Developing NICE Guidelines: the manual

NICE National Institute for Health and Care Excellence

Consultation on draft updated Manual – deadline for comments 17.00 on Monday 25 June 2018 email: GuidelinesManualUpdate2018@nice.nhs.uk

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Organisation name – (if you are responding as an individual please leave blank):	British Association for Counselling and Psychotherapy (BACP)			
Name of person completing form:	Dr Naomi Moller, Joint Head of Research			
Comment number	**Document** (Chapter number / Appendix / Glossary)	**Page number** Or **'general'** for comments on the whole document	**Line number** Or **'general'** for comments on the 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.
1	Main	General		**Failure to consider specific guidelines for mental health Guidelines:** We welcome the revision of the NICE manual for development of NICE Guidelines. We are however disappointed by the generic nature of the guidance and the failure to incorporate refinements for Guideline development methodologies focused on treatment guidelines for mental health conditions. We make this argument on the basis that a core intervention (talking therapy) under investigation in mental health is different in significant ways from interventions which consist of provision of medication, use of particular medical techniques or technologies, and that the un-nuanced adoption of methodologies developed for other forms of intervention results in incomplete and/or misleading conclusions. A key recommendation is that when reviewing the evidence base for treatment of mental health conditions, NICE needs to move away from a sole reliance on the medical paradigm as the underlying assumptions and consequent empirical practices of this approach provide a poor fit when the intervention under investigation consists of counselling and psychotherapy. This point is further developed below.
2	Main	General		**The need to use established methodologies:**

				In our view, methodological choices, at all levels, need to include scientifically proven and validated approaches – including measures/ criteria as well as techniques. We make this point on the back of our experience of responding to the 2nd consultation on CG90, NICE's Guideline for depression in adults, which incorporated the use of novel approaches and methodologies which had not been subject to wider empirical evaluation (e.g. definitions of levels of depression severity as one example). Furthermore, it is our view that if a novel method/approach/technique is required, to avoid methodological flaws in the process, then there should be a transparent development process which incorporates opportunities for review by external/ NICE-independent researchers.
3	Main	General		**Additional guidance for Guideline Committee:** The manual should provide clear guidelines on what a Guideline Committee should do when a treatment is being recommended that is not an established treatment model in the UK - as this raises questions of availability, training provision and the extra costs to make the NICE recommended treatment available. This is especially the case when the recommended 'new' treatment is being recommended over established treatments for which there is an evidence base, even if that evidence base might not, at the time of Guideline development, be as strong.
4	Main	5	15	**Real world data:** We broadly endorse NICE's approach to "explore" the inclusion of the impact of real world data in guideline development however we are concerned by the failure to develop this proposal further in this document. For example, outcome data from the Improving Access to Psychological Therapies (IAPT) programme has been in existence since the beginning of the initiative in 2008 and provides key evidence as to how the recommended interventions in the NICE Guidelines for both depression and anxiety disorders work in practice. Considering this evidence from NHS practice (alongside research from research trials) in evaluating the effectiveness of NICE recommended interventions is common sense - particularly given that the

				database comprises the outcomes from millions of British NHS patients, in comparison to the 'mere' thousands of mostly non-British/ non-NHS patients who are represented in any type of meta-analytic examination performed by NICE – this was particularly exemplified in the recent network meta-analysis conducted in development of the guideline for depression in adults.
5	Main	5 + 35		**Membership of decision-making committees:** In our view, research experts should be explicitly and routinely included in the makeup of the committee. Currently NICE includes service user, carers, and clinicians, but not specific research experts in the composition of their guideline committees. Research experts are particularly important given the complexity of research methods and the enormous range of evidence that is drawn on by NICE in developing their Guidelines. Research expertise should include both methodological experts (e.g. for network meta-analysis which is highly complex) and researchers with broad discipline expertise. In our view without this the Guidelines committee is less able to rigorously evaluate any NICE-sponsored analyses. In addition, membership of committees which develop mental health guidelines should assure that there is appropriate representation from the various 'schools' of therapy modalities, to protect against any unconscious effects of modality 'allegiance' (see next box).
6	Main	36 + 45		**Committee members declaration of interest and failure to consider member 'allegiance':** The manual considers potential conflicts of interest (p36) as well as declaration of interests for committee members (p45). However, the interpretation of what constitutes a potential biasing interest is not appropriate for use in the development of mental health Guidelines because it does not explicitly consider theoretical orientation as a potential bias. This is key due to the evidence that 'allegiance' has a significant biasing impact on rigorously conducted RCT research (e.g. Munder et al., 2013), an effect which is as great as the effect size of many mental health interventions. It is important to state that 'allegiance' is not about deliberate bias but is assumed to result from non-

				conscious/ subtle factors that influence how favoured versus not-favoured therapy modalities are investigated and evaluated. Allegiance is controlled for in appropriately conducted meta-analyses in the discipline and in our view it also needs to be controlled for in the Guideline committee. There are various methods for assessing allegiance however, at a minimum, members should publicly state if they have had any training in any of the assessed interventions, if they practice or supervise practitioners/ trainees using any of the intervention, if they have conducted research or supervised PhD students on any of the interventions, as well as how they themselves would identify their own preferred therapy modality.
7	Main	17 +27		**Defining the scope of the Guideline (p17) and Identifying the main outcomes (p27):** In our view, defining the scope for a guideline cannot solely be guided by following a medical/ symptom-based paradigm/ model which assumes that 'recovery' from a mental health disorder needs to be considered only in terms of change in designated symptoms. The conceptual framework of the mental health problem needs to be understood more developmentally, in order acknowledge the complexity of aetiology in mental health and to incorporate the evidence of developmental pathways to mental health. Further, and in line with evidence of service user preferences, recovery must be considered more holistically, to include areas such as relational and employment functioning as well as broader psychological functioning. We make this point while noting the text in the Draft Manual that the main outcomes "should always include quality of life and some important condition-or service-specific outcomes that are important to people receiving care and support or using services" (p27). This point is also stressed in the current Guideline however in the Draft Guideline for Depression (2nd consultation) the focus on narrow symptom change was justified by the claim that not enough studies reported such measures. The critical necessity of this broader perspective requires that limited data availability should not be a reason for not considering these broader outcomes. A final point is that in our view, it is critical to include long-term outcomes in any analysis picture, given that some mental health conditions are prone to recurrence. Without considering the longer-term picture, it is impossible to properly judge the effectiveness of any mental health treatment.

8	Main	19	12	**The scoping search and inclusion of service user experience, views and concerns:** In our view, the scoping search must include a search for evidence on service user views and experiences of the condition that is the focus of the Guideline, so that the experiences, views and concerns of service users fully guides the Guideline development.
9	Main	33	3-4	**Right to not publish consultation responses:** In our view, NICE should only have the right to not to publish comments if they are unlawful (e.g. defamatory), not for any other reason. Stakeholders can be asked to keep their comments concise and clear, however, any comments should be published without alteration, in keeping with the overall aim of transparency.
10	Main	60	4-7	**Over focus on RCTs:** On page 60 there is the statement that: "A review question about the effectiveness of an intervention is usually best answered by a randomised controlled trial (RCT), because a well-conducted RCT is most likely to give an unbiased estimate of effects". We would argue strongly that this statement does not hold for research on mental health treatments. One reason for this is that the RCT method is a poor fit for this type of intervention – for example, it is impossible to conduct double-blind designs in counselling and psychotherapy. Another key issue is whether the participants in RCTs are generalisable to the population who present for services in settings such as the NHS (further on this point and problematic aspects of RCTs in Barkham, Moller & Pybis, 2017). In the view of BACP, given the issues around RCTs, other types of evidence should always be reviewed, not "may in some circumstances be reviewed in addition" (p60).
11	Main	66		**Approach to inclusion of service user perspectives in developing review questions:** We believe that in order to avoid tokenism, and to ensure that service user views, experiences and priorities are central to guideline development in the context of mental health, it is key to incorporate service user perspectives in all aspects of the Guideline development. Further that this needs to include not only inclusion of service user members on committees but also formal consideration of the research

				base on service user experiences of the condition and of treatment for the condition.
12	Main	83		**Sources of, and methods to locate, evidence and the approach to managing publication bias:** In our view, evidence presented in books should not be routinely excluded as in some areas this may be a key data source. The process to access relevant research should include contacting investigators where needed e.g. required data not clearly reported in published papers. In addition, it is important to search out unpublished studies and studies in progress; one recommendation would be to include a general call to solicit unpublished data to address publication bias. More broadly, the approach to managing publication biases needs to be specified in any guideline.
13	Chapter 6	102		**Network Meta-Analysis (NMA)** The need for an adequate method to address the limitations of meta-analyses has been stressed and the utilisation of network meta-analysis has gained popularity (Sutton et al., 2008). An advantage is that it can improve precision of the direct estimates (Bucher et al., 1997) and allows for the exploration of biases that are difficult to assess in standard meta-analyses (Cipriani et al., 2013). Thus, we welcome the decision of using an approach that aims at mitigating known limitations of standard meta-analysis. However, NMA is a novel experimental technique for analysing evidence and, as yet, no formal expert consensus exist on its appropriateness for clinical guidelines (Kanters et al., 2016). There are serious concerns and unique risks associated with network meta-analysis over and above that of standard meta-analyses (Keefe, 2015; del Re et al., 2013; Kibet et al., 2014) that need to be taken into consideration when applying it. Due to these, in line with the Canadian Agency for Drugs and Technologies in Health (Wells et al., 2009), we would like to stress that findings from indirect or mixed comparisons should only be used to supplement evidence derived from direct comparisons. As some commentators have noted: 'Nonetheless, a network meta-analysis is not a substitute for a well conducted randomized controlled trial' (Kanters et al., 2016, p. 783). More immediately, perhaps, there needs to be a debate as to the appropriateness of using pill placebo as the appropriate comparator in

				relation to decision-making (see current depression guideline). To use a non-clinically viable intervention as the appropriate comparator – something a patient experiencing depression would never be offered – does not appear to be the most useful benchmark for informing decision-making regarding differing interventions. However, as stated previously, RCTs are also problematic in relation to evaluating the psychological therapies. Overall, the appropriateness of NMA relies on particular conditions (network connectivity, network consistency or transitivity and similarity of trials regarding study design and populations), which, if not met, render the outcome invalid and unreliable. Thus, we would like to stress the need in the updated manual to clearly spell these out and emphasise that this type of technique can only be used when **all** of the conditions are met and when the method provides added value relative to traditional meta-analyses (Kanters et al., 2016). Currently, NICE are over-interpreting trial data using network meta-analysis whilst ignoring these large standardised routine datasets and thereby distorting the weight of evidence. For example, the current depression guideline under re-consideration has over-used NMA to such an extent that it is not possible to track back to the findings of individual studies. The output suggests that counselling should be a 2nd tier intervention and that it is not recommended for severe depression. By contrast, all the evidence from high-quality datasets (i.e., IAPT and the National Audit for Psychological Therapies) consistently shows there to be no difference. **References:** • Bucher, H.C., Guyatt, G.H., Griffith, L.E., and Walter, S.D. (1997) The results of direct and indirect treatment comparisons in meta-analysis of randomized controlled trials. Journal of Clinical Epidemiology, 50, 683-91. • Cipriani, A., Higgins, J., Geddes, J.R., and Salanti, G. (2013). Conceptual and technical challenges in network meta-analysis. Annuals of Internal Medicine, 159, 130-137 • Kanters S, Ford N, Druyts E, Thorlund K, Mills EJ, Bansback N. (2016). Use of network meta-analysis in clinical guidelines. Bull World Health Organ;94:782-4. • Keefe, J. (2015). Heightened risk of false positives in a network meta-analysis of social anxiety. The Lancet, 2, 292-293. • del Re, A.C., Spielmans, G.I., Flückiger, C., and Wampold, B.E. (2013). Efficacy of new

				generation antidepressants: Differences seem illusory. PLoS One, 8, e63509. • Kibret, T., Richer, D., and Beyene, J. (2014). Bias in identification of the best treatment in a Bayesian network meta-analysis for binary outcome: a simulation study. Clinical Epidemiology, 6, 451–60. • Sutton, A., Ades, A.E., Cooper, N., Abrams, K. (2008) Use of indirect and mixed treatment comparisons for technology assessment. Pharmacoeconomics, 26, 753-67. • Wells, G.A., Sultan, S.A., Chen, L., Khan, M. and Coyle, D. (2009). Indirect Evidence: Indirect Treatment Comparisons in Meta-Analysis. Ottawa: Canadian Agency for Drugs and Technologies in Health.
14	Main	104		**Evaluating qualitative evidence, meta-synthesis and case studies:** We would suggest that the references in this section should be reviewed and extended as they are limited and in many cases, are outdated and not representing current developments. For example, there is no references to the latest techniques of qualitative meta-synthesis. Also in the counselling and psychotherapy area systematic case studies are a key form of evidence and should be included.
15	Main	168		**Interpreting the evidence to make recommendations, reporting decision process:** A key function of the Guideline Committee is to assess and interpret the evidence to make recommendations (p168). While this section provides guidance on how this should be done, there is no guidance about how the process of or criterion used for the interpretation should be reported in the final document. In our view transparency around how what may be a vast, highly complex and potentially flawed/ incomplete evidence base and series of analyses, is 'interpreted' and boiled down into a limited number of recommendations is key. It is our recommendation that guidance for how this work of the committee should be clearly reported be included, so that stakeholders can understand clearly the grounds on which final recommendations are made.
16	Main	185		**Comments on the validation process, length of the consultation period:** It is our view that the importance of stakeholder involvement should be emphasised more and supported better, through consultation periods which flexible, allowing for longer consultation periods for more

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				complex/longer consultation documents/analyses and/or those which are relevant for larger populations of patients. Consultation periods longer than 6 weeks are key to allow serious perusal of draft Guidelines; without this the value of a consultation period with stakeholders risks being seriously undermined.

Insert extra rows as needed

Checklist for submitting comments

- Use this comment form and submit it as an **Word document (not a PDF).**
- Include **page and line number (not section number)** of the text each comment is about.
- Combine all comments from your organisation into 1 response. **We cannot accept more than 1 response from each organisation.**
- **Do not paste other tables into this table** – type directly into the table.
- Underline and highlight any confidential information or other material that you do not wish to be made public.
- Do not include medical information about yourself or another person from which you or the person could be identified.
- Spell out any abbreviations you use
- For copyright reasons, comment forms **do not include attachments** such as research articles, letters or leaflets (for copyright reasons). We return comments forms that have attachments without reading them. The stakeholder may resubmit the form without attachments, but it must be received by the deadline.

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.

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