13.2	Lancaster University	Lack of admission might be as big an issue for people with learning disabilities as too many admissions for complications.
CCG5	13.2	?	stress for staff to get the targets
CCG5	13.2	Association of British Clinical Diabetologists	No
CCG5	13.2	Liverpool LA public health team	no
CCG5	13.2	Boehringer Ingelheim	Lower limb amputation is a long term indicator of management and the measurement of CV risk would be more effective.
CCG5	13.2	Association for the study of obesity	No
CCG5	13.2	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	no
CCG5	13.2	All Party Parliamentary	This indicator is an important tool for shedding light on the important

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		Group on Vascular Disease	issue of diabetes-related health complications. The impact of the indicator is positive; removal of this indicator would risk dis-incentivising CCGs from focusing on such an important disease area.
CCG5	13.2	RCGP	The RCGP identifies the immense variation between different areas (Commentator 1) to be the main potential unintended consequences.
Question 13.3: Do you think there is potential for differential impact (in respect of age, disability, gender and gender reassignment, pregnancy and maternity, race, religion or belief, and sexual orientation)? If so, please state whether this is adverse or positive and for which group.3			
CCG5	13.3	Medtronic Limited	Applies to all patient groups
CCG5	13.3	London Borough of Redbridge	No
CCG5	13.3	Lancaster University	Yes, people with learning disabilities (adverse)
CCG5	13.3	Individual comment	many non English speaking Asian diabetics do not engage with structured diabetic education schemes; their control is poorer and their complication rate is higher; they already use a lot of resource; this indicator will demoralise practices trying to provide care to this population
CCG5	13.3	Individual comment	don't know
CCG5	13.3	Association of British Clinical Diabetologists	No
CCG5	13.3	Liverpool LA public health team	no
CCG5	13.3	Boehringer Ingelheim	No
CCG5	13.3	Association for the study of obesity	No

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CCG5	13.3	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	no
CCG5	13.3	All Party Parliamentary Group on Vascular Disease	Diabetes and its associated complications can affect all people; in particular Type 2 diabetes.
CCG5	13.3	RCGP	The RCGP has not identified any potential for differential impact for this indicator.
Question 13.4: Do you have any general comments on this indicator?			
CCG5	13.4	Individual comment	This indicator will be very dependent on good information and could be skewed very easily.
CCG5	13.4	Individual comment	There are a cohort of diabetes patients, particularly some with type 2, who are less knowledgeable about their condition, or in denial of their diabetes. If, when admitted to hospital, an opportunity is taken to reverse this belief and begin educating them in self-management, and lifestyle changes, with hospital processes factoring this in within the pathway (in every ward & department) this opportunity can be missed to reduce future impact of complication rates.
CCG5	13.4	London Diabetes Strategic Clinical Network	There are a cohort of diabetes patients, particularly some with type 2, who are less knowledgeable about their condition, or in denial of their diabetes.

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			If, when admitted to hospital, an opportunity is taken to reverse this belief and begin educating them in self-management, and lifestyle changes, with hospital processes factoring this in within the pathway (in every ward & department) this opportunity can be missed to reduce future impact of complication rates.
CCG5	13.4	Primary Care Diabetes Society	MORE CLARITY NEEDED
CCG5	13.4	Medtronic Limited	We recommend that an indicator is included to monitor the number of adults who have had an emergency admission for hypoglycaemic events as these have an adverse effect on good long term diabetic management and poorer outcomes. Nearly 60,000 hospital admissions last year were as a result of severe hypoglycaemic attacks in people with Type 1 diabetes, costing the NHS approximately £55 million
CCG5	13.4	London Borough of Redbridge	We welcome this indicator which will provide an indication of good diabetes management to prevent complications requiring hospital admissions in the CCG area
CCG5	13.4	[Lancaster University]	Disaggregation by learning disabilities would be helpful.
CCG5	13.4	Primary Care CVD Leadership Forum	We support this indicator as it will promote local analysis of and improvement in the quality of care provided to people with diabetes. Provision of the 9 care processes and achievement of the key treatment targets does reduce complication rates. The significant variation between practices in achievement of these targets demonstrates the significant potential for improvement in care.
	13.4	Association of British Clinical Diabetologists	ABCD supports the motivation behind this indicator. The proportion of people with diabetes in a population who are admitted to hospital because of a complication of diabetes is an indicator of the

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			quality and functionality of the integrated model for diabetes care for that population. In particular the proportion of people with diabetes undergoing a **major** lower limb amputation is a marker of the quality and functionality of the integrated diabetic foot care pathway. Apart from amputations and admissions with diabetic ketoacidosis there are other important complications of diabetes and its treatment. Hyperosmolar hyperglycaemic state is a feature of acute metabolic decompensation in elderly patients and carries a high mortality rate. Hypoglycaemia is a complication of treatment with insulin and oral hypoglycaemic agents, but is avoidable in most cases. It can also often be managed safely without admission to hospital. Several health economies have invested in schemes that allow paramedics to treat the patient at the scene and leave them at home, requesting a follow-up call from the diabetes specialist team to establish the cause and suggest how best to prevent a recurrence. The problem with this indicator is the absence of adequate diagnostic codes for the complications of interest, and the inconsistency of coding by hospitals. This should not prevent this proposed indicator going ahead, but ABCD calls for the development and implementation of better diagnostic codes for diabetes-related complications.
CCG5	13.4	Liverpool LA public health team	This appears to be a good idea, as important outcome of a good diabetes service. However, difficult to implement as issues with hospital admissions coding. One in ten people in hospital have diabetes whether it is a contributing factor, causal or incidental.
CCG5	13.4	Public Health England	We support this indicator as it will promote local analysis of and improvement in the quality of care provided to people with diabetes. Provision of the 9 care processes and achievement of the key treatment targets does reduce complication rates. The significant variation

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			between practices in achievement of these targets demonstrates the significant potential for improvement in care. However it needs to be more specific. It would be helpful to monitor complication rates separately. Need to monitor admissions related to diabetic foot disease complications separately and ensure that all minor amputations are included. Would also be useful to have OPD attendance in Ophthalmology for those with diabetes previously unknown to diabetic eye screening programmes' (i.e. what programmes are currently asked to audit) The existing indicator, CCG OIS: C2.8: Complications associated with diabetes, includes the following complications: DKA, Angina, Myocardial infarction, heart failure, stroke, RRT and amputations. Long term CVD/Renal complications will be significantly determined by care greater than 5 years ago so could make interpretation of this indicator difficult.
CCG5	13.4	Boehringer Ingelheim	Addition of monitoring of complications associated with macro-vascular risk, ie fatal and non-fatal MI and stroke and heart failure, declining renal function and other microvascular complications. Reintroduction of annual renal monitoring to ensure patients receive appropriate medicines.
CCG5	13.4	Diabetes UK	This indicator appears vague. Should it spell out the specific complications?

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CCG5	13.4	British Medical Association	It is not clear how a 'complication' is commonly defined and what level of severity is regarded as a complication. Patients could be admitted primarily for another reason and the 'complication' is an incidental coding but not the main reason for admission.
CCG5	13.4	Association for the study of obesity	No
CCG5	13.4	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	This appears to be a good idea, as important outcome of a good diabetes service. However, difficult to implement as issues with hospital admissions coding. One in ten people in hospital have diabetes whether it is a contributing factor, causal or incidental.
CCG5	13.4	NHS England	NHS England supports this indicator as it will promote local analysis of and improvement in the quality of care provided to people with diabetes. Provision of the 9 care processes and achievement of the key treatment targets does reduce complication rates. The significant variation between practices in achievement of these targets demonstrates the significant potential for improvement in care. However there is a need for clarity on how this indicator interrelates with CCG OIS C2.8 Complications associated with diabetes, including emergency admission for diabetic ketoacidosis and lower limb amputation. It would also be very helpful to have this developed as a GP practice level indicator in order to help information variation at this level.
CCG5	13.4	All Party Parliamentary Group on Vascular Disease	This indicator ensures that a vitally important issue – lower limb amputations as a result of diabetes – is recognised at an important level, encouraging CCGs to take action to reduce unnecessary lower

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			limb amputations. People with diabetes constitute around 7% of the population. 50% of the amputations that take place nationally are in people with diabetes. As diabetes prevalence increases, so too does the prevalence of diabetes-related health complications. Diabetes, if not managed appropriately, can lead to Peripheral Arterial Disease, Critical Limb Ischaemia and, ultimately, lower limb amputation. The national average for major amputation is 0.8 per 1000 people with diabetes per year, however regional variation is significant. Amputation is twice as likely for patients in the South West than in London. Having a national indicator is crucial in order to ensure that all areas have an equal responsibility and expectation to tackle this issue.
CCG5	13.4	British Holistic Medical Association	No
CCG5	13.4	MSD UK	MSD would like to request that the specific complications in question should be mentioned in the document. Additionally, as complications represent 69% of diabetes spending, MSD think that the potential use of ICD10 and HRG for micro- and macro-vascular complications as the particular measures used for this indicator would have a positive impact.
CCG5	13.4	RCGP	The RCGP feels that this indicator needs clarification (Commentator 1),

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			particularly about what constitutes “complications” and how to ascertain it is due to diabetes. (Commentator 2) The RCGP would also recommend basing it on more recent data. (Commentator 3)

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Question 14.1: Do you think there are any barriers to implementing the care described by this indicator?			
CCG6	14.1	Individual	No
CCG6	14.1	Individual	There are process and system issues which are barriers.
CCG6	14.1		Many practices will have very small numbers of children with diabetes; small changes in numbers could lead to a large change in the score on the indicator
CCG6	14.1	Individual	This care tends to be provided in specialist care. Need to ensure good communication between primary and specialist care. Poor access to psychological support - GPs may feel it is inappropriate to do 'psychological assessment' if there are no services to access.
CCG6	14.1	London Diabetes Strategic Clinical Network	There are process and system issues which are barriers.
CCG6	14.1	Primary Care Diabetes Society	Many children with diabetes do not attend their General Practitioner. They remain in Hospital setting and do not engage with primary Care..This indicator is a reflection on secondary care practice and Primary Care documentation is taken from clinic letters. This is an inappropriate QOF indicator for Primary Care
CCG6	14.1	Medtronic Limited	Lack of understanding of the health complications that can arise as a result of diabetes in children and young people often acts as a barrier to effective adoption of steps which would help to achieve this indicator. An improvement in education for patients and healthcare professionals working in primary and community care, on diabetes care

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CCG6	14.1	London Borough of Redbridge	No
CCG6	14.1	Individual	this largely happens in the hospital sector and the quality of care will reflect the hospital service rather than primary care services
CCG6	14.1	Individual	Children are looked after almost exclusively by Secondary care so this isn't a suitable marker for primary care to be judged on despite being well intentioned
CCG6	14.1	Nightingale Valley Surgery.	I think that this is good and something to aim for but again resourcing of this I would imagine would be an issue and I would see this as a secondary responsibility.
CCG6	14.1	Individual	staff time
CCG6	14.1	Individual	Assumes cost effectiveness, and that GPs' have effecting way of influencing weight and exercise. Some Should be PHE responsibility. Some Should be politician responsibility (Sugar Tax, stop selling playing fields for houses.)
CCG6	14.1	Royal National Institute of Blind People	No
CCG6	14.1	Association of British Clinical Diabetologists	No
CCG6	14.1	Liverpool LA public health team	no
CCG6	14.1	Association for the	No

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		study of obesity	
CCG6	14.1	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	no
CCG6	14.1	University of Surrey	Psychological assessment should be clearly defined.
CCG6	14.1	RCGP	The RCGP would recommend a definition of “psychological assessment” and clarification about who should carry it out. (Commentator 1). Most children and young people receive their diabetic care through a specialist team rather than a GP (Commentator 2). If there is poor access to psychological support, GPs may feel it is inappropriate to do a ‘psychological assessment’. (Commentator 3) The RCGP also recommends taking into account patient co-operation and choice and the importance of not over-medicating. (Commentator 4)
CCG6	14.1	VISION 2010 UK	No
Question 14.2: Do you think there are potential unintended consequences to implementing / using this indicator?			
CCG6	14.2	Individual	No
CCG6	14.2	London Diabetes Strategic Clinical Network	No
CCG6	14.2	Medtronic Limited	As the management of children and young people is also undertaken in

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			secondary care there is a concern of the potential of unnecessary repeated testing in primary care which can be distressing to the patient and expensive. Measures should be put in place to mitigate this risk such as sharing of data platforms, improved pathways and communication
CCG6	14.2	London Borough of Redbridge	No
CCG6	14.2	Individual	as always; opportunistic cost due to less time to do other things
CCG6	14.2	Individual	making patients insecure
CCG6	14.2	Individual	Increased work load in GP without transfer of resources from Hospital where this work can be done more efficiently with more highly trained staff.
CCG6	14.2	VISION 2020 UK	No
CCG6	14.2	Royal National Institute of Blind People	No
CCG6	14.2	Association of British Clinical Diabetologists	No
CCG6	14.2	Liverpool LA public health team	no
CCG6	14.2	Association for the study of obesity	No
CCG6	14.2	Cheshire and Merseyside Directors of Public Health, Champs Public Health	no

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		Collaborative	
CCG6	14.2	RCGP	The RCGP has not identified any potential unintended consequences to implementing / using this indicator.
Question 14.3: Do you think there is potential for differential impact (in respect of age, disability, gender and gender reassignment, pregnancy and maternity, race, religion or belief, and sexual orientation)? If so, please state whether this is adverse or positive and for which group.			
CCG6	14.3	Individual	Main issue is the teenage years when they can often “disengage” from paediatric services and reject the transition process and adult services – they are then sometimes “lost” to follow-up.
CCG6	14.3	London Diabetes Strategic Clinical Network	Main issue is the teenage years when they can often “disengage” from paediatric services and reject the transition process and adult services – they are then sometimes “lost” to follow-up.
CCG6	14.3	Medtronic Limited	Applies to all groups
CCG6	14.3	London Borough of Redbridge	No
CCG6	14.3	Lancaster University	Yes, children/young people with learning disabilities (adverse).
CCG6	14.3	Individual	don’t know
CCG6	14.3	VISION 2020 UK	The VISION 2020 UK Ophthalmic Public Health Committee particularly welcomes the proposal to break down the indicator into age bands. However, the indicator as drafted does not provide an age definition for children and young people. Given that the diabetic eye screening indicator IND CCG7 is defined in terms of people with diabetes aged 18 years and older, it may be implied that indicator IND CCG6 defines children and young people aged 17 years or under. However, this ought

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			to be specifically stated.
CCG6	14.3	Royal National Institute of Blind People	We would like the wording to state that the final age bracket is 16-17 years old, as 18 years and over is classed as adult.
CCG6	14.3	Association of British Clinical Diabetologists	No
CCG6	14.3	Liverpool LA public health team	no
CCG6	14.3	Association for the study of obesity	No
CCG6	14.3	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	no
CCG6	14.3	RCGP	The RCGP has not identified any potential for differential impact for this indicator.
Question 14.4: Do you have any general comments on this indicator?			
CCG6	14.4	Individual	This should be the minimum we deliver to ensure we are serving this vulnerable population properly. We need to have stronger process across the UK to join up diabetes data so that is Type 1 patients go to Uni / work elsewhere they can still be within the diabetes community.
CCG6	14.4	Individual	A lot of the care of children with diabetes is done by consultants in acute Trusts, with their teams. Often data is not shared well with primary care. There is a significant risk that the children will be called in

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			for extra attendances in primary care for data gathering purposes, with negligible benefit to their care.
CCG6	14.4	London Diabetes Strategic Clinical Network	This should be the minimum we deliver to ensure we are serving this vulnerable population properly. We need to have stronger process across the UK to join up diabetes data so that is Type 1 patients go to Uni / work elsewhere they can still be within the diabetes community.
CCG6	14.4	Primary Care Diabetes Society	Should there be a start age at which screening should be done ?
CCG6	14.4	London Borough of Redbridge	The indicator does not explicitly state how often (for example, annual eye screening) the care processes need to be checked / measured.
CCG6	14.4	Individual	Not my field of experience
CCG6	14.4	Individual	what is the evidence to bring this in?
CCG6	14.4	Individual	It should be extended to all age groups and not limiting those over 18 to just eye checks as part of QOF. All patients need all checks. This is preventive and will reduce those getting complications. See the Parliamentary Accounts Committee who say in their report: “The cost of complications (such as amputation, blindness, kidney failure and stroke) accounts for 69% of these costs.3 The Committee of Public Accounts last took evidence on diabetes services in 2012. In its report, the Committee concluded that too many people with diabetes were developing complications because they were not receiving the

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			care and support they needed.”
CCG6	14.4	VISION 2020 UK	The VISION 2020 UK Ophthalmic Public Health Committee particularly welcomes the proposal to break down the indicator into age bands. However, the indicator as drafted does not provide an age definition for children and young people. Given that the diabetic eye screening indicator IND CCG7 is defined in terms of people with diabetes aged 18 years and older, it may be implied that indicator IND CCG6 defines children and young people aged 17 years or under. However, this ought to be specifically stated.
CCG6	14.4	Primary Care CVD Leadership Forum	We support this indicator as it will promote local analysis of and improvement in the quality of care provided to children and young people with diabetes. Provision of the care processes does reduce complication rates. The national diabetes audit has shown that children and young people are significantly less likely to receive these care processes than adults.
CCG6	14.4	Association of British Clinical Diabetologists	ABCD supports this indicator. The data will be provided by the paediatric diabetes team in order to claim the best practice tariff.
CCG6	14.4	Liverpool LA public health team	Unclear about the usefulness of all these assessments at this age, e.g. eye screening and foot examination
CCG6	14.4	Public Health England	We support this indicator as it will promote local analysis of and improvement in the quality of care provided to children and young people with diabetes. Provision of the care processes does reduce complication rates. The national diabetes audit has shown that children and young people are significantly less likely to receive these care processes than adults. However it needs to be much more specific. Different denominators included in the care processes e.g. eye screening from 12 onwards –

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			not all children with diabetes. “Foot examination” – very non-specific. This can’t be measured the way it’s written. Need to be specific if this is Diabetic Eye Screening, as it could mean vision screening Should a diabetic ketoacidosis (DKA) based measure be included?
CCG6	14.4	British Medical Association	We believe that having an ‘all-in-one’ indicator is a bad idea and does not acknowledge the realities of general practice, nor individualised care. Bundling the payment for annual tests cannot be justified when there is no evidence for the annual tests themselves. Although possible to do on the patients who come to diabetic clinics, it will disincentivise GPs from doing opportunistic testing on hard-to-reach patients where, for example, a foot test can be performed for a patient who the GP knows will never bring in a urine sample. The result of this will be to decrease the resources that practices have to care for their diabetic patients, and this decrease will disproportionally affect the practices who care for the most challenging patients. Some of the elements of the indicators are not possible to collect from some patients, such as BMI for patients with severe mobility difficulties, or ACRs for patients with incontinence. Practices should not be denied the funding needed to care for these difficult patients on such a basis. The rationale for bundling these indicators, namely the difference between the QOF achievement figures and the diabetes audit, has also been shown by Professor Sparrow to be due to differences in statistics rather than clinical care, so there is no justification for this change. This

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			is also likely to result in an increase in exception reporting.
CCG6	14.4	Association for the study of obesity	BMI requires both height and weight measures to be made.
CCG6	14.4	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	Unclear about the usefulness of all these assessments at this age, e.g. eye screening and foot examination
CCG6	14.4	NHS England	NHS England supports this indicator as it will promote local analysis of and improvement in the quality of care provided to children and young people with diabetes. Provision of the care processes does reduce complication rates. The national diabetes audit has shown that children and young people are significantly less likely to receive these care processes than adults. This is a helpful addition, and also backs up the best practice tariff for children's diabetes care, which incentivised providers around these care processes, but which is still subject to high levels of variation nationally
CCG6	14.4	British Holistic Medical Association	This is all sensible.
CCG6	14.4	MSD UK	MSD believe that there should also be a similar indicator for adults with diabetes.
CCG6	14.4	RCGP	The RCGP notes that these patients will be under secondary care so there would be no value in primary care collecting this data.

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			(Commentator 1). We would also recommend clarification on the need for psychological assessment for every child with diabetes. (Commentator 2)
Question 14.5: If the data are available should this indicator be broken down into age bands of perhaps 5 years – ie, 0 – 5 years, 5 – 10 years, and 10 – 15 years etc.			
CCG6	14.5	Individual	Yes
CCG6	14.5	London Diabetes Strategic Clinical Network	Yes
CCG6	14.5	Primary Care Diabetes Society	Due to poor engagement with Primary Care at all these ages , this reflects secondary care management. Is there any evidence to suggest cholesterol and eye screening are of benefit in the younger ages?
CCG6	14.5	Medtronic Limited	Optimal management for the different age groups is challenging and so age bands would be helpful.
CCG6	14.5	London Borough of Redbridge	Certainly – it will be very useful to have it broken down by age bands. This is also particularly useful for those young people who are at the point of transition to adult services as often there is a gap in appropriate service provision to meet the needs of these young people.
CCG6	14.5	Lancaster University	5-year age bands sensible.
CCG6	14.5	VISION 2020 UK	The Committee noted that the proposed aged bands were 0-5, 5-10, 10-15 etc. Thus presumably the final age bands would also cover 16 and 17 year olds. For information, the diabetic eye screening programme is offered to all people with diabetes aged 12 or over, and

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			so NICE may wish to take this into account when choosing the final specific age groups.
CCG6	14.5	Royal National Institute of Blind People	We would like the wording to state that the final age bracket is 16-17 years old, as 18 years and over is classed as adult.
CCG6	14.5	Liverpool LA public health team	not necessary
CCG6	14.5	Diabetes UK	It would be better to have age bands as not all the processes are applicable to all children. We propose two bands; children under 12 years, and those 12 years and over.
CCG6	14.5	Association for the study of obesity	This breakdown into categories could be of value as BMI can often become elevated in those reaching adolescence. Age groups at most risk of obesity could be identified. This is valuable in order to make certain that BMI is reported by age category.
CCG6	14.5	Cheshire and Merseyside Directors of Public Health, Champs Public Health Collaborative	not necessary
CCG6	14.5	University of Surrey	Yes, absolutely.
CCG6	14.5	British Holistic Medical Association	No.
CCG6	14.5	RCGP	The RCGP feels it would be useful additional information as it may allow targeting of intervention to improve those areas with poor outcomes (Commentator 1), however this may not be helpful for all the processes, for example: smoking is unlikely under age 5 and it is not clear how psychological assessment would be scored. (Commentator 2)

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Appendix B: Equality impact assessment for diabetes

Table 1

Protected characteristics
Age
Disability
Gender reassignment
Pregnancy and maternity
Race
Religion or belief
Sex
Sexual orientation
Other characteristics
Socio-economic status Depending on policy or other context, this may cover factors such as social exclusion and deprivation associated with geographical areas or inequalities or variations associated with other geographical distinctions (e.g. the North/South divide, urban versus rural).
Marital status (including civil partnership)
Other categories Other groups in the population experience poor health because of circumstances often affected by, but going beyond, sharing a protected characteristic or socioeconomic status. Whether such groups are identifiable depends on the guidance topic and the evidence. The following are examples of groups covered in NICE guidance: • Refugees and asylum seekers • Migrant workers • Looked after children • Homeless people.

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Indicator Equality Impact Assessment form

Development stage: Consultation

Topic: Diabetes

1. Have any equality issues impacting upon equality groups been identified during this stage of the development process? • Please state briefly any relevant equality issues identified and the plans to tackle them during development.
No comments were received to suggest there are any issues impacting on equality at this stage of development.
2. Have relevant bodies and stakeholders been consulted, including those with a specific interest in equalities? • Have comments highlighting potential for discrimination or advancing equality been considered?
Yes – stakeholders across England were encouraged to comment on the potential new indicators as part of the NICE consultation.
3. Have any population groups, treatments or settings been excluded at this stage in the process? Are these exclusions legal and justified? • Are the reasons for justifying any exclusion legitimate?
These indicators are relevant to people with diabetes and reflect the scope of the quality standard and guidance on which they are based and the topic-specific nature of most QOF/CCG OIS indicators.
4. Do any of the indicator statements make it impossible or unreasonably difficult in practice for a specific group to access a test or intervention? • Does access to the intervention depend on membership of a specific group? • Does a test discriminate unlawfully against a group? • Do people with disabilities find it impossible or unreasonably difficult to receive an intervention?
Comments from the consultation exercise suggest that the CCG4, CCG5 and CCG6 will make a differential impact in practice for people with learning difficulties. CCG4 – A stakeholder feels that it may prove difficult for a service to be available within 1 week for non-English speaking women in order to implement this indicator. CCG7 - South Asian, Black African and African Caribbean people are at higher risk of diabetes so screening will have a positive effect on these groups and potentially save their sight from any diabetes related eye conditions
5. Do the indicator statements advance equality? • Please state if the indicator as described will advance equalities of opportunity, for example by making access more likely for certain groups, by tailoring the service to certain groups, or by making reasonable adjustments for people with disabilities?
There were no consultation comments to suggest that the indicators would necessarily advance equalities

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in terms of people with protected characteristics or other relevant characteristics.