**Uncertainties: Do PROMS improve outcomes in patients with depression in primary care?**

**Box 1: What you need to know**

* Self-reported patient questionnaires, also called PROMS, are used in the initial assessment of patients with depression and for monitoring progress with treatment.
* There is insufficient evidence, and mostly of low quality, that routine monitoring with PROMS in primary care leads to improvement in outcomes in terms of symptoms of depression.
* PROMs can readily demonstrate the number of depressive symptoms patients have, and what treatment might be indicated, but PROM scores should be interpreted with caution, alongside patients’ statements of how they feel overall, coexisting anxiety symptoms, and quality of life.

Patient reported outcome measures (PROMs) are questionnaires, or brief interviews, assessing patients’ symptoms, functional status and health-related quality of life.1 The use of PROMs in the assessment of severity of depression and follow-up monitoring of patients is widely promoted in primary care, psychological therapy and mental health care settings in the UK, USA, and Europe (Box 2). PROM results provide feedback on patients’ responses to treatment to health care practitioners who may then adjust treatment or refer for alternative interventions. Patients can feel more involved in their care and more informed of their progress1. Commissioners of services may also use PROM results to evaluate services. Similar measures can be used to screen for depression and aid diagnosis, but here we focus on their use in assessing initial severity and response to treatment.

Several PROMs are used for monitoring treatment outcomes in adults with common mental health disorders including depression and anxiety (Box 3). In the NHS England Improving Access to Psychological Therapies (IAPT) programme, PROMs for depression, anxiety, and social functioning are routinely administered at every treatment session3. PROMs are relatively quick surrogate measures for longer interview-based assessments of symptoms and functioning, which provide standardised results, readily understandable to other practitioners, and to patients themselves after brief explanations of their meaning.

It is uncertain however whether assessing severity and monitoring response to treatment using patient feedback from PROMs, leads to changes in treatment and improves patient outcomes in terms of symptoms, individual functioning, and social functioning in depression.2

**Box 2: Organisations recommending the use of PROMs for the monitoring of outcomes in the treatment of depression**

UK National Institute for Health and Care Excellence (NICE)

<https://www.nice.org.uk/guidance/qs8/chapter/Quality-statement-1-Assessment>

NHS England Increasing Access to Psychological Therapies (IAPT) programme

<https://www.england.nhs.uk/wp-content/uploads/2020/05/iapt-manual-v4.pdf>

US Federal Health Resources and Services Administration

<https://bphc.hrsa.gov/qualityimprovement/clinicalquality/behavioralhealth/index.html>

US Department of Veterans Affairs / Department of Defense

<https://www.healthquality.va.gov/guidelines/MH/mdd/>

American Psychiatric Association

<https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf>

American Psychological Association

<https://www.apa.org/depression-guideline/assessment/>

Kaiser Permanente Health Maintenance Organisation

<https://wa-provider.kaiserpermanente.org/static/pdf/provider/patient-ed/screenings/bhi-monitoring-tool.pdff>

Nederlands Huisartsen Genootschap (Dutch Society of General Practitioners) <https://richtlijnen.nhg.org/standaarden/depressie#volledige-tekst-3-beoordelen-van-de-ernst-van-de-depressieve-stoornis>

**Box 3: PROMs used to monitor the treatment of depression and of anxiety**

* **Depressive symptoms** e.g. the Patient Health Questionnaire (PHQ-9), Beck Depression Inventory (BDI or BDI-II), Hospital Anxiety and Depression Scale questionnaire (HADS) depression subscale (HAD-D), and Montgomery-Asberg Depression Rating Scale (MADRS)
* **Anxiety symptoms** e.g. the Generalised Anxiety Disorder questionnaire (GAD-7), HADS anxiety subscale (HAD-A), and Beck Anxiety Inventory (BAI)
* **Social functioning** e.g. the Work and Social Adjustment Scale (WSAS) or the Social Adjustment Scale (SAS)
* **Depression and anxiety combined** e.g. the HADS, the Hopkins symptom checklist (SCL-90) or the Mini-International Neuropsychiatric Interview (MINI)
* **Combinations of symptoms, individual functioning, and social functioning** e.g. the 45-item Outcomes Questionnaire (OQ-45), Clinical Outcomes in Routine Evaluation Outcome Measure (CORE-OM), and the Outcome Rating Scale (ORS)
* **Health-related quality of life** e.g. the Medical Outcomes Study Short Form questionnaire (SF-36), and EuroQol five item questionnaire (EQ-5D)

(See Kendrick et al., Routine use of patient reported outcome measures (PROMs) for improving treatment of common mental health disorders in adults, Cochrane Review, 2016, for references to individual scales)2

**What is the evidence of uncertainty?**

There is insufficient evidence on using PROMS in primary care for monitoring outcomes of treatment in patients with common mental health disorders including depression and anxiety. There is some evidence of benefit for their use in routine monitoring in specialist mental health and psychological therapy services, specifically for patients at high risk of treatment failure based on initial response to therapy. The evidence is however of low quality.

Two meta-analyses of trials of PROMs in mental health and psychological therapy settings reported benefits in terms of depression outcomes.4,5 The benefit identified in psychological therapy settings was mostly for participants assessed as ‘not on track’ or ‘NOT’ in terms of progress early in the course of treatment, compared to their expected trajectory of response to treatment (see table).5

A Cochrane review published in 2016 (17 studies, 8787 participants) evaluated the effect of using PROMS to monitor progress in patients with common mental health disorders across all settings, including primary care. There was a lack of evidence that using PROMS improved patient symptoms or led to changing their management over the course of their treatment.2 The quality of evidence was low as all included studies were at high risk of bias with considerable attrition at follow-up. Very few studies reported impact on health-related quality of life and social functioning, adverse events, or costs. A post-hoc sub-group meta-analysis (10 studies, 923 participants) found there was evidence of improvement in symptom scores in ‘NOT’ cases.2 The effect was small (standardised mean difference -0.22, 95% Confidence Interval -0.35 to -0.09) and the quality of evidence low. In another sub-group analysis PROM use also appeared to result in shorter treatment for ‘on track’ patients, increasing service efficiency (see table).2

Since the 2016 review two studies have evaluated routine use of the PHQ-9 for depression6 and GAD-7 for anxiety6 at every patient contact in the NHS England IAPT services.7, 8 Therapists were trained to review expected treatment response graphs with patients and discuss ‘NOT’ cases with their clinical supervisors. The first study confirmed outcome feedback could enhance service efficiency and reduce costs, although it did not report improved patient outcomes, and it was limited by its non-randomised design using historical controls.7 The second did find that ‘NOT’ patients allocated to outcome feedback were less depressed and anxious after treatment than those in usual care, supporting its implementation in IAPT services (see table).8

*Primary care*

Evidence of benefit from psychological therapy settings may not generalise to primary care however, where only a proportion of patients have mental health problems and routine administration of PROMs for depression and anxiety to all patients is not justified. Only two studies included in the 2016 Cochrane review were conducted in primary care, both in the USA, and they reported opposite findings in terms of both changes in management and improvement in outcomes.2,9,10 (see table).

Between 2009 and 2013 the NHS general practitioner (GP) Quality and Outcomes Framework financially incentivised the follow-up assessment of depression with depression symptom PROMs 5-12 weeks after diagnosis.11  Examination of the records of 604 patients assessed using the PHQ-9 suggested that GP treatment changes (increasing or switching antidepressants, or specialist referrals), were nearly five times as likely for patients who showed an inadequate response to initial treatment on the questionnaire at follow-up.11 However patient outcomes after treatment changes were not reported (see table).

Two more recent trials in primary care have also reported conflicting findings on benefit of PROMS in improving depression symptoms12, 13. These studies were both small and probably underpowered to detect clinically meaningful changes in outcomes (see table).

**Box 4 Search strategy: sources and selection criteria:**

We have used the Cochrane review published in 2016 in preparing this article2. For studies published subsequently, we used the search terms from the Cochrane review to search the PsycINFO (EBSCOhost) and Cochrane CENTRAL databases up to 18 April 2020. We used variations of terms including *clinical trials, primary care, general practice, family practice, patient, client, mental health, mental disorder, psychological phenomena, patient-reported, near testing, information, progress, outcome, feedback, treatment outcomes, psychotherapeutic outcomes, etc.* Both authors screened titles and abstracts, and subsequent full papers, for inclusion. The full strategy is described in the Appendix.

*Patient and provider preferences*

Qualitative research from the UK suggest that patients with depression value the use of symptom questionnaires to assess their condition and the effectiveness of their treatment.14 Using PROMs can present practical challenges however. In time-limited consultations practitioners must build rapport, ensure patients can tell their stories, and discuss options with them. Some practitioners dislike these questionnaires as they intrude in consultations and undermine their autonomy.14 Some doubt their validity, preferring to use their own judgement to assess severity and treatment response, and some use them with selected patients only (see Box 5).14,15

*Potential harms*

Only one study in the Cochrane review reported any findings in relation to adverse events, with no immediate suicide risk discerned. Adverse events from prescribed medication were not assessed in any of the included studies.2

**Box 5: Illustrative quotes from qualitative research on PROMs for depression in primary care**

**General Practitioners**

*“The whole kind of detection and management of depression is something that primary care hasn’t been enormously good at historically and I think if we’ve got a, a tool which helps us, collectively, do it better, then, then I think that’s a good thing”*14

*“I don’t have sufficient confidence that it’s an objective enough tool, really, to measure trends”*14

*“Men in their forties can be very hard to convince [that they are depressed]. They prefer to have an ulcer diagnosis.”*15

*“With questionnaires, it feels like going back in development and starting at a more basic level where you give every detail the same importance although you in reality can drop most information rather quickly and concentrate on a few things in order to get a clue.”*15

**Patients**

*“I didn’t understand how you could ask somebody questions and think whether they were depressed or not. More recently I did it with the [measure]. They had a lot more questions and did it on the computer. It was a lot better and was more methodical”*14

*“I think it gives doctors a more accurate picture. As it is laid out for the doctor so there is no slip-up of things being left out.”*14

*“It sort of quantifies that you have problems, but I feel that it is like you’re trying to, like, tie a number to the diagnosis which isn’t necessary. It isn’t necessarily a yes or a no, and it’s very difficult to put a description to it.”*14

**Is ongoing research likely to provide relevant evidence?**

Three trials are currently underway in the UK, Europe and Canada. Two of these are being exclusively run in primary care and the third study in both primary and secondary care. They are all recruiting larger samples of patients, providing more training for practitioners, administering PROMs remotely, and providing automatic feedback of the results to practitioners (see table).16-18 They should provide better evidence on the use of PROMS for monitoring depression in primary care settings, and on facilitating its integration into routine practice for busy practitioners.

**Box 6: Recommendations for further research**

**Population:** Primary care patients with depression, usually mixed with anxiety

In particular, studies should be conducted with:

* adolescent patients (who have been neglected in primary care research so far)
* people treated with drugs, psychological therapies, or both
* patients with multiple physical conditions (who have a high prevalence of depression and greater overall morbidity, mortality and health care costs)

**Intervention:** Brief symptom measures, including both depressive and anxiety symptoms, administered routinely (preferably remotely via the Internet or telephone (especially during COVID-19 related restrictions on face to face contacts), with automated processing of results and feedback to practitioners and patients).

**Comparison:** Administration of the PROMs without feedback of results to practitioners or patients.

**Outcomes:** Depressive and anxiety symptoms (including total symptoms, remission and improvement), quality of life, social functioning, adverse effects (including drug side effects), satisfaction with care, use of services, and costs for cost-effectiveness estimation. Studies should ideally follow up patients for longer than six months.

**What should we do in the light of the uncertainty?**

Given the uncertainty of usefulness of PROMS to improve outcomes in patients with depression, their routine use in primary care is not yet established. The UK NICE depression guideline recommends practitioners should *consider* using routine outcome monitoring with a validated outcome measure for all interventions, including drug treatment as well as psychological interventions, but emphasises that a comprehensive assessment of depression should not rely simply on a symptom count, but should take into account the degree of functional impairment.19

PROMS might provide particular benefits in certain patients15:

* Patients who do not readily report symptoms or articulate well how they have been progressing, when asked an open question about how they are feeling
* Patients who need evidence of symptoms to justify specialist referral, or to obtain sickness benefit payments
* Patients unsure if they have depression, demonstrating the number of symptoms they have, and what treatment might be indicated

The figure shows an infographic used in the ongoing PROMDEP trial of the PHQ-9, as an example of written feedback given to patients on the meaning of their scores, including suggestions for possible treatments to be discussed with practitioners.18

However, symptom questionnaires may not capture depression severity accurately. Recent research has shown a mismatch occurs quite commonly between patients’ PHQ-9 scores and their global rating of how they feel (i.e. better, worse, or just the same, in response to an open question), often related to anxiety symptoms and poor quality of life, which are not covered by the PHQ-9.20 PROM scores should therefore be interpreted with caution, alongside patients’ statements of how they feel overall, coexisting anxiety symptoms, and quality of life.

Integrating PROMS into practice presents a challenge to assessing their usefulness. It is important that PROMs do not distort consultations: the focus should not be just the PROM results, but rather the patient as a whole. PROMS can however free up time, if completed before consultations, and/or remotely, by directing the practitioner’s attention to which symptoms are most frequent. They can also promote safety by automatically including a direct enquiry for suicidal thoughts.

Patients should be advised that completing symptom questionnaires as PROMs can inform the initial assessment of their depression, and help them to give feedback on how they are feeling after they have had some treatment, which might help them feel more involved in their own care. Whether or not PROMs are used should be agreed with patients however, informing them first that evidence that they help to improve recovery from depression is uncertain, but more research is underway that may provide clarity.

**Box 7**: **How patients were involved in the creation of this article**

We asked a patient and public involvement (PPI) colleague, Bryan Palmer, who is providing advice on the PROMDEP study18 to comment on this article. He checked the text for its readability for a lay audience, and emphasised that the patient infographic should refer to the ‘score’ rather than the ‘result’ of the PHQ-9 test, as it’s only a score on a questionnaire which suggests a certain level of depression, rather than a definitive ‘result’ in terms of a diagnosis. We are grateful for his input.

**Box 8: What patients need to know**

* More than one in ten people suffer from depression or anxiety, or both.
* Questionnaires on patients’ symptoms can be used as part of the initial assessment of depression, and as patient reported outcome measures (PROMs) helping them to give feedback on how they are feeling after they have had some treatment.
* Some patients report that using symptom questionnaires helps them feel that they have been assessed more thoroughly, that they can follow their progress more easily, and that they feel more involved in their own care.
* The evidence that PROMs help to improve patients’ recovery from depression is uncertain, but more research is underway that may provide clarity

**Box 9: Education into practice**

* Reflect on consultations with patients where you used questionnaires for depressive or anxiety symptoms: Why did you use them? To what extent do you think they changed the interaction? How did your patient feel about using this?
* How might you alter your approach in the future? How would you discuss using PROMS with your patient?

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