# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# HEALTH AND SOCIAL CARE DIRECTORATE

# QUALITY STANDARD CONSULTATION

# SUMMARY REPORT

## 1 Quality standard title

Bipolar disorder in adults.

Date of Quality Standards Advisory Committee post-consultation meeting:
22 April 2015.

## 2 Introduction

The draft quality standard for bipolar disorder in adults was made available on the NICE website for a 4-week public consultation period between 27 February and 27 March 2015. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 13 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically

not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1 and 2.

# 3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

3. For each quality statement what do you think could be done to support improvement and help overcome barriers?

Stakeholders were also invited to respond to the following statement specific questions:

1. For draft quality statement 1: are there definite criteria or a recognised list of additional symptoms that should result in a referral for a specialist mental health assessment? Please provide a reference.

2. For draft quality statement 2: does statement 2 improve the quality of care for adults with bipolar disorder above and beyond that of a generic mental health care plan as included in statement 8 in Quality standard for service user experience in adult mental health which reads: People using mental health services jointly develop a care plan with mental health and social care professionals, and are given a copy with an agreed date to review it. Please explain your reasons.

3. For draft quality statement 2, is there a definition of social and emotional recovery goals that health and social care professionals use? Please provide a reference.

# 4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- the quality standard is seen as useful
- accurate key areas are reflected
- additional areas should be addressed

**Consultation comments on data collection**

- Concerns were raised that secondary care would struggle to collect data for statement 1.
- Concerns were raised that changes to QOF indicators will result in missing data relevant to statement 6

# 5 Summary of consultation feedback by draft statement

## *5.1 Draft statement 1*

Adults presenting in primary care with depression are offered a referral for a specialist mental health assessment if they have experienced additional symptoms.

**Consultation comments**

Stakeholders made the following comments in relation to draft statement 1:

- the statement needs to be more specific
- the population could be changed to depression with suspicion of underlying bipolar disorder
- specific subgroup of the population could be defined
- the rationale could be improved

**Consultation question 4**

Stakeholders made the following comments in relation to consultation question 4:

- using “additional symptoms” points to a change in the complex mental state which is desirable
- the symptoms suggested as triggering the referral included:
  - psychotic thoughts
  - suicidal intent
  - irritability
  - hyperactivity
- as bipolar disorder comprises of a spectrum or range of conditions, multiple symptoms and diagnostic signs may make implementation of this standard difficult and result in excess referrals
- there is currently no applicable screening tool

## *5.2 Draft statement 2*

Adults with bipolar disorder have their social and emotional recovery goals included in a care plan that is reviewed at least annually.

**Consultation comments**

Stakeholders made the following comments in relation to draft statement 2:

- social and emotional recovery goals are too narrow
- difficult to achieve or measure social and emotional recovery goals

**Consultation question 5**

Stakeholders made the following comments in relation to consultation question 5:

- this is already covered by NICE quality standard 14 Quality standard for service user experience in adult mental health
- these considerations are general part of usual patients’ recovery plan

## *5.3 Draft statement 3*

Adults with bipolar disorder are offered psychological interventions specific for their disorder.

**Consultation comments**

Stakeholders made the following comments in relation to draft statement 3:

- more holistic approach to psychological therapy is needed –linked to a training need
- person centred psychological input
- Importance of psycho-education
- being offered psychological interventions when appropriate is important but evidence supporting this statement is poor while financial implications for commissioning substantial

## *5.4 Draft statement 4*

Adults with bipolar disorder prescribed lithium have their plasma lithium levels monitored regularly and maintained at 0.6 –0.8 mmol per litre.

**Consultation comments**

Stakeholders made the following comments in relation to draft statement 4:

- regular monitoring is implied by maintaining the levels at certain level
- the suggested range is too narrow and not appropriate to all patients on lithium; statement on lithium should be focused on providing the patients with information about its' effectiveness in suicide prevention
- a regular personalised medication review is needed
- the requirement to monitor plasma lithium levels every 3 months should be applied to everyone

## *5.5 Draft statement 5*

Women of childbearing potential are not prescribed valproate for long-term treatment or to treat an acute episode of bipolar disorder.

**Consultation comments**

Stakeholders made the following comments in relation to draft statement 5:

- women should be able to make an informed choice
- the statement should focus on informing women prescribed valproate about its teratogenic potential
- the wording “for long-term treatment or to treat an acute episode of bipolar disorder” appears unnecessary
- mentioning valproate and not the other medications used in cases of bipolar disorder which may cause damage to a foetus seems to inadvertently imply that the other medications are unproblematic

## *5.6 Draft statement 6*

Adults with bipolar disorder have a physical health assessment at least annually.

**Consultation comments**

Stakeholders made the following comments in relation to draft statement 6:

- the statement mentions the importance of transferring responsibilities from secondary to primary care but it should highlight it even more
- the rationale does not address the major causes of reduced life expectancy
- consider application in inpatient settings

## *5.7 Draft statement 7*

Adults with bipolar disorder who wish to find or return to work are offered supported employment programmes.

**Consultation comments**

Stakeholders made the following comments in relation to draft statement 7:

- appropriate awareness and competencies among mental health professionals are needed to raise the topic of employment early and include in all recovery planning
- workplace adjustments such as sick leave are needed as well
- issues around under performance and absenteeism are highly relevant

# 6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements:

- support for carers
- medication usage and reviews
- referral to specialist services for patients presenting in mania or bipolar depression (moderate to severe)
- variation of appropriate treatment timing and spectrum of BPD
- comorbidity- impact of drug and alcohol, co morbid mental health problems e.g. personality disorders, neuroses.
- advance statements on information sharing with family and carers
- continuity of therapeutic relationship
- high prevalence of onset in adolescence – access to appropriate support and importance of transitions
- Perinatal mental health and bipolar disorder and need for specialist mental health care

# Appendix 1: Quality standard consultation comments table – registered stakeholders

| ID | Stakeholder | Statement number | Comments |
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| 1 | Department of health | General | I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation. |
| 2 | The Royal College of Nursing | General | This is to inform you that the Royal College of Nursing has no comments to submit to inform on the above quality standard consultation. Thank you for the opportunity to participate. |
| 3 | College of Mental Health Pharmacy | General | "There is evidence of an increased incidence and differences in the manner of presentation of bipolar disorder in people from black and minority ethnic groups."<br>As NICE is notably prescriptive about the prominence and importance of psychological therapies one of the standards should be that these should be available for all people who suffer from bipolar disorder, regardless of race, language or ethnic background. |
| 4 | NHS England | General | Dear NICE, Thank you for the opportunity to comment on the above Quality Standard. I wish to confirm that NHS England has no substantive comments to make on this consultation. |
| 5 | Rethink Mental Illness | General | Rethink Mental Illness recommends that a quality statement about support for carers is added to this quality statement. Given that support for carers is mentioned in CG185 as a priority for implementation, it is disappointing that this is not included in the standard. Assessments for carers (recommendation 1.1.12) and carer-focused education and support programmes (recommendation 1.1.18) would be a good basis for the development of a quality statement. It would also echo the psychosis and schizophrenia in adults quality standard (QS80, statement 8). |

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| 6 | Cheshire and Wirral Partnership NHS Foundation Trust | General | Section 1 introduction under Why this quality standard is needed:<br>- I would believe relevant to specify suicidal risk (attempt and completed). It directly feeds into the NHS outcome framework<br>- I would believe also relevant to specify the morbidity associated with Bipolar Disorder (WHO) in time lost in illness equivalent. It also feeds into the NHS outcome framework<br>- People suffering from Bipolar would experience most illness time in the depressive phase (Judd et al.) and that the depressive phase is the most likely to be associated with suicide. It also feeds into the NHS outcome framework<br>- It would be useful to clarify the important co-morbidity associated with Bipolar disorder, obviously with substance misuse but also physical conditions such as cardiovascular and diabetes. It also feeds into the NHS outcome framework |
| 7 | Cheshire and Wirral Partnership NHS Foundation Trust | General | Consideration to add that patients have been consulted regarding having an open dialogue with their carers should they become unwell. |
| 8 | Cheshire and Wirral Partnership NHS Foundation Trust | General | I would suggest adding that patients presenting with mania and on antidepressant; there has been consideration to discontinue the antidepressant. |
| 9 | Cheshire and Wirral Partnership NHS Foundation Trust | General | Patients presenting in mania or Bipolar Depression moderate to severe are promptly referred to specialist services if not already under their care. |
| 10 | Cheshire and Wirral Partnership NHS Foundation Trust | General | NICE is very specific on the use of some molecules at certain stages of illness such as;<br>In depression; Quetiapine on its own, Olanzapine with Fluoxetine or Lithium<br>In remission; Lithium when in remission,<br>In mania; Quetiapine or Olanzapine or Risperidone or Haloperidol (not licensed for Bipolar) when in mania; would that warrant their own quality standards? |
| 11 | Cheshire and Wirral Partnership NHS Foundation Trust | General | I would also quote NICE guideline for antenatal and postnatal mental health (cg192) and ECT to "Related NICE quality standards". |

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| 12 | ISPS-UK | General | The Quality Statement itself is useful, but is by no means the only statement that is not specific to bipolar disorder that it would be useful to include. For example, a Quality Statement such as 'Adults with bipolar disorder are provided with a therapeutic relationship characterised by consistency, reliability and trustworthiness' would carry considerable significance for service users, and would be no more difficult to monitor (and if the monitoring were conducted in good faith would be less likely to degrade into an exercise in box-ticking, since it would rely on input from the service user). Similarly, a statement about the need to adapt psychological input to the individual needs of the service user would be a valuable addition, increasing the client-centredness of the quality standard. |
| 13 | HQT Diagnostics | General | Many mental problems have an underlying physical cause.<br>Before talking therapies and pharmaceutical drugs are used, physical tests should be done by GPs.<br>These should include tests for Fatty Acids.<br>Major improvements in mental health have been seen within 3 months of supplementing levels of Omega-3 Fatty Acids to:<br>• Omega-3 Index >8%<br>• Omega-6/3 Ratio <3:1<br>Sources:<br>www.expertomega3.com/omega-3-study.asp?id=38<br>www.hqt-diagnostics.com/Products/HQT-Analysis |
| 14 | HQT Diagnostics | General | Many mental problems have an underlying physical cause<br>Before talking therapies and pharmaceutical drugs are used, physical tests should be done by GPs.<br>These should include tests for Vitamin D<br>Major improvements in mental health have been seen within 3 months of supplementing levels of Vitamin D so that 25(OH)D is between 100-150 nmol/L<br>Sources:<br>http://vitamindwiki.com/tiki-index.php?page_id=1309<br>http://vitamindwiki.com/tiki-index.php?page_id=3873 |

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| 15 | ISPS-UK | General | We think that the quality statement could go further in encouraging a patient-centred approach. As mentioned on page 1 of the draft, bipolar disorder "is often comorbid with other disorders ..." – people may have needs for other psychological interventions not specific to bipolar disorder, and addressing these needs may be important in helping achieve recovery goals and improving quality of life. As worded, the draft runs the risk of influencing professionals to respond to one particular aspect of their difficulties rather than to the patient as a whole. Therefore it seems more appropriate to state that people should be offered psychological interventions tailored to their individual need, arising from an individual formulation of their difficulties (cf Johnstone L & Dallos R (eds), 2013, Formulation in Psychology and Psychotherapy, 2nd ed, Hove:Routledge) . Of course this is not to say that specific interventions for bipolar disorder should not be offered, just that as worded it sounds as if this is all that services need to offer this group by way of psychological input.<br>Another key area for improvement concerns the diagnosis of 'bipolar disorder type II'. There seems to be little consensus on the borderline between disorder or no disorder here, and a growing trend towards diagnosing bipolar II, which many people feel to be a result of overdiagnosing bipolar II in people who have mood instability linked, for instance, to borderline personality features.<br>One of the drivers for diagnosing borderline type problems as bipolar may be the stigmatisation and discrimination (in mental health services) against people believed to have borderline personality. We think there is an equality issue here.<br>When quality standards (and associated monitoring) do not specifically mention the need for crucial aspects of care (such as the quality of the therapeutic relationship, and treatment adapted in the light of proper formulation to individual needs), then there is a very real danger of diversion of resources and attention from these, particularly when there are very pressing resource constraints. |
| 16 | The Association for Family Therapy and Systemic Practice in the UK. | Question 1 | The bipolar disorder in adults briefing paper asserts the importance of family members and carers being consulted, and involved in the processes of assessment, care planning, risk management planning, psychological intervention, and long-term management, with adults who have, or may be given, a diagnosis of bipolar disorder (see below). The draft quality standard does not accurately reflect the importance and value of the involvement of family members and carers. Adult mental health services continue to tend to be individually focused, rather than see the person in the context of their relationships, and it is important to the quality of services that the person, and their family members and carers, can make an informed choice about their involvement. |

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| | | | (The bipolar disorder in adults briefing paper refers to the NICE guideline for Bipolar Disorder CG185 (2014) which recommends that assessment of suspected bipolar disorder includes that possible factors associated with changes in mood should be discussed including relationships, and recommends that people should be encouraged to invite a family member or carer to give a corroborative history (p.14). The briefing paper refers to the recommendations in the NICE guideline for Bipolar Disorder CG185 (2014) that the person is encouraged to share their care plan (and risk management plan) with their carers (p.14, 15, 17, 30). The bipolar disorder in adults briefing paper refers to the NICE guideline for Bipolar Disorder CG185 (2014) which recommends that people with bipolar depression are offered psychological interventions, including a high-intensity psychological intervention such as behavioural couples therapy (p.26), and recommends that people with bipolar disorder are offered a family intervention in line with the NICE clinical guideline on psychosis and schizophrenia in adults, or a structured psychological intervention (such as a family intervention) which has been designed for bipolar disorder and which has a published evidence-based manual (p. 27, 44). The bipolar disorder briefing paper refers to the recommendation in the NICE guideline for Bipolar Disorder CG185 (2014) which states that a risk management plan should be developed with the person and their carer if possible (p.30). The bipolar disorder in adults briefing paper refers to the recommendation in the NICE guideline for bipolar disorder CG185 (2014) which states after each episode of depression or mania the longer term management of the bipolar disorder should be discussed with the person and their carer if possible, and that the longer term management includes the involvement of carers (p.43). The bipolar disorder in adults briefing paper refers to the recommendation in the NICE guideline for bipolar disorder CG185 (2014) which states that a carer focused education and support program should be offered as soon as possible and that this could be part of a family intervention (p.44). The briefing paper reports the views of stakeholders about the importance of involving relatives in care and shared decision making where appropriate (p.42). The briefing paper reports stakeholder views that the family has a critical role in maintaining wellness and long-term stability for the individual, and that the condition can impact on the family. Stakeholders assert that despite strong evidence, people with bipolar disorder and their families find it difficult to access family intervention therapies (p.42, 46).) |

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| 17 | The Royal College of General Practitioners | Question 1 | No<br>Key areas not addressed are:<br>1. Awareness of increased suicide risk with bipolar disorder compared to unipolar disorder<br>2. Variation of appropriate treatment timing and spectrum of BPD (cyclothymia, rapid cycling, BD I & II), No options or standards around cyclothymia<br>3. Medication reviews for people starting on medication, pregnancy and medication, treatment options-medication (Li, CBZ, Valproate, Antipsychotics), appropriate use of antidepressant medication<br>4. Importance of psycho-education<br>5. Comorbidity- impact of drug and alcohol, co morbid mental health problems e.g. personality disorders, neuroses.<br>6. High prevalence of onset in adolescence and therefore need for access to EIS approach and the importance of transitions<br>7. Perinatal mental health and bipolar disorder and need for specialist mental health care<br>(LE) |
| 18 | The Royal College of Psychiatrists | Question 1 | YES |
| 19 | The Royal College of Psychiatrists | Question 2 | YES - although in secondary care we will struggle to collect data for statement 1. |
| 20 | The Royal College of Psychiatrists | Question 3 | Statement 1. Adults presenting in primary care with depression are offered a referral for a specialist mental health assessment if they have experienced additional symptoms.<br>This is dependent on primary care practitioners believing that symptoms suggestive of current or previous (hypo)mania will impact management, knowing the questions to ask, having a clear referral pathway and having a belief that secondary care will assess such patients and that secondary care will offer appropriate advice. |
| 21 | The Royal College of Psychiatrists | Question 3 | Statement 2. Adults with bipolar disorder have their social and emotional recovery goals included in a care plan that is reviewed at least annually.<br>This requires patients to be in secondary care and to be linked to the CMHT (not just to be on a consultant's output list.) |

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| 22 | The Royal College of Psychiatrists | Question 3 | Statement 3. Adults with bipolar disorder are offered psychological interventions specific for their disorder.<br>This is a tremendous standard and it may well be that many health care organisations don't meet this. It requires a change in the way that patients are managed and the availability and use of appropriate staff resource. |
| 23 | The Royal College of Psychiatrists | Question 3 | Statement 4. Adults with bipolar disorder prescribed lithium have their plasma lithium levels monitored regularly and maintained at 0.6 –0.8 mmol per litre<br>The challenge here is partly about clear communication (including direct IT links) between primary and secondary care and about being able to monitor compliance with this standard at an organisational level as well as at the level of individual practitioners. |
| 24 | The Royal College of Psychiatrists | Question 3 | Statement 5. Women of childbearing potential are not prescribed valproate for long-term treatment or to treat an acute episode of bipolar disorder.<br>Monitoring of valproate use at an organisational level with input from pharmacy. |
| 25 | The Royal College of Psychiatrists | Question 3 | Statement 6. Adults with bipolar disorder have a physical health assessment at least annually.<br>Again, clear communication between primary and secondary care. |
| 26 | The Royal College of Psychiatrists | Question 3 | Statement 7 - Adults with bipolar disorder who wish to find or return to work are offered supported employment programmes<br>A change in ethos (it is not OK that patients can't access employment) and the availability of practitioners who can facilitate such programmes and/or access to any available programmes |
| 27 | The Royal College of Psychiatrists | Question 4 | For quality statement 1, are there a definite criteria or a recognised list of additional symptoms that should result in a referral for a specialist mental health assessment? Please provide a reference.<br>Past or recent hypomania, mania or rapid cycling mood; significant risk of self-harm, suicide, self-neglect or harm to others; discharged bipolar patients presenting with relapse; adverse effects with medication for bipolar disorder (such as low eGFR whilst on lithium) |

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| 28 | The Royal College of General Practitioners | Question 4 | Additional symptoms might include psychotic thoughts, suicidal intent, as well as irritability and hyperactivity. I like the term “additional symptoms” because it points to a change in the complex mental state – especially when dual or triple diagnosis. (JA)<br>As Bipolar disorder comprises of a spectrum or range of conditions, there are multiple symptoms and diagnostic signs which may make implementation of this standard difficult as could result in excess referrals, also inevitably risks sacrificing specificity to sensitivity. No current easily applicable screening tool available. Primary Care Companion CNS Disord. 2011; 13(4): PCC.10r01097.doi: 10.4088/PCC.10r01097<br>Some studies have supported the presence of hypersomnia and motor retardation during depression as symptoms suggestive of bipolar depression, whilst others have supported excessive sleep and appetite, irritability of mood, and anger as suggestive of bipolar depression. Other features like earlier age of onset and family history of bipolar disorder have also been described as helpful in differentiating bipolar depression from unipolar depression.<br>In addition, high comorbidity of bipolar disorder with other psychiatric and medical diagnoses also makes diagnosis difficult (alcohol and drug abuse or dependence, panic disorder, obsessive compulsive disorder, social phobia, eating disorders, attention deficit hyperactivity disorder (ADHD), and personality disorders). (LE) |
| 29 | The Royal College of Psychiatrists | Question 5 | Does statement 2 improve the quality of care for adults with bipolar disorder above and beyond that of a generic mental health care plan as included in statement 8 in Quality standard for service user experience in adult mental health which reads: People using mental health services jointly develop a care plan with mental health and social care professionals, and are given a copy with an agreed date to review it. Please explain your reasons<br>It can – only if we have a clear and pragmatic definition of social and emotional (and not only symptomatic) recovery, specific to bipolar disorder. There are specific measures for bipolar disorder such as the bipolar recovery questionnaire (http://www.ncbi.nlm.nih.gov/pubmed/23182591) but these are not widely used except in research.<br>Patients not on CPA (only on consultant caseloads) don’t have detailed care plans and most stable patients with bipolar disorder are not on CPA |

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| 30 | The Royal College of Psychiatrists | Question 6 | For quality statement 2, is there a definition of social and emotional recovery goals that health and social care professionals use? Please provide a reference<br>The most usual measures are the generic Wellness Recovery Action Plan (WRAP) and Recovery star; however these are usually used for those on CPA only.<br>http://www.workingtogetherforrecovery.co.uk/Documents/Wellness%20Recovery%20Action%20Plan.pdf<br>http://www.centreformentalhealth.org.uk/pdfs/Recovery_star_user_guide.pdf |
| 31 | The Royal College of General Practitioners | Qustion 5 | This is already in place?<br>People using mental health services jointly develop a care plan with mental health and social care professionals, and are given a copy with an agreed date to review it. Care plans should include the needs of the individual service user, activities promoting social inclusion such as education, employment, volunteering and other specified occupations, such as leisure activities and caring for dependents.<br>NICE 2011: Quality standard for service user experience in adult mental health (LE) |
| 32 | The Royal College of Psychiatrists | Statement 1 | Clarity about which symptoms would trigger referral will be important. We suggest (see Q4)- Past or recent hypomania, mania or rapid cycling mood; significant risk of self-harm, suicide, self-neglect or harm to others; discharged bipolar patients presenting with relapse; adverse effects with medication for bipolar disorder (such as low eGFR whilst on lithium) |
| 33 | Cheshire and Wirral Partnership NHS Foundation Trust | Statement 1 | This is too vague. Mild to moderate depression can be successfully managed in primary care. Would suggest depression with suspicion of underlying Bipolar Disorder, in order to be clear and specific. Also possible consider adding and special populations such as ladies with perinatal conditions presenting with or known to suffer from Bipolar Disorder. |
| 34 | ISPS-UK | Statement 1 | Statement 1 - We think the statement could be improved by reflecting more clearly the importance of the decision to refer being based on an individual assessment of need, including consideration of what is wanted from the referral. |

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| 35 | The Royal College of General Practitioners | Statement 2 | Social and emotional are too narrow in scope – how would we include reviving an interest in playing a musical instrument or going to concerts? (Spiritual?) Also physical goals are so intertwined with emotional and social – like returning to the gym or taking part in physical or sporting activities, or making new health gains (such as gaining or losing weight, control of migraines or abnormal eating patterns, taking regular medications for other conditions as well as emotional conditions. (ref multi-morbidity of bipolar patients). "Goals" is also non specific – people often feel strongly about what they Do want and what they Do not want. Positive and negative could qualify it? GPs often feel that the "care plan" belongs to the mental health team because it is always what suits the team. The service user QS put it the other way. The QS should state that the service user reviews the plan otherwise it leaves it open to non engagement and tick box by the MH team. (JA)<br><br>This is already in place?<br>People using mental health services jointly develop a care plan with mental health and social care professionals, and are given a copy with an agreed date to review it. Care plans should include the needs of the individual service user, activities promoting social inclusion such as education, employment, volunteering and other specified occupations, such as leisure activities and caring for dependents.<br>NICE 2011: Quality standard for service user experience in adult mental health (LE) |
| 36 | Cheshire and Wirral Partnership NHS Foundation Trust | Statement 2 | This would be difficult to achieve or measure and probably best removed from standards. These considerations are general part of usual patients' recovery plan. |
| 37 | The Royal College of General Practitioners | Statement 3 | "are offered" is so passive and unengaged! How about "enabling the service user to access" or "enabling continuity with at least one healthcare professional and demonstrating engagement". (Relationship is key and we must find a way of demonstrating and measuring it). GPs can provide continuity of relationship in partnership with the mental health team, rather than opting out of the mental health side once referred. (JA)<br>Psychological interventions are an important part of the management of Bipolar disorder but also need to include the need for effective psychoeducation and medication management which are equally as important. (LE) |

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| 38 | Association for Cognitive Analytic Therapy (ACAT) | Statement 3 | 'Adults with bipolar disorder are offered psychological interventions specific for their disorder.'<br>It is of note that many people with Bipolar Disorder have also experienced some degree of abuse and / or neglect in early life which presents additional relational problems in combination with the Bipolar Disorder that manifests itself in adulthood. Some patients therefore would be best offered a psychological therapy that is specific to Bipolar Disorder but also can address relational problems and unhelpful personality traits. Dr Mark Evans has completed a pilot RCT of CAT in Bipolar Disorder that is being submitted for publication. (Details can be provided). CAT is well placed to offer a more holistic psychological therapy to patients who fall into both categories. |
| 39 | Cheshire and Wirral Partnership NHS Foundation Trust | Statement 3 | There is poor evidence to support the benefit of psychological intervention SPECIFIC to Bipolar Disorder, and this could potentially bring an important commissioning issue across services in the country already struggling with general psychological interventions. It would appear however very relevant that individuals with Bipolar Disorder are offered psychological interventions when appropriate, as there is also limited evidence of the efficacy when ACUTELY unwell. I would refrain to use the term "their" bipolar; it is not theirs…they suffer from it. |
| 40 | ISPS-UK | Statement 3 | Firstly we believe a crucial aspect of psychological intervention is recognition of the need for treatment to be adapted in the light of adequate formulation (bio-psycho-social), so that it is shaped by an understanding of the individual's needs that goes deeper than the mere identification of a diagnosis. As a corollary of this, there needs to be education – for professionals and public – about formulation as a prerequisite of psychological intervention. |
| 41 | College of Mental Health Pharmacy | Statement 4 | Frequency of monitoring : Can we please point out to NICE about the practicalities, ambiguity and dangerous implications of the recommendation that:<br><br>"Plasma lithium levels should be measured weekly until they are stable, then every 3 months, for the first year. After the first year, plasma lithium levels should be measured every 6 months, or every 3 months for people who are in any of the following groups:<br>• older people<br>• people taking drugs that interact with lithium<br>• people who are at risk of impaired renal or thyroid function, raised calcium levels or other complications<br>• people who have poor symptom control |

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| | | | • people with poor adherence<br>• people whose last plasma lithium level was 0.8 mmol per litre or higher. “<br><br>The requirement should remain at 3-monthly because everyone is at risk of impaired renal function if levels are above 1.0mmol/l (ref. Below). The practicalities are that the 3-monthly recommendation is rarely achieved in the community and that every 4-5 months is practically what occurs, even with a system as tight and well-controlled as that with a lithium database recall system such as in Norfolk. To recommend 6-monthly means that, practically, samples will be taken every 6-9 months. A patient could thus be exposed to levels above 1.0mmol/l for an extended period, leaving them at risk of renal impairment. So, everyone should have levels 3-monthly because everyone is at risk of impaired renal function.<br><br>“One lithium level >1.0 mmol/L causes an acute decline in eGFR: findings from a retrospective analysis of a monitoring database.”<br>Kirkham E, Skinner J, Anderson T, Bazire S, Twigg MJ, Desborough JA. BMJ Open. 2014 Nov 7;4(11):e006020.<br>Conclusion: These results show for the first time that a single incident of a lithium level >1.0 mmol/L is associated with a significant decrease in eGFR in the following 3 months when compared to patients whose lithium levels never exceeded 0.8 mmol/L. It is still not known whether the kidneys can recover this lost function and the impact that more than a single exposure to a level within these ranges can have on renal function. These results suggest that lithium level monitoring should be undertaken at least every 3 months, in line with current UK guidelines and not be reduced further until the impact of more than one exposure to these lithium levels has been fully established. |
| 42 | College of Mental Health Pharmacy | Statement 4 | This range is too narrow. It refers specifically to physically healthy "working age" adults. It would be perfectly reasonable clinically to have a patient maintained on a slightly lower levels if they were older or if their renal function was poor, it would also be acceptable to have some patients maintained on higher levels if they are known to become unwell with lower levels. And clearly newly initiated people during the titration stage will by definition have lower levels before a maintenance dose is identified. Therefore this range is too narrow to act as a wide standard which includes all patients. We recommend changing to 0.4-1.0mmol/L as per the BNF. |

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| 43 | College of Mental Health Pharmacy | Statement 4 | One of the standards for lithium should really be that patients must be informed clearly and in writing that:<br>• lithium reduces suicide if taken regularly and reliably (32 RCTs, n=3458, Cipriani et al, Am J Psychiatry 2005;162:1805–19)<br>• stopping lithium suddenly can lead to relapse and this increases the risk of suicide (Baldessarini et al, J Clin Psychiatry 1996;57:441–8; Baldessarini et al, Am J Psychiatry 1997;154:551–3; Yazici et al, J Affect Disord 2004;80:269–71)<br>The evidence for this is well-known in mental health circles, but presumably not so well understood by other healthcare professionals and agencies. An effective standard would be that patients have been told these vital aspects and understand them. |
| 44 | Cheshire and Wirral Partnership NHS Foundation Trust | Statement 4 | It would be useful to remind practitioners of the importance of checking lithium levels, maybe accordingly to local protocols, rather than being very specific on the 0.6-0.8 which would vary greatly from patient to patient. Or introduce a variation possibility. |
| 45 | The Royal College of General Practitioners | Statement 4 & 5 | Lithium is only one medication option used in bipolar disorder. Other medications have side effects and require monitoring. Medications used include lithium, carbamazepine, atypical antipsychotics, antidepressants and sodium valproate. A regular personalised medication review (and also triggered reviews e.g. relapse, development of psychosis, concomitant use of drugs or alcohol, increased stress) should be implemented which would assess individual need for ongoing medication, physical healthcare monitoring related to medication e.g. blood tests, appropriateness around specific times in people's lives such as pregnancy, perinatal period, use of other medications with comorbidity. Women of childbearing age with bipolar disorder should be referred to specialist perinatal mental health services. (LE) |
| 46 | The Royal College of Psychiatrists | Statement 5 | The wording "for long-term treatment or to treat an acute episode of bipolar disorder" appears unnecessary and the statement could thus be shortened |

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| 47 | College of Mental Health Pharmacy | Statement 5 | Although this is a NEW treatment guidance there are hundreds of women of child bearing potential already well maintained on valproate. Therefore they should be allowed to make their own informed choice to continue on this treatment if they understand the risks. Many may well be of child bearing potential and have no intention to become pregnant. Therefore it would not be appropriate for practitioners to then deny them access to an established treatment which they are currently responding to. This should either be re-worded or removed (if it then becomes difficult to measure.). The important fact to establish is that "Any woman of child bearing potential who is prescribed valproate has been informed about its teratogenic potential". |
| 48 | ISPS-UK | Statement 5 | Montioning valproate and not the other medications used in cases of bipolar disorder which may cause damage to a foetus seems to inadvertently imply that the other medications are unproblematic. |
| 49 | The Royal College of General Practitioners | Statement 6 | Rationale not fully supported by the evidence and does not address the major causes of reduced life expectancy (see below)<br>On average, women with bipolar disorder died 9.0 years earlier (mean age, 73.4 years vs 82.4 years) than women in the general population. Men with bipolar disorder died 8.5 years earlier (mean age, 68.9 vs 77.4 years) than other men.<br>Both men and women with bipolar disorder had an increased risk for death from ischemic heart disease, diabetes, COPD, and influenza and pneumonia.<br>The researchers report that the disorders associated with the largest HRs for mortality were as follows:<br>• Influenza and pneumonia (3.7-fold for women; 4.4-fold for men)<br>• Diabetes (3.6-fold for women; 2.6-fold for men)<br>• COPD (2.9-fold for women; 2.6-fold for men)<br>The researchers report that bipolar disorder was strongly associated with increased mortality from suicide, with a 10-fold increased risk among women (aHR, 10.37; 95% CI, 7.36 - 14.60) and an 8-fold increase among men (aHR, 8.09; 95% CI, 5.98 - 10.95).<br>JAMA Psychiatry. Published online July 17, 2013 (LE) |

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| 50 | Rethink Mental Illness | Statement 6 | We are concerned about the data sources cited in this section of this quality statement. The use of NICE QOF menu will not adequately capture data on all the physical health parameters. In 2014/15, some of the physical health checks for people affected by mental illness were retired - these were BMI, cholesterol and blood glucose or HbA1c. In current plans for data capture under this quality statement, these measures will therefore not be captured, even though they are specifically mentioned under recommendation 1.2.12. This quality statement could also be more explicit in stating that this applies to inpatient settings too, where processes other than QOF might be in place.<br>We would also recommend that this section also includes a point about health professionals being aware of, and utilising, referral pathways for any necessary follow up physical health care. |
| 51 | Rethink Mental Illness | Statement 6 | This quality statement mentions the importance of shared care arrangements where responsibility for physical health monitoring transfers from secondary to primary care. This was a welcome clarification in CG185 (recommendation 1.2.11). Commissioners and service providers have a responsibility for ensuring these arrangements are in place and that information systems and local processes facilitate the transfer of this responsibility. This should be highlighted under this quality statement. |
| 52 | The Royal College of General Practitioners | Statement 7 | People with bipolar disorder face problems with employment (Stang et al., 2007). Marwaha et al (2013) also found that the disorder can lead to workplace underperformance and absenteeism resulting in a downward drift in employment status over time. Taken together this evidence provides a clear target for employers to support individuals with bipolar disorder by making workplace adjustments such as clear job descriptions or using sick leave for emotional symptoms as well as physical illness. Marwaha et al. 2013 also suggest the current evidence provides support for extending the early intervention paradigm to bipolar disorder. (LE) |
| 53 | Rethink Mental Illness | Statement 7 | We know from our work on employment that the attitudes of health professionals can be a significant barrier to people accessing employment support. Many practitioners may be worried about broaching the subject of employment for fear of making people anxious or feel under pressure to return to work. This can mean that these conversations happen at quite a late stage in someone's recovery when they could, and should, happen much earlier and be included in all recovery planning. With this in mind, we feel some comment here about health professionals having the appropriate awareness and competencies to raise the topic of employment early with people would be appropriate. |

## *Registered stakeholders who submitted comments at consultation*

- Association for Cognitive Analytic Therapy (ACAT)
- Cheshire and Wirral Partnership NHS Foundation Trust
- College of Mental Health Pharmacy
- Department of health
- HQT Diagnostics
- International Society for Psychological and Social Approaches to Psychosis UK (ISPS-UK)
- NHS England
- Rethink Mental Illness
- The Association for Family Therapy and Systemic Practice in the UK
- The Royal College of General Practitioners
- The Royal College of Nursing
- The Royal College of Psychiatrists

# Appendix 2: Quality standard internal checks table

| Comment number | Stakeholder | Statement number | Comments |
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| 1 | QS Team | Statement 1 | More specific wording is needed in this statement. |
| 2 | QS Team | Statement 2 | QS14 already covers this area. |
| 3 | QS Team | Statement 3 | Is this statement realistic? Could it be treated as a developmental statement? |
| 4 | QS Team | Statement 4 | Change to: Adults with bipolar disorder prescribed lithium have their plasma lithium levels maintained at 0.6 –0.8 mmol per litre. |
| 5 | Audit support | Statement 5 | Antenatal and postnatal mental health: clinical management and service guidance CG192 could also be listed as source guidance for this statement. Recommendation 1.2.3 states:<br>Do not offer valproate for acute or long term treatment of a mental health problem in women of childbearing potential. |
| 6 | Audit support | Statement 5 | The CG192 Antenatal and postnatal mental health clinical audit tool clinical audit statement 1 can be referenced as a data source for the process measure. |
| 7 | QS Team | Statement 7 | Change to: Adults with bipolar disorder who wish to find or return to work are receive supported employment programmes |