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

Development feedback report on piloted indicators

QOF indicator area: Gestational diabetes

Pilot period: 1st October 2016 – 28th February 2017

Potential output: Recommendations for NICE menu

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Summary of recommendations

Indicator

1. The percentage of women who have had gestational diabetes, diagnosed more than 12 months ago, who have had an HbA1c test in the preceding 12 months.

Acceptability recommendation:

Band 2: 60-69% of practices support inclusion

Implementation recommendation:

Band 2: minor problems identified during piloting or anticipated to arise in wider implementation.

Cost effectiveness recommendation:

See summary report.

Issues to consider:

Issue	Detail	Mitigating activity
Frequency and duration of follow-up	Current guidance recommends an annual HbA1c following a diagnosis of gestational diabetes. This was queried by some practices, especially when the HbA1c was within the normal range.	
Exception reporting	During piloting we only modelled a limited amount of exception reporting. We would expect exception reporting rates to increase on implementation in QOF.	
Reliability	There are small register sizes at the practice level which negatively impacts upon measure reliability and was a concern for a small number of practices.	

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:	29
Number of practices dropping out:	2
Number of practices unable to interview:	0
Number of practices interviewed:	27

[26 GPs, 6 practice nurses, 9 practice managers and 1 health care assistant = 42 primary care staff]

All percentages reported have been calculated using the 29 practices recruited to the pilot as the denominator.

Piloted indicators

1. The percentage of women who have had gestational diabetes, diagnosed more than 12 months ago, who have had an HbA1c test in the preceding 12 months.

Assessment of clarity, reliability, feasibility, and acceptability

Clarity

No concerns about clarity were noted during the GP focus group or piloting.

Reliability and feasibility

We were able to develop business rules to support this indicator.

The target population for this indicator is 1) women with a recorded diagnosis of gestational diabetes more than 12 months before the data extraction date (to exclude those currently or recently pregnant) or 2) women who have been recorded as having a history of gestational diabetes. Women who have subsequently been diagnosed with diabetes are excluded. However, this exclusion only applies when the date of the diagnosis of diabetes was more than 12 months before the data extraction date. This ensures that women diagnosed with diabetes as a result of their latest annual follow-up remain in the indicator denominator for that year.

Issues to be resolved prior to implementation:

Issue	Detail	Mitigating activity
Exception codes	Exception codes will need to be requested for informed dissent and patient unsuitable if this is adopted into QOF.	

Acceptability

Twenty-two practices (75.9%) thought that this was a suitable topic for quality measurement with 19 of these (65.5%) stating that this indicator was suitable for inclusion in QOF. The majority of practices recognised this as good practice, and a sensible clinical activity, as these women are at increased risk of developing diabetes in the future. It was felt that regular monitoring would aid early identification of diabetes.

"It seems sensible to continue monitoring when they've had that. I think there is some evidence that, yeah, they're definitely more prone to then going on and getting diabetes." (GP, Practice ID05)

"As an indicator, it's actually not that difficult to do. You can identify those patients and keep track of them with a register quite easily and then do something, even if it is just healthy lifestyle advice. You can do that quite simply." (GP, Practice ID10)

"I think it's a good area, it's specific, it's finite in terms of what you're looking at, it's a grouping that is at high risk of becoming diabetic, so I think it's very appropriate in that sense, it's a well-defined…indicator in that sense and we essentially do…do undertake this assessment when we see women who have got gestational diabetes." (GP, Practice ID20)

"So I think the evidence is very strongly that we should be doing that, and it should be in QOF." (GP, Practice ID29)

Ten practices (34.5%) stated that they were already attempting to do this prior to the pilot, although their approach differed in terms of organising and monitoring this follow-up. It was felt that a focus upon measurement, and potentially inclusion in QOF, would prompt practices to improve their systems through the setting up of a call and recall system. It was anticipated that this would have a positive health benefit for these women, who were often a forgotten group.

"They're an at-risk group, we should monitor them, have their annual HbA1c, it is a marker of quality. Often this group is forgotten, after the first one or two tests, which come back normal." (GP, Practice ID07)

"So I think it was in QOF to make sure we'd do it for the register every single year and ring, send them a [reminder]." (GP, Practice ID11)

"I think they are a group that get overlooked. That's if they've ever been coded…" (GP, Practice ID32)

Six practices (20.7%) noted the impact of lifestyle upon the future risk of diabetes and that regular checking of HbA1c also provided an opportunity to revisit related issues such as diet, obesity and exercise, to mitigate the risk of diabetes and cardiovascular disease.

"Again if you formalise these type of things which are, at the end of the day what are we trying to do, we're trying to identify people early and try to reduce the risk of heart attack and stroke in individual life, simple as that, so I think this should be included, yeah." (GP, Practice ID07)

"You can get a young population; a woman, thinking about health and lifestyle at an earlier age before it becomes a problem. I was quite keen about this one." (GP, Practice ID10)

However, seven practices (24.1%) expressed concern that they would find it difficult to encourage women to maintain annual testing over a long time period. Practices who were already attempting to do this had fewer concerns in relation to this and described this group of patients as being motivated to engage in preventative care, especially if they had required insulin during their pregnancy.

"They're actually an easy enough group to get to come because they're coming with babies for vaccinations, for screening and they're also likely to be coming for contraception themselves." (GP, Practice ID08)

"We think this is a group of people who are quite motivated. These women who've had gestational diabetes, they've obviously experienced what it's like to have insulin regularly and therefore they want to avoid that in the future, so they're quite a motivated group. We would find generally that they are very receptive to having their HbA1c monitored." (GP, Practice ID14)

Concerns were also expressed in relation to the accuracy of recording of gestational diabetes. Participating in the pilot had prompted many practices to review how this diagnosis was recorded in the medical record. For some practices this highlighted weaknesses in communication between the practice, antenatal midwives accessing the clinical system and local obstetric departments as well as Read coding practices in the surgery. For one practice, this prompted a significant event review. Coding of historical diagnoses was also noted as being potentially problematic.

"....we're better, probably better at it in recent years but a number of women from the five to 10 years who … won't have been recoded at the time properly…. So there needs to be some historical search … it would be a difficult register to get completely accurate." (GP, Practice ID11)

"I haven't got anybody from a long time ago that I've been able to find, 'cause that's the other thing. Actually, it wasn't always coded by their GP [right], that it was gestational diabetes." (GP, Practice ID22)

"Okay, the challenge we've found is the communication and the identification of gestational diabetics between us and the midwifery team … In that whole 12 months that our current Midwife is

with us, we've only actually had one gestational diabetic actually diagnosed at the time, so our numbers aren't big. …. they're clearly screening for gestational diabetes but it's interesting that actually we didn't know the gestational diabetic because they look after all of the ante-natal care that was diagnosed and they were hospital managed from their risk factor and everything and so we've only just identified that lady by chance who had delivered about four weeks ago. So, it's an interesting sort of challenge because even though the Midwife is here once a week, she's not using our clinical system, she's not coding anything on our clinical system, blood tests are being done through us, so it's raised quite a significant event for us." (GP, Practice ID23)

"…I'm not sure how well in the past we would have coded patients with gestational diabetes. … obviously we've only been able to pick up the ones that have been coded yeah so I mean I think going forward it will hopefully make us much more aware that we do need to code, er, those patients." (GP, Practice ID25)

" … maybe there are more that we don't know about and judging by this communication with the midwives, I think we're probably not being informed." (PN, Practice ID30)

Four practices (13.8%) did not support this indicator being considered for inclusion in QOF. This was due to the small numbers of patients at a practice level, a lack of awareness amongst some clinicians of the ongoing increased risk of diabetes experienced by these women, over-medicalisation and anticipated difficulties in encouraging women to attend for HbA1c testing on an annual basis.

"So, five years after her gestational diabetes, she had a completely normal … HbA1C. Why would you do her annually? I think you're just asking for a problem. … when I'm doing some other bloods, I would just do some other things and that's fine. So, I've just got a feeling we should just be careful about over medicalising people. We already over-medicalise people, and I think that's just making it far, far worse." (GP, Practice ID22)

"We ran a search about three times over the past few months. There was only one patient." (GP, Practice ID24)

Assessment of implementation

Assessment of piloting achievement

	Baseline	Final
Number of practices uploading	14	14
Practice population (from NHAIS)	118,341	119,968
Register	239	263
Excluded		
Rule 1: women with gestational diabetes in the last 12 months	2	2
Exception reported		
Rule 5 Recent registration	3	6
Rule 6 recent diagnosis	0	0
Total exceptions	**5**	**8**
Exceptions as a % of eligible population	**2.09**	**3.04**
Denominator	234	255
Numerator	14	3
Numerator as a percentage of denominator	**5.98**	**1.18**
Prevalence	**0.20**	**0.22**

Whilst overall prevalence is low this is comparable with current QOF indicators for Osteoporosis which had a prevalence of 0.1% in 2015/16. At a practice level, register size averaged 19 patients across the cohort (range 4-34), with associated issues in terms of measure reliability. However, given the poor coding of gestational diabetes it is likely that this is an underestimate.

Achievement rates were low during the pilot, but this is also exacerbated by coding issues in relation to HbA1c testing which did not become apparent until the end of the pilot. The pilot business rules had not included a commonly used code for HbA1c recording. Previously published figures of follow up of women with gestational diabetes in general practice over 5 years averaged at approximately 20%.[1]

Changes in practice organisation

Practices acknowledged that if this indicator was included in QOF then it would require new systems to be implemented in order to ensure ongoing follow-up of these patients. This was generally viewed as positive.

Resource utilisation and costs

Whilst no specific concerns were raised about increased resource utilisation and costs, given the current low rates of follow-up, improved performance would result in an increase in phlebotomy and associated laboratory costs.

[1] McGovern A, Butler L, Jones S, van Vlyman J, Sadek K, Munro N, Carr H, de Lusignan S. Diabetes screening andter gestational diabetes in England: a quantitative retrospective cohort study. *BJGP*: 2014; e17.

Barriers to implementation

Four potential barriers to implementation were identified: clinician education in relation to need for annual follow-up, motivation/ ability of this group to attend for annual follow up, small numbers at the practice level and access to HbA1c testing in the absence of a diabetes diagnosis.

Whilst most clinicians acknowledged the increased risk of diabetes experienced by this group of patients there was some disagreement as to the frequency and duration of follow-up. Some practices queried the need to annual follow-up in women with an HbA1c consistently in the normal range and the need for them to be followed-up for a lifetime. Some practices suggested that follow-up could be extended to every 3 years in patients with normal HbA1c levels, which is in line with the American College of Obstetrics and Gynaecologist recommendations. They noted that this could then be aligned with cervical screening which might be more convenient for patients.

Some practices also expressed concern that women's motivation to be tested might wane following a few years of normal results. However, other practices expressed the view that these women were particularly motivated and open to monitoring and diabetes prevention activities as many had experience of requiring insulin during pregnancy and were keen to avoid this in the future.

Small numbers at a practice level were also perceived as a potential barrier to implementation. From a practice perspective this was expressed as having the potential for them to be unfairly penalised if patients did not attend. From a technical perspective, small numbers negatively impacts upon indicator reliability.

Two practices (one in Scotland and one in the England) also described not being able to request HbA1c testing in women without a diagnosis of diabetes. Within the data extraction specification, we looked for a record of either an HbA1c or a fasting plasma glucose test, but it was noted that a fasting plasma glucose is not as convenient as HbA1c testing and cannot be performed opportunistically. We did not include codes for oral glucose tolerance testing, but these may need to be considered in areas with limited access to HbA1c testing.

Assessment of exception reporting

During the pilot period exception reporting was low (2.09% at baseline and 3.04% at final extraction). However it is likely that this would increase if the indicator was adopted into QOF as we were unable to estimate discretionary exception reporting e.g. informed dissent/ patient unsuitable due to Read code availability.

Assessment of potential unintended consequences

No unintended consequences were identified.

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

Whilst there are no overlaps with existing QOF indicators, there are potential overlaps with the diabetes prevention indicators which were piloted during the same period.

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 28 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 one strata which is shown by the numbers in the table. Two practices in England withdrew from the pilot prior to it starting reducing the total numbers of pilot practices to 26 in England, 2 in Northern Ireland and 1 in Scotland.

	List size		
IMD Score	Low	Medium	High
Low	**2/3**	**3/4**	**1/5**
Medium	3/3	4/4	**1/4**
High	5/4	4/4	3/3

Appendix B: Indicator development

Following the June 2016 Advisory Committee meeting the NCCID was asked to develop new indicators for HbA1c monitoring in women with a history of gestational diabetes.

GP focus group

A focus group to discuss potential indicators was held on 20th July 2016 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 try to ensure a balance of men and women, representation from minority ethnic groups and a range of ages.

Of those invited, 14 attended the meeting. Nine (60%) were male. Approximately one third of the participants described themselves as being of white ethnicity (n=5). Participants were reimbursed £250 for their attendance.

Anneka Patel and Shaun Rowark attended on behalf of NICE. Gemma Ramsey and Ross Ambler attended on behalf of NHS Digital.

One indicator was presented to the group in relation to annual HbA1c recording in this group of patients. This was generally viewed as straightforward, although a question was raised as to whether a register indicator might be required in order to encourage practices to code effectively, particularly in relation to historical diagnoses.

One indicator was progressed to piloting.

Indicator wording as piloted

1. The percentage of women who have had gestational diabetes, diagnosed more than 12 months ago, who have had an HbA1c test in the preceding 12 months.

Appendix C: Acceptability and Implementation recommendations

Acceptability recommendations

One of the following recommendations is made based upon reported acceptability of the indicator to pilot practices.

Band 1: ≥70% of practices support inclusion

Band 2: 60-69% of practices support inclusion

Band 3: 50-59% of practice support inclusion

Band 4: <50% of practices support inclusion.

Implementation recommendations

One of the following recommendations is made based upon an assessment of issues or barriers to implementation reported during piloting.

Band 1: no problems identified during piloting or anticipated to arise. Indicator terms precisely defined.

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.

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.

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