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

### Development feedback report on piloted indicator(s)

QOF indicator area: Depression

Pilot period: 1<sup>st</sup> October 2011–30<sup>th</sup> April 2012

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 patients with depression who have had a bio-psychosocial assessment by the point of diagnosis
- 2. The percentage of patients with a new diagnosis of depression (in the preceding 1 April to 31 March) who have been reviewed within 10-35 days of the date of diagnosis

Number of practices participating in the pilot: 34

Number of practices withdrawing from the pilot: 4

Number of practices where staff were interviewed: 30

(33 GPs, 7 Practice Nurses, 16 Practice Managers, 1 Health Care Assistant, 2 Administrative Managers= 59 primary care staff most involved in the QOF pilot)

### 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<sup>1</sup> and Feasibility

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

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:

<sup>1.</sup> No problems to implement in live with other indicators

Minor re-work before it can go live with other indicators
 Major re-work but do-able without recourse to anyone outside of the process

<sup>4.</sup> Major considerations to be made before the indicator can go live - possibly need to speak to CFH / suppliers

<sup>5.</sup> Not feasible

Comments	Response	NHSIC Summary
The current depression register in live QOF looks for the latest first or new episode after 01/04/2006 and before the REF_DAT, what should be used for the pilot	The pilot looked for the latest first or new episode after 01/10/2011 and before the REF_DAT	The date of the live QOF register may need to change.
For the depression indicators, surely we don't need to handle "depression resolved"  Indicator 1 is interested in the bio-psychosocial assessment before diagnosis – so if the presence of a depression resolved code after diagnosis is immaterial.  Likewise for indicator 2 where one is interested in a review after 10-35 days, the presence of an indicator resolved code added after 42 days is likewise immaterial. What to do if added after 20 days though?	Maybe pragmatically we choose not to handle 'resolved' in the rules, but discuss the issues with the practices  If this makes into a 'recommendation for live', then maybe we flag it up in negotiations.	The current live depression register excludes patients from the register if they have a record of 'depression resolved' after their latest episode of depression.  Will the register need to deal with 'depression resolved'?
Indicator 1 - What is the timescale for the bio- psychosocial assessment and can it only be before the diagnosis of depression?	Bio-psychosocial assessment must be before or on day of assessment.	For the pilot the bio-psychosocial assessment could occur up to 3 months before the diagnosis of depression. This may need to change for live QOF.

### Acceptability

### General comments

These indicators were generally viewed as an improvement on the existing depression indicators and as being more reflective of good clinical practice and NICE guidance.

### Acceptability indicator 1

Practices were divided as to whether this indicator should be considered for inclusion in QOF with just less than half supportive of its inclusion, approximately a third against its inclusion, 4 were ambivalent and 1 did not express a view either way.

Despite these mixed views regarding inclusion in QOF, most practices felt that this indicator reflected their current clinical practice. The focus upon a qualitative and more holistic approach to patient assessment was generally viewed positively:

"Um I think the bio-psychosocial assessment, is a lot more ... you can incorporate it into your consultation, it's a lot less intrusive and um, and it's something which you would naturally do anyway, it's not much of a deviation from what feels the best for your patient" (GP, Practice ID: 2).

However, two practices preferred the structure offered by the current quantitative assessment tools:

"I think for me, personally, I like structure, and although I'm not terribly keen on tick boxes it does help to have a list and a structure" (GP, Practice ID: 8).

Eight practices commented on the different, but potentially complimentary, nature of this indicator and the existing DEP6 indicator. Their comments suggest that this indicator could be considered for inclusion in QOF alongside the existing DEP6<sup>2</sup> rather than just as a replacement:

"Erm, I'm not sure it's an improvement. I just think it's different. ... when you do PHQ9 ... it's almost about criteria for depression whilst this is ... more about how, how it impacts on the patient..." (GP, Practice ID: 6).

"I think they've each got their own role, erm, so one is not exclusively used without the other, but if you've got the bio-psychosocial assessment, erm that is part of the assessment, and the PHQ9 is also part of the assessment" (GP, Practice ID: 17).

Others noted the utility of the quantitative tools:

"And to be fair, the PHQ9 has been ... it's a useful barometer of severity" (GP, Practice ID: 20)

"I mean I find the PHQ9, having been a little bit sceptical about those sort of things to start with, they are actually quite useful in that you can demonstrate to the patients an improvement and quite often you can demonstrate to the patient that they actually

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<sup>&</sup>lt;sup>2</sup> DEP6: In those patients with a new diagnosis of depression, recorded between the preceding 1 April to 31 March, the percentage of patients who have had an assessment of severity at the time of diagnosis using an assessment tool validated for use in primary care.

are depressed when they don't think they are. So it's quite a useful tool" (GP, Practice ID: 16).

Some practices felt that inclusion of this indicator, which of itself codifies existing good practice has the potential to improve quality of care across the board:

"I mean we, we, sort of, do it informally, but obviously ... having then introduced it in the pilot, er, you're formalising what we would normally do, which is, sort of, the whole essence of QOF" (GP, Practice ID: 6).

Conversely, others expressed concern that this formalisation could be unhelpful to the doctor-patient relationship:

"...I think there's a definite risk of, er, formalising something inappropriately and might put up barriers between the doctor and the patient rather than actually being helpful" (GP, Practice ID: 16).

"I think you end up spending all your time asking the questions and not seeing how the patient really is" (GP, Practice ID: 22).

Practices identified two main issues which influenced their perception of the acceptability of the indicator: firstly, the time required to undertake the bio-psychosocial assessment and secondly, recording and auditing concerns.

Practices differed in their views as to whether the bio-psychosocial assessment increased their workload.

The content of the bio-psychosocial assessment in the pilot, based on NICE guidance was:

- 1. personal history of depression
- 2. family history of mental illness
- 3. co morbid mental health or physical disorders
- 4. any past history of mood elevation (to determine if the depression may be part of a bipolar disorder)
- 5. any past experience of, and response to, treatments
- 6. the quality of interpersonal relationships- partner/children/parents
- 7. living conditions
- 8. assessment of social support
- 9. awareness of sources of help
- 10. employment/financial worries
- 11. alcohol and substance use current and past
- 12. current symptoms including duration and severity (the use of formal assessment questionnaires such as PHQ9/HADS/BDI2 is encouraged but **not** mandated).

- 13. *suicidal ideation* (because suicide accounts for nearly 1% of all deaths and nearly two-thirds of this figure occur in people with depression).<sup>3</sup>
- 14. discussion of patient's views of the cause of their symptoms
- 15. discussion of treatment options
- 16. discussion of need for follow up

This information could be gathered in the three months prior to the diagnosis (an arbitrary timeframe that was explored during pilot QOF visits) as clinically appropriate, and then recorded with a single Read code entry no later than the date of diagnosis.

Many practices felt that they routinely considered these issues so the only change in practice for them was in recording that they had done this. The content of the assessment was generally felt to be clinically relevant, but possibly over comprehensive for some patients. There was no consensus amongst practices as to which elements were essential for all patients, although the 11 elements highlighted in italics were the ones seen as part of current 'standard practice'.

Some practices were also concerned that existing consultation times would be inadequate for the completion of the assessment and estimated that they would need a minimum of 20 minutes per patient, which would result in surgeries running late.

One third of practices expressed a very clear opinion around time frames for collecting BPS data; however there was no consensus over what this time frame might be. Views ranged from all data collected at time of diagnosis to up to six months before. The modal value (20% of practices) was that this information should all be recorded in the same consultation.

A fifth of practices expressed concern as to how this indicator would be recorded and evaluated, **even if** supportive of the intent of the indicator:

"... I think these standards are excellent but it's how you're going to measure it without turning the consultation into [a] data gathering exercise which is, becomes quantifiable and detract[s] from the consultation ..." (GP, Practice ID: 18).

"I think in theory it's good, but in practice it's a matter of getting the code in. How do you identify it's actually been done? ... What can you say is adequate? ... Erm and how do you prove it? How do you document it? How do you audit it?" (GP, Practice ID: 13).

Concerns were expressed that if practices were asked to record each element of the assessment separately, that this could become a tick box exercise and would prevent tailoring of the assessment to individual patient need:

"... what I'm concerned with is that that [individual read code recording for each element of the assessment] will then become a tick box exercise, is that we will have to recode that we've done all 16 things and if we haven't done all 16 things we won't get paid 'cause you'll set a target won't you ..." (GP, Practice ID: 18).

<sup>&</sup>lt;sup>3</sup> Sartorius N. The economic and social burden of depression. *Journal of Clinical Psychiatry*, 2001; 62 (Suppl. 15): 8–11.

However this was balanced against other concerns that the indicator was open to gaming if only a single overarching code was required, with the assessment detail being entered as free text:

"Well you'd have people saying they've done it, in which case it then becomes meaningless 'cause how can you measure it?" (GP, Practice ID: 18).

"Er, I think if it was just like one Read code I'd, I'd taken the bio-psychosocial history, you know, for, I don't think it would be that useful because you have, you have people that have taken a very, very detailed bio-psychosocial history, have spent a lot, a lot of time trying to understand ... And then you'll get other people who'll just say 'how's things at home, oh okay' and move on and not even, not eve, er, engage with the answer and just say 'kerching I've done that'" (GP, Practice ID: 21).

### Acceptability indicator 2

Just over three quarters of practices were supportive of this indicator being considered for inclusion in QOF, a further 5 practices were ambivalent but only 1 practice was against its inclusion. One practice did not express a view either way.

The majority of practices felt that the time frame for review of 10-35 days was more reflective of their current clinical practice than the existing DEP74 and would be easier to implement.

"I always refer, review, my patients a minimum of two weeks from diagnosis" (GP, Practice ID: 6).

"It's closer to reality and it's closer to providing optimal care" (GP, Practice ID: 22).

A qualitative review of the patient was also felt to be more patient centred than the current DEP7:

"They [patients] think I am more interested in the questionnaire than in their condition, four weeks later, how are they feeling, yeah, so I think it would be better to remove that second PHQ9" (GP, Practice ID: 10).

### 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.

The difference in timing between this indicator and that which was piloted is that the timing of this review starts from the date of the initial PHQ9 assessment which may be the same date as the depression diagnosis or up to 28 days later. The timing of the piloted indicator starts from the date of the depression diagnosis.

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<sup>&</sup>lt;sup>4</sup> DEP7: In those patients with a new diagnosis of depression and assessment of severity recorded between the preceding 1 April to 31 March, the percentage of patients who have had a further assessment of severity 2-12 weeks (inclusive) after the initial recording of the assessment of severity. Both assessments should be completed using an assessment tool validated for use in primary care.

### 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 patients with depression who have had a bio-psychosocial assessment by the point of diagnosis

DEPRESSION INDICATOR 1	Baseline	Final
Number of Practices Uploading	12	12
Practice Population	84,698	85,057
0	0	0
Patients on Depression Register	4,540	4,992
Excluded regardless of whether they meet Numerator criteria	less	less
Depression Diagnosis dated too early	4,162	4,629
Excluded if they do not meet Numerator criteria		
Registered within last 3 months	10	16
Exclusion within last 15 months	12	16
Diagnosis within last 3 months	106	177
Total Exclusions	4,290	4,838
0	equals	equals
Depression Indicator 1 Denominator	250	154
Depression Indicator 1 Numerator	0	5
Numerator as % of Denominator	0.00%	3.25%

This was a new Read code so baseline levels are 0%.

2. The percentage of patients with a new diagnosis of depression (in the preceding 1 April to 31 March) who have been reviewed within 10-35 days of the date of diagnosis

DEPRESSION INDICATOR 2	Baseline	Final
Number of Practices Uploading	12	12
Practice Population	84,698	85,057
0	0	0
Patients on Depression Register	4,540	4,992
Excluded regardless of whether they meet Numerator criteria	less	less
Depression Diagnosis dated too early	4,162	4,629
Excluded if they do not meet Numerator criteria		
Registered within last 3 months	10	16
Exclusion within last 15 months	12	16
Diagnosis within last 3 months	106	178
Total Exclusions	4,290	4,839
0	equals	equals
Depression Indicator 2 Denominator	250	153
Depression Indicator 2 Numerator	0	14
Numerator as % of Denominator	0.00%	9.15%

This was not a new Read code but baseline levels are 0% reflecting probable lack of routine recording in primary care during these timeframes.

### Summary

### Changes in practice organisation

Specific comments indicator 1

No specific comments.

Specific comments indicator 2

Some practices felt that this might reduce the DNA rate for depression follow-up and the associated administrative work in chasing them up.

During the RAND panel the potential for this review to be completed as a telephone consultation was discussed, following on from the widely cited work of Simon *et al.*<sup>5</sup>. The consensus of the RAND group was that the review should be a face to face consultation, but that this should be explored further during piloting. The majority view (70%) of the pilot practices was that this might be suitable for completion through a telephone consultation subject to certain caveats, including how well they knew the patient, the severity of the depression, that it should be completed by a clinician and the experience of the clinician completing the review. However the caveats themselves may not work within QOF, since they are hard to define clearly and to audit.

<sup>&</sup>lt;sup>5</sup> Simon G, Ludman Y, Tutty S et al. Telephone psychotherapy and telephone care management for primary care patients starting antidepressant treatment. *JAMA* 2004; 292: 935-42.

"If you have been selective, if you know the patient, which is the normality of general practice, yeah, if you know your patient, you'd know. I'm quite comfortable with it" (GP, Practice ID: 7).

"I don't have a problem with telephone follow up but again, it's you know, does it then become a tick box exercise where receptionist phones the up and goes 'are you alright, fine, ok', tick phone call made" (GP, Practice ID: 18).

Those who thought this should always be performed as a face-to-face review stressed the importance of observing body language of this patient group.

"I would rather prefer face to face. We definitely need to read the face as well" (GP, Practice ID: 11).

"I think the first review should be face to face. Erm, subsequent ones I would be happy to do on [the] telephone, but I think the first one should be face to face, because you cannot pick up non-verbal cues on the telephone..." (GP, Practice ID: 3).

### Resource utilisation and costs

### Specific comments indicator 1

A number of practices expressed concern about the length of time required to undertake a comprehensive bio-psychosocial assessment, with some practices estimating a minimum of 20 minutes being required.

#### Specific comments indicator 2

Assuming that this indicator replaced the existing DEP7<sup>6</sup> then it was felt that there would be no increase in workload.

### **Barriers to implementation**

### Specific comments indicator 1

Two potential barriers to implementation were identified. Firstly, the time required to undertake a bio-psychosocial assessment and secondly, ensuring that the indicator can be reliably monitored by QOF assessors.

### Specific comments indicator 2

No specific comments.

<sup>&</sup>lt;sup>6</sup> DEP7: In those patients with a new diagnosis of depression and assessment of severity recorded between the preceding 1 April to 31 March, the percentage of patients who have had a further assessment of severity 2-12 weeks (inclusive) after the initial recording of the assessment of severity. Both assessments should be completed using an assessment tool validated for use in primary care.

### **Assessment of exception reporting**

Specific comments indicator 1

No specific comments.

Specific comments indicator 2

No concerns were raised about exception reporting. It was however noted that the time frame of 10-35 days was more in keeping with the time in which practices reviewed these patients which could help keep exception reporting to a minimum.

### Assessment of potential unintended consequences

### General comments

No specific comments.

### 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 DEP6 and DEP7.

DEP6: In those patients with a new diagnosis of depression, recorded between the preceding 1 April to 31 March, the percentage of patients who have had an assessment of severity at the time of diagnosis using an assessment tool validated for use in primary care.

DEP7: In those patients with a new diagnosis of depression and assessment of severity recorded between the preceding 1 April to 31 March, the percentage of patients who have had a further assessment of severity 2-12 weeks (inclusive) after the initial recording of the assessment of severity. Both assessments should be completed using an assessment tool validated for use in primary care.

The first piloted indicator (bio-psychosocial assessment) is presented here for consideration either in addition to, or as a replacement for, the existing DEP6.

The second piloted indicator (review in 10-35 days) is presented as a potential replacement to the current DEP7.

### 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 1

The percentage of patients with a <u>new</u> diagnosis of depression <u>in the preceding 1<sup>st</sup> April to 31<sup>st</sup> March</u> who have had a bio-psychosocial assessment by the point of diagnosis.

Should the committee wish to recommend this indicator their advice is sought on the following issues:

- 1. The acceptable timeframe for the collection and recording of the elements of the bio-psychosocial assessment.
- 2. Whether this indicator should be recommended as an addition to the Depression domain or as a replacement of the existing DEP6
- 3. Whether the elements of the assessment should be recorded and coded individually or whether an overarching code should be used, supported by free text. If the latter option is preferred, guidance is sought on the elements of the assessment considered to be mandatory for all patients.

### Suggested amendments to indicator 2

Should the committee wish to recommend this indicator their advice is sought as to whether this should be as part of a face-to-face consultation only.

### **Appendix A: Indicator details**

### Recommendation(s) presented and prioritised by the Advisory Committee

The Committee were presented with papers that highlighted the low quality of the evidence base underpinning current QOF depression indicators focused on assessment of severity of depression at diagnosis and its use to inform treatment.

### NICE clinical guideline recommendations

National Clinical Practice Guideline 90. *Depression: the treatment and management of depression in adults* (updated edition) National Collaborating Centre for Mental Health commissioned by the National Institute for Health & Clinical Excellence. The British Psychological Society and The Royal College of Psychiatrists. 2010.

### NICE recommendation 5.2.13.6

When assessing a person who may have depression, conduct a comprehensive assessment that does not rely simply on a symptom count. Take into account both the degree of functional impairment and/or disability associated with the possible depression and the duration of the episode.

### NICE recommendation 5.2.13.7

In addition to assessing symptoms and associated functional impairment, consider how the following factors may have affected the development, course and severity of a person's depression:

- any history of depression and co morbid mental health or physical disorders
- any past history of mood elevation (to determine if the depression may be part of bipolar disorder)
- any past experience of, and response to, treatments
- the quality of interpersonal relationships
- living conditions and social isolation.

### NICE recommendation 5.2.13.11

Always ask people with depression directly about suicidal ideation and intent. If there is a risk of self-harm or suicide:

- assess whether the person has adequate social support and is aware of sources of help
- arrange help appropriate to the level of risk
- advise the person to seek further help if the situation deteriorates

## Summary of Committee considerations (taken from the June 2011 Committee minutes)

The Committee asked NICE to consider a review of the recommendations contained in the relevant NICE clinical guidelines on depression with a view to developing high quality evidence based indicators for consideration for the QOF.

### **Pre-RAND** indicators

- 1: The percentage of patients with depression who have had a biopsychosocial assessment by the point of diagnosis (i.e. recorded on the day of diagnosis)
- 1a: The percentage of patients with depression who have had a bio-psychosocial assessment by the point of diagnosis<sup>7</sup>
- 2: The percentage of patients with a new diagnosis of depression (in the preceding 1 April to 31 March) and who are prescribed an antidepressant who have been reviewed within 4 weeks of starting treatment
- 3: The percentage of patients with a new diagnosis of depression (in the preceding 1 April to 31 March) and who are prescribed an antidepressant who have been reviewed within 5 weeks of starting treatment
- 3a: The percentage of patients with a new diagnosis of depression (in the preceding 1 April to 31 March) who have been reviewed within 10-35 days of the date of diagnosis

### Final indicators as piloted

- 1. The percentage of patients with depression who have had a bio-psychosocial assessment by the point of diagnosis
- 2. The percentage of patients with a new diagnosis of depression (in the preceding 1 April to 31 March) who have been reviewed within 10-35 days of the date of diagnosis

<sup>&</sup>lt;sup>7</sup> Indicators in italics text reflect modifications to wording made by the panel during round 2 Primary Care Quality and Outcomes Framework Advisory Committee 13<sup>th</sup> and 14<sup>th</sup> June 2012

## NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

### **Quality and Outcomes Framework Programme**

**QOF topic: Depression** 

**Output: Recommendations for the NICE menu** 

### Introduction

- 1. As outlined in the QOF process manual, NICE has a duty to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people from different groups. The purpose of this form is to document the consideration of equality issues in each stage of the development process before reaching the final output that will be approved by the NICE Guidance Executive. This equality analysis is designed to support compliance with NICE's obligations under the Equality Act 2010 and Human Rights Act 1998.
- 2. Table 1 lists the equality characteristics and other equality factors NICE needs to consider, i.e. not just population groups sharing the 'protected characteristics' defined in the Equality Act but also those affected by health inequalities associated with socioeconomic factors or other forms of disadvantage. Taking into account each of the equality characteristics in Table 1, the form should be used to:
- confirm that equality issues have been considered
- ensure that the indicator statements do not discriminate against any of the equality groups
- highlight planned action relevant to equality
- highlight areas where indicator statements may advance equality of opportunity
- 3. This form is completed by the NICE quality systems team and will be completed at each stage within the development process:
  - Prioritisation of areas for new indicator development
  - Piloting of indicators
  - Public consultation of piloted indicators
  - Review of existing indicators in the clinical domains

The initial prioritisation may identify equalities associated with a topic area whereas piloting and consultation will assess equalities against specific indicators. For further information on the development of specific indicators please refer to the <a href="committee">committee</a> outputs page and the <a href="NICE menu of indicators">NICE menu of indicators</a>.

### Table 1

Protected characteristics
Age
Disability
Gender reassignment
Pregnancy and maternity
Race
Religion or belief
Sex
Sexual orientation
Other characteristics
Socio-economic status
Depending on policy or other context, this may cover factors such as social exclusion and deprivation associated with geographical areas or inequalities or
variations associated with other geographical distinctions (e.g. the North/South
divide, urban versus rural).
Other categories

Other groups in the population experience poor health because of circumstances often affected by, but going beyond, sharing a protected characteristic or socioeconomic status. Whether such groups are identifiable depends on the guidance topic and the evidence. The following are examples of groups covered in NICE guidance:

- Refugees and asylum seekers
- Migrant workers
- Looked after children
- Homeless people.

### QOF equality analysis form

**Development stage: Piloting of indicators** 

**Indicator title: Depression** 

## 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. Have relevant bodies and stakeholders been consulted, including those with a specific interest in equalities?

• Have comments highlighting potential for discrimination or advancing equality been considered?

Not relevant at this stage.

## 3. Have any population groups, treatments or settings been excluded at this stage in the process? Are these exclusions legal and justified?

· Are the reasons for justifying any exclusion legitimate?

These indicators, as piloted, exclude people younger than 18 years because the treatment protocols and recommendations are different for this younger age group.

## 4. Do any of the indicators 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?

None identified at this stage.

### 5. Do the indicators advance equality?

Please state if the indicator as described will advance equalities of opportunity, for example by
making access more likely for certain groups, by tailoring the service to certain groups, or by making
reasonable adjustments for people with disabilities?

None identified at this stage.