University of Birmingham and University of York Health Economics Consortium (NCCID)

Development feedback report on piloted indicators

QOF indicator area: Diabetes

Pilot period: 1st October 2015 – 31st March 2016

Potential output: Recommendations for NICE menu

Contents

Summary of recommendations

Indicator

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

Acceptability recommendation:

- Band 2: 60-69% of practices support inclusion.

Implementation recommendation:

- Band 4: major problems identified during piloting. Not immediately resolvable. Indicator not recommended for wider implementation.

This recommendation is made on the basis of the low denominators reported for some practices which impacts upon reliability.

Cost effectiveness recommendation:

See summary report.

Issues to consider:

Issue	Detail	Mitigating activity
Care of people with type 1 diabetes may be shared between primary and secondary care	Many patients with type 1 diabetes receive care from specialist services, especially in relation to glucose control. There was a perception that these patients are difficult to engage with primary care as they view this as duplication. It was noted that there was a risk that this aspect of care might fall through the gap.	The committee may wish to consider measuring this indicator at CCG rather than practice level.

Indicator

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

Acceptability recommendation

- Band 4: <50% of practices support inclusion.

Implementation recommendation

- Band 3: major problems identified during piloting or anticipated in wider implementation. Possibly resolvable through the actions described in band 2 but indicator requires further development work and/or piloting.

This recommendation is made on the basis of concerns about over medicalisation and potential harms, particularly in the elderly.

Cost effectiveness recommendation

See summary report.

Issues to consider:

Issue	Detail	Mitigating activity
Appropriateness of this target for all people with diabetes.	This level of HbA1c control was described as only being suitable for a minority of people with diabetes.	
Potential unintended consequences of encouraging a lower HbA1c target.	It was noted that in order to achieve this level of control practices would be likely to increase prescribing with an associated potential for over medicalisation, side effects and associated adverse events.	

Indicator

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

Acceptability recommendation

- Band 4: <50% of practices support inclusion

Implementation recommendation

- Band 2: minor problems identified during piloting or anticipated to arise in wider implementation. Problems resolvable prior to implementation through either 1) an amendment to indicator wording, 2) an amendment to the business rules and/or 3) by giving further clarification of indicator terms in associated guidance.

Cost effectiveness recommendation

See summary report.

Issues to consider:

Issue	Detail	Mitigating activity
Appropriateness of this target for all people with diabetes.	This level of HbA1c control was described as only being suitable for a minority of people with diabetes.	
Potential unintended consequences of encouraging a lower HbA1c target.	It was noted that in order to achieve this level of control practices would be likely to increase prescribing with an associated potential for over medicalisation, side effects and associated adverse events.	

Background

As part of the NICE-managed Quality and Outcomes Framework (QOF) process, all clinical and health improvement indicators are piloted, using an agreed methodology, in a representative sample of GP practices across England, Scotland, Wales and Northern Ireland.

The aim of piloting is to test whether indicators work in practice, have any unintended consequences and are fit for purpose.

Practice recruitment

Number of practices recruited:	33
Number of practices dropping out:	1
Number of practices unable to interview:	0
Number of practices interviewed:	32

[31 GPs, 10 practice nurses, 11 practice managers, 1 health care assistant and 1 administrative staff = 54 primary care staff most involved in QOF piloting]

All percentages reported have been calculated using the 33 practices recruited to the pilot as the denominator.

Piloted indicators

1. The percentage of patients with type 1 diabetes who meet the following criteria: aged over 40 years, and who have either diabetes for more than 10 years, or who have established nephropathy or other CVD risk factors; the percentage currently treated with a statin.
2. The percentage of patients with diabetes in whom the last IFCC-HbA1c is 53 mmol/mol or less in the preceding 12 months.
3. The percentage of patients with diabetes in whom the last IFCC-HbA1c is 58 mmol/mol or less in the preceding 12 months.

Assessment of clarity, reliability, feasibility, and acceptability

Clarity

During the focus group it was noted that the CVD risk factors for people with type 1 diabetes would need to be clearly specified. Practices were provided with a definition of the relevant CVD risk factors prior to piloting which were supported in the business rules: proteinuria (latest ACR >30mg/mmol, current or ex-smoker, latest BMI ≥25, hypertension, hyperlipidaemia and/or family history of CVD.

Reliability and feasibility

We were able to develop business rules to support these indicators.

Issues to be resolved prior to implementation:

Issue	Detail	Mitigating activity
Diabetes resolved codes used in the Pilot (relating to Indicator 1)	The current Read codes for diabetes resolved do not specify the type of diabetes.	Speaking with the HSCIC clinical advisors it is felt that if this indicator was to go forward to live QOF then there would be new Read codes required for the indicator to work as intended as the current Read codes used for diabetes resolved may not be suitable for use when we are splitting the diabetes types into Type 1 and Type 2 (in live QOF there is just a single diabetes cluster which includes both types of diabetes). Next opportunity for new Read codes to be released will be April 2017.

Acceptability

Indicator 1: Statin prescribing for people with type 1 diabetes

Twenty two practices (66.7%) thought this indicator should be considered for inclusion in QOF. Eight practices (24.2%) did not think this indicator should be considered for inclusion and a further two practices (6.1%) were ambivalent about its inclusion.

All practices stated that people with type 1 diabetes who are over 40 were usually prescribed a statin as standard practice. This was described as good quality of care due to their increased risk of developing cardiovascular disease. This group of patients were described as generally receptive to taking statins due to an awareness of the benefits to their health.

"It should be considered for type 1 because they're the high risk patients...it's not actually a lot of work and those patients are very much at risk so they should be on the right treatment. You're only going to have a handful of patients if that." (GP, Practice ID10)

"I think a statin would be sensible; certainly, if you're over 40 because we know that their risk shortens their life, so we need to do everything we can to improve the quality of life and stop them getting small vessel disease and furring up of their arteries." (GP, Practice ID24)

"Patients in this group, diabetic, or diabetic for ten years… the evidence is very, very strong, and they do seem to be more amenable to accepting a statin prescription as well." (GP, Practice ID12)

In most practices this patient group were primarily managed in secondary care where the initial discussion surrounding statins would usually take place. Where this had not taken place or patients were not being prescribed a statin, some practices noted that this was an example of how primary care could ensure that these patients didn't fall between the gap between primary and secondary care. However, one practice commented that there was usually a sensible rationale as to why statin treatment had not already been advised by the hospital.

"As GPs we feel often they don't get optimal management in hospital the type 1s. I mean they're very good at concentrating on insulin but these other are risk factors they're not that great at controlling. I think it's a good measure of quality of care, actually, because we should be picking up those that haven't been put on a statin by the hospital. The hospital should focus on their insulin because that's pretty specialist and we should be managing all their other kind of vascular risk factors. Just because they're under hospital care for their type 1 diabetes doesn't mean we can't contribute." (GP, Practice ID13)

"Often because it's been considered in secondary care there's a reason why if they're not on a statin...I look why they're not on it so it's a question that arises why aren't they on it and there's usually a good reason." (GP, Practice ID23)

Despite all people with type 1 diabetes being invited to general practice for annual reviews and diabetes clinics, several practices commented that some were challenging to engage with and rarely attended. Practices perceived that these patients viewed these appointments as a duplication care.

"They regularly go to the secondary care clinic there are quite a few people who are reluctant to come in and have things duplicated here in primary care in terms of their approach" (GP, Practice ID23)

"There's definitely a group of people who feel that their diabetes is looked-after by the hospital, and not by us, and they're a difficult group because I can think of a number of people who, I've tried to have discussions with statins, in fact I was pushing it harder than the hospital was, and then … they say, 'Well, the hospital doesn't want me to do this,' and actually I'm in a very difficult position. Now, you could say, 'That's fine.' I've offered it. So from the point of view of this indicator, I've offered it. So … the bottom line I'm coming to is I think it would be challenging to implement it, but it is a good indicator. I.e. these people should be on this treatment. A very high-risk group of individuals." (GP, Practice ID03)

Due to the potential for care to be shared across primary and specialist services some practices described this indicator as a measure of quality across the services which a patient was accessing

rather than being specifically attributable to primary care. One practice suggested quality measurement at CCG level may be useful.

"There's a Primary and a Secondary Care input here and if there's a way in which you can do that and perhaps that should be CCG led, then maybe that's the way to do it." (GP, Practice ID25)

"It's not entirely a primary care issue so I think that makes it slightly controversial. I don't want to be penalised for what the hospital doesn't do....It's not necessarily a marker of quality in general practice" (GP, Practice ID32)

Indicator 2: The percentage of patients with diabetes in whom the last IFCC-HbA1c is 53 mmol/mol or less in the preceding 12 months.

Four practices (12.1%) thought this indicator should be considered for inclusion in QOF. Twenty six practices (78.8%) did not think this indicator should be considered for inclusion in QOF and a further two practices (6.1%) were ambivalent about its inclusion.

Indicator 3: The percentage of patients with diabetes in whom the last IFCC-HbA1c is 58 mmol/mol or less in the preceding 12 months.

Fourteen practices (42.4%) thought this indicator should be considered for inclusion in QOF. Seventeen practices (51.5%) did not think this indicator should be considered for inclusion in QOF and a further one practice (3%) were ambivalent about its inclusion.

An HbA1c target of 53 mmol/mol was viewed as a very strict target for the majority of people with diabetes across almost all practices. Some viewed it as only suitable for a small proportion of their population such as younger people, the newly diagnosed and those with optimal lifestyles. There were concerns that in order to achieve this level of control practices would need to intensify treatment with the risk of increased side-effects and that less attention would be given to other aspects of care such as diet and lifestyle change. These concerns were intensified in relation to elderly patients with comorbidities for whom it was felt that the risks associated with increasing medication to achieve tighter HbA1c control outweighed any potential benefit.

Due to these potential adverse effects, an HbA1c of 53 mmol/mol was not viewed as good quality care for most people with diabetes and practices would only aim for this level of control in a minority of patients.

"I really thought maybe it could be more tapered to age and we can see the point of trying to get it down to 53 in the younger people and in the type 1s but in the type 2s, the elderly, keeping someone strictly below 53 we thought was probably a bit extreme and you end up chasing someone and adding different medications, switching their medication, creating more side effects for not much gain. Whereas 58 we thought was fine and more easy for the elder population. But we did just feel that we would then spend a lot of time chasing targets that for extra gain in the elder population,

that's maybe slightly ageist but at risk of giving them more side effects and different medication wasn't really worth it." (GP, Practice ID12)

"My concern would be that this is going to make GP's increase medication." (GP, Practice ID08)

"Our overall feeling is that these figures are tight. Certainly, for some elderly folk the 53 target particularly, I think maybe too low for some individual patients who perhaps have had diabetes for some time and the consequences of medication to get them down to that level might not be feasible." (GP, Practice ID14)

"I think that the type 1 then below 53 is almost impossible. Because their glucoses go up and down and so the HbA1c is always going to come out, if they get below that they're usually having too many hypos and that was the reason for raising the levels again a little while ago so you can aim for it but I think trying to catch that, is it quality, I'm not sure it is…" (GP, Practice ID27)

Practices viewed an HbA1c target of 58 mmol/mol as more realistic and reflective of good quality care for a larger proportion of their patients with diabetes. However, some practices still viewed this target as too tight for many people and associated with the same potential risks as a target of 53 mmol/mol, but to a lesser extent. Concerns were also expressed about the potential for increased exception reporting.

"We're always worried about exception reporting. But I think if you make the targets really strict you're likely to get more exception reporting as a result and therefore I don't think you're improving clinical care and if the point of QOF is improve clinical care then, then I think it negates that." (GP, Practice ID15)

Current QOF targets incentivise control of HbA1c to 59 mmol/mol, 64 mmol/mol and 75 mmol/mol. Practices described difficulties in achieving these indicators, with some questioning the value of having target indicators. Some practices find target indicators demotivating as they perceived achievement or otherwise as being out with of their control due to patient factors such as diet and adherence to medication. In their view target indicators do not necessarily reflect the effort they have made. Existing targets were useful for audit purposes and to assist practices in identifying patients whose HbA1c was above a certain level (usually 75 mmol/mol). The loosest target of 75mmol/mol was not recognised as being a marker of quality. One practice raised concerns that the inclusion in QOF of inappropriate targets, both high and low, had the potential to impact negatively upon patient care.

"Obviously, we want the best outcome for the patient but if we're giving the maximum tolerated treatment and we still can't get their HBa1C down beyond a certain level you almost feel like you're failing, when there isn't really anything else that you might be able to do at that moment in time...You can do everything you can do but if a patient isn't compliant in other ways you're never gonna hit that target. So these targets I would have more of an issue with because sometimes you just can't achieve some and there's nothing you can do about it...And you can end up spending a lot

on some patients trying to get their HBa1C down when you probably don't have much hope of being able to do it." (GP, Practice ID15)

" We're having difficulty attaining the current levels and when I go through, a lot of them are on their maximum tolerated dose, they can't increase any further because of side effects." (GP, Practice ID29)

"The QOF targets almost start becoming slightly Gospel, don't they, they're not necessarily based on the up-to-date guidelines, it's just that happens to be the QOF target." (GP, Practice ID25)

Some practices considered alternative methods to approaching the assessment of glycaemic control in primary care. These included individual patient targets, annual percentage reductions in HbA1c to a given level (58mmol/mol) and clinical action measures. Clinical action measurement is an approach to quality which focuses upon the actions which clinicians have taken in response to sub-optimal control. The potential for individual patient targets was considered by the committee in June 2015. Since this time we have been considering how this could be operationalised within the QOF measurement framework, without being too open to gaming. This could occur for example as a result of setting inappropriately high individual targets and difficulties associated with identification of a target HbA1c within the record. This concern was also shared by the practices who suggested this approach.

Assessment of implementation

Assessment of piloting achievement

Table 1: patients with type 1 diabetes aged over 40 years, treated with a statin

% patients with type 1 diabetes aged over 40 years currently treated with statins	Baseline	Final
Number of practices uploading	23	23
Practice population	156,999	159,040
Register	598	620
Exception reported		
Rule 2 True (recent registration)	7	7
Rule 3 True (diabetes exception)	37	49
Rule 4 True (recent diagnosis)	35	48
Rule 6 True (statin exception)	16	53
Total exceptions	**95**	**157**
Exceptions as a % of the eligible population	**15.89**	**25.32**
Denominator	503	492
Numerator	330	337
Numerator as a percentage of denominator	**65.61**	**68.50**
Underlying patient achievement (%)	**55.18**	**54.35**

The register figure reported above identifies only patients with type 1 diabetes who are over 40 years old and have either had diabetes for at least 10 years or have established nephropathy or other recorded cardiovascular risk factors. The average register size across this practice cohort was 26 patients (range 1-59) raising questions about indicator reliability at the practice level. There are also known issues in relation to the recording of type of diabetes with approximately 2% of cases potentially miscoded, so we may not be identifying all patients with type 1 diabetes.

Table 2: patients with diabetes with an HbA1c ≤53 mmol/mol

% patients with diabetes with an HbA1c of 53 mmol/mol or less	Baseline	Final (6 months)	Final (12 months)
Number of practices uploading	25	25	25
Practice population	177,017	179,513	179,513
Register	9,336	9,456	9,456
Exception reported			
Rule 2 True (serum fructosamine recorded)	5	0	5
Rule 3 True (blood test exception)	4	2	2
Rule 4 True (recent registration)	225	242	212
Rule 5 True (diabetes exception)	515	674	654
Rule 6 True (recent diagnosis)	186	211	184
Rule 7 True (maximum tolerated therapy)	662	559	550
Total exceptions	**1,597**	**1,688**	**1,607**
Exceptions as a % of eligible population	**17.11**	**17.85**	**16.99**
Denominator	7,739	7,768	7,849
Numerator	4,137	3,265	4,440
Numerator as a percentage of denominator	**53.46**	**42.03**	**56.57**
Underlying patient achievement (%)	**44.31**	**34.53**	**46.95**

Table 3: patients with diabetes with an HbA1c ≤58mmol/mol

% of patients with diabetes with an HbA1c of 58 mmol/mol or less	Baseline	Final (6 months)	Final (12 months)
Number of practice uploading	25	25	25
Practice population	177,017	179,513	179,513
Register	9,336	9,456	9,456
Exception reported			
Rule 2 True (serum fructosamine recorded)	5	0	5
Rule 3 True (blood test exception)	4	2	2
Rule 4 True (recent registration)	188	207	170
Rule 5 True (diabetes exception)	486	641	613
Rule 6 True (recent diagnosis)	122	158	125
Rule 7 True (maximum tolerated therapy)	593	534	520
Total exceptions	**1,398**	**1,542**	**1,435**
Exceptions as a % of the eligible population	**14.97**	**16.31**	**15.18**
Denominator	7,938	7,914	8,021
Numerator	5,366	4,221	5,686
Numerator as a percentage of denominator	**67.60**	**53.34**	**70.89**
Underlying patient achievement (%)	**57.48**	**44.64**	**60.13**

Changes in practice organisation

No specific changes to practice organisation were identified.

Resource utilisation and costs

There could be a potential for costs associated with increased prescribing of diabetes medications as a result of implementing HbA1c targets of 53 mmol/mol and 58 mmol/mol. Both the HbA1c indicators and the statin treatment indicator would result in an increased need for review which would potentially impact upon number and duration of consultations. There is also a potential impact upon laboratory services due to increased HbA1c monitoring.

Barriers to implementation

There was a tendency for people with type 1 diabetes to primarily be managed in secondary care. For this reason some of this patient group rarely engaged with general practice. This may be a barrier to discussing statin treatment for people with type 1 diabetes. The committee may wish to consider whether this indicator should be considered a measure of system wide care and assessed at the CCG level.

Practices expressed anxiety surrounding the implementation of HbA1c targets of 53 mmol/mol and 58 mmol/mol. They were concerned about side-effects of intensifying treatment, especially in the elderly, and potential adverse effects associated with this.

Assessment of exception reporting

Exception reporting against indicator 1 (statin therapy) increased by 10% from 15.89% to 25.32% during the pilot period. This appears to be due to a change in exception reporting habits with a greater proportion of patients being excepted due to statin contraindications/ intolerance by the end of the pilot. Pre-pilot this accounted for 16.84% of exception reporting which increased to 33.76% post pilot. A concurrent drop in the use of generic exception reporting codes was also observed suggesting a shift to more specific coding.

Practices expressed concern that more rigorous HbA1c targets would result in increased exception reporting. Exception reporting at the 6 month final upload was 17.85% for 53 mmol/mol and 16.31% for 58 mmol/mol. These values follow the pattern of exception reporting observed in the current QOF indicators (see Table 4 below).

HbA1c target	In QOF	Payment threshold	Points	Average achievement 2014/15	Average exception reporting 2014/15	Pilot achievement (6 months)	Pilot exception reporting (6 months)
≤75 mmol/mol	Y	52-92%	10	86.95%	8.83%	-	-
≤64 mmol/mol	Y	43-83%	8	77.47%	11.68%	-	-
≤59 mmol/mol	Y	35-75%	17	69.76%	13.48%	-	-
≤58 mmol/mol	N	-	-	-	-	53.34%	16.31%
≤53 mmol/mol	N	-	-	-	-	42.03%	17.85%

Table 4: Achievement and exception reporting rates for existing HbA1c control indicators 2014/15

Assessment of potential unintended consequences

Practices expressed concerns regarding implementing low HbA1c targets. Concerns were raised that some practices might focus on treatment intensification in order to achieve these rather than supporting lifestyle change. Concern was also raised about the risks to patients of unrecognised hypoglycaemia.

Assessment of overlap with and/or impact on existing QOF indicators

There is some overlap with the existing HbA1c indicators:

DM007: The percentage of patients with diabetes, on the register, in whom the last IFCC-HbA1c is 59 mmol/mol or less in the preceding 12 months. Achievement threshold: 35–75%. Indicator points: 17.

DM008: The percentage of patients with diabetes, on the register, in whom the last IFCC-HbA1c is 64 mmol/mol or less in the preceding 12 months. Achievement threshold: 43-83%. Indicator points: 8.

DM009: The percentage of patients with diabetes, on the register, in whom the last IFCC-HbA1c is 75 mmol/mol or less in the preceding 12 months. Achievement threshold: 52–92%. Indicator points: 10.

It was intended that the piloted indicators could potentially replace these.

Suggested amendments to indicator wording

None.

Appendix A: Practice recruitment

We planned to recruit 34 practices in England and 2 in each of the Devolved Administrations. English practices were to be representative in terms of practice list size, deprivation and clinical QOF score. Given the limited variability in clinical QOF score we excluded practices with a score of ≤ 10th centile. Practice list size and IMD scores were divided into tertiles and a 3x3 matrix created with target recruitment numbers for each cell. These are detailed in the table below.

	List size		
IMD Score	Low	Medium	High
Low	3	4	5
Medium	3	4	4
High	4	4	3

As previously presented to the Committee, practice recruitment has been extremely challenging. At the beginning of this pilot we had recruited 30 practices in England and 3 in the Devolved Administrations (2 in Northern Ireland, 1 in Scotland). Practice recruitment by strata is shown in the table below with cells in bold where we failed to meet target numbers. We also over recruited in two stratas which is shown by the numbers in the table.

	List size		
IMD Score	Low	Medium	High
Low	**2/3**	4/4	**2/5**
Medium	3/3	4/4	**2/4**
High	5/4	4/4	3/3

Appendix B: Indicator development

Following the June 2015 Advisory Committee meeting the NCCID was asked to develop new indicators for diabetes.

GP focus group

A focus group to discuss potential indicators was held on 9th July 2015 where all potential indicators were discussed. Focus group attendees were volunteers recruited via our database of GPs who had responded to previous invitations. From the volunteers we purposively selected 15 GPs to attend the focus group to ensure an equal balance of men and women, representation from minority ethnic groups and a range of ages.

13 of those invited attended the meeting. Eight (61.5%) were male. Approximately one third of the participants described themselves as being of white ethnicity (n=5). Participants were reimbursed £250 for their attendance.

Stephanie Birtles and Dr Karen Slade attended on behalf of NICE.

Four indicators were presented to the group. The potential indicator relating to statin prescribing for people with type 1 diabetes was well received although the group specified that the CVD risk factors would need to be specified. Three indicators for revised HbA1c targets were piloted. Participants expressed concerns about these revised HbA1c targets, especially 48 mmol/mol which was viewed as largely unachievable in most practice populations. Participants also foresaw significant increases in exception reporting and the potential for patient harm. The HbA1c target of 48 mmol/mol was not progressed to the piloting piloting.

Three indicators are to be progressed to piloting.

Indicator wording as piloted

1. The percentage of patients with type 1 diabetes who meet the following criteria: aged over 40 years, and who have either diabetes for more than 10 years, or who have established nephropathy or other CVD risk factors; the percentage currently treated with a statin.
2. The percentage of patients with diabetes in whom the last IFCC-HbA1c is 53 mmol/mol or less in the preceding 12 months.
3. The percentage of patients with diabetes in whom the last IFCC-HbA1c is 58 mmol/mol or less in the preceding 12 months.