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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

QUALITY AND OUTCOMES FRAMEWORK (QOF) INDICATOR DEVELOPMENT PROGRAMME

Consultation report on piloted indicator(s)

QOF indicator area: Serious mental illness: preconception care and advice

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

Potential output: Recommendations for NICE Menu

Contents

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Introduction

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

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

Indicator(s) included in the consultation

ID	Indicator	Evidence source
IND-8	The percentage of women with schizophrenia, bipolar affective disorder or other psychoses under the age of 45 years who have been given information and advice about pregnancy, conception or contraception tailored to their pregnancy and contraceptive intentions recorded in the preceding 12 months.	NICE clinical guideline 38: Bipolar disorder (2006) NICE clinical guideline 45: Antenatal and postnatal mental health (2007) SIGN guideline 131: Management of schizophrenia (2013)
IND-9	The percentage of women with schizophrenia, bipolar affective disorder or other psychoses aged 45 years or less who have been prescribed psychotropic medication in the preceding 12 months who have been advised of the risks of these medications during pregnancy in the preceding 12 months.	NICE clinical guideline 38: Bipolar disorder (2006) NICE clinical guideline 45: Antenatal and postnatal mental health (2007) SIGN guideline 131: Management of schizophrenia (2013)

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

- Indicators 8 and 9 relate to people with serious mental illness. Which of these indicators do stakeholders feel is the highest priority for the QOF?

Overarching comments on the indicators

Mixed comments were received from stakeholders regarding the proposed preconception care and advice indicators for serious mental illness.

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Some stakeholders including the Royal College of Psychiatrists commented that providing regular contraceptive advice to women of child bearing age receiving drug treatment for bipolar and schizophrenia was very important.

Conversely other stakeholders felt these indicators were not a priority for the QOF at this time.

A number of stakeholders including the General Practitioners Committee (GPC) of the British Medical Association (BMA) commented that a timeframe of 24 months would be more appropriate for both indicators. It was felt that people may simply ignore information if provided too often. Another stakeholder highlighted that people with serious mental illness may feel irritated by being asked this too often.

Considerations for the Advisory Committee

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

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

The Advisory Committee is asked to consider:

- Whether people with infertility due to sterilisation, hysterectomy, or current use of long acting-reversible contraceptives be excluded from this indicator.
- Whether these should be annual indicators or if a longer timeframe should apply e.g. 24 months.
- Whether all three elements of advice are required in order to achieve indicator IND-8.

Summary of responses: comments by indicator (IND-8)

> *The percentage of women with schizophrenia, bipolar affective disorder or other psychoses under the age of 45 years who have been given information and advice about pregnancy, conception or contraception tailored to their pregnancy and contraceptive intentions recorded in the preceding 12 months.*

The Care and Quality Commission (CQC) felt this is an important indicator as it will help inform work on how well services are provided for mothers, children and young people, and those experiencing mental health problems.

A stakeholder commented that this question would have to be asked in a sensitive, individualised manner to prevent it being viewed as stigmatising.

NHS England and NHS Employers commented that this may be a difficult indicator to achieve as it is focused on a hard to reach group. They therefore recommended that thresholds should reflect this. NHS England and NHS Employers also queried if all three elements of advice would be required to achieve this indicator.

The Royal College of Nursing commented that the indicator, because it is focussed on a diagnosis regardless of prescription of psychotropic medication, could adversely discriminate against women with severe mental illness. This is because they felt it gives the impression that the risks being addressed are more associated with the condition than the treatment and potentially reinforcing stigma associated with people with these conditions.

The GPC of the BMA also commented that these indicators should exclude people with infertility due to sterilisation, hysterectomy, or current use of long acting-reversible contraceptives.

Summary of responses: comments by indicator (IND-9)

> *The percentage of women with schizophrenia, bipolar affective disorder or other psychoses aged 45 years or less who have been prescribed psychotropic medication in the preceding 12 months who have been advised of the risks of these medications during pregnancy in the preceding 12 months.*

One stakeholder commented that this is an important indicator as it will ensure that the issue of pregnancy is addressed when medication is prescribed.

The Royal College of Nursing suggested that barriers to implementation of this indicator would be accuracy of records, accessibility to data and documentation and the availability of Family planning counselling in GP services tailored for women with mental health issues.

One stakeholder highlighted that a potential problem with this indicator is that the psychotrophic medication may not be picked up by the general practitioner. This would be the case for example if the medication was

prescribed by the specialist mental health services. Another stakeholder commented that only a small number of women would be eligible for inclusion within this indicator.

The GPC of the BMA also commented that these indicators should exclude people with infertility due to sterilisation, hysterectomy, or current use of long acting-reversible contraceptives.

Indicator specific question and responses

Stakeholders were asked:

> *Indicators 8 and 9 relate to people with serious mental illness. Which of these indicators do stakeholders feel is the highest priority for the QOF?*

Stakeholders made the following comments in relation to this question:

- NHS England and NHS Employers, Unity Health York, Dieticians in Obesity Management UK, a CCG, a GP practice and Pfizer Ltd felt indicator 8 was highest the priority. Dieticians in Obesity Management UK commented they preferred indicator 8 as it will cover all women with SMI including both those prescribed and not prescribed psychotropic medication.
- The Royal College of Psychiatrists, a foundation trust and the Royal College of Nursing felt indicator 9 was the highest priority. The foundation trust commented that they felt indicator 9 was the highest priority due to the potential risk to the foetus of psychotropic medication.

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Appendix A consultation comments

General comments

ID	Stakeholder organisation	Type of comment	Comment
IND-8	Corbett Medical Practice	General comments	I don't think a GP having a chat about pregnancy necessarily has proven benefit for this patient group
IND-8	Unity Health, YORK	General comments	I think that this should be a combined indicator within the mental health domain for fertile women So everyone under 50 (av age menopause is 52) in that denominator to be given advice about pregnancy and contraception
IND-8 -9	Forest Health Care GP surgery	General comments	Single entry after diagnosis. Not annual please! This turns reviews into very tick-box oriented and not appropriate to keep repeating information. It is a doctor's duty to advise patients of any medications that are prescribed that could cause problems in pregnancy. Once a year may not be appropriate! Poor indicator.
IND-8	Royal College of Psychiatrists	General comments	Overall suggested changes seem appropriate for Serious Mental Illness.

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IND-8	Lancashire Care NHS Foundation Trust	General comments	If the GP has a full understanding of an individual's circumstances re this topic then I feel it would be appropriate to discuss this matter. I am concerned though that unless it is handled in a sensitive, individualised manner it could be viewed as stigmatising.
IND-8	Wye Valley NHS Trust and Herefordshire & Worcestershire Diabetic Eye Screening Programme	General comments	No preference. Pregnancy increases risk of retinopathy progression. Retinopathy should be included as QOF indicator.
IND-8	Newark and Sherwood CCG	General comments	Agree
IND-8 - 9	The British Cardiovascular Society	General comments	As a cardiovascular disease interest group we are not qualified to comment.
IND-8	Care Quality Commission	General comments	Our new approach to inspection will look at how well services are provided for specific groups of people. Relevant groups within our early thinking also include: People in vulnerable circumstances, Mothers children and young people, and those experiencing

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			mental health problems. We support this proposal as additional insight in this area would be useful for our reviews.
IND-8-9	Sanofi	General comments	Sanofi broadly supports the introduction of these indicators. However we would also call for the reinstatement of: EP003 - 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. We understand the need to reduce box ticking and bureaucracy that is adding to the practice workload, and to allow GPs to exercise clinical judgment when caring for patients. However, it is critical that those taking antiepileptic medicines receive appropriate information and counselling about conception and pregnancy. The appropriate treatment of epilepsy during pregnancy is highly complex and uncontrolled seizures in pregnancy may pose substantial risks to the mother and unborn child. Sodium valproate remains one of the most effective treatments of generalised epilepsy and for many patients it is the only medicine that will provide adequate seizure control. Since their introduction in 1989, patient package leaflets for sodium valproate have referred patients to the need to discuss treatment with their doctor in the event that the patient was planning a pregnancy. A decision to use sodium valproate by women of child-bearing age should only be taken after a very careful evaluation, between the patient and her treating physician, if the benefits of its use outweigh the risks to the unborn child. This decision is to be taken before Epilim is prescribed for the first time as well as before a woman already treated with sodium

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			valproate is planning a pregnancy. Doctors treating patients with epilepsy are well aware of possible risks to the foetus arising from the use of anti-epileptic drugs in pregnancy. Reinstating indicator EP003 will mean GPs continue to have the incentive to ensure this important process takes place and that the information is recorded.
IND-8-9	Individual stakeholder	General comments	Every 24 months seems an appropriate time frame rather than 12. When you speak to patients it is clear that a lot of them simply ignore information if it is sent out too regularly to them. This happens across all areas and needs to be recognised as a fact and a factor even if difficult to believe or understand for the decision makers.
IND-9	Unity Health, YORK	General comments	Any prescriber should review this when issuing prescriptions Also consider the actual numbers who would be included (very small numbers for most practices)
IND-9	Lancashire Care NHS Foundation Trust	General comments	This may not be picked up if eg clozaril is prescribed by the specialist mental health services
IND-9	Newark and Sherwood CCG	General comments	Specify 16-45y

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Response to questions 1-4

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

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

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

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

ID	Stakeholder organisation	Type of comment	Comment
IND-8	General Practitioners Committee, British Medical	Response to questions 1-4	These indicators should exclude those with infertility due to sterilisation, hysterectomy, or current use of long-acting reversible contraceptives. We would consider the inclusion of this indicator with the caveat above, and if other existing QOF indicators of less priority were removed from QOF, but also is the frequency was more than 12 months. Repeatedly asking

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	Association		women the same question every year can appear insulting to many.
IND-8-9	Pfizer Ltd	Response to questions 1-4	There are no obvious barriers to implementation, but consideration could be given to how contraceptive use could be made easier for the patient. In particular, we would advise that the guidance specifically includes advice on the use of Long Acting Reversible Contraceptive (LARCs). In the CEU guidance on progesterone injectable contraceptives, there is no restriction on use in depressive disorders. Prescribing evidence suggests that the prescriber might be more likely to recommend the Oral Contraceptive Pill (OCP)as current practice favours the OCP over LARCs in a general population (47 % OCP Vs 30% LARCs) . For the same reasons long acting anti-psychotics were developed to overcome challenges of adherence in these patient groups, it is likely that adherence to contraceptive medication use in mental health patients might be similarly challenging. In this case it could result in increased risk of unintended pregnancy. NICE considers that LARC methods are more effective than oral contraceptives because they demand much less – or are independent of the need for – adherence. NICE goes on to state that LARCs are more effective than OCPs at reducing unintended pregnancies and more cost effective. This group of patients is already vulnerable and unintended pregnancy is likely to have much graver consequences for them, their babies and their carers. Hence it is more important they are given the most effective contraceptive advice.

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IND-8	Royal College of Nursing	Response to questions 1-4	The indicator seems to focus on the diagnosis of psychoses as necessitating information and advice, rather than whether the patient is prescribed psychotropic medication – therefore could be adversely discriminating against people with severe mental illness – giving the impression that the risks being addressed are more associated with the condition than the treatment, potentially reinforcing stigma associated with people with these conditions. Barriers: Accuracy of records, accessibility to data and documentation. It will need close collaboration with CPN.
IND-8	National Obesity Forum	Response to questions 1-4	NOF is concerned that the proposed new indicator on mental health will have the unintended consequence of causing health care practitioners to, potentially, not consider an individual's full range of health needs. NOF is extremely disappointed that the elements of the indicator which required GPs to identify the percentage of mentally ill individuals with cholesterol: hdl ratio, blood glucose and a record of BMI have been retired. It is important to record the percentage of individuals who fall into these categories so that clinicians have a way of identifying those who may need assistance with managing their weight. This is especially important since the ability to assist overweight and obese individuals is dependent on those individuals presenting themselves. Omitting those aspects of the

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			mental health indicator which considered lifestyle interventions could, therefore, lead to GPs overlooking weight issues that mentally ill individuals may have in order to meet the other targets set out in this proposed indicator, thereby creating a gap in the provision of care in some instances.
IND-8	NHS England and NHS Employers	Response to questions 1-4	Reasonable and achievable. Low bench mark required as hard to reach group. Also some episodes of psychosis are isolated and how long would diagnosis remain as active? - Wording consistency - Exception vs. achievement? Will all three elements of advice be required in order for achievement?
IND-8	Healthwatch Bucks	Response to questions 1-4	Many physical issues for people with serious mental health issues are overlooked and the of contraception and pregnancy advice and support is such an important issue that both these indicators are important. This indicator is the more important but ..
IND-9	General Practitioners Committee, British Medical Association	Response to questions 1-4	These indicators should exclude those with infertility due to sterilisation, hysterectomy, or current use of long-acting reversible contraceptives.

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IND-9	Royal College of Nursing	Response to questions 1-4	Barriers: Accuracy of records, accessibility to data and documentation Availability of Family planning counselling in GP services tailored for women with mental health issues Ethical issue - Mental Heath capacity versus patient choice; basic human rights
IND-9	NHS England and NHS Employers	Response to questions 1-4	Reasonable and achievable - Wording consistency
IND-9	Healthwatch Bucks	Response to questions 1-4	The wellbeing of pregnant women and their unborn children must be reinforced and the indicator will ensure that the issue of pregnancy is in the forefront of minds when medication is prescribed

Response to question 11

11. Indicator 8 and 9: From a patient perspective do stakeholders consider annual provision of pregnancy, conception or contraception advice to people with SMI appropriate?

ID	**Stakeholder organisation**	**Type of comment**	**Comment**

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IND-8-9	Corbett Medical Practice	Question 11	No
IND-8-9	Corbett Medical Practice	Question 11	N/A
IND-8-9	Unity Health, YORK	Question 11	Yes just like epilepsy No different
IND-8-9	Newark and Sherwood CCG	Question 11	Yes
IND-8-9	General Practitioners Committee, British Medical Association	Question 11	We do not believe this should be done annually and when done so in other QOF indicators it was often not appreciated by patients.
IND-8-9	Forest Health Care GP surgery	Question 11	I would be very irritated if I were a patient by repetition of this.
IND-8-9	Dietitians in Obesity	Question 11	Yes.

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	Management UK		
IND-8-9	Royal College of Psychiatrists	Question 11	Yes. Providing regular contraceptive advice to women of child bearing age receiving drug treatment for bipolar and schizophrenia is most commendable. However, what about other groups? From a child welfare perspective women who abuse street drugs and alcohol are a much bigger group. For example while 1 in a 100 women of child bearing age have schizophrenia, whereas 1 in 10 have an alcohol problem. Furthermore, parental substance misuse presents more risks to the child which in turn are harder to detect and manage. For example parental substance misuse is a major feature in 2 in 3 care proceedings.Engagement and compliance with contraceptive advice amongst substance misusing women is likely to be disappointing. However that doesn't mean it is not worth targeting.
IND-8-9	Whalebridge Practice, Swindon	Question 11	It can be appropriate based on patient needs and circumstances. However it is probably unhelpful to set a target here as sensitivity to social and personal circumstances is vital.
IND-8-9	Wye Valley NHS Trust and Herefordshire & Worcestershire Diabetic Eye	Question 11	No opinion. Broadly in favour

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	Screening Programme		
IND-8-9	Pfizer Ltd	Question 11	This would depend on the type of contraceptive used. LARCs only require bi-annual or less frequent review, but some still need to be seen every 12 weeks for their injection. Given these frequencies of visit to a health professional, these products would make it easier for prescribers, carers and patients to be confident in their adherence and most likely to avoid unintended pregnancy.
IND-8-9	Royal College of Nursing	Question 11	Yes it is very important to include as some psychotropic medications may affect foetus.
IND-8-9	The British Cardiovascular Society	Question 11	As a cardiovascular disease interest group we are not qualified to comment.
IND-8-9	NHS England and NHS Employers	Question 11	Probably too often but should allow clinical assessment of frequency and perhaps minimum of three years.

Response to question 12

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12. Indicator 8 & 9: Indicators 8 and 9 relate to people with serious mental illness. Which of these indicators do stakeholders feel is the highest priority for the QOF?

ID	Stakeholder organisation	Type of comment	Comment
IND-8-9	Unity Health, YORK	Question 12	The first ie 8
IND-8-9	Newark and Sherwood CCG	Question 12	8
IND-8-9	General Practitioners Committee, British Medical Association	Question 12	Patients actively being treated with psychotropic medication should be the priority.
IND-8-9	Forest Health Care GP surgery	Question 12	Neither.
IND-8-9	Dietitians in Obesity	Question 12	Of these two options, indicator 8 will cover all women including those prescribed and nor prescribed psychotropic medication. For this reason indicator 8 is in our view the highest

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	Management UK		priority.
IND-8-9	Royal College of Psychiatrists	Question 12	9
IND-8-9	PHE Midlands and East Regional Team	Question 12	Have indicators on prevention and management of physical illness amongst this group of people been included elsewhere? For me the critical issue is the extent to which people with mental illness and learning disabilities have access to health promotion, disease prevention and high quality diagnostic & treatment facilities. Clearly, pregnancy is one such issue where access maybe poor but there are many of these which need to be proactively tackled. The risk which is now beginning to become obvious is that many people with learning disabilities and mental illness have health destructive lifestyles and the consequent LTCs.
IND-8-9	Lancashire Care NHS Foundation Trust	Question 12	I would suggest indicator 9 due to the potential risk to the foetus of psychotropic medication. However I would expect that the prescriber of the medication should take responsibility for having this discussion.
IND-8-9	Whalebridge Practice, Swindon	Question 12	I would prefer 8 to 9. Nine may make the GP sound like a broken record year after year.

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IND-8-9	Wye Valley NHS Trust and Herefordshire & Worcestershire Diabetic Eye Screening Programme	Question 12	No preference
IND-8-9	Pfizer Ltd	Question 12	We would consider indicator 8 to have the highest priority as it is potentially more comprehensive with a focus on empowering the patient through provision of information. This is vital for the patient to make an informed decision and increase the likelihood of adherence. It would be further improved if it gave a steer to prescribers to give consideration to the use of LARCs.
IND-8-9	Royal College of Nursing	Question 12	Indicator 9
IND-8-9	The British Cardiovascular Society	Question 12	As a cardiovascular disease interest group we are not qualified to comment.

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IND-8-9	NHS England and NHS Employers	Question 12	8