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

Development feedback report on piloted indicator(s)

QOF indicator area: Erectile dysfunction in men with diabetes

Pilot period: 1st April – 30th September 2011

Potential output: Recommendations for NICE menu

Contents

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 male patients with diabetes with a record of being asked about erectile dysfunction in the preceding 15 months.
2. The percentage of male patients with diabetes who have a record of erectile dysfunction with a record of advice and assessment of contributory factors and treatment options in the preceding 15 months.

Number of practices participating in the pilot:	31
Number of practices withdrawing from the pilot:	2
Number of practices where staff were interviewed:	31

(24 GPs, 3 PNs, 2 PMs, 1 data manager and 2 group interviews (1 x GP, PN, PM and 1 x GP and PM))

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

Clarity

- Indicator wordings as stated, rated as clear and unambiguous by the RAM panel.

- The NHS IC has confirmed that they have been able to write Business Rules (and/or an Extraction Specification)**.**

Reliability[1] and Feasibility

Indicator	Feasibility	Reliability	Implementation
1	3	3	3
2	3	3	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

Comments	Response	NHSIC Summary
Are we sure that 'asked about 'is suitable for an indicator definition	The RAM panel were happy with this.	
Code for erectile dysfunction Please note that many of these codes have term of impotence rather than erectile dysfunction – might be worth considering additional Read Code requests for the October release.	Review of clusters required.	After review clusters may need updating and new codes may need requesting.
Should patients with established erectile dysfunction be included in indicator 1? Currently (in the pilot) they are included because indicator 1 is based on all men on the diabetes register.	Needs to be considered.	If patients with established erectile dysfunction are to be excluded from indicator 1 this would require an update to the current business rules.
Indicator 2 includes patients with either an ED or complaining of ED code. Is it possible to have an ED code which is superseded by a not/no longer complaining of ED code?	It is appropriate for this to be an annual check as a patient's erectile dysfunction may only resolve because they are on treatment so they will still require advice and assessment of contributory factors and treatment options.	

Acceptability

General comments

There was a generally positive response to the inclusion of erectile dysfunction (ED) as an issue to raise with men with diabetes. A majority of practices already asked about ED as part of their routine diabetes review.

Most GPs felt this was a quality of life issue and that they could improve this by raising what is, for many patients, a sensitive subject.

However, in three practices, there was some confusion over the purpose of the inclusion of this problem, specifically about whether it was solely a quality of life issue or whether its purpose was to initiate closer monitoring of potential circulatory deterioration.

The reported reaction of patients was mixed. A very small number of patients were 'affronted' by the line of questioning, but far more patients expressed relief at having been asked about a problem they had not themselves been able to raise. One practice reported that about a third of new patients admitted that ED was a problem, which equated to three new cases during the pilot period that may not have been identified previously.

Three practices reported that their approach was aided by providing information to patients prior to appointments. Two practices wrote to their patients informing them that ED would be discussed, and one of these practices mentioned that patients came in 'clutching the letter and that gave them a way to talk about it.' Another practice added ED to the information sheet, listing the aspects of care that would be covered, that they send out with the patient diabetes clinic appointment letter. One practice in a more remote area, where the practice nurse knew many of the patients in person, adopted a system where she gave each man a letter at the end of clinic that invited them to see the GP if they had a problem with ED that they wished to discuss. This system seemed to work well.

Acceptability indicator 1

A majority of practices (67.7%) thought that ED1 was a worthwhile indicator, representing good quality of care. Some highlighted that they had already been monitoring erectile dysfunction with their male patients with diabetes specifically as part of their annual review.

There were, however, a number of reservations about its inclusion in QOF, even amongst those who accepted the clinical value of the issue. These reservations included: the marginal difference that this made; whether this was a good use of QOF points, particularly given that ED assessments were routine in many practices; whether there were more important issues requiring attention and QOF points; and whether ED1 could stand alone without a subsequent step proposed in ED2.

Acceptability indicator 2

Opinions were divided about this indicator. Just over half (54.8%) thought ED2 should be included in QOF and just under a third (32.3%) thought that it should not. As with ED1 there was a general consensus about the value of this indicator area, but respondents were on the whole more ambivalent about ED2.

Some viewed this indicator as a natural follow-up to ED1, as it delivers quality care once the issue of ED has been raised. However, others thought that the level of detail in this indicator (the record of advice and assessment of contributory factors) was unnecessary on the basis that a good clinician should act upon ED1 accordingly.

Some deemed this unnecessary for QOF on the basis that it was already part of routine care. Others felt that patients wanting this level of care would raise the issue themselves, thus making ED2 an unnecessary addition to workload.

It should be noted that ED2 was not designed solely as a subsequent step to ED1, and therefore ED2 applied to all patients with a history or complaint of ED and the denominator for ED2 is not a subset of the numerator for ED1.

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.

Implementation

Assessment of piloting achievement

1. The percentage of male patients with diabetes with a record of being asked about erectile dysfunction in the preceding 15 months.

DIABETES INDICATOR 1	Baseline	Final
Number of Practices Uploading	**23**	**23**
Practice Population	**164,511**	**165,694**
Patients on Diabetes Register	**6,564**	**7,079**
Excluded regardless of whether they meet Numerator criteria	*less*	*less*
Female Patient	2,883	3,097
Excluded if they do not meet Numerator criteria		
Registered in last 3 months	37	26
Diabetes Exclusion in last 15 months	212	146
Diabetes Diagnosis within last 3 months	60	71
Total Exclusions	**3,192**	**3,340**
	equals	*equals*
Diabetes Indicator 1 Denominator	**3,372**	**3,739**
Diabetes Indicator 1 Numerator 1	**0**	**238**
Diabetes Indicator 1 Numerator 2	**0**	**306**
Diabetes Indicator 1 Numerator BOTH	**0**	**544**
Numerator as % of Denominator	**0.00%**	**14.55%**

2. The percentage of male patients with diabetes who have a record of erectile dysfunction with a record of advice and assessment of contributory factors and treatment options in the preceding 15 months.

DIABETES INDICATOR 2	Baseline	Final
Number of Practices Uploading	**23**	**23**
Practice Population	**164,511**	**165,694**
Patients on Diabetes Register	**6,564**	**7,079**
Excluded regardless of whether they meet Numerator criteria	*less*	*less*
Female Patient	2,883	3,097
No Erectile Dysfunction/Erectile Dysfunction Complaint	2,402	2,432
Excluded if they do not meet Numerator criteria		
Registered in last 3 months	8	5
Diabetes Exclusion in last 15 months	48	36
Erectile problem within last 3 months	26	110
Diabetes Diagnosis within last 3 months	5	3
Total Exclusions	**5,372**	**5,683**
	equals	*equals*
Diabetes Indicator 2 Denominator	**1,192**	**1,396**
Diabetes Indicator 2 Numerator	**0**	**210**
Numerator as % of Denominator	**0.00%**	**15.04%**

Summary

- An issue raised by practice staff related to the age of patients and whether there should be an upper age limit included in the wording of these indicators. Practice staff reported predictable scenarios where older patients felt that the line of questioning was unnecessary and uncomfortable and wondered whether older patients might be exception reported from the questioning in live QOF based on their age and/or frailty. However, a number of staff also recognised that this could be seen as ageist and reported cases where older patients had found ED to be a significant problem for them whilst other younger patients felt that ED was a problem that they could live with. Therefore, an age range could be difficult to decide upon and could exclude patients unfairly.
- A number of practices also raised concerns about the frequency of implementing this indicator, questioning whether it should form part of the annual diabetes review or whether the timescale for asking patients about ED could be extended to 2-3 years, given that this is not a clinically urgent issue and that more frequent assessment could be intrusive.
- Finally, it should be noted that the baseline figure is '0' despite many practices reporting that they already recorded ED because new Read codes were used.

Changes in practice organisation

General comments

There were some issues raised regarding the division of labour of these indicators, between GPs and PNs.

Specific comments indicator 1

There was a fairly even split between who conducted the work towards this indicator – whether GPS or PNs – though there were slightly more PNs asking about ED1 as part of regular diabetes monitoring.

Where ED was found to be a problem and nurses had to refer patients to GPs, this added to GP workload. In a very small number of these cases, there was some anxiety reported as a result of the transfer from one health professional to another. and caused some anxiety in patients.

Specific comments indicator 2

The advice and assessment of contributory factors in ED2 was predominantly GP led.

It was commented that, when raised, the issue had to be dealt with promptly as it was too sensitive to ask patients to come back, which meant that this resulted in longer consultation times and appointments running late. This might require longer diabetes clinic appointments.

Resource utilisation and costs

General comments

There were minimal resource utilisation and costs associated with these indicators. Identification of ED generally resulted in discussion of the problem, sometimes followed by a review of potentially contributory medication. A small number of practices (approximately 5) pursued a pharmacological treatment option, i.e. prescriptions of drugs for ED (phosphodiesterase type 5 (PDE-5) inhibitors))).

Specific comments indicator 1

Where PNs referred patients to GPs, there was a slightly increased workload.

Specific comments indicator 2

Where GPs were having to advise patients and assess contributory factors, there was a slightly increased workload.

Barriers to implementation

General comments

Many practices expressed some discomfort with asking about ED due to embarrassment and/or the risk of jeopardising the relationship between the patient and practice staff. Two practices reported instances of inappropriate responses from patients, where one patient became flirtatious and another used this as an opportunity to discuss his sex life, which the PN concerned felt uncomfortable about.

Two practices also raised concerns about patient confidentiality and sensitivity, highlighting the difficulty in raising the issue when a patient was accompanied by a third party (partner/children).

Specific comments indicator 1

This could require additional training for PNs to help them broach the topic in case of any discomfort.

Specific comments indicator 2

Diabetes reviews already take 30 minutes, so the level of detail required for ED2 would lengthen appointment times and add to workload.

Assessment of exception reporting

General comments

Some practices were unsure of whether to exception report if the patient was elderly and frail.

Assessment of potential unintended consequences
General comments

None.

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

None.

Overall recommendation

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

None.

Appendix A: Indicator details

Recommendation(s) presented and prioritised by the Advisory Committee

The Committee members were presented with the following recommendations, taken from NICE clinical guidance 66 (type 2 diabetes) and NICE clinical guidance 15 (type 1 diabetes):

NICE clinical guidance 66 (type 2 diabetes)	NICE recommendation 123 Review the issue of erectile dysfunction with men annually.
NICE clinical guidance 66 (type 2 diabetes)	NICE recommendation 124 Provide assessment and education for men with erectile dysfunction to address contributory factors and treatment options.
NICE clinical guidance 66 (type 2 diabetes)	NICE recommendation 125 Offer a phosphodiesterase-5 inhibitor (choosing the drug with the lowest acquisition cost), in the absence of contraindications, if erectile dysfunction is a problem.
NICE clinical guidance 66 (type 2 diabetes)	NICE recommendation 126 Following discussion, refer to a service offering other medical, surgical, or psychological management of erectile dysfunction if phosphodiesterase-5 inhibitors have been
NICE clinical guidance 15 (type 1 diabetes)	NICE recommendation 1.11.4.1 Men should be asked annually whether erectile dysfunction is an issue.
NICE clinical guidance 15 (type 1 diabetes)	NICE recommendation 1.11.4.2 A PDE5 (phosphodiesterase-5) inhibitor drug, if not contraindicated, should be offered where erectile dysfunction is a problem.
NICE clinical guidance 15 (type 1 diabetes)	NICE recommendation 1.11.4.3 Referral to a service offering other medical and surgical management of erectile dysfunction should be discussed where PDE5 inhibitors are not successful.

The Committee considered a briefing paper, including an Equality Impact Assessment form, on the topic of erectile dysfunction in men with Diabetes.

The NEC advised that there may be some definitional issues with the indicators and suggested developing indicators to include both type 1 and type 2 diabetes. Cost effectiveness analysis would be possible, as studies have taken place and there are publications available.

The External Technical Adviser said that there would be technical issues regarding the term 'offer'. For clarification, the NICE clinical consultant adviser advised that the term 'offer', in respect to clinical guideline recommendations, was used to emphasise shared decision making. It should in this case be interpreted as meaning 'should be given' and that it was therefore appropriate to measure actual receipt of drug therapy in any subsequent QOF indicator.

The Committee acknowledged that the impact of this condition on quality of life extends beyond those with erectile dysfunction. The Committee also noted that there is evidence that intervention improves quality of life. The Committee noted that there is evidence that the existence of erectile dysfunction can be a good predictor of CHD.

The Chair stated that this is an important area and added that there is a strong evidence base for this topic to go forward for further development.

Summary of Committee considerations (taken from the December 10 2011 Committee minutes)

The Committee agreed that recommendations 123, 124, 156 and 126 from NICE clinical guidance 66 (type 2 diabetes) and recommendations 1.11.4.1, 1.11.4.2 and 1.11.4.3 from NICE clinical guidance 15 (type 1 diabetes) given in the table above should be progressed for indicator development.

Pre-RAND indicators

1. The percentage of male patients with diabetes who have had a diabetes review that includes a record of being asked about erectile dysfunction in the preceding 15 months.
2. The percentage of male patients with diabetes with a record of being asked about erectile dysfunction in the last 15 months.
3. The percentage of male patients with diabetes who have a record of erectile dysfunction with a record of advice and assessment of contributory factors and treatment options in the preceding 15 months.
4. The percentage of male patients with diabetes with a record of erectile dysfunction who are (currently) treated with phosphodiesterase-5 inhibitor (unless a contraindication or side effects are recorded).
5. The percentage of male patients with diabetes with a record of erectile dysfunction who have a record of either unsuccessful treatment with phosphodiesterase-5 inhibitor or a contraindication (or side effects) are recorded, who have been subsequently referred for further investigation.

Final indicator as piloted

1. The percentage of male patients with diabetes with a record of being asked about erectile dysfunction in the preceding 15 months.

2. The percentage of male patients with diabetes who have a record of erectile dysfunction with a record of advice and assessment of contributory factors and treatment options in the preceding 15 months.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

QUALITY AND OUTCOMES FRAMEWORK (QOF) INDICATORS EQUALITY IMPACT ASSESSMENT FORM

As outlined in the QOF process manual NICE has a duty to take reasonable action to avoid unlawful discrimination and promote equality of opportunity. The purpose of this form is to document that equality issues have been considered in each stage of indicator development prior to reaching the final output which will be approved by Guidance Executive.

Taking into account **each** of the equality characteristics below the form needs to:

- Confirm that equality issues have been considered at **every stage** of the process (from topic suggestion and scoping, prioritisation, development including consultation and piloting)
- Confirm that equality issues identified in the topic suggestion and scoping stages have been considered in the prioritisation, development stages including consultation and piloting
- Ensure that the recommendations do not discriminate against any of the equality groups
- Highlight planned action relevant to equality
- Highlight areas where recommendations may promote equality

This form is completed by the NICE QOF internal team and the NICE external contractor (NEC) **for each new indicator that is developed at each of the stages (from topic selection and scoping, prioritisation, development including consultation and piloting, and also in the future for sets of indicators in clinical domains.** The form will be submitted with the final outputs to the Primary Care QOF Indicator Advisory Committee for validation, prior to sign off by NICE Guidance Executive

EQUALITY CHARACTERISTICS
Sex/gender • Women • Men
Ethnicity • Asian or Asian British • Black or black British • People of mixed race • Irish • White British • Chinese • Other minority ethnic groups not listed • Travellers
Disability • Sensory • Learning disability • Mental health • Cognitive • Mobility • Other impairment
Age[1] • Older people • Children and young people • Young adults 1. Definitions of age groups may vary according to policy or other context.
Sexual orientation & gender identity • Lesbians • Gay men • Bisexual people • Transgender people
Religion and belief
Socio-economic status Depending on policy or other context, this may cover factors such as social exclusion and deprivation associated with geographical areas (e.g. the Spearhead Group of local authorities and PCTs, neighbourhood renewal fund areas etc) or inequalities or variations associated with other geographical distinctions (e.g. the North/South divide, urban versus rural).
Other categories[2] • Refugees and asylum seekers • Migrant workers • Looked after children • Homeless people 2. This list is illustrative rather than comprehensive.

QOF INDICATORS EQUALITY IMPACT ASSESSMENT FORM: EACH STAGE OF DEVELOPMENT PROCESS

Topic title: Erectile Dysfunction
Development stage: Piloting of indicators

1. Have relevant equality issues been identified during this stage of development?

- Please state briefly any relevant issues identified and the plans to tackle them during development

None identified

2. If there are exclusions listed in the clinical or health improvement indicator areas (for example, populations, treatments or settings) are these justified?

- Are the reasons legitimate? (they do not discriminate against a particular group)
- Is the exclusion proportionate or is there another approach?

None identified

3. Do any of the recommendations make it impossible or unreasonably difficult in practice for a specific group to access a test or intervention?

- Does access to the intervention depend on membership of a specific group?
- Does a test discriminate unlawfully against a group?
- Do people with disabilities find it impossible or unreasonably difficult to receive an intervention?

No

4. Have relevant bodies and stakeholders been consulted?

- Have relevant bodies been consulted?
- Have comments from stakeholders that highlight potential for discrimination or promoting equality been considered in the final draft?

Yes by NICE

5. Do the indicators promote equality?

Please state if the indicator as described will promote equalities, for example by making access more likely for certain groups, or by tailoring the intervention to certain groups?

These indicators may raise issues around age.