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Time for a Change:

NICE Guideline Need to Revise their Methodology

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Case in Point: Draft Revision of the 2009 Guideline for Depression in Adult

The screenshot shows the cover page of a draft guideline. At the top left, it says 'draft guideline 1-112ad - Adobe Acrobat Reader DC'. The main header is 'National Institute for Health and Care Excellence' with 'Version 1.0' below it. The title is 'Depression in adults: treatment and management' and 'Full guideline'. At the bottom, it says 'NICE Guideline <...>', 'Methods, evidence and recommendations', and '18 July 2017'.

The screenshot shows the comments form for the draft guideline. The title is 'Depression in adults: recognition and management' and the NICE logo is present. The form includes a 'Disclosure' section, a 'Name of commentator' section (filled with 'Dr Felicitas Rort'), and a 'Type' section (filled with 'Official use only'). Below this is a table for 'Comments' with columns for 'Comment number', 'Document', 'Page number', and 'Line number'. The table contains three rows of example comments and one row for a specific comment. The specific comment is numbered '1' and refers to a paragraph in the 'Context' section.

Comment number	Document	Page number	Line number	Comments
Example 1	Full	16	45	We are concerned that this recommendation may imply that ...
Example 2	Full	16	45	Question 1: This recommendation will be a challenging change in practice because ...
Example 3	Full	16	45	Question 1: Do you have had experience of implementing this approach and would be willing to submit its experiences to the NICE Clinical Evidence Database? Contact:
1	Short	37	12-20	We are concerned about this paragraph as it does not include the references where the data was taken from. We are furthermore concerned that the wording of the Context section as a whole is not sensitive to individuals and communities with lived experience of depression. We recommend a revision of this section to that effect, including adequate citation of the supporting evidence.

Outline of concerns focused on today

- a) Proposed categorisation/classification system of depression
- b) Methodological choices for inclusion and exclusion criteria of studies
- c) Chosen measurement time points and narrow focus on symptom outcome
- d) Statistical choices made that are associated with serious and unique risks
- e) Overemphasis on evidence of treatment efficacy

McPherson, Rost, Town & Abbass, *Epistemological flaws in NICE review methodology and its impact on recommendations for psychodynamic psychotherapies for complex and persistent depression*, in press

Proposed Categorisation

- Would be out of line with DSM-5 (APA, 2013) and EPA (Jobst, 2016).
- Definition is still descriptive and symptom based rather than explanatory.
- It divides the trial populations by dichotomising baseline severity as 'more severe' and 'less severe' using a method that has not been validated.
- Separation of Chronic Depression, TRD, and complex depression highly problematic

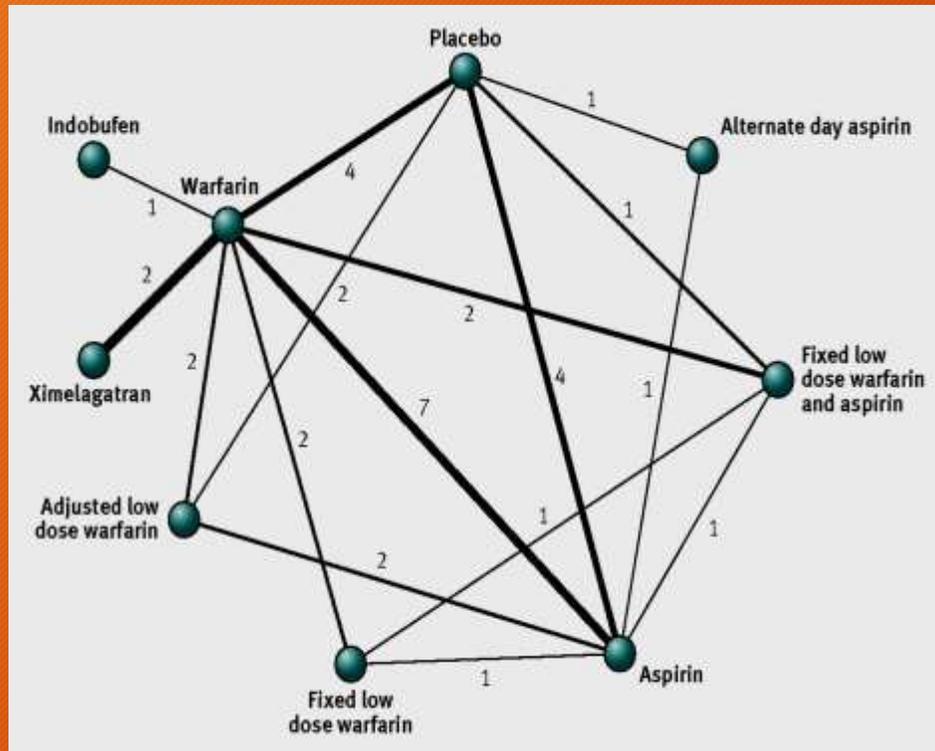
Inclusion and Exclusion Criteria

- The GRADE system was utilized and applied without adaptation despite the complex endeavour of comparing psychological and medical treatments.
- Relevant criteria concerning the nature of depression should be included.
- Long-term follow-up data should be a must
- Need to evaluate and report on a range of outcome measures, which represent what service users stress as important criteria of change.

Measurement Point

- Measurement point of 6 month or 12 month is arbitrary and has inherent conceptual problems making a comparison unfeasible.
- No long-term follow-up despite repeated calls (e.g. McPherson et al, 2005; Goodyer et al, 2008; Goodyer et al, 2011; Goodyer et al, 2017, Rawlins, 2008).
- Principles of Parity of Esteem not met.
- *“The aim of intervention is to restore health through the relief of symptoms and restoration of function, and in the longer term, to prevent relapse “(p. 40, l.31-32).*

Statistical choices made: Network Meta-analysis (NMA)



- Network meta-analysis (...) is a meta-analysis in which multiple treatments are being compared using both direct comparisons of interventions within RCT and indirect comparisons across trials based on a common comparator
- (Mills et al. 2013)

Graph from: BMJ, Mills, Thorlund & Ioannidis (2013)

Statistical Choices made

- There are serious concerns and unique risks associated with network meta-analysis over and above that of standard meta-analyses that need addressing (Keefe, 2015; del Re et al., 2013; Kibet et al., 2014).
- These have not been adequately resolved and thus render resulting treatment recommendations unreliable.
- Overall, findings from indirect and mixed comparisons should only be used to supplement evidence from indirect comparisons (Canadian Agency for Drugs and Technologies in Health; Wells et al., 2009).

Overemphasis on evidence of treatment efficacy

- Creating sound public policy requires that we draw on a diverse range of evidence (Health Foundation, 2017; Thomas, 2017).
- Qualitative evidence maximizes the value of reviews to policy and practice decision-making (Cochrane Collaboration, 2011).
- Case study and qualitative evidence should inform the existing Guideline as part of a ‘multi-level synthesis’ (ibid) in which qualitative evidence is not merely supplementary, but intrinsic to the generation of a clinically representative picture.

Section on Service user Experience not updated

- There is no evidence that depression is a static biological phenomenon (Kendelr, 2016). Experience of depression is intertwined with the social and economic context in which people live.
 - The impact of austerity on depression
 - Changes which impact on the extent to which stigma features in client experience. E.g. “time to change” (Henderson et al, 2016)
 - Recent policy changes include the Care Act
- There are numerous primary research on experiences of depression and treatments since 2009, which has been ignored.

Sole focus on RCTs is a restricted model of science

- RCTs, like observational studies, have advantages and disadvantages. Thus guidelines that ignore important evidence for psychological therapies as they occur in clinical practice (NHS settings) are concerning.
- RCTs are an important part in the research cycle (Roth & Parry, 1997; Fonagy, 2005), but are inappropriately elevated above observational studies ('illusory hierarchy', Rowlinson, 2008)
- There is a need for the appraisal of all evidence.

The methodology is not changed:

- The guideline will force a U-turn on the progress made in providing equity of access to a wide range of psychological therapies.
- It will discriminate against psychological therapies in spite of service users preference over pharmacological alternatives (Dekker et al, 2008; Van et al, 2009).
- It will restrict patient choice and shared decision making stressed by the NHS reform (2009).

Conclusion

- A one-size-fits-all model in mental health is untenable.
- A range of treatments have been shown to be effective, the ambition to identify *the most effective* treatment restricts patient choice and shared decision making.
- Acknowledging the fact that overall 50% of all patients benefit from psychological treatments and medication, we ought to focus on the endeavour to find out who benefits and who does not from which treatment at what particular point in time.

Thank you very much for your
attention!

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