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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

QUALITY AND OUTCOMES FRAMEWORK (QOF) INDICATOR DEVELOPMENT PROGRAMME

Consultation report on piloted indicator(s)

QOF indicator area: Diabetes: care processes

Consultation period: 06/01/2014 – 03/02/2014

Potential output: Recommendations for NICE Menu

Contents

Introduction 2
Indicator(s) included in the consultation 2
Considerations for the Advisory Committee 3
Summary of responses: comments by indicator (IND-1) 3
Appendix A consultation comments 6

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Introduction

This report provides a summary of the responses received from the recent consultation on potential new indicators for inclusion in the NICE menu. The Committee is also provided with the full consultation comments in appendix A of this paper.

The Committee is asked to consider the results of the consultation alongside the pilot reports produced by the National Collaborating Centre for Indicator Development and cost effectiveness analysis by York Health Economics Consortium where available.

Indicator(s) included in the consultation

ID	Indicator	Evidence source
IND-1	The percentage of patients with diabetes who have had the following care processes performed in the preceding 12 months: • BMI measurement • BP measurement • HbA1c measurement • Cholesterol measurement • Record of smoking status • Foot examination • Albumin: creatinine ratio • Serum creatinine measurement	NICE clinical guideline 87: Type 2 diabetes: The management of type 2 diabetes (2009)

A summary of comments relating to the specific question below is provided following the summary of responses to the standard consultation questions:

- Retinal screening is not currently included within this composite indicator as it was considered to be outside the control of GPs. Do stakeholders consider it appropriate to include retinal screening in this indicator?

Overarching comments on the indicators

Generally stakeholders responded that the inclusion of a composite indicator in QOF is reasonable. However, the potential negative unintended consequence of dis-incentivising care for people in whom it is difficult to achieve all 8 care processes was highlighted i.e. achievement awarded for

completion of all 8 care process may result in patients receiving none if 1 or more of the components is unattainable.

Stakeholders provided mixed responses to the question of whether it would be appropriate to include retinal screening in this indicator.

Considerations for the Advisory Committee

The specific issues that the Advisory Committee is asked to consider when making recommendations on which indicators should be published on the NICE menu for the QOF are stated below.

These issues are also addressed in the indicator development reports which will include suggestions for possible amendments to how the indicators should be specified following piloting and public consultation.

The Advisory Committee is asked to consider:

- What the possible exceptions are for this indicator
- Whether retinal screening should be included in this indicator

Summary of responses: comments by indicator (IND-1)

The percentage of patients with diabetes who have had the following care processes performed in the preceding 12 months:

- *BMI measurement*
- *BP measurement*
- *HbA1c measurement*
- *Cholesterol measurement*
- *Record of smoking status*
- *Foot examination*
- *Albumin: creatinine ratio*
- *Serum creatinine measurement*

Generally stakeholders responded that this indicator was acceptable. For example, the Care Quality Commission (CQC) stated support for this indicator, commenting that it will better inform assessment of overall care provided.

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The CQC commented that they strongly support this diabetes composite indicator. The CQC noted that a composite approach would assist them in their reviews of GP practices.

Stakeholders queried if a practice would achieve the indicator where exception reporting against one element occurred or if this is an 'all or nothing' indicator. A number of stakeholders including Diabetes UK, NHS England and NHS Employers and the GPC of the BMA commented on the potential for negative consequences of an 'all or nothing' indicator. For example, if all 8 care processes are difficult to achieve in some people, is there a risk that the indicator may act as a disincentive and these people may not receive any of the care processes (if the incentive is rewarded only for completion of all eight)? Clarity about the role of exceptions was requested.

The PHE Midlands and East regional team commented that BMI is not sufficiently sensitive amongst all communities within England and in particular those from Asia. They therefore felt that waist circumference should also be considered as part of the composite indicator.

The Royal College of Nursing highlighted accuracy of records and the timing of blood results as potential barriers to implementation of this indicator.

Indicator specific question and responses

Stakeholders were asked:

> *Retinal screening is not currently included within this composite indicator as it was considered to be outside the control of GPs. Do stakeholders consider it appropriate to include retinal screening in this indicator?*

Stakeholders made the following comments in relation to this question:

- A number of stakeholders including NHS England and NHS Employers commented that retinal screening should not be included. Public Health England also commented that retinopathy screening is a fundamental part of the care pathway for patients diagnosed with diabetes and the screening programme aims to reduce the risk of sight loss among people with diabetes by the early detection and treatment, if needed, of diabetic retinopathy. For this reason they felt retinopathy screening should be included in this indicator. However another stakeholder commented that as a

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GP cannot make a person attend retinopathy screening it would be unfair to include it. However, it was noted that GPs do receive the results and are therefore able to encourage people who do not attend to attend for subsequent appointments.

- Another stakeholder felt that excluding retinopathy screening from QOF is likely to reduce GPs incentives to cooperate with retinopathy screening programmes in ensuring an accurate diabetic register and could lead to patients not being screened.
- The Royal College of Nursing also highlighted retinopathy screening is an essential aspect of diabetic screening.

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Appendix A consultation comments

General comments

Indicator no.	Stakeholder organisation	Type of comment	Comment
IND-1	Corbett Medical Practice	General comments	Seems reasonable
IND-1	Unity Health, YORK	General comments	I think that the delivery of a care bundle is appropriate in this area I would be interested to know how practices are able to achieve all 8 items at present and if so which areas patients are likely to be excepted for?? This does not require delivery of achievement targets but delivery of the full care bundle
IND-1	Dryland Medical Centre	General comments	I feel to group all 8 of these together in 1 marker would be VERY ILL ADVISED. This goes against the original intention of QOF and the encouragement of high quality but individualised care. Getting all 8 for a large number of patients will be achievable but I feel that certain patients could easily be neglected from care by practices who feel unable to score all 8 so don't bother to try to score 6 or 7.
IND-1	National Kidney Federation	General comments	conjunction with NICE guidance on CKD

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IND-1	Central and North West London NHS Foundation Trust	General comments	I feel that Albumin Creatinine ration should be a separate point rather than in cumulative reporting so that it is not missed. It is vital that this test is carried out and if positive treated. Postitive ACR increases risk of not only progression to diabetic nephropathy but also is a predictor of CVD risk.
IND-1	Diabetes UK	General comments	We are concerned that the information in the topic overview is not all accurate. Information is provided in italics below to amend the following sentences for their inclusion in the formal indicator guidance. “People with Type 2 diabetes have a life expectancy that is reduced by up to 10 years and are at risk of increased cardiovascular risk”. Life expectancy is reduced, on average, in both types of diabetes. People with diabetes in England and Wales are 37.5% more likely to die than their peers. For Type 1 diabetes, mortality is 129% greater than expected and for Type 2 diabetes it is 34.5% greater . Cardiovascular disease is a major cause of death and disability in people with diabetes, accounting for 44 per cent of fatalities in people with Type 1 diabetes and 52 per cent in people with Type 2 . “Adults with Type 1 and Type 2 diabetes have their condition managed in primary care, however, it is common for adults with Type 1 diabetes to experience related complications requiring hospital admission”. Adults with Type 2 are mostly managed in primary care. Type 1 diabetes support should be coordinated primarily from secondary care. All people with diabetes must have access to specialist services when they require them, as well as services in community and primary care. “The risk of complications associated with diabetes may be reduced by carrying out each of the 9 care processes.” The risk of complications associated with diabetes may be reduced if each of the 9 care processes is carried out as part of the annual review and care planning process and that each of the tests and investigations lead to action

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			being taken where necessary on the basis of results.
IND-1	Wye Valley NHS Trust and Herefordshire & Worcestershire Diabetic Eye Screening Programme	General comments	Failure to include diabetic eye screening as a qof indicator is likely to reduce GPs incentives to cooperate with diabetic eye screening programmes in ensuring an accurate diabetic register and could lead to patients not being screened.
IND-1	Royal college of paediatrics and child health	General comments	This should specifically refer to ADULTS with diabetes as it does not all refer to children. Children over the age of 12 years are currently advised by NICE to have all these except lipids and creatinine measurements. These guidelines are currently under review. This guideline should state preferably adults over the age of 19 years as all children under the age of 19 (ie up to 18.99) will be funded by the best practice tariff which includes completion of screening.
IND-1	Society of Chiropodists and Podiatrists	General comments	Recommendation 1.1.2.1: Regular (at least annual) visual inspection of patients' feet, assessment of foot sensation, and palpation of foot pulses by trained personnel is important for the detection of risk factors for ulceration All patients with Diabetes should, as a minimum, be seen for a full annual risk screening process. This should consist of: all pedal pulses palpated. If non-palpable, pedal pulses should be listened to via a hand held Doppler. All patients with Diabetes should have the sensation in their feet checked through use of a 10g monofilament. Following the assessment the patient should be told their risk category, what this means and be given supportive literature. If the patient is in 'at risk' or 'high risk' of active foot disease category they should be referred to their local Podiatry service/ Foot Protection Team for intervention, in line with NICE CG 10. The need to document risk of each individual with diabetes was incorporated in QOF targets in April 2011. The 2011 NICE Quality Standard 10 and the

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			Diabetic Foot Risk Stratification and Triage (SIGN 116) also states that all people at increased risk will receive regular review by a member of a Foot Protection Team (FPT). People with diabetes should be aware of their risk status and this entitlement. All people at increased risk should be referred promptly to a member of the FPT. All practices need to maintain an up to date risk status of their patients and a record of onward referral, in line with NICE CG 10. Recommendation 1.11.3.1: Structured foot surveillance should be at 1-year intervals, and should include educational assessment and education input commensurate with the assessed risk. It is necessary that those who examine the feet to determine risk status have the necessary training and competence. Training will be a role which can be provided by the FPT. An essential part of the annual review of feet is patient education. The person with diabetes should be aware of the reason for the examination being undertaken, the results of the examination, the services to which they should have access if they require specific preventive measures and action to be taken if they develop a foot problem. It is necessary that those who examine feet to determine risk status have the necessary training and competence. An essential part of the annual review of feet is patient education. The person with diabetes should be aware of the results of the examination, the services to which they should have access if they require specific preventive measures and action to be taken if they develop a foot problem. A footcare pathway which supports NICE guidance and which has been agreed by organisations of diabetologists, podiatrists, people with diabetes and other experts has been published by Diabetes UK. http://www.diabetes.org.uk/Documents/Professionals/Education%20and%20skills/Footcare-pathway.0212.pdf We have concerns about a composite indicator as the risks of a quality foot assessment may compromise this and national foot outcomes may continue

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			to fail. The risk of foot assessment getting lost or diluted within an aggregated indicator is high. A composite indicator must not result in a reduction of the specific information provided to people with diabetes about their individual records.
IND-1	Royal College of Physicians	General comments	The RCP is grateful for the opportunity to comment on the indicator consultation. We wish to draw attention to the organisation responses submitted by the Association of British Clinical Diabetologists and Diabetes UK which are relevant to indicator 1 (diabetes) and the specific question on retinal screening. In general, we wish to stress that steps should be taken to develop QOF indicators that act as 'gauges of patient care' rather than simply 'incentives to measure'.
IND-1	Keele University	General comments	We wish to highlight an important issue of health inequality for people with severe mental illness, principally schizophrenia and bipolar disorder. In the first instance it links to your consultation on the diabetes domain but goes beyond simply the issue of retinal screening. Please see the attached summary of our collective response.
IND-1	Keele University	General comments	We wish to highlight an important area of health inequality for people with severe mental illness (SMI), principally schizophrenia and bipolar disorder. In the first instance it links to your consultation on the diabetes domain. It goes beyond your specific consultation point on retinal screening. We are concerned that introducing this proposed new indicator for diabetes may disadvantage people with SMI. We would ask you to consider how this might be introduced in a way that avoids creating health inequalities for this population who receive poorer diabetes care. This would include your specific consultation point on retinal screening as this population have been shown to receive fewer routine eye checks, as well as poorer glycaemic and

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			lipid control (Frayne et al., 2005). A further, and more serious issue, is that from April 2014, in England, the Quality and Outcome Framework (QOF) domain for those with SMI will no longer require the regular monitoring of body mass index, glucose or cholesterol. This is of considerable concern as the prevalence of type 2 diabetes is 2-3 fold higher in people with severe mental illness compared with the general population, and rates of undiagnosed diabetes are up to 70% in people with schizophrenia compared with about 25% in the general population. The changes to the QOF contract for 2014/15 in England will almost certainly undermine systematic monitoring and reduce opportunities to both detect and prevent diabetes, as well as cardiovascular disease in people with SMI. Prior to the QOF 2014/15 contract announcement, the NICE advisory committee had advised that maintaining these indicators would protect this population from health inequalities (NICE, QOF Advisory Committee Sept, 2013). Moreover the committee regarded the evidence supporting these indicators as 'strong' and noted they were derived from recommendations in the relevant NICE guidance for adults with schizophrenia (CG 82 2009). These recommendations were no less strong in the consultation draft of the NICE update CG 178 and it is unlikely the final version will disagree (personal communication with Professor Kendall, director of NCCMH) when it is launched on Feb 12th 2014. The situation is even more complicated as the decision to retire these QOF indicators has been made in England but not in Scotland. In Wales the creation of a Directed Enhanced Service (DES) will continue to encourage systematic screening for these measures. Thus, the creation of health inequalities is both by disease and by geography within the UK. Brief resume of the current evidence People with severe mental illnesses, such as schizophrenia and bipolar disorder, are at higher risk of developing diabetes as well as experiencing

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			marked reduction in life expectancy due mainly to premature cardiovascular disease. Compared to the general population: • Life expectancy is reduced by around 15-20 years (Wahlbeck et al., 2011). • About 70% of premature deaths arise from physical disorders (Nordentoft et al., 2013). • Cardiovascular disease is the single biggest and potentially preventable cause of premature mortality, much more common than suicide (Brown et al., 2010). This can be linked to higher rates of potentially modifiable risk factors for obesity, diabetes and cardiovascular disease Table 1: Prevalence of modifiable cardiovascular risk factors in people with severe mental illness and relative risk compared to general population. Adapted from De Hert et al 2009 Prevalence Relative Risks Smoking 50-80% 2-3 Obesity 45-55% 1.5-2 Diabetes 10-15% 2-3 Hypertension 19-58% 2-3 Dyslipidaemia 25-69% ≤5 Metabolic syndrome 37-63% 2-3 1. Low rates of detection of type 2 diabetes (and those at high risk) in people with severe mental illness a. A European study screening people with schizophrenia who were not known to have diabetes discovered that 10% had type 2 diabetes and 38% were at high risk of type 2 diabetes. The average age of this population was only 38 years (Manu et al., 2012). b. A Scottish study of 314 general practices compared the nature and extent of physical health comorbidities between 9,677 people with psychosis and

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			schizophrenia and 1,414,701 controls (Smith et al., 2013). Based on the presence of a possible recorded diagnosis for 32 index physical conditions, the study found that people with schizophrenia were more likely to experience multiple physical comorbidities. However, the odds ratio for the recording of a diagnosis of diabetes was only 1.52, lower than the expected 2-3 fold increased rate. There was also lower than expected rates of CVD leading the authors to conclude there was a systematic under-recognition and under-treatment of CVD in people with schizophrenia in primary care. 2. Cardiometabolic risk is apparent within weeks of onset of psychosis and accelerates rapidly a. Similar prevalence of metabolic syndrome compared to a matched population without psychiatric illness at the onset of psychosis (Fleischhacker et al., 2013). b. Within 8 weeks, adverse changes in lipid metabolism, glucose handling and insulin resistance, and weight gain were apparent and worsened over the 12 months studied. (Foley & Morley, 2011). 3. These cardiometabolic effects are common and cumulative a. Over a third of patients experiencing their first episode of psychosis developed metabolic disturbance by 8 months (Curtis et al., 2011). b. By age 40yrs there was four-fold increased prevalence of metabolic syndrome in a Finnish cohort of people with schizophrenia compared with matched population without psychiatric illness (Saari et al., 2005). 4. The association between antipsychotics and weight gain is established. A systematic reappraisal of evidence concluded that antipsychotic-induced weight gain had been underestimated three to four fold in those with first episode psychosis (Figure 1 from Alvarez-Jimenez et al., 2008). Weight gain is a particularly important issue for people with severe mental illnesses not only in terms of risking future diabetes and cardiovascular disease but also in its stigmatising effect (in addition to the psychosis). 5. Notwithstanding the adverse effects of antipsychotics, this population are

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			also at further risk from problematic tobacco and substance use, poor nutrition and lack of physical exercise (McCreadie et al., 1998). This population has 2-3 fold higher rates of tobacco smoking (Brown et al., 2010). These factors contribute to their vulnerability to CVD and diabetes. 6. The high risk of developing CVD, obesity and type 2 diabetes may be further compounded by inequalities in healthcare, perhaps reflecting the stigma towards those with SMI prevalent at all levels within the NHS (Corrigan et al.,, 2012). The National Audit of Schizophrenia (NAS) (Royal College of Psychiatrists, 2012) found that only 29% of 5091 patients randomly selected from 60 (out of 64) Mental Health Trusts/Health Boards across England and Wales had a record of adequately assessed cardiometabolic risk in the previous 12 months (weight, smoking status, glucose, lipids, BP). Weight had not been unrecorded in 43%. Moreover NAS demonstrated that when cardiometabolic risk factors were identified these were frequently ignored with, for example, only 53% of patients with abnormal glucose metabolism having any appropriate intervention. The problem of risk factors being ignored in clinical practice in those with SMI when compared with patients without mental illness has previously been documented (Mitchell et al., 2009).
IND-1	Unknown	General comments	We would ask NICE to consider the following: That the requirement to measure, monitor and act on measures of body mass index, cholesterol and glucose as part of an annual review process would mitigate health inequalities for patients with SMI living in England. We are not advocating necessarily that these measures simply be reinstated in England as previously. The issue of low rates of attendance in primary care for annual review requires consideration of what reasonable adjustments might overcome this potential obstacle, an area which requires renewed focus (Sayce & Boardman, 2008). The vehicle of enhanced services now being chosen in Wales may offer a way to overcome barriers.

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			For instance, a significant subset of this population may be particularly hard to engage and benefit from a proactive, outreach approach. Furthermore a DES might facilitate simple adjustments in routine practice as outlined by the late Professor Lester in the 2012 James McKenzie lecture (Lester, 2013) allowing more emphasis on prevention through proactive engagement, and therefore less unpredictable/crisis management. Another potential weakness of the system, as it currently stands across the UK, is the setting of a minimum age threshold of 40 yrs for glucose and cholesterol estimation when it is evident that cardiometabolic risk accelerates rapidly in a group of patients who are often in their late adolescence and early adulthood, when schizophrenia and other psychotic disorders most commonly presents (Kirkbride et al.,2006). Thus primary care can define a group in their 20s and 30s, at ages primary care would not normally consider for active primary or secondary CVD prevention, who are at high risk of dying young. Nor is this a particularly large number of patients – probably one new presentation every one to two years for a GP with an average list size. Finally we would ask NICE to consider whether a shift towards outcomes might be encouraged for this population. For instance measures which demonstrated offering targeted smoking cessation and structured education-lifestyle interventions (along the lines of evidence-based programmes like DESMOND for people at high risk of developing diabetes) would support recommendations due to appear in the pending NICE update on psychosis & schizophrenia guidelines (NICE CG178 2014).
IND-1	The British Cardiovascular Society	General comments	This is a rationalisation of the current QOF indicators. All these measurements are currently required but under separate indicators. This composite approach is acceptable. Presumably targets for blood pressure, cholesterol and HbA1c will still be required as separate indicators? It is important to have targets and in the matter of blood pressure the best

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			evidence is for the target of 140/90.
IND-1	Merck Sharp and Dohme Ltd	General comments	The effort to improve the outcomes of patients with diabetes by considering this composite indicator is welcomed. We acknowledge that these care processes have individual indicators currently within QOF (DM002, DM003, DM004, DM006, DM007, DM008, DM009, DM012), with specific targets for BP, HbA1c and cholesterol. It is a concern that upon introduction of this composite indicator the individual targeted indicators will be retired. MSD would like to see the targets for BP, HbA1c and cholesterol incorporated in this composite indicator to be consistent with the existing indicators (DM002, DM003, DM004, DM007, DM008 and DM009). Since the inception of QOF and specific indicators targeting BP, HbA1c and cholesterol in various clinical domains, the improvement in the outcomes for patients with CVD and diabetes should be applauded (e.g. mortality rates for patients under 75 with CVD have reduced by 40% between 2001 and 2010). In relation to this proposed indicator, there are approximately 2.7 million people in England diagnosed with Type 2 diabetes, and this number is only set to increase along with the associated health complications. In addition, a number of reports have detailed that the number of patients not achieving HbA1c targets and the HbA1c levels across the population are increasing. The State of the Nation report 2013 detailed that over time the number of patients meeting the HbA1c targets was decreasing. In addition, a new study has shown that between 2006 to 2012 the mean HbA1c levels in the UK increased during this period. This adds increasing weight to the importance of targets in this composite indicator. In summary, this is a good indicator, however, it is vital for the health of the patient that targets for BP, HbA1c and cholesterol are retained within QOF and included in this composite indicator.

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IND-1	Imperial College Healthcare NHS Trust	General comments	The measurement of albumin: creatinine ratio is such an important indicator of future risk of diabetic nephropathy and cardiovascular it should not be part of a composite indicator but a separate one There is a very strong evidence base dating back 30 years that microalbuminuria is predictive of diabetic nephropathy . Multiple clinical trials over the last 20 years have convincingly shown that early intervention in the management of microalbuminuria with renin–angiotensin inhibitors (angiotensin converting enzyme inhibitors and angiotensin receptor blockers) are renoprotective , for both subjects with type 1 and type 2 diabetes.This class of drugs also protect against cardiovascular disease Appropriate intervention and timely intervention with these drugs reduce the risk of progression from microalbuminuria to macroablbuninurea and slows the progression from chronic kidney disease to end stage renal failure and the need for renal replacement therapy .
IND-1	Alzheimer's Society	General comments	Alzheimer's Society welcomes this indicator, as the effective management of diabetes will likely have a beneficial effect on the risk of developing vascular or mixed dementia. However, we would recommend the inclusion of a regular assessment of cognitive function. The symptoms of dementia could act as a barrier to the implementation of these care processes. Comorbid dementia can negatively impact on the management of diabetes and increase likelihood of hospital admission. The NICE guideline for diabetes (2008) acknowledges the increased risk of carotid artery disease, commonly stroke and/or dementia. Increased cardiovascular risk tends to be most commonly associated with vascular or mixed dementia, rather than Alzheimer's Disease. Vascular and mixed dementia account for 27% of all cases of dementia (Dementia UK, 2007). In the UK, 216,000 people currently have vascular or mixed dementia. People with vascular dementia may experience:

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			o problems with speed of thinking, concentration and communication o depression and anxiety accompanying the dementia o symptoms of stroke, such as physical weakness or paralysis o memory problems (although this may not be the first symptom) o seizures o periods of severe (acute) confusion. The topic overview for this indicator highlights that effective management of type two diabetes could reduce complications that require hospital admissions. The symptoms of comorbid dementia can impact on and individual's ability to manage their condition and increase the likelihood of preventable hospital admission. Alzheimer's Society would recommend the inclusion of a cognitive assessment care process. Alzheimer's Society has worked with academic partners to review the different cognitive assessment tools available. This can be found online at www.alzheimers.org.uk/cognitiveassessment. It is worth reiterating that memory problems may not be the first symptom in vascular or mixed dementia, so tests that assess cognition more broadly are preferable. For people who currently have both a diagnosis of diabetes and dementia, clinicians may have more difficulty carrying out these care processes. To mitigate against this health professionals involved in the processes should be fully informed about the nature and progression of dementia and how to effectively manage comorbid dementia.
IND-1	British Renal Society	General comments	Agree with these but need to add eGFR to creatinine measurement
IND-1	Care Quality Commission	General comments	We would strongly support the diabetes composite indicator, as this approach would assist in our reviews of GP practices. Specifically it will help us look at the overall care provided to the person with diabetes, rather than

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			individual indicators. This will provide insight and context to our lines of enquiry, with regard to the management and experiences of people with diabetes in a practice.
IND-1	Bayer Plc	General comments	Please see comments regarding retinal screening below. Also as part of this indicator it would be important to ensure that male patients with diabetes are being asked about erectile dysfunction (ED) on an annual basis. ED is common among diabetic men, with estimates of prevalence ranging from 35% to 90%. The age-adjusted probability of ED has been shown to be three times greater in patients with treated diabetes than in those without diabetes. ED is associated with a poorer quality of life in men with diabetes,3 in one study it was also shown that "erectile dysfunction was associated with higher levels of diabetes-specific health distress and worse psychological adaptation to diabetes, which were, in turn, related to worse metabolic control." There is also evidence to suggest that ED is a marker of underlying asymptomatic coronary artery disease and predicts future cardiovascular events in men with type 2 diabetes as well as in otherwise healthy men. NHS diabetes have stated that “the importance of ED as a symptom of cardiovascular disease is generally poorly recognised by healthcare professionals” and recommend that “the annual review offers the opportunity to identify ED as an early sign of atherosclerosis and heralds future cardiovascular events.” The GDG of the NICE type 2 diabetes guideline also noted that erectile dysfunction is sometimes not adequately discussed and that the issue of erectile dysfunction should be explored regularly where appropriate. This discussion was previously covered by QOF indicators DM015 and DM016, and is in line with recommendations from NICE clinical guidelines

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			8710 and 15, and with quality statement 8 of the 'diabetes in adults' quality standard which includes 'sexual dysfunction' as a complication for which people should receive an annual assessment of the risk and presence. Indicators DM015 (and DM016) were retired from the QOF following the review in 2013, after just one year. The removal of these important indicators, which were derived from the evidence based clinical guidelines, after such a short period of time means that they were unlikely to have had adequate time to embed into clinical practice. When reviewing the QOF indicators in September 2013, the independent QOF advisory committee made the suggestion that these indicators (DM015 and DM016) could be "included within the structured education programme (DM0014)…" An alternative approach that we propose here is to include them within this composite indicator, which would form a close correlation with quality statement 8 of the 'diabetes in adults' quality standard,9 and would ensure that GPs continue to be encouraged and incentivised to discuss ED, in order to improve diagnosis and treatment rates and determine the existence of any serious underlying conditions, if present.
IND-1	Upton Group Practice	General comments	Diabetes Mellitus Disease DM005 current rule set. I have a patient that has Proteinuria and is on both the Diabetes and CKD registers. He passes the test for CKD004 as he has had an ACR taken in Nov 2013 but, because he has proteinuria, a protein:creatinine ratio was performed instead of an albumin:creatinine ratio. However, as the DM005 test does not include the protein:creatinine ratio as an alternative test for Diabetes patients with proteinuria, he fails on DM005. DM005 only allows albumin:creatinine ratio or microalbumin:creatinine ratio and does not allow for proteinuria at all but should as per CKD004. This will affect all Diabetes register patients that present with proteinuria and have urine tests done in the current Qof year. I have discussed this with our clinical system provider

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			and they have told me to submit here.
IND-1	University of Bedfordshire	General comments	Cholesterol targets and the composite indicator for diabetes: Data from the Steno 2 trial and UKPDS trial both indicate that lipid management is the prime target for patients with diabetes. Analysis of the QOF data for example in South East Essex for example demonstrated that only 30.8% of patients were achieving the NICE target of 4mmol/l and only 68.2% achieving the target of 5mmol/l, leaving a large % of patients under treated, in addition BP targets were achieved in only 32.2% only 14.7% of patients achieved all targets. Removing individual targets will only make the situation worse in my opinion. The NICE pilot using a target cholesterol of 4mmol/l in diabetes was apparently successful and should be implemented. This will be very cost effective with the advent of powerful generic statins.
IND-1	Royal Free Hospital London	General comments	Response to NICE re withdrawal of QoF indicators DM005 and DM011for 2014/5 and intended introduction of composite indicator for 2015/6: The removal of the clinical indicators relating to urinary albumin creatinine (ACR) measurement and retinal screening. ACR: Withdrawal of this indicator risks clinicians in primary care not intervening early to prevent development of these debilitating and costly complications of diabetes. ACR measurement is a vital screening tool to identify those at risk of developing future significant renal problems and cardiovascular disease. These are major outcomes we are trying to prevent in people with diabetes and hence removal of this clinical tool for as a primary indicator in general practice poses a danger which may prevent optimal patient care which may lead to worse outcomes in these domains. Removal of the indicator for retinal screening suggests to primary care colleagues that retinal screening is no longer vital ? although diabetic retinopathy remains the most common cause of blindness for working age people in the United Kingdom. Experience in North Central London indicates primary care has an essential role to play in encouraging

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			uptake of screening, especially when dealing with a culturally diverse population. Opportunistic retinal screening in secondary care should remain for the minority of patients who are at risk and have not had comprehensive screening in the community. It is my opinion that these key indicators should be reinstated at the next opportunity and future decisions on QOF indicators are not proposed without prior specialist consultation.
IND-1	Abbott Diabetes Care	General comments	The 9 care processes are nationally agreed standards of care derived from the NSF and NICE guidance on diabetes and as such, Abbott Diabetes Care would support an indicator in QOF that included the care processes to improve the outcomes of care for people with diabetes. We would also propose that it would be advantageous to be able to make a clear distinction between type 1 and type 2 diabetes. This differentiation would allow more meaningful analysis of where improvement in service and therefore outcomes could be made in accordance to the differing requirements of each cohort.

Responses to questions 1 – 4

1. Do you think there are any barriers to the implementation of the care described by any of these indicators?

2. Do you think there are potential unintended consequences to the implementation of any of these indicators?

3. Do you think there is potential for differential impact (in respect of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex and sexual orientation), if so please state whether this is adverse or positive and for which group?

4. If you think any of these indicators may have an adverse impact in different groups in the community, can you suggest any guidance on adaptation to the delivery of the indicator to different groups which might reduce health inequalities?

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Indicator no.	Stakeholder organisation	Type of comment	Comment
IND-1	Marcham Road Health Centre	Response to questions 1-4	I am seriously worried that this proposal, rather than improving quality of care and outcomes, might have a perverse negative effect. The point is illustrated by retinal screening: if included, clearly, as we cant make a patient attend for this it would be unfair. But at least in the current system we have an interest in reminding and encouraging patients to attend. We have a significant number of patients who will attend for diabetes review but find it difficult to remember to bring a urine sample , and don't drop one back in afterwards. As a result we cant check for urinary microalbumin. If BP good, creatinine stable and HbA1c are all good the risk is low to that patient. I do not think GPs and practice teams should we be denied payment for the work done in measuring and managing the other parameters, and feel the amount of work needed to pursue patients for all 8 processes is sometimes disproportionate to the benefit. My concern is some practices may think that with hard to reach patients that it simply isn't worth the effort to pursue them at all , as there is a very low chance of achieving all 8 processes. This might well adversely and perversely effect care. I am also concerned that this sort of issue might disadvantage practices with high BME populations in whom getting patients in for review is already disproportionately difficult (Peter v Eichsdorff, personal communication, based on an audit in E Oxford) I am well aware of the headlines this measure has generated following on from the Diabetes UK publication of data: and we are including it in the local diabetes audit for this year , and will be sharing the outcomes with practices, but I strongly disagree with it

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			becoming a part of QOF.
IND-1	Newark and Sherwood CCG	Response to questions 1-4	I think linking all processes into one indicator is likely to have several unintended consequences, especially for care home residents and the housebound. They are often disenfranchised in chronic disease management and QOF actively discriminates against good care because these tend to be the patients who are excepted even though they may not be palliative care only patients. Currently most of them will have some of the measures assessed but I believe it will be more likely that they will have none or fewer assessed.
IND-1	University of Leeds	Response to questions 1-4	I wish to make a case that for every foot examination all systolic ankle blood pressures ought to be recorded on a proper template just like brachial pressures. At the moment either ankle pressures are not measured at all or are being recorded as free text. It becomes more important as NICE recommends measurement of ankle–brachial index for identifying peripheral arterial disease independent of diabetes. Although NICE has suggested screening over the age of 65 for peripheral arterial disease it becomes important to carry out these measurements in first year of diagnosis of diabetes. South Asians get diabetes at a younger age and we might be missing peripheral arterial disease in them by not doing ankle pressures. http://annals.org/article.aspx?articleid=1814436 Peripheral artery disease can be defined by an abnormally low or high ankle–brachial index (ABI), and both increase cardiovascular mortality. Most studies define peripheral artery disease by an ABI less than 0.9. An ABI does not discriminate between the independent predictive values of systolic ankle blood pressure and systolic brachial blood pressure, and these might differ in diverse

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			populations. Although the benefits of screening for and treating high blood pressure in adults is established, the U.S. Preventive Services Task Force's screening recommendations based on a threshold of the systolic brachial blood pressure miss more than one half of those who have undiagnosed diabetes .. Increased systolic ankle blood pressure is associated with diabetes and higher hazard ratios for fatal and nonfatal cardiovascular events in Europeans. South Asians (more than a billion persons globally) continue to have increasing rates of visceral obesity, diabetes, and cardiovascular mortality at a younger age, but the prevalence of hypertension and its association with cardiovascular disease in this population do not significantly differ from that of Europeans. The prevalence of an ABI less than 0.9 is known to be lower even in South Asian participants with diabetes, but systolic ankle blood pressure increases with diabetes; this increase, along with the association with cardiovascular disease, is greater in South Asians than in Europeans . Therefore, in certain populations, the value of increased systolic ankle blood pressure (as one of the earliest signs of subclinical atherosclerosis) might be greater than that of increased systolic brachial blood pressure at a relatively younger age with short lifetime exposure to risk factors.

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IND-1	Tower House Practice Runcorn	Response to questions 1-4	I have been a Health Authority/PCG/PCT/ CCG (Halton) Primary Care Diabetes Clinical Lead for 15 years and have constantly striven to improve funding for diabetes in primary care in order to encourage GP colleagues to take on this challenging work. In my opinion the QoF has been a major factor in improving the quality of diabetes care in this area and has significantly reduced the number of referrals to secondary care. The funding made available through the QoF has facilitated the employment and training of many Practice Nurses to deliver these improvements. In the context of reduced Practice funding in the current financial year, I am concerned that the effect of the proposed changes to the diabetes indicators will effectively reduce funding even further and push Practices beyond the tipping point whereby they throw in the towel, cut Practice Nurse employment and simply refer patients with diabetes back into secondary care; thus undoing all the good work done in the past 10 years or more. In my opinion and experience, the consistent achievement of a composite indicator such as this would be so difficult and unpredictable that the proposed changes are a serious threat to the continued provision of high quality diabetes care in primary care England. A far better way forward would be to retain the existing indicators and add a composite indicator such as this as an additional indicator (similar to the old "holistic care" indicator).
IND-1	PHE Midlands and East Regional Team	Response to questions 1-4	BMI is not sufficiently sensitive amongst all communities within England and in particular those from Asia. Waist circumference should also be considered as part of the composite indicator.

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IND-1	The Association of British Clinical Diabetologists	Response to questions 1-4	There is a strong feeling within the Association that these indicators are now no more than incentives to carry out measurements. As important as it may be to carry out the measurements, this in no way equates to quality of care or indeed caring for an individual. There are moves afoot to consider indicators which are better indicative of quality of care. The NICE model contract for diabetes offers many such indicators which might usefully be employed. The CQC initiative looking at care pathways, while in its infancy, may also offer future opportunities. If these indicators are explicitly to provide fumding to primary care for testing, then these indicators are appropriate. Future iterations, however, may wish to look for indicators of patient care.
IND-1	Diabetes Network	Response to questions 1-4	All these care processes should remain in the composite as they form part of the checks that patients should receive annually. Otherwise we risk patients not receiving essential checks
IND-1	General Practitioners Committee, British Medical Association	Response to questions 1-4	The GPC believes 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 disincentive 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

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			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. It is quite wrong for practices to 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 to by Professor Sparrow to be due to differences in statistics rather than clinical care, so there is no justification for this change. This is also likely to result in an increase in exception reporting.
IND-1	Diabetes Think Tank	Response to questions 1-4	We welcome the alignment of this indicator with the 8 of the 9 key care processes recommended by the National Institute for Health and Care Excellence. In answer to the specific questions raised: Do you think there are potential unintended consequences to the implementation of any of these indicators? • We recommend careful piloting of this indicator to ensure the composite indicator does not create a perverse incentive to retrench existing standards of care. There is a distinct risk, for example, that once a practice misses one of the processes (for example, where a patient forgets to bring in a urine sample) then the introduction of a composite indicator will mean that the practice has no incentive to complete any of the other processes. • The indicator also fails to recognise the right of an individual patient to withhold their consent to participate in any of the individual care processes. There is a risk, therefore, that patients may be pressured to take a course of action that they would not otherwise

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			take • We would support, in addition to the inclusion of a composite indicator, the maintenance of incentives to deliver individual care processes to mitigate the risks outlined above. The maintenance of individual indicators alongside a composite indicator will ensure that GPs have appropriate incentives both to undertake all care processes together with patients, but also to undertake individual processes – thus avoiding the perverse incentives set out above. • We would expect GPs to have to continue to report on their performance at the level of individual care processes, and for this individual-level reporting to help determine their performance against both the individual and the composite indicators. We would expect continued monitoring of performance against the individual indicators to be specified in the QOF's business rules If you think any of these indicators may have an adverse impact in different groups in the community, can you suggest any guidance on adaptation to the delivery of the indicator to different groups which might reduce health inequalities? We have three observations to make: • First, although outside the scope of this consultation specifically, we would like to register our concern that the introduction of a composite indicator might lead to a material reduction in the number of QOF points available to treat diabetes once the recommendations are opened to negotiation between the BMA and NHS Employers – and that any such deprioritisation of diabetes care would have an adverse impact on health inequalities. • Second, we note that achievement of QOF intermediate targets (for HbA1c, blood pressure and cholesterol) has not improved since 2006-07. In order to tackle diabetes – and the health inequalities which result – the composite indicator will need to be designed to

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			ensure that achievement is elevated above these levels • Third, we recommend that NICE considers amending the composite indicator in relation to foot complications to ensure patients get appropriate care: we recommend that, as well as incentivising the delivery of checks for diabetes-related foot conditions, the QOF should also incentivise the referral of patients to foot protection clinics where foot checks suggest an increased risk of complications
IND-1	Forest Health Care GP surgery	Response to questions 1-4	I am concerned these are being grouped together: does this mean that work done for all but one indicator would not receive any payment? This would not be justifiable if so. This should also be 15 months to allow for the variations in when patients are seen annually (eg patient on holiday when annual review due). The 12 month periods are causing great difficulty with the recall system if 3 reminders are to be sent to allow exception reporting for patients who refuse to engage with monitoring.
IND-1	Dietitians in Obesity Management UK	Response to questions 1-4	We agree that these indicators are appropriate for this condition, in particular BMI. However we would suggest that in addition to BMI, consideration is given to including waist circumference (WC) in those with a BMI ≤35kg/m2, since accumulation of excessive abdominal fat is related to the pathology of obesity-related co-morbidities such as diabetes. With regard to barriers to implementation, all staff need appropriate training in the correct and sensitive measurement of both BMI and WC. Potential for differential impact lies in the possibility of lower cut-off points for BMI and WC in different ethnic population subgroups. Despite a lack of evidence to make recommendations about

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			different cut-off points for different groups, nonetheless it appears that some groups are at higher risk at lower BMI and WC than others (e.g. those of South Asian origin). If this is not recognised by staff, then measurement of these indicators will not necessarily trigger action, with potential disadvantage to those at high risk. Lack of effective weight management and other services at a local level may additionally have an impact; this risk will vary by locality. In addition in areas with a high prevalence of ethnic minority groups such as south Asians, the use of obesity prevalence data to aid in the decision-making process about the geographical location of services may result in inequities of provision. This is because their increased health risk is likely to be under represented by the prevalence data due to the cut-off points used.
IND-1	Diabetes UK	Response to questions 1-4	We support the piloting of this indicator because we are concerned that there are a number of potential unintended consequences of moving to a composite indicator that need to be mitigated against. As explained above, the following need to be considered: - Moving to a composite indicator should not result in a reduction in the number of people who are getting all the care processes. There is a risk that if people aren't able to get some of the processes they won't get any (if the incentive is rewarded only for completion of all eight). - In addition to collecting the aggregate, it must also be possible to break down the composite to show completion of the individual care processes. Our assumption would be that practices would still need to do and record each care process and then this would be aggregated electronically for use in the QoF. This needs to be confirmed through the pilot.

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			- A composite indicator must not result in a reduction of the specific information provided to people with diabetes about their individual records. We would support the introduction of a composite indicator into the QoF if testing can show that it would ensure that people with diabetes receive ALL of their NINE care processes (as included in NICE guidelines) as part of their annual review and care planning process, and as appropriate. In this case, we would suggest that the indicator be re-worded (as shown in bold opposite) to make it clear that the QoF points are payable for carrying out the care processes as part of the annual review; that the care processes should be conducted as part of ongoing care and that each of the tests and investigations lead to action being taken where necessary on the basis of results. It is important that each of the care processes are still undertaken as part of the care planning annual review and the results/outcomes recorded. The outcome indicators will need to be retained to drive the treatment and advice given and goals agreed to manage an individual's diabetes and achieve outcomes within recommended guidelines rather than just the completion of processes. This applies equally to other essential quality indicators such as referral to structured education. Should any amendment result in a reduction of the QoF points available for the provision of diabetes care, this released funding must be reinvested in diabetes care.

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IND-1	Whalebridge Practice, Swindon	Response to questions 1-4	There may be practical difficulties for practices in monitoring their achievement of this indicator. Practice systems are currently very good at showing which indicators a patient has yet to achieve but poor at looking “inside” an indicator. It may be difficult for practices to identify which code has been missed.
IND-1	South London Health Innovation Network	Response to questions 1-4	1. Some in general practice may find it very hard to meet this composite indicator. This may in turn lead to reduced motivation to match the individual indicators. 2. Unintended consequence – reduced motivation as in 1. 3. In certain groupings – i.e. elderly care homes – some indicators might be more appropriate than others. Annual cholesterol measurement may become irrelevant, or a less frequent measurement more appropriate, whilst foot checks may become very important. 4. There should be the option to exempt an individual indicator if not appropriate, but only if not appropriate (as in 3 above). Should not be a means of exempting just where a patient declines to get and ACR done event though hugely appropriate.
IND-1	Foot in Diabetes UK (FDUK)	Response to questions 1-4	FDUK comments related to recommendations 1.1.2.1 and 1.11.3.1. • The risk stratification should be clearly defined • Level of required education should be defined for each risk • The recommendations should include a specific requirement for onward referral based on the assessed risk. • Needs clarification on when on-ward referral is necessary and to whom. • Without a specific requirement for on-ward referral these indicators are unlikely to reduce amputation rates in people with diabetes • Needs to be a specific requirement to ensure people in nursing

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			homes receive foot examination as these are the highest risk group often with the poorest outcomes.
IND-1	Primary Care Diabetes Society	Response to questions 1-4	The PCDS recognises the potential benefit to the organisation of diabetes care through the introduction of this indicator. It promotes and supports the tradition (likely to exist in most but not all practices) of an annual, comprehensive and systematic review appointment with a clinician, e.g. a practice nurse. It discourages the alternative, opportunistic approach in which the different individual performance measures are achieved in piecemeal fashion throughout the QOF year without a dedicated annual review appointment. A systematic approach is a valuable part of structured care and facilitates discussion over other ongoing issues that may be important to the person with diabetes. However, it is important that practices do not feel dis-incentivised to achieve individual indicator measures, which should continue to attract payments. The success of this proposal in improving diabetes care will depend on the threshold (not stated in this document) selected as a basis for this proposed performance measure. In response to questions 1-4: 1.The only barrier we foresee would be confusion over whether measurement of albumin: creatinine ratio (and retinopathy if it is included) is or is not a QOF indicator, if it is only included in this list, but not in the QOF otherwise. Reminder systems in general practice include screen messages that appear when a patient's QOF indicators are not fulfilled. Inconsistencies may create a problem with programming the protocols that support the reminders which are an important process in primary care. 2. Regarding potential unintended consequences, the selection of the appropriate threshold will be important to ensure that this

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			proposed indicator confers overall benefit. If it is set too high, the focus of care may move towards the subgroup of patients motivated to attend for a dedicated annual review, to the detriment of those who can only achieve a proportion of their indicator measures. 3. Those, who for example, for professional reasons who are unable to attend for a comprehensive review, might suffer if the threshold was set too high. For instance, if the majority of points were transferred to this indicator, practices might be dis-incentivised to carry out the less than complete checks that are possible in such patients. 4. This depends on the threshold selected. We suggest that this should be based on a study of the proportions achieving 1, 2, 3 etc individual indicators, The target can then be set to move in the direction of a more systematic 'annual review' based care without being unrealistic.
IND-1	Pfizer Ltd	Response to questions 1-4	Because of the multiple co-morbidities associated with diabetes it is essential that the care processes listed are performed routinely and systematically. It is also essential that where results of these measurements and recordings are directive of either further testing or management, then we believe this sign posting needs to be captured here. Raised blood pressure, dyslipidaemia, smoking status etc, which will be identified through the measurements highlighted in this indicator, will need addressing by the clinician. NICE has clear guidance associated with managing these and we believe this indicator should highlight and signpost the clinician to these. For example NICE Quality Standard 43 (Smoking cessation - supporting people to stop smoking) includes five quality statements

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			which ensure people receive the best quality of care available: 1) people are asked if they smoke by their healthcare practitioner, and those who smoke are offered advice on how to stop 2) offer people who smoke a referral to an evidence-based smoking cessation service 3) they offer behavioural support with pharmacotherapy to people who have been referred to an evidence-based smoking cessation service 4) they offer a full course of pharmacotherapy to people who seek support to stop smoking and who agree to take pharmacotherapy 5) people who smoke who have set a quit date with an evidence-based smoking cessation service are assessed for carbon monoxide levels 4 weeks after the quit date
IND-1	Sanofi	Response to questions 1-4	Sanofi provides administrative support for the Parliamentary and Stakeholder Diabetes Think Tank. Following a meeting looking at the QOF in 2013, we support the recommendations made by this group. These recommendations are set out below: Do you think there are potential unintended consequences to the implementation of any of these indicators? □ We recommend careful piloting of this indicator to ensure the composite indicator does not create a perverse incentive to retrench existing standards of care. There is a distinct risk, for example, that once a practice misses one of the processes (for example, where a patient forgets to bring in a urine sample) then the introduction of a composite indicator will mean that the practice has no incentive to complete any of the other processes. □ The indicator also fails to recognise the right of an individual

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			patient to withhold their consent to participate in any individual care process. There is a risk, therefore, that patients may be pressured to take a course of action that they would not otherwise take • We would support, in addition to the inclusion of a composite indicator, the maintenance on incentives to deliver individual care processes to mitigate the risks outlined above. The maintenance of individual indicators alongside a composite indicator will ensure that GPs have appropriate incentives both to undertake all care processes together with patients, but also to undertake individual processes – thus avoiding the perverse incentives set out above. • We would expect GPs to have to continue to report on their performance at the level of individual care processes, and for this individual-level reporting to help determine their performance against both the individual and the composite indicators. We would expect continued monitoring of performance against the individual indicators to be specified in the QOF's business rules. If you think any of these indicators may have an adverse impact in different groups in the community, can you suggest any guidance on adaptation to the delivery of the indicator to different groups which might reduce health inequalities? We have three observations to make: • First, although outside the scope of this consultation specifically, we would like to register our concern that the introduction of a composite indicator might lead to a material reduction in the number of QOF points available to treat diabetes once the recommendations are opened to negotiation between the BMA and NHS Employers – and that any such deprioritisation of diabetes care would have an adverse impact on health inequalities. • Second, we note that achievement of QOF intermediate targets (for HbA1c, blood pressure and cholesterol) has not improved since

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			2006-07. In order to tackle diabetes – and the health inequalities which result – the composite indicator will need to be designed to ensure that achievement is elevated above these levels Third, we recommend that NICE considers amending the composite indicator in relation to foot complications to ensure patients get appropriate care: we recommend that rather than incentivising the delivery of checks for diabetes-related foot complications, the QOF should incentivise the referral of patients to foot protection clinics where foot checks suggest an increased risk of complications.
IND-1	British Dietetic Association	Response to questions 1-4	Supported. GP practices have recorded the individual measures for some time with, in general, very good results: they should continue to do so. Having a composite measure may improve results e.g. all may be done at a single appointment thus increasing patient attendance. Full compliance should not be anticipated (e.g. patients may refuse one or more measures and/or be excluded for medical reasons such as already dialysing, thus the albumin: creatinine ratio is meaningless). If non-compliance with one or measures, there could be the risk that the GP may not bother with achieving the rest of the measures for this indicator (i.e. “Why bother – we’ve already failed”). The comment below may prevent this situation. Suggest each measure of the composite indicator be published separately alongside the overall GP Practice performance. Good that albumin: creatinine ratio is included still, rather than the less sensitive PCR used in the past.

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IND-1	Royal College of Nursing	Response to questions 1-4	Barriers: Accuracy of records; timing of blood results Funding Consequences – variations in interpretations of outcomes
IND-1	The British In Vitro Diagnostics Association	Response to questions 1-4	About the British In Vitro Diagnostics Association (BIVDA) BIVDA is the national industry association for the manufacturers and distributors of IVD products in the UK. We currently represent more than 95% of the industry and over a hundred organisations, ranging from British start-up companies to UK subsidiaries of multinational corporations. BIVDA members currently employ over 8,000 people in the UK, with a total industry turnover of approximately £900 million. BIVDA aims to spread awareness of the value of diagnostics throughout healthcare. Ongoing innovation in medical science means that diagnostics offers important opportunities in not only disease treatment, but also prevention. Cardiovascular risk, cancer, diabetes, infectious diseases and osteoporosis are just some of the areas where significant breakthroughs are proving possible. By working with the industry and all interested bodies to provide comprehensive information, a robust regulatory framework and in-depth outcome studies, BIVDA strives to ensure these opportunities are not missed. Introduction BIVDA welcomes the proposed inclusion of these indicators in the QOF for 2015/16. We also support the move to bundle these

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			indicators together but, if implemented, we would suggest it will be important to carefully monitor the impact this change would have on tests being carried out in general practice. In particular, it will be important to monitor the impact that this bundling might have on reducing unjustified variations in the number of tests being carried out. The recently published Atlas of Variation in Diagnostic Services and Pathology Quality Assurance Review have both flagged up the wide variation in diagnostic services across the country. We hope by bundling indicators, practices will be encouraged to carry out all of these tests and unnecessary variations can be avoided. Consultation questions 1. Do you think there are any barriers to the implementation of the care described by any of these indicators? BIVDA recognises that bundling these processes into one QOF indicator is ambitious. If implementation of all of the tests is perceived as being or proves too burdensome in practice, there is a concern that this bundling will act as a disincentive to test people and widen the gap between the best performing

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IND-1	National Obesity Forum	Response to questions 1-4	NOF believes a potential unintended consequence of having a composite indicator that focuses solely on whether a set number of tests have been conducted is that such an indicator could perpetuate a 'tick box' approach by healthcare professionals to helping diabetic patients manage their condition instead of encouraging the provision of holistic care. To ensure that this proposed indicator does encourage health care professionals to adopt such an approach, consideration must be given to the close relationship between obesity and type 2 diabetes, which necessitates many who have diabetes as a consequence of being obese also having to manage their weight in order to control blood glucose levels. NOF submits that, to ensure optimum care is provided, this proposed indicator should include a reference to providing support for diabetic individuals trying to manage their weight. This, in turn, should be linked to an indicator on obesity which awards Quality and Outcome Framework points to GPs to advise, prescribe and recommend appropriate guidance and support for weight management from the wide range of sources available in the community. Given the fact that diabetes is a common comorbidity of obesity, coupled with the growing obesity epidemic which could see more than half the population obese by 2050, it is imperative that this proposed indicator for diabetes is linked to a similarly thorough indicator for obesity, one which incentivises GPs to actively assist individuals seeking to lose or manage or their weight and not just record the number of overweight or obese individuals who present themselves.
IND-1	Boehringer Ingelheim	Response to	We support the use of this composite measure to encourage delivery of all of the 8 care processes - the most recent national

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		questions 1-4	diabetes audit (2011/12) confirming only 62.6% of people with type 2 diabetes, and 43.2% of people with type 1 diabetes received all 8 care processes. However, does the use of a composite measure risk some patients not getting any of the care processes? Have composite measures been used before? This issue would need to be carefully considered before introducing this indicator. Also, does it go far enough in terms of HbA1c monitoring? NICE recommend 6 monthly reviews once blood glucose levels are stable. Should the HbA1c measure be 6 monthly, in line with NICE guidelines?
IND-1	NHS England and NHS Employers	Response to questions 1-4	This seems reasonable as it is all included in current templates and should be achievable assuming from a lab perspective A:CR is readily available to all GPs, if not would question whether it stays in -Should HbA1c be HbA1C or blood glucose? We were previously looking at taking this out and were asked to put it back in -How will exceptions work? If a patient is excepted due to one element, do they still achieve if they achieve the other elements or are they excepted from the entire indicator? - Wording will require updating for consistency with live (13/14) QOF, i.e. "The percentage of patients with diabetes, on the register, who have a record of the following care processes in the preceding 12 months [DN: or 1 April – 31 March?]"

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IND-1	NHS England (London Region) Diabetes Strategic Clinical Network	Response to questions 1-4	1. Composite indicator possibly very hard to achieve in some areas with high turnover of patients (up to 30% some areas London). 2. Potential disengagement of GP's if not achieving – removing motivation to measure some single indicators – i.e. ACR. 3. Not all indicators equally important to differing patient groups – i.e. cholesterol may not be vital in elderly care setting whereas foot checks may be. 4. Risk that achievement of very important single indicators, which are harder to achieve such as measurement of ACR and foot checks - will be sacrificed. 5. In particular we believe that younger people with less evidence and less immediate risk of cardiovascular disease, will remain undetected and untreated if ACR screening is downgraded as a composite marker.
IND-1	AstraZeneca UK Ltd	Response to questions 1-4	AstraZeneca welcomes the introduction of a new QOF indicator that recognises the complexity of diabetes care and encourages a holistic approach to treating diabetes patients. We would like to advocate that beyond the measurement of these indicators, appropriate clinical action is taken to record and publish the outcomes of these indicators and to take subsequent clinical action to address any clinical needs. For example, beyond BMI measurement, a recording of obesity status should be published. Care will need to be taken to ensure that the implementation of this indicator does not increase healthcare inequalities. Any gaming in this indicator would differentially adversely affect those patients who are least able to access healthcare services and as a consequence would increase inequalities in access to healthcare and patient outcomes. It has been suggested that this indicator could potentially replace

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			some or all other current diabetes QOF indicators (e.g. DM003, DM007). We would be opposed to this and would strongly urge that the current indicators measuring outcomes of these tests remain as additional standalone QOF indicators, as these drive delivery of healthcare outcomes. In addition, some commentators have suggested that achievement of this proposed indicator might be a gateway or prequalification indicator for the current QOF indicators. AstraZeneca would be opposed to this - we believe that it is important to remove the risk of gaming as this could adversely impact patient care. E.g. if a clinician is unable to perform one test on a patient, then they could potentially 'exclude' that patient from all tests – as a consequence the patient receives less-than-ideal overall care and worse outcomes.
IND-1	Healthwatch Bucks	Response to questions 1-4	See no adverse consequences or impact for any of these. These should not be one-off measurements, but repeated during treatment as appropriate. Patients need reassurance that they receive effective treatment- and require regular measurements for some of these parameters. A single measurement does not necessarily indicate good patient management. Unclear why full NICE recommendations are not carried out.

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Response to question 5

5. Indicator 1: Retinal screening is not currently included within this composite indicator as it was considered to be outside the control of GPs. Do stakeholders consider it appropriate to include retinal screening in this indicator?

Indicator no.	Stakeholder organisation	Type of comment	Comment
IND-1	Corbett Medical Practice	Question 5	It is outside our control so we could get penalised for other parties under performance
IND-1	Unity Health, YORK	Question 5	I don't think that it is outside our control but again would like to see existing exception rates for this area
IND-1	National Kidney Federation	Question 5	Although we have no specialist knowledge in this area, we would consider that Retinal Screening should be carried out within a specialist location where the best quality screening can be carried out.
IND-1	Newark and Sherwood CCG	Question 5	Yes as a new and separate indicator encouraging GP's to actively contact patients who default
IND-1	Hillingdon Hospital NHS Foundation Trust	Question 5	Retinal Screening should become part of the QOF indicators, as there is overwhelming evidence that primary care engagement has a huge impact, not only on the uptake of retinal screening but also on the diabetic screening programme's database, DNA chasing/patient education etc. I believe exclusion of retinal screening from QOF will have very detrimental effects on all Diabetic Eye

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			Screening Programmes across the country and will result in very severe consequences for patients who mainly belong to the working age population.
IND-1	Hillingdon Hospital NHS Foundation Trust	Question 5	I believe strongly that removing retinal screening from QoF will have very detrimental effects not only on the diabetic eye screening programme's performance but most importantly on the patients themselves.
IND-1	Hammersmith and Fulham CCG	Question 5	Yes, primary care has a key role to play in encouraging patients who have not attended retinal screening to do so.
IND-1	PHE Midlands and East Regional Team	Question 5	The question under-estimates the influence of the GP. There is considerable scientific literature on this and just as an example many of the studies looking at brief advice utilised GPs as the provider and these demonstrate that GPs do have a considerable impact on how pts “behave”. The indicator should include retinal screening.
IND-1	The Association of British Clinical Diabetologists	Question 5	The Association representatives are unanimous in voicing the opinion that retinal screening uptake, if not outcome, must be included. As outlined above, the group who undertake to carry out the various tests also has a duty of care. This includes the duty to ensure that every individual with diabetes has their eyes examined at least annually. It is not acceptable to contend that this indicator can be omitted simply on the grounds that primary care does not own this service. The duty of care

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			is to ensure that this vital process is carried out and if necessary, to ensure that the service is commissioned appropriately
IND-1	Diabetes Network	Question 5	Retinal screening should be an essential part of the diabetes care offered by primary care. Primary care currently manages most patients with Type 2 diabetes and a considerable number of patients with Type 1 diabetes. Our experience in Hounslow CCG is that primary care initiates all referrals for retinal screening and they are in a privilege position to encourage patients to attend for retinal screening. If retinal screening is removed from the QOF indicators uptake and coverage figures are likely to worsen and patients will be missing on essential checks.
IND-1	Lambeth, Lewisham and Southwark Diabetic Eye Screening Programme	Question 5	I do not believe that GP's have no control of diabetic eye screening uptake and I fear that if diabetic eye screening is not re-instated as a QOF indicator for 2015/2016, many more diabetics will fail to attend screening and risk losing sight. There are several reasons for this • Most Programmes rely on the GP surgeries to provide manual lists of all newly diagnosed diabetes which will cease when the QOF indicator stops. • Additionally if GP's are no longer referring patients for eye screening- patients will get the wrong message that eyes are not important and do not need to be screened. • Once the QOF is removed there will be no incentive for GP's to cleanse their lists making it impossible for

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			Screening Programmes improve their uptake. • We currently rely very much on GP's to discuss screening results with patients and improve systemic control of those with early R1, M0 or R1,early M1 as they often don't require ophthalmic care at this early stage. When the QOF is removed there will be very little involvement in eye screening by GP's. • Every year several type I diabetics go blind from proliferative disease as they do not engage with the screening Programme. It is essential that GP's engage with these individuals and refer them for screening as they have a better understanding of other possible mental health, physical health issues, fears that the patients may have. This communication is likely to worsen once the QOF is dropped. • Currently we have a very high DNA rate in screening clinics and eye clinics for diabetic patients that have been referred from screening. We rely on the GP's to encourage attendance at appointments. Again this is likely to be less effective once the QOF is dropped.
IND-1	General Practitioners Committee, British Medical Association	Question 5	We do not think that retinal screening should be included. It was removed from QOF for the reason that it was outside GP control and therefore should not be re-introduced.
IND-1	Diabetes Think Tank	Question 5	We believe that retinopathy screening should remain part of the QOF to encourage attendance. This might be through inclusion of retinal screening in the composite indicator, or through the maintenance of an individual

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			indicator for retinal screening (which would be our preferred option). Although we understand that it is neither commissioned nor delivered by GPs, we strongly feel that the role of primary care in treating diabetes is not necessarily about providing all nine care processes directly, but about ensuring that all nine are completed.
IND-1	Forest Health Care GP surgery	Question 5	I think it is reasonable to leave this outside as this is dealt with through the retinal screening service. Perhaps a code within 3 months of diagnosis to confirm referral to screening service would be reasonable.
IND-1	Dietitians in Obesity Management UK	Question 5	Yes. We recognise that this lies outside the scope of control of GPs. However GPs can refer patients to retinal screening and if included in QOF as an indicator in our view GPs may be more likely to enquire whether patients have had the screening, and refer them if not.
IND-1	Midlands and East Quality Assurance Team, Public Health England	Question 5	I believe that Retinal Screening should be included as a QOF indicator as there is evidence within the programme that GPs are not engaged with the DESP programme otherwise and patients are not being referred to the programme timely. Additionally GPs have the ability to encourage an increased uptake, support an accurate DESP database and chase DNA patients.
IND-1	Medical Imaging UK Ltd	Question 5	I believe taking this indicator out per se is a retrograde step and potentially undermines the screening programme. Whilst delivery of screening is not under the

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			direct control of GPs, they have responsibility for: • referring their patients into the programme; • participating in regular list validation (at least quarterly) and • encouraging their patients to attend this important test – particularly persistent DNAs. GPs and screening programmes need to be encouraged to work in partnership with each other to ensure that patients receive the care to which they are entitled and reduce the risk of sight loss due to retinopathy. Retaining this indicator, which is an essential part of diabetic care, will encourage this. Alternative indicators that are GP specific could include: 1. The percentage of patients with a new diagnosis of diabetes in the preceding 1st April to 31st March who were referred to the retinal screening programme within 6 months of diagnosis 2. The percentage of patients with a pre-existing diagnosis of diabetes who have moved into the practice in the preceding 1st April to 31st March who were referred to the retinal screening programme within 3 months of being registered. It should be noted that in some areas the diabetic foot check is not delivered/controlled by the GP but this indicator is still included, so why not diabetic retinopathy? The Diabetes indicator should reflect the quality of care patients receive so including this appropriate.

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IND-1	Central and North West London NHS Foundation Trust	Question 5	Retinal screening should have points of its own and if not should definitely be in the composite. It is within GP control to the extent that they can chase patients who have not been screened and emphasise how important it is too them. In addition to this those that have found to have retinopathy can be followed up and control of BP / glucose / lipids improved to prevent worsening of their condition. In addition to that through the CCG they can raise issues with screening thus this is not out side the control of the GPs.
IND-1	Diabetes UK	Question 5	We suggest that 'record of retinal screening' be included in the pilot of this composite indicator. Although retinal screening is not carried out by GPs, the NHS Diabetic Eye Screening Programme is required to ensure that: - primary care is made aware of a service user's failure to attend appointments; - primary care is made aware of a service user's screening results. This is to ensure that the screening results integrate with the overall diabetes care for that person, which should be discussed within care planning consultations to focus on management of blood pressure, HbA1c & cholesterol outcomes. As stated above, if this indicator is introduced to drive the completion of processes as part of the care planning annual review it is essential that all of the nine care processes are included in this and that, wherever possible, the results of care processes are linked together as part of diabetes management. Separating

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			retinal screening would cause confusion to people with diabetes as this implies that it is not important if it is not discussed in primary care. Furthermore, including this process in the indicator would not be particularly onerous for the GP but it would reinforce the importance of maintaining the link with integration of diabetic retinal screening with ongoing holistic and person centred diabetes management.
IND-1	Whalebridge Practice, Swindon	Question 5	This indicator is also “all or nothing”. The message sent is that 7 out of 8 is no better than 0/8 Exception reporting can certainly help but this adds yet another layer of complication and difficulty in coding. Where patients are less engaged there will be less incentive to take meet any of the criteria.
IND-1	Wye Valley NHS Trust and Herefordshire & Worcestershire Diabetic Eye Screening Programme	Question 5	Yes absolutely: GPs can be closely involved with the local screening programmes, their involvement is vital in populating the retinopathy database. They are in a uniquely strong position to advise patients to engage with screening and can respond to screening results to improve patient care.

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IND-1	South London Health Innovation Network	Question 5	Retinal screening is a vital indicator. Primary care can play a huge part in encouraging uptake of screening through the annual review process and care planning consultations, as well as being responsible through correct diagnosis (and referral in some areas) that people are placed on retinal screening registers. Primary care is also best placed to act upon results of retinal screening, for many the reduction in progression or retinopathy (or indeed regression) is dependent in improved blood pressure control and blood glucose control – something primary care is uniquely responsible for the vast majority of people with diabetes. Diabetic retinopathy remains the most common cause of blindness for people of working age in the United kingdom. Failure to include retinal screening sends out a perverse message that diabetic eye disease is not important and that its detection and management are not roles for primary care. This would be a sad and negligent state of affairs.
IND-1	Primary Care Diabetes Society	Question 5	It was felt that prevention of retinopathy is extremely important and that, whilst it is provided and organised outside the practice, general practice teams are in a key position to influence uptake. We therefore felt that there would be an advantage to including it, provided that practices were able to exempt people who repeatedly failed to respond to invitation.
IND-1	NHS England – Derbyshire & Nottinghamshire	Question 5	GP's and practice staff are essential in the Retinal

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	Area Team		Screening pathway. There is a risk that if retinal screening is not included long term in Qof payments, GP Practices may be less likely to educate patients, encourage attendance, chase DNA's, make prompt referrals, complete validation exercises etc
IND-1	NHS England - Essex area team	Question 5	I do think that it is appropriate for retinal screening to be part of the diabetes care QOF indicator. This is because retinal screening should be viewed by GPs (and patients) as an integral part of a diabetes care package and patients should be consistently referred to their local screening programme. There are solid commissioning arrangements in place to ensure that patients referred to screening programmes are screened appropriately and so it is important that patients are referred in a timely manner. Incorporating retinal screening into the QOF should provide the required encouragement needed for some practices to set up and maintain failsafe methods of referring patients with a diagnosis of diabetes to local screening programmes. This should ultimately contribute to the overall aim of retinal screening, reducing the risk of sight loss for those with diabetes.
IND-1	Sanofi	Question 5	We believe that retinopathy screening should remain part of the QOF to encourage attendance. This might be through inclusion of retinal screening in the composite indicator, or through the maintenance of an individual indicator for retinal screening (which would be our preferred option). Although we understand that it is neither commissioned nor delivered by GPs, we strongly

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			feel that the role of primary care in treating diabetes is not necessarily about providing all nine care processes directly, but about ensuring that all nine are completed.
IND-1	West Herts Diabetic Eye Screening Programme	Question 5	I strongly feel that invitation to diabetic eye screening should be a QOF indicator. Throughout the year our Failsafe Officer regularly validates GP diabetic patient lists against the programme's software. Most GPs are compliant, but some need regular chasing. As a result of the current QOF incentive, however, by year end most practices have submitted their patient lists and then refer any patients not already known to us. • GPs currently receive payment for the various annual tests carried out for their diabetic patients, eg blood pressure, cholesterol, blood sugars etc – diabetic eye screening is the only service that all diabetics should be referred to. If patients do not have eye screening this will reduce the amount a GP can claim on their QOF submission • Every year around this time GPs are pulling together their information to identify patients who have not been referred to screening, hence the significant increase in new referrals between November and February • From the programme's point of view this makes it difficult to plan the number of clinics we require up to the end of the financial year, ie 31st March, as we do not know how many patients have been missed to referral throughout the preceding year ; this also makes it difficult to plan staff leave

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			• More importantly, if GPs were not required to submit their data on diabetic patients for QOF payment, we do not know how many patients will not get the opportunity to be invited to screening and hence be exposed to sight threatening diabetic retinopathy which is the main cause of sight loss in working age people I attach a spreadsheet which shows the referral trend since April 2012; you will note from the 2012/13 chart the referral pattern is quite unpredictable but there is a definite spike from November to February. The 2013/14 chart shows a steadier pattern of referrals, which has resulted from the activity of our Failsafe Officer, but despite this there is again a significant spike from November onwards.
IND-1	Royal college of paediatrics and child health	Question 5	We think retinopathy should be included in the screening quality requirements even though the process is outside GP control. There should then be some penalties for the screening service for this one rather than GPs.
IND-1	West Herts DESP	Question 5	If GPs are not required to submit their data on diabetic patients for QOF payment, I am concerned how this will affect GP referrals and may mean that many patients will not be invited to screening as we are unaware of them. This will then expose the patient to the risk of sight threatening diabetic retinopathy. Diabetic retinopathy is the main cause of sight loss in working age people and we should be doing everything we can

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			to ensure that all people with diabetes are referred to their local DESP programme for screening. I have attached a graph which shows, that despite our best efforts to encourage GPs to refer as a patient is diagnosed with diabetes, there are still many more referrals sent between Dec and March to ensure they do not miss out on QOF payment and although this puts pressure on our service, I would rather this than those patients not be referred at all, which is what I feel would happen if diabetic retinal screening was not included within the indicator.
IND-1	West Herts Diabetic Eye Screening Programme	Question 5	As the Clinical Lead for the West Hertfordshire Diabetic Eye Screening Programme (DESP), I am alarmed to hear that the QOF indicator for diabetic eye screening may be removed from the QOF register for General Practice. Annual Retinal screening in West Herts from a centralised database has been in progress for approximately 23, 000 patients since 2007. We have consistently noted that referrals to the service for screening increases in November/December/January, which we believe is due to the GP surgeries checking their QOF status and realising that patients have not been referred for screening. My fear is that without this incentive, these patients may not be picked up at all, and there will be either a further delay, or a non- referral, which will ultimately lead to an increased risk of sight threatening retinopathy due to failure to screen in time. GP's are ultimately responsible

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			for referral of their patients for screening, but I strongly believe that QOF provides a failsafe that enabes these patients to be picked up if they fall through the net. Eventually, when the national DESP organize GP2DRS with automatic transfer of diabetic registers to the eye screening service, that would be an appropriate time to cease this particular QOF indicator. Until then, for the best interests of the patients, I feel it should remain as an indicator. I enclose our figures of referrals through the past two years. In January alone, we received 313 referrals which is 16% of our total years referrals. Expected would be 8% if referrals were equal throughout the year.
IND-1	Public health England East anglia	Question 5	My comments re the removal of QOF for retinal screening. Gp practices are a vital factor in ensuring all people are on the screening register. To take this away risks even less engagement with the practices in identifying the correct cohort. GP2 DRS is not yet in a position to take over and I believe will still require input from the practices. It will be highly risky to take this target away
IND-1	British Dietetic Association	Question 5	No – with reservations. Is the take up of this vital test being monitored via the NHS Diabetes Eye screening programme (which is better placed than the GP to provide relevant data)? GPs should still be checking that their patients with diabetes have annual retinal screening.

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IND-1	Royal College of Nursing	Question 5	Yes. It is an essential part of diabetic screening.
IND-1	Derbyshire Diabetic Eye Screening Programme	Question 5	Absolutely. It is difficult to get some GP practices on board to assist and support in educating patients on the importance of regular diabetic eye screening. In previous years the service has received calls / queries from practices actively chasing up patients who have not attended, mostly in the 3rd - 4th quarter of the financial year, keen to ensure that they meet their Qof quota. Will these practices still be so keen to follow-up patients with no Qof measurement in the future? Also, retinal screening requires support from practices with patients who do not reply to our invite, or DNA on a regular basis. We need practices to assist us by promptly referring new patients, we do not want the first sight of a diabetic patient with severe eye disease to be via A&E. During a recent data validation exercise we identified over 600 patients that had not been referred, a lot of these patients were recent referrals but some were patients that had been diagnosed 12 months plus or had recently moved into the area, so it is already hard enough to ensure that every diabetic patient is given the opportunity to be screened. Without measurement of this – would patients continue to be referred promptly? Will practices be so keen to assist us to identify "missing" patients? With regards to patients who DNA/DNR - It is quite clear that input from a GP increases patient uptake. Eye screening is only a part of a complete package

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			offered to diabetics, therefore it should form some part of the Qof measurements that apply to the complete package. Plus for those practices that are already supporting the service and are "going the extra mile" to help us to support their patients, surely they deserve the recognition of their hard work and commitment that is linked to this indicator.
IND-1	The British In Vitro Diagnostics Association	Question 5	Currently, the QOF indicator tracks the percentage of patients with diabetes who have a record of retinal screening in the previous 15 months. This indicator has seen a steady increase in retinal screening since it was introduced (from 89.6% in 2007 – 92% in 2013). However, the indicator does appear to have plateaued in recent years (2011 = 92%, 2012 = 92.2%). Overall our hope is that by bundling process indicators together you will increase uptake across the board. It is possible that by including retinal screening you may provide the necessary jolt to ensure that we can move beyond this 92% figure. Furthermore, this would be in line with the Government's drive for all parts of the NHS to consider a patients needs holistically. Although we recognise that this is directly outside a GPs control, they do perform such a vital part of a patient's pathway that reinforcing the importance of retinal screening in the QOF would be welcomed. Of course, if on balance, the view is taken that the

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			bundle itself is potentially too administratively complex already, we believe that the benefits of implementing the bundle without the retinal screening would be better than not implementing the bundle at all.
IND-1	Moorfields Eye Hospital NHS Foundation Trust	Question 5	Whilst I appreciate that retinal screening falls outside of the domain of the GP's treatment as screening is done within the community, referrals into screening need to be instigated by the GP for their retinopathy and maculopathy. To ensure that all diabetics receive this annual screen it is imperative that GP's continue to keep the local screening programme updated of any changes to their diabetic register. The message that removing this indicator gives to the GP and practice staff is that retinal screening is not important when diabetes remains the leading cause of blindness in the UK. Monitoring the retinopathy and maculopathy through the community eye screening programme on a regular basis will ensure that any deterioration is treated via a referral to the local hospital eye service. The removal of this indicator in lay man's terms means that the GP is under no obligation to inform the screening programme of those patients with diabetes and thus makes the work of the local programmes harder and could ultimately mean that their patients are at a greater risk of blindness.

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IND-1	Boehringer Ingelheim	Question 5	Diabetes is the leading cause of blindness in working age people in the UK and people should be offered an appointment for eye screening when their diabetes is diagnosed and once a year after that. It is estimated that in England every year there are 1,280 new cases of blindness caused by diabetic retinopathy. It is estimated screening could save more than 400 people per year from sight loss in England. It is therefore, important that retinopathy screening is part of the care planning discussion and should definitely be included within QOF composite indicator in order to facilitate this
IND-1	The British Cardiovascular Society	Question 5	We would agree with this statement. GPs do not have any control over retinal screening and therefore should not be responsible for the provision of this service.
IND-1	NHS England and NHS Employers	Question 5	Retinal Screening should not be included.
IND-1	Public Health England	Question 5	The NHS Diabetic Eye Screening Programme as part of Public Health England consider it highly appropriate to include retinal screening in this indicator. We have also consulted with our stakeholders and they support our proposal for its inclusion. Diabetic retinopathy is a complication of diabetes and is the most common cause of sight loss in people of working age. It is estimated that in England every year 4,200 people are at risk of blindness caused by diabetic retinopathy and there are

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			1,280 new cases of blindness caused by diabetic retinopathy. Retinopathy screening is a fundamental part of the care pathway for patients diagnosed with diabetes and the screening programme aims to reduce the risk of sight loss among people with diabetes by the early detection and treatment, if needed, of diabetic retinopathy. . The NHS Diabetic Eye Screening Programme (as specified in the national service specification and commissioned by NHS England) is required to: - Work with GP practices to create, validate and maintain on at least a quarterly basis a register of all people with diabetes age 12 and over who are eligible to be invited for screening - Ensure that GPs are made aware of a service user's failure to attend appointments - Ensure that GPs are made aware of a service user's screening results in order to ensure integration with the overall diabetes care of that service user - Ensure the service user has a local point of contact to discuss any aspect of the delivery and outcomes from the screening programme The screening programme relies solely on GPs for the timely referral of patients diagnosed with diabetes for eye screening and referral for screening is one way GPs meet their duty of care in relation to persons diagnosed with diabetes. Information on persons diagnosed with diabetes, in order to invite them for screening is not

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			available elsewhere. It is essential that eye screening is linked to the other diabetes care processes in primary care in order to effectively manage diabetes as a whole. It is vital for patients with diabetes that their screening results integrate with the overall diabetes care for that person, which should be discussed within care planning consultations. Changes in the retina may be the first indication that there are problems with the management of diabetes in some patients. Separating retinal screening would cause confusion to people with diabetes as this implies that it is not important if it is not discussed in primary care. The inclusion of this indicator would not be problematic for GPs as there is a national diabetic eye screening service available to all patients diagnosed with diabetes to which GPs are able to refer patients. GPs are not required to provide diabetic eye screening themselves. The inclusion of the diabetic retinopathy indicator in the QoF has enabled screening services to make real and measurable improvements in achieving an accurate register of persons to invite for screening, which has resulted in improving uptake for screening. Removal of this indicator has been met with widespread concern by all stakeholders (including screening services and GPs themselves) as a reduction in accurate coding and referrals for screening is likely to occur, resulting in a risk of increased levels of sight loss relating to diabetic retinopathy.

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			We would welcome a review of the inclusion and exclusion criteria for this indicator to ensure it accurately reflects the national diabetic eye screening exclusion policy and also reflects eye screening undertaken as part of a quality assured national screening programme.
IND-1	Imperial College Healthcare NHS Trust	Question 5	As GPs are vital to improving glycaemic and BP control in patients with any form of retinopathy as this slows progression of any form of retinopathy to sight threatening retinopathy. While early intervention that improves either glycaemic and BP control reverses retinopathy (ref 1). This QoF indicator should continue to be part of the Diabetes QoF. In this large population study by Liu Y et al, (ref. 1) of 44,871 observed DR events between the calendar years 1990 and 2011 for 4,758 diabetic patients who were diagnosed at 35 years of age or older it wa shown that: 1. An increase in HbA1c level by 1 SD (15.83 mmol/mol, 1.4%) had a 42% increased risk of progression from no retinopathy state to mild BDR,a 32% increased risk of progression from mild BDR to observable BDR, and a 123% increased risk in progression from observable BDR to severe non-PDR/PDR 2. Conversely, a reduction in the HbA1c level by 1 SD was associated with a 24% increased possibility of recovering from mild BDR to the retinopathy-free state, but the HbA1c level was unrelated to the regression from observable BDR to mild BDR in this cohort.

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			3. A raised level of DBP by 1 SD (10.41 mmHg) elevated the risk for developing observable BDR from the mild BDR by 87%. 4. SBP was also a significant risk factor for progression to mild BDR from the initial retinopathy-free state, and the reduction in SBP by 1 SD (17.28 mmHg) was associated with a 20% increased chance of regression back to the retinopathy-free state 1. Liu Y, Wang M, et al (2013). Glycaemic exposure and blood pressure influencing progression and remission of diabetic retinopathy. Diabetes Care 36: 3979-3984.
IND-1	NHS England (London Region) Diabetes Strategic Clinical Network	Question 5	Retinal screening should definitely be included. GP's are responsible for the practice based registers and the referrals that underpin screening and for the patient education of the importance of attendance Withdrawal sends out message that it is not important and not the responsibility of the GP. Primary care retains significant responsibility for ensuring attendance at retinal screening and in responding to results by improving blood pressure and glycaemic control. Please see attached letter from London Diabetes Strategic Clinical Leadership Group
IND-1	AstraZeneca UK Ltd	Question 5	Whilst we agree that retinal screening should be carried

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			out, it sits mostly outside the control of GPs and hence we agree that it should not be included within this composite indicator.
IND-1	British Renal Society	Question 5	Retinal screening should be included. Increasing numbers of DM cases are managed entirely in primary care and they need access to the same level of surveillance as those in secondary care. GPs need to be under pressure to ensure that these services are adequately commissioned.
IND-1	West Herts Diabetic Eye Screening Programme	Question 5	strongly feel that invitation to diabetic eye screening should be a QOF indicator. Throughout the year our Failsafe Officer regularly validates GP diabetic patient lists against the programme's software. Most GPs are compliant, but some need regular chasing. As a result of the current QOF incentive, however, by year end most practices have submitted their patient lists and then refer any patients not already known to us. • GPs currently receive payment for the various annual tests carried out for their diabetic patients, eg blood pressure, cholesterol, blood sugars etc – diabetic eye screening is the only service that all diabetics should be referred to. If patients do not have eye screening this will reduce the amount a GP can claim on their QOF submission • Every year around this time GPs are pulling together their information to identify patients who have not been referred to screening, hence the significant increase in

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			new referrals between November and February • From the programme's point of view this makes it difficult to plan the number of clinics we require up to the end of the financial year, ie 31st March, as we do not know how many patients have been missed to referral throughout the preceding year ; this also makes it difficult to plan staff leave • More importantly, if GPs were not required to submit their data on diabetic patients for QOF payment, we do not know how many patients will not get the opportunity to be invited to screening and hence be exposed to sight threatening diabetic retinopathy which is the main cause of sight loss in working age people I attach a spreadsheet which shows the referral trend since April 2012; you will note from the 2012/13 chart the referral pattern is quite unpredictable but there is a definite spike from November to February. The 2013/14 chart shows a steadier pattern of referrals, which has resulted from the activity of our Failsafe Officer, but despite this there is again a significant spike from November onwards.
IND-1	Medical Imaging UK Ltd	Question 5	Yes. GPs are responsible for the identification of the diabetic population to the screening programme and currently we have no power to obtain this information where it is not forthcoming. We cannot invite patients to attend for screening if we do not know who is eligible and we also routinely invite 'bad' names which is a huge waste of resource.

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			GPs can also currently report that patients have had screening when they might not have had nationally compliant screening which potentially is unsafe. GPs should have to report not only an accurate register to the DESPs but also should only be able to count screening as an outcome received from the DESP provider. This would forge strong working relationships between GPs and DESPs and improve the quality of the service immensely. GPs are central to high quality metabolic control and holistic care of the secondary complications as a result of diabetes. It is paramount that GPs are accountable for meeting objectives in order to improve the care people with diabetes receive and help DESP providers delivery safe/effective services.
IND-1	Hinchingbrooke Hospital	Question 5	Diabetic Eye Screening - Unsure how else GP practices are going to identify their diabetic patients as this is what is currently utilised to update the screening programmes. (Recently raised an issue of 12-17 yr olds not being referred appropriately)Code indicators are not absolutely accurate in a GP setting which means that patients are missed or added unnecessarily. How can eye screening programmes know that they have 100% patients from a practice? Having QOF associated assisted in GP practices being aware of the need to refer.

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IND-1	Bayer Plc	Question 5	We would consider it appropriate for retinal screening to be included in this indicator. Retinal screening of people with diabetes is important for preventing avoidable sight loss. It has been estimated that “screening could save more than 400 people per year from sight loss in England.” Quality statement 8 of the ‘diabetes in adults’ quality standard includes ‘retinopathy’ as a ‘complication’ for which people should receive an annual assessment of the risk and presence. Recommendations on which this quality statement are based are derived from NICE clinical guideline (recommendation sections 1.8–1.14), and NICE clinical guideline 15 (recommendation sections 1.10–1.11), and these recommendations not only include the initiation and annual performance of the screening, but also include that “the reasons for, and success of eye surveillance systems [should be explained] so that attendance is not reduced by ignorance of need or fear of outcome” (recommendation 1.13.2 NICE clinical guideline 87 and recommendation 1.11.1.4 NICE clinical guideline 15) Therefore, we agree with the statement included in the briefing note developed for the NICE QOF committee meeting of the 18th September 2013 which suggests that whilst “GPs are not responsible for providing retinal screening, they are responsible for ensuring that patients have received retinal screening.” As part of this, we believe that GPs have an important role to play in reminding individuals of the importance of retinal

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			screening so that attendance is not “reduced by ignorance of need or fear of outcome” as outlined in the aforementioned clinical guidelines. The briefing note also included that “evidence suggests the success of screening depends on continued high levels of uptake” (from NICE clinical guideline 15). While the most recently available annual report from the diabetic retinopathy eye screening programs shows that in 2011/12, coverage (proportion of people identified with diabetes who were screened) was 73.9%, and uptake (proportion of people offered screening who were screened) was 80.9%. It also reports that there was “considerable regional variation” with the coverage varying from 52% to 95%.16 The uptake of retinal screening was previously covered by QOF indicator DM011 – “the percentage of patients with diabetes on the register who have a record of retinal screening in the preceding 12 months”. We note that the independent QOF committee agreed that DM011 was important to retain in the QOF when undertaking their review in September 2013/12, however, despite this recommendation, the indicator has been retired, and subsequently we are concerned that there is a risk that regional variation will not be addressed, and uptake could decline, therefore we suggest that consideration of this important care process should continue to be incentivised through this composite indicator.

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IND-1	Hillingdon Hospital NHS Foundation Trust	Question 5	Retinal screening. Retinal screening needs to be composite indicator and GP does take a crucial role in ensuring the lists forwarded to screeners are kept updated . If this is removed there will no incentive and uptake of screening will fall. There is no other robust mechanism or alternative to ensure eye screening happens as secondary care in most areas do not have results. There still remains confusion among pts the difference between digital eye screening and normal eye tests. Eye screening also means the eye department can effectively reinforce the need for improvement in glycaemic control and in fact we should be lobbying for access to HAb1c for screening programme and not remove the DESP as composite indicator. The view that GP don't have a role is probably representative of few GPs who shirk duties and certainly don't reflect majority. It also facilitates discuss at integrated care meetings developed to improve chronic care
IND-1	Hillingdon Hospital NHS Foundation Trust	Question 5	Diabetes QOF indicator 1 I would strongly disagree with the intention to remove retinal screening from the new QOF on the basis this will reduce local uptake of this screening process and disincentivise GP surgeries from sending updated diabetes register data to central DESS programme and thus destabilising the whole retinal screening programme. This programme has proven health outcome benefits and acts as both a surrogate marker of more widespread microvascular disease and a useful tool for patients' understanding of the diabetes

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			disease process.
IND-1	Healthwatch Bucks	Question 5	Retinal screening is now common and is recognised as being very important for early detection of visual impairment. We believe that this is highly important and should be mandatory