

**UNIVERSITY OF BIRMINGHAM AND
UNIVERSITY OF YORK HEALTH ECONOMICS CONSORTIUM
(NICE EXTERNAL CONTRACTOR)**

Development feedback report on piloted indicator(s)

QOF indicator area: Diabetes

Pilot period: 1st October 2012– 31st March 2013

Potential Output: Recommendations for NICE menu

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Background

As part of the NICE-managed Quality and Outcomes Framework (QOF) process, all clinical and health improvement indicators are piloted, using 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.

Piloted indicators

1. The percentage of women with diabetes under the age of 55 years who have been given information and advice about pregnancy, conception or contraception tailored to their pregnancy and contraceptive intentions recorded in the preceding 15 months.
2. The percentage of women with diabetes under the age of 55 years who have a record of information and counselling about contraception, conception and pregnancy in the preceding 15 months.

Number of practices participating in the pilot: 37

Number of practices withdrawing from the pilot: 5

Number of practices where staff were interviewed: 32

(29 GPs, 6 Practice Nurses, 19 Practice Managers = 54 primary care staff most involved in the QOF pilot)

Given the similarity between the two indicators, practices were randomly allocated to pilot one or the other. Fifteen practices piloted indicator 1 and seventeen practices piloted indicator 2. During the end of pilot interview practices were asked about the indicator they had piloted and about whether they would have preferred the alternative wording and why.

Assessment of clarity, reliability, acceptability, feasibility, and implementation

Clarity

- Indicator wordings as stated, rated as clear and unambiguous by the experts and frontline GPs.
- The NHS IC has confirmed that they have been able to write Business Rules (and/or an Extraction Specification)

Reliability¹ and Feasibility

Indicator	Feasibility	Reliability	Implementation
1	2	2	2/3
2	2	2	2/3
GPES conversion			3

¹ NHSIC provide guidance on whether the piloted indicators are, from a business rule perspective, suitable to become 'live' indicators. A notional 'scoring' system is used:

1. No problems to implement in live with other indicators
2. Minor re-work before it can go live with other indicators
3. Major re-work but do-able without recourse to anyone outside of the process
4. Major considerations to be made before the indicator can go live - possibly need to speak to CFH / suppliers
5. Not feasible

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Acceptability

General comments

There was general agreement that general practice should be engaged with patients regarding these care processes with twenty-eight practices (76%) being supportive of an indicator going into QOF. Two practices did not support either indicator being included in QOF and two did not express a preference.

Where practices were supportive of one of these indicators being included in QOF this was because they recognised its clinical importance and thought it was legitimate role for primary care.

“Well, this one we loved... one of the junior doctors presented all the evidence for why we should be doing this. And we all kind of thought we have totally left this to secondary care, for young women that are diabetic.... But err patients had never been told this information before. It was a kind of overwhelming horror that we realised.” (GP:ID32)

“And it just makes good clinical sense.” (GP:ID13)

“Well I think the diabetologists and the obstetricians would say it’s vital that people really do plan their pregnancies so I think they’re going to say that it is cost effective nationally if we have done some of the ground work with the patients beforehand and have referred them” (GP:ID20)

“The outcomes are measurably, perceivably different in a short timeframe.” (GP:ID24)

Practices that did not support the inclusion of this in QOF did not think it was clinically important, would be inappropriate for the vast majority of patients and therefore become a tick box exercise which had the potential to be damaging to the doctor patient relationship.

“... it is important to ensure that people with diabetes have their diabetes well managed and that pregnancies are well planned. But I’m not sure that a tick box in QOF actually necessarily helps achieve that.” (GP:ID5)

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“... asking these set of three questions to every female of childbearing years who has diabetes is going to be very intrusive. So I think on balance what we feel is we are damaging our doctor/patient relationship by this target...” (GP:ID3)

Twelve practices expressed concern about the upper age limit of 54 years stipulated in the indicators². Predominantly this was unease about asking older women about their pregnancy plans on an annual basis and concern that patients might be offended. Four practices suggested that the upper age limit be reduced and suggested that this could be 40 years (two practices) or 45 years (two practices).

“... you feel a bit stupid asking a patient how would you feel, a 55 year old woman that you talk about contraception, conception, and pregnancy?” (PN:ID7)

“So the age problem - the age was a problem. Really anybody over the age of about 40 [yeah] was not interested in talking to us about contraception or pregnancy plans.” (GP:ID32)

“... the first thing I would do is probably take the age, I'd reduce it down to the age of 40 not the age of 50.” (GP:ID3)

“I thought, I thought 45. 45. 55 is a bit - because fertility's already low after 40, but it does happen. 45 I thought, you know, you actively start saying that, 'If you get pregnant, you know, you must let us know and if you are taking a tablet, this, this, this, you know, effect on the baby,' and all that. But at 55 patient comes, they [get] too annoyed.” (GP:ID30)

One practice expressed some concern about the lower age limit of 17 years³ and that some patients may get missed in the transition from paediatric to adult services.

However, where practices reported patient response this was largely positive, with no reports of patients expressing offence. Practices noted that these issues would need to be addressed sensitively, especially where women were having problems conceiving.

² An upper age limit of 54 years ensures consistency with EPILEPSY9/EP003 and with the Additional Services Contraception indicators.

³ The lower age limit occurs as a result of the diabetes register which only includes people aged 17 years and over.

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“No big issue, depends how nicely you do it.” (GP:ID20)

Acceptability indicator 1 (tailoring advice to pregnancy intentions)

Eleven of the fifteen practices who piloted this indicator were supportive of this particular wording being included in QOF. Three practices expressed a preference for the wording of indicator 2 and one practice did not think that either indicator should go into QOF.

Acceptability indicator 2 (giving information on contraception, preconception and pregnancy)

Five of the seventeen practices who piloted this indicator were supportive of this particular wording being included in QOF. Nine practices expressed a preference for the wording of indicator 1. Two practices did not express a preference and one practice did not think that either indicator should be included in QOF.

Preference for indicator 1 or 2

Twenty practices (54%) expressed a preference for indicator 1: tailoring the advice given to women’s reproductive intentions. Eight practices (22%) expressed a preference for indicator 2: giving women information on pre-conception, pregnancy and contraception. Two practices did not think that either indicator should be included in QOF and a further two practices did not express a preference.

The reasons for preferring indicator 1 were varied and included involving the patient in their care, avoiding giving unnecessary information in order to tick the box, more reflective of existing clinical practice and reducing the need for exception reporting where all three pieces of advice were not relevant for an individual woman.

“I think – I think it’s gonna have to be tailored to the individual. “ (GP:ID20)

“... yes I think you would have to say it would be, there’s going to more ownership if it’s more tailored to the individual.” (GP:ID21)

“... the tailoring approach is a more appropriate one because if you have a lady who’s 52 years of age... for example with the epilepsy one we would put patient not suitable, we’re not going to give advice on preconception at the age of 52, it’s patient is unsuitable and I would free text that, you

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know, patient has no plans to have more children so to make it tailored would be a better way to do it, yes.” (GP:ID6)

The main reason for preferring indicator 2 was that pregnancies were not always planned and it was important that women were given preconception advice just in case.

“... I suppose you want to make them aware even if they haven’t any definite intentions. So I think yes, probably that I would think it’s probably better to do the whole group en mass and even if they’re not planning a pregnancy just to make them aware.” (GP:ID14)

“I think we should give them conception advice to everyone, especially the younger age group, we should give them that information, you know, that you should be going on folic acid and things like that, we need to refer you earlier, I'm talking mainly the type 1 diabetics more than anything, to take into account.” (PN:ID7)

Acceptability recommendation indicator 1

- There are barriers/risks/issues/uncertainties identified from the pilot in terms of acceptability that in themselves may not be sufficient to prevent an indicator being recommended by the AC, but require the particular attention of the AC.

Acceptability recommendation indicator 2

- There are barriers/risks/issues/uncertainties identified from the pilot in terms of acceptability that in themselves may not be sufficient to prevent an indicator being recommended by the AC, but require the particular attention of the AC.

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Implementation

Assessment of piloting achievement

1. The percentage of women with diabetes under the age of 55 years who have been given information and advice about pregnancy, conception or contraception tailored to their pregnancy and contraceptive intentions recorded in the preceding 15 months.

DIABETES A INDICATOR P704	Baseline	Final
Number of Practices Uploading	12	12
Practice Population	77,013	76,053
Diabetes Register	3,858	3,928
Excluded regardless		
Patient is not female	2,157	2,214
Patient aged 55 or over	1,302	1,317
Patient has had hysterectomy	26	24
Patient has been sterilised	32	34
Excluded if they do not meet Numerator criteria		
Patient has 3 valid exceptions	0	0
Registered in last 3 months	5	7
Diabetes Exception in last 12 months	28	18
Diabetes Diagnosis in last 3 months	8	0
Total Exclusions	3,558	3,614
Diabetes Denominator	300	314
Diabetes Numerator	42	65
Numerator as % of Denominator	14.00%	20.70%

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- The percentage of women with diabetes under the age of 55 years who have a record of information and counselling about contraception, conception and pregnancy in the preceding 15 months.

DIABETES B INDICATOR P705	Baseline	Final
Number of Practices Uploading	12	12
Practice Population	80,820	80,666
Diabetes Register	3,008	3,138
Excluded regardless		
Patient is not female	1,708	1,782
Patient aged 55 or over	953	990
Patient has had hysterectomy	26	22
Patient has been sterilised	30	30
Excluded if they do not meet Numerator criteria		
Patient has 1 valid exception	0	0
Registered in last 3 months	5	4
Diabetes Exception in last 12 months	19	25
Diabetes Diagnosis in last 3 months	4	10
Total Exclusions	2,745	2,863
Diabetes Denominator	263	275
Diabetes Numerator	1	4
Numerator as % of Denominator	0.38%	1.45%

Changes in practice organisation

General comments

All practices indicated that they had, or would, integrate this into the diabetes annual review.

Specific comments indicator 1

None.

Specific comments indicator 2

None.

Resource utilisation and costs

General comments

Four practices expressed concern about a potential increase in workload due to the increasing content and therefore length of a diabetes annual review.

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Specific comments indicator 1

In the majority of practices the initial enquiry about pregnancy intentions was made by the practice nurse undertaking the diabetes review with referral to the GP if necessary.

Specific comments indicator 2

None.

Barriers to implementation

General comments

Twelve practices expressed concern about raising these issues with older women and that it might be cause offence, especially if the question was perceived as irrelevant.

Eight practices identified learning needs for staff, primarily nursing staff, in relation to specific contraceptive and preconception advice.

Specific comments indicator 1

None.

Specific comments indicator 2

None.

Assessment of exception reporting

General comments

Practices noted that exception reporting criteria would need to be carefully defined and supported within the rule sets. Issues which emerged during piloting related to both the woman herself e.g. sterilisation, hysterectomy, being post-menopausal and those relating to her partner e.g. having had a vasectomy.

Specific comments indicator 1

It was thought that exception reporting was less likely to be problem with this indicator as only the relevant piece of advice was required.

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Specific comments indicator 2

No specific comments were made about exception reporting. The 2011/12 exception reporting rate in England for EPILEPSY⁴ (on which this indicator was modelled) was 36.7%⁵. It is possible that exception reporting in this context would be similar.

Assessment of potential unintended consequences

General comments

Women who are having difficulty conceiving may find these questions upsetting, especially when being asked on an annual basis.

Pilot practices also demonstrated a tendency to focus upon women with type 1 diabetes. The specific needs of women with type 2 diabetes will need to be highlighted in any QOF Guidance.

Implementation recommendations

Implementation recommendation indicator 1

- There are barriers/risks/issues/uncertainties identified from the pilot in terms of implementation that in themselves may not be sufficient to prevent an indicator being recommended by the AC, but require the particular attention of the AC.

Implementation recommendation indicator 2

- There are barriers/risks/issues/uncertainties identified from the pilot in terms of implementation that in themselves may not be sufficient to prevent an indicator being recommended by the AC, but require the particular attention of the AC.

Assessment of overlap with existing QOF indicators and potential changes to existing QOF indicators

These indicators overlap with the existing EP003.

⁴ In England for 2013/14 this indicator has been relabelled as EP003 and the timeframe reduced to 12 months.

⁵ <http://www.hscic.gov.uk/catalogue/PUB08661>

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EP003: The percentage of women aged 18 or over and who have not attained the age of 55 who are taking antiepileptic drugs who have a record of information and counselling about contraception, conception and pregnancy in the preceding 12 months.

Practices expressed a view that there should be consistency between indicators in terms of coding. Again they were divided as to whether this indicator should be rewritten to encompass tailoring of advice.

Overall recommendations

Overall recommendation indicator 1

There are barriers/risks/issues/uncertainties identified from the pilot that in themselves may not be sufficient to prevent an indicator being recommended by the AC, but require the particular attention of the AC.

Overall recommendation indicator 2

There are barriers/risks/issues/uncertainties identified from the pilot that in themselves may not be sufficient to prevent an indicator being recommended by the AC, but require the particular attention of the AC.

Suggested amendments to indicator wording

Suggested amendments to indicator 1

None suggested.

Suggested amendments to indicator 2

None suggested.

For discussion by the AC

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The committee is asked to consider which, if any, of these indicators should be recommended for inclusion on the NICE menu.

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Appendix A: Indicator details

NICE Quality Standard recommendations

Quality standard 8: Women of childbearing age with diabetes are regularly informed of the benefits of preconception glycaemic control and of any risks, including medication that may harm an unborn child. Women with diabetes planning a pregnancy are offered preconception care and those not planning a pregnancy are offered advice on contraception.

This quality standard and potential indicators arising from it were discussed with NICE diabetes expert, Prof Kamlesh Khunti. The issues discussed and their outcomes are detailed in the table below.

Potential indicators	Questions/ issues for expert discussion	Expert comment
<p>The percentage of women with diabetes who have a record of a discussion regarding pregnancy and contraceptive intentions recorded in the preceding 15 months.</p> <p>The percentage of women with diabetes who have been given information and advice about pregnancy, conception or contraception tailored to their stated pregnancy and contraceptive intentions.</p> <p>The percentage of pregnant women with diabetes who had an HbA1c of <10% in the 6 months prior to the pregnancy</p>	<p>Is this too intrusive? Although it is a recommendation in CG63.</p> <p>Might need new codes.</p> <p>Need to define what is meant by ‘information and advice’ in each of these contexts. Would need to be able to link the advice code to the appropriate pregnancy intention code.</p> <p>Potential outcome marker for effective engagement with women with diabetes in preconception care. The recommendation in CG63 is for women to aim for an HbA1c of 6.1% and women with an HbA1c greater than 10% should be</p>	<p>It was felt that these were good potential indicators since increasing tight targets require greater use of medication which itself has teratogenic side effects e.g. statins- so counselling women pre and during and post is good clinical practice but that they needed the addition of an age range.</p> <p>He was not supportive of the last two and reiterated concerns about identifying the point at which pregnancy is confirmed.</p>

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consider the clarity, feasibility and validity of the indicators, to suggest improvements where possible and to highlight specific issues that would need to be explored during piloting. The following indicators were discussed in turn.

NICE Recommendation	Potential indicators	Questions/ issues for discussion
<p>Quality standard 8: Women of childbearing age with diabetes are regularly informed of the benefits of preconception glycaemic control and of any risks, including medication that may harm an unborn child. Women with diabetes planning a pregnancy are offered preconception care and those not planning a pregnancy are offered advice on contraception.</p> <p>From recommendation in CG63.</p>	<p>The percentage of women with diabetes under the age of 55 years who have a record of a discussion regarding pregnancy, conception and contraceptive intentions recorded in the preceding 15 months.</p> <p>The percentage of women with diabetes under the age of 55 years who have been given information and advice about pregnancy, conception or contraception tailored to their stated pregnancy and contraceptive intentions.</p> <p>The percentage of pregnant women with diabetes who had an HbA1c of <10% in the 6 months prior to the pregnancy being confirmed.</p>	<p>Might need new codes- check with Paul.</p> <p>Need to define what is meant by ‘information and advice’ in each of these contexts. Would need to be able to link the advice code to the appropriate pregnancy intention code.</p> <p>Potential outcome marker for effective engagement with women with diabetes in preconception care. The recommendation in CG63 is for women to aim for an HbA1c of 6.1% and women with an HbA1c greater than 10% should be advised against becoming pregnant.</p> <p>Is 6 months the right timeframe?</p> <p>Can we identify the point at which a pregnancy is confirmed?</p>

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	<p>The percentage of women with diabetes under the age of 55 years who have a record of information and counselling about contraception, conception and pregnancy in the preceding 15 months.</p>	<p>What do we do with women who have an unwanted pregnancy or pregnancy loss?</p> <p>Mirror of current epilepsy indicator. Would this be better as three separate indicators?</p>
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Summary of discussion

- GPs supported the general move, citing the small number of patients involved but the importance of managing diabetic medication according to contra- and conception needs.
- The issue of exception codes was raised in relation to cases of long-acting reversible contraception (LARCs), sterilisation, hysterectomies and miscarriages, and the appropriate frequency of repeating the question about pregnancy intentions in these cases
- It was agreed that it was more natural to ask patients about their intentions and tailoring advice accordingly, rather than providing blanket advice in all three areas & risk this indicator sounding to patients like a tick-box exercise.
- A significant measurement issue was raised in relation to the time of recording the reported pregnancy (in relation to suggested indicator 3).
- It was highlighted that patients with an HbA1c of <10% may not be cared for in primary care (in relation to suggested indicator 3).
- There was some discussion around the current QOF indicator EPILEPSY6, which the forth suggested diabetes/contraception indicator was modelled around. This, compared to the first & second suggested indicators, would not require the advice given to be necessarily tailored according to stated intentions (though it was likely to be in practice). It was agreed that tailoring advice represented an improvement in quality care, therefore that the first and second suggestions were

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technically better indicators, though the fourth suggestion was the more pragmatic option (requiring less free text information that would be difficult to code).

- There was some concern that an indicator specifying tailored advice (i.e. the second suggested indicator) would entail a 'double recording burden' and QOF assessors would be required to check that the advice given matched the code entered for the stated intention, thus potentially creating complex coding/free texting recording issues.

- It was suggested that the timeframe of 15 months should be added to the second suggested indicator.

- The first, second (with the added timeframe) and the fourth suggested indicators were now to be progressed to pilot.

Indicators for piloting post focus group

The percentage of women with diabetes under the age of 55 years who have a record of a discussion regarding pregnancy, conception and contraceptive intentions recorded in the preceding 15 months.

The percentage of women with diabetes under the age of 55 years who have been given information and advice about pregnancy, conception or contraception tailored to their stated pregnancy and contraceptive intentions in the preceding 15 months.

The percentage of women with diabetes under the age of 55 years who have a record of information and counselling about contraception, conception and pregnancy in the preceding 15 months.

Final indicators as piloted

1. The percentage of women with diabetes under the age of 55 years who have been given information and advice about pregnancy, conception or contraception tailored to their pregnancy and contraceptive intentions recorded in the preceding 15 months.
2. The percentage of women with diabetes under the age of 55 years who have a record of information and counselling about contraception, conception and pregnancy in the preceding 15 months.