|  |
| --- |
| **Checklist for submitting comments*** Use this comments form and submit it as a **Word document (not a PDF)**.
* Complete the disclosure about links with, or funding from, the tobacco industry.
* Include **document name,** **page number and line number** of the text each comment is about.
* Combine all comments from your organisation into 1 response form. **We cannot accept more than 1 response from each organisation**.
* **Do** **not** paste other tables into this table – type directly into the table.
* Ensure each comment stands alone; **do not** cross-refer within one comment to another comment.
* **Clearly mark any confidential information or other material that you do not wish to be made public. Also, ensure you state in your email to NICE that your submission includes confidential comments.**
* **Do not name or identify any person or include medical information about yourself or another person** from which you or the person could be identified as all such data will be deleted or redacted.
* Spell out any abbreviations you use.
* For copyright reasons, **do not include attachments** such as research articles, letters, or leaflets. We return comments forms that have attachments without reading them. You may resubmit the form without attachments, but it must be received by the deadline.
* **We do not accept comments submitted after the deadline stated for close of consultation.**

You can see any guidance that we have produced on topics related to this guideline by checking [NICE Pathways](http://pathways.nice.org.uk/).**Note:** We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.Comments received during our consultations are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments we received, and are not endorsed by NICE, its officers or advisory Committees.  |

|  |  |
| --- | --- |
|  | **Please read the checklist above before submitting comments.** **We cannot accept forms that are not filled in correctly.** We would like to hear your views on the draft recommendations presented in the guideline, and any comments you may have on the rationale and impact sections in the guideline and the evidence presented in the evidence reviews documents. We would also welcome views on the Equality Impact Assessment.In addition to your comments below on our guideline documents, we would like to hear your views on these questions. **Please include your answers to these questions with your comments in the table below.**1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.
2. Would implementation of any of the draft recommendations have significant cost implications?
3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)
4. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication.

See [[Developing NICE guidance: how to get involved](http://www.nice.org.uk/process/pmg22/chapter/how-you-can-get-involved)](https://www.nice.org.uk/process/pmg20/resources/developing-nice-guidelines-how-to-get-involved-2722986687/chapter/commenting-on-a-draft-guideline) for suggestions of general points to think about when commenting. |
| Organisation name (if you are responding as an individual rather than a registered stakeholder please specify). | The College of Mental Health Pharmacy |
| Disclosure (please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry). | N/A |
| Name of person completing form | Helen Pinney |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Comment number** | **Document**[e.g. guideline, evidence review A, B, C etc., methods, EIA] | Page number**‘General’** for comments on whole document | Line number**‘General’** for comments on whole document | Comments* Insert each comment in a new row.
* Do not paste other tables into this table, because your comments could get lost – type directly into this table.
* Include section or recommendation number in this column.
 |
| Example 1 | Guideline | 016 | 045 | Rec 1.3.4 – We are concerned that this recommendation may imply that ………….. |
| Example 2 | Guideline | 017 | 023 | Question 1: This recommendation will be a challenging change in practice because …… |
| Example 3 | Guideline | 037 | 016 | This rationale states that… |
| Example 4 | Evidence review C | 057 | 032 | There is evidence that … |
| Example 5 | Methods | 034 | 010 | The inclusion criteria … |
| Example 6 | Algorithm | General | General | The algorithm seems to imply that … |
| Example 7 | EIA | 010 | 002 | We agree the barriers to access listed, and would also like to add …. |
| 1 | Draft Guideline | general |  | We found the flow of the whole document rather hard to follow, not intuitive to follow, it seemed to jump back and forth on the topic of medication, meaning that the reader often missed aspects of the guidance eg 1.3 is titled “Choice of treatment” but there is no specific guidance in that section about the choice of antidepressant, this is elaborated on in a new section called “Delivery of treatment”.It did not match the patients’ pathway through treatment.  |
| 2 | Draft Guideline | 5 | 12 | “can make it hard for people to access mental health services….” Please delete “mental”. |
| 3 | Draft Guideline | 6 | 1.1.3 | Please outline what this “information” should be about. Eg the illness? Or drug treatments? Or talking therapies?, or delete. |
| 4 | Draft Guideline | 8 | 1.2.6 | Please advise practitioners as to commonly used assessment tools such as the PHQ9 which may be used as *part* of the initial assessment. |
| 5 | Draft Guideline | 8 | 1.2.13 | Please advise practitioners as to commonly used assessment tools for anxiety which may be used as *part* of the initial assessment. |
| 6 | Draft Guideline | 10-11 | 1.3 | This whole section reads as though it is to be used in primary care and with patients who are able a have the capacity to discuss all these nuances in treatment choices. Commonly this is not the case, either due to concurrent dementia, acuity of illness (depression) or concurrent illnesses, and is rarely the case for patients in secondly care mental health services.This needs to be acknowledged and provision given for the scenarios when clinicians *have* to make decisions about initial treatment on behalf of the patients without their full involvement.  |
| 7 | Draft Guideline | 12 | Line 19 | “working” this reviewing should not just be reviewing whether the antidepressant is effective, it should also be looking at adherence (first) and tolerability.  |
| 8 | Draft Guideline | 12 | Line 19-20 | The timeframe here is “2-4 weeks”. This should be 2 weeks if it is to be meaningful and help avoid worsening of depression and suicides. Studies show that patients commonly stop new medications within 10 days therefore waiting for 4 weeks to re-assess whether an antidepressant is helping or not is far too late. It is likely that they will have stopped it and therefore will have been untreated for several weeks. Please revise this advice to 2 weeks, and 1 week for younger people and those at high risk or self harm and/or suicide, as per the previous guideline. |
| 9 | Draft Guideline | 13 | 1.4.7 | “Starting an antidepressant” Please add in that this should normally be an SSRI |
| 10 | Draft Guideline | 13 | 23-25 | Rephrase to: “Discuss the possible side effects and discontinuation / withdrawal effects…..”.  |
| 11 | Draft Guideline | 14 | 9-11 | The timeframe here is “2-4 weeks”. This should be 2 weeks if it is to be meaningful and help avoid worsening of depression and suicides. Studies show that patients commonly stop new medications within 10 days therefore waiting for 4 weeks to re-assess whether an antidepressant is helping or not is far too late. It is likely that they will have stopped it and therefore will have been untreated for several weeks. Please revise this advice to 2 weeks, and 1 week for younger people and those at high risk or self harm and/or suicide, as per the previous guideline. |
| 12 | Draft Guideline | 14 | 1.4.8 | Please emphasise that antidepressants are not addictive in the sense that individual will not crave them, or require escalating doses to deliver the same benefits.  |
| 13 | Draft Guideline | 14 | 24 | “Some side effects may persist throughout treatment” –please add some advice. Eg balance of tolerability vs benefits and how and when to stop a treatment. |
| 14 | Draft Guideline | 15 |  | This whole section on “Stopping antidepressant medication” feels very imbalanced. There are three pages of text emphasising how to stop these when you have not yet given the detailed advice about how to start them, or what benefits that may confer. The overall impression given is that these have no purpose, and should be stopped.Please readdress this balance and set out that these can be beneficial and how to optimise this. For example the text doesn’t address adherence; the need to take them regularly in order to actually gain clinical benefit from them. Please re-order the text so that the advice on what to start, and how to prescribe well, is read before the extensive advice on stopping. Advise clinicians on which antidepressants to use first. Please advice that these should be used as monotherapy first – this has been omitted. Please advise prescribers to remember to check that other antidepressants aren’t already prescribed for other indications such that this would lead to polypharmacy. eg patients already on antidepressants at doses for neuropathic pain, or Stress Urinary Incontinence (SUI). |
| 15 | Draft Guideline | 15 | 1.4.12 | Please balance this message to say that these mild withdrawal symptoms are spate from a relapse in depression. |
| 16 | Draft Guideline | 15 | 20 | “…withdrawal symptoms can be mild, appear within a few days” please add “MAY appear within a few days” |
| 17 | Draft Guideline | 15 | 22 | Please start the following sentence with “Rarely”; “However, they can last longer…..” |
| 18 | Draft Guideline | 15 | 1.4.12 | This would not happen with fluoxetine due to the long half life. Please add context to keep this section balanced as currently it reads as though this is true for every antidepressant. Please outline which antidepressants are more likely to induce withdrawal effects due to their short half lives, vs others such as fluoxetine.  |
| 19 | Draft Guideline | 16 | 11-12 | This reads as though it is advice for every antidepressant every time it is stopped in a planned manner. This is not always necessary, plus not every antidepressant is available as a liquid. Please add balance and context to this advice. |
| 20 | Draft Guideline | 16 | 22 | “Monitor and review” – what? Please spell out, as this is also about a relapse in their illness of depression, not just about possible withdrawal symptoms.  |
| 21 | Draft Guideline | 17 | 1.4.17 | Line 15, withdrawal symptoms are described as “common”. In treatment terms “Common” means >1 in 10.Withdrawal effects do not happen to >1 in 10 patients. Please re word, or add a specific incidence. |
| 22 | Draft Guideline | 18 | 15 | “4 weeks” this is too long.This should be 2 weeks if it is to be meaningful and help avoid worsening of depression and suicides. Studies show that patients commonly stop new medications within 10 days therefore waiting for 4 weeks to re-assess whether an antidepressant is helping or not is far too late. It is likely that they will have stopped it and therefore will have been untreated for several weeks. Please revise this advice to 2 weeks, and 1 week for younger people and those at high risk or self harm and/or suicide, as per the previous guideline. |
| 23 | Draft Guideline | 19 | 1.4.22 | Also should not routinely start MAOIs |
| 24 | Draft Guideline | 19 | 1.4.23 | Please add that older people take longer to respond to antidepressants. |
| 25 | Draft Guideline | 19 |  | “Use of lithium” please add that this should never be used as monotherapy in unipolar depression. It is an augmentation strategy that should be used alongside an antidepressant.  |
| 26 | Draft Guideline | 19 |  | “Use of lithium” please add that this should only be newly started by secondary care services.  |
| 27 | Draft Guideline | 19 | 1.4.24 | Requiring calcium levels every 3-6 months is not necessary. plus this section is contradicted by 1.4.25 which says levels can be done as infrequently as every 6 months. Yet all other tests still need to be done 3 monthly – this doesn’t make sense. Everything should be decreased to 6 monthly in stable medically well individuals – as per the bipolar NICE Guidelines.  |
| 28 | Draft Guideline | 20 | 1.4.28 | First take a CVD history before doing an ECG |
| 29 | Draft Guideline | 21 | 1.4.30 | This point is helpful. But it makes a very interesting comparison to the huge emphasis placed on stopping antidepressants. Those on lithium as an augmentation strategy will be the much more severely depressed. So to give only 2 lines of guidance to this seems disproportionate to the 3 pages on with drawing antidepressants. There’s no advice about the importance of maintaining the antidepressant or reviewing for signs of relapse in depression or follow up care.  |
| 30 | Draft Guideline | 21 |  | “Use of antipsychotics” please add that this should never be used as monotherapy in unipolar depression. They are always an augmentation strategy that should be used alongside an antidepressant. Only one antipsychotic should be used at a time. |
| 31 | Draft Guideline | 21 |  | “Use of antipsychotics” please add that this should only be newly started by secondary care services. |
| 32 | Draft Guideline | 21 |  | Please give advice about the preferred antipsychotic options to use, either as an augmentation strategy or for psychotic symptoms. There are different indications and therefore choices and this requires advice.  |
| 33 | Draft Guideline | 22 |  | Making shared care mandatory again seems unhelpful, and not consistent with other guidelines such as those for schizophrenia. Furthermore this is less relevant now with ICSs, and is commonly not relevant for this patient group for whom antipsychotic use may be relatively short term.  |
| 34 | Draft Guideline | 22 | 1.5 | Heading, confusingly this heading is virtually repeated on page 23 line 10. |
| 35 | Draft Guideline | 22 | 1.5 | This section is hard to follow, doesn’t flow well.Doesn’t seem to cover the other health advice that needs to be provided concurrently eg about sleep hygiene, healthy eating and exercise, not over using alcohol, relationships and daily activities.  |
| 36 | Draft Guideline | 23 | Table 1 | This is a very unhelpful way of displaying this information as a portrait table over 8 pages. |
| 37 | Draft Guideline | 30 | 2 | This title needs reviewing as there are many other things that would “NOT be recommended” eg ECT, MAOIs, carbamazepine, stimulants etc etcI suggest this section is just re-titled to “St Johns Wort”, as that is the focus of the message. SJW would not be recommended for “less severe depression” – as per your current heading, but equally it would not be recommended for more severe depression as well. So this needs adding.  |
| 38 | Draft Guideline | 31 | Table 2 | First line option is CBT plus “an antidepressant” – please add some advice in the boxes about choice eg try an SSRI first. Don’t put “see below” and leave this advice to the second page. Again this makes the message feel imbalance, the reader needs everything in the first box.  |
| 39 | Draft Guideline | 31 | Table 2 | First line option is “CBT plus an antidepressant” – how should clinician proceed if CBT is not immediately available? |
| 40 | Draft Guideline | 32 and following | Table 2 | There doesn’t appear to be a mention of augmentation drug treatments. Lithium and antipsychotics appear to have been omitted. |
| 41 | Draft Guideline | 37 | 1.7 | Re flow of the document. This section doesn’t seem to sit comfortably here.  |
| 42 | Draft Guideline | 38 | 1.8 | Re flow of the document. Much of this section has been said before, but some hasn’t. so partly feels repetitive and doesn’t flow wee. Please revise in order to ensure people can read the full message. |
| 43 | Draft Guideline | 38 | 1.8.3 | And excess alcohol consumption.  |
| 44 | Draft Guideline | 39 | 1.8.5 | Please advise, what do you mean by continuing, at the same dose? And a gradually reduced dose? |
| 45 | Draft Guideline | 40 | 1.8.11 | Good that you suggest using a “formal validated rating scale” here, as this was avoided during this initial assessment in section 1.2.6.  |
| 46 | Draft Guideline | 41 | 1.9.1 | This section is titled “Further-line treatment” but a review at 4 weeks is not “further”. That would be common to review treatment at 4 weeks, and if an antidepressant is used there should be an assessment of adherence, and a review of the dose. This section of advice should be placed much earlier in the document as it is quite early in the treatment pathway. The treatment options outlined in the rest of section 1.9 should not be visited at 4 weeks. They are much later on in the treatment pathway. Many of which should be done in secondary care. This section needs careful revision and separating into second line drug treatment steps, and then “later” drug treatment steps.  |
| 47 | Draft Guideline | 43 | 3 | Please change “medication” to “antidepressant” as that is what the sentence refers to.Please add some recommended timeframes form switching treatments  |
| 48 | Draft Guideline | 43 | 4 | Remove MAOIs form this list to emphasise that these are not equivalent choices, as you say in lines 8-9 MAOIs are not easily swapped and this should be done with great care (more so than with other antidepressants).  |
| 49 | Draft Guideline | 43 | 9 | MAOIs should only be started in secondary care. |
| 50 | Draft Guideline | 43 | 10 | We should not be advising prescribers to switch TO dosulepin given the safety concerns.  |
| 51 | Draft Guideline | 43 | 1.9.7 | Please rephrase to emphasise that the 3rd line placement for vortioxetine was due to the weak evidence to support efficacy, and therefore its use could not be justified earlier on. Not that it is reserved as a more effective third line option for treatment resistant cases – which is how this can currently be misunderstood. Otherwise people may choose vortioxetine when they should be stepping up care and adding in an augmentation strategy.  |
| 52 | Draft Guideline | 44 |  | This section needs careful revision and separating into second line drug treatment steps, and then “later” drug treatment steps. |
| 53 | Draft Guideline | 44 | 13 | Use the term “second generation antipsychotic” rather than “atypical”.  |
| 54 | Draft Guideline | 44 | 13-17 | Please add guidance around the choice of antipsychotic. Again this section feels that it is partly repetition of earlier sections, but also not fully address in either place. Please add advice around antipsychotic choice as an augmentation strategy and secondly for psychotic symptoms. These are different choices.  |
| 55 | Draft Guideline | 44 | 18-20 | Triiodothyronine is actively NOT recommended by NHSE making this inconsistent.  |
| 56 | Draft Guideline | 45 | 1.10 | This section feels as though it should have the “third” or “later” choices.  |
| 57 | Draft Guideline | 45 | 1.10.2 | Please add in advice about the place of lithium and antipsychotics in here. |
| 58 | Draft Guideline | 46 | 12-14 | We are unclear about the evidence base to pick out support a specific role for amisulpride and yet not giving any context for any other named antipsychotics. We suggest this section on amisulpride is deleted.  |
| 59 | Draft Guideline | 47 | 1.11 | Please add some text around trying to set realistic expectations of drug treatment with popele who have a personality disorder and depression. |
| 60 | Draft Guideline | 48 | 20 | “does not wish to take antipsychotic medication” please add in “does not wish to ***also*** take antipsychotic medication” |
| 61 | Draft Guideline | 49 | 1.12.5 | “The decision when to stop” please rephrase to “***if*** and when”.  |
| 62 | Draft Guideline | general | general | We could not see any guidance about the times when it IS appropriate to abruptly stop an antidepressant. The whole tenor of the text was about the risks of stopping, but did not advise clinicians how to proceed if a patient developed an acute adverse reaction or presentation eg serotonin syndrome, mania, GI bleed etc where following the advice to slowly reduce the dose of many months or weeks who be extremely dangerous.  |
| 63 | Draft Guideline | general | general | In section 1.8.4 there is reference to antidepressants increasing the risk of bleeds. This needs to be expanded on, explain that this is serotonin related, and that PPIs should be prescribed to patients in high at risk groups.  |
| 64 | Draft Guideline | 12 | 1.4.2 | Frequency of review should be individualised? 2 and 4 weeks maybe not good for patients at risk should it reference 1.4.21 |
| 65 | Draft Guideline | 19 | 1.4.23 | Antidepressants in older peopleExample given re hyponatraemia – should more detail for monitoring of sodium levels when starting antidepressants in this patient group not be included e.g. U&Es after 1 month. |
| 66 | Draft Guideline | 19 | 1.4.24 | LithiumShould monitoring recommendation not be every three month – not “3-6 months” – given evidence that closer monitoring of lithium reduces risk of longer renal effects? |
| 67 | Draft Guideline | 41 | 1.9 | Further-line treatmentShould there be a clearer algorithm for next-step treatments, instead of relatively vague examples. |
| 68 | Draft Guideline | 45 | 1.10 | Chronic depressive symptoms? recommending TCA before trial of SNRI e.g. venlafaxine(Dosulepin is not formulary in some CCGs? At least in Devon)Why specific recommendation of low dose amisulpride? is moclobemide available |

Insert extra rows as needed

**Data protection**

The information you submit on this form will be retained and used by NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties.Please do not name or identify any individual patient or refer to their medical condition in your comments as all such data will be deleted or redacted. The information may appear on the NICE website in due course in which case all personal data will be removed in accordance with NICE policies.

By submitting your data via this form you are confirming that you have read and understood this statement.

For more information about how we process your data, please see our [privacy notice](https://www.nice.org.uk/privacy-notice).