

RESEARCH ARTICLE

Risk of Bias from Inclusion of Currently Diagnosed or Treated Patients in Studies of Depression Screening Tool Accuracy: A Cross-Sectional Analysis of Recently Published Primary Studies and Meta-Analyses

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Abstract

Background

Depression screening can improve upon usual care only if screening tools accurately identify depressed patients who would not otherwise be recognized by healthcare providers. Inclusion of patients already being treated for depression in studies of screening tool accuracy would inflate estimates of screening accuracy and yield. The present study investigated (1) the proportion of primary studies of depression screening tool accuracy that were recently published in journals listed in MEDLINE, which appropriately excluded currently diagnosed or treated patients; and (2) whether recently published meta-analyses identified the inclusion of currently diagnosed or treated patients as a potential source of bias.

Methods

MEDLINE was searched from January 1, 2013 through March 27, 2015 for primary studies and meta-analyses on depression screening tool accuracy.

Results

Only 5 of 89 (5.6%) primary studies excluded currently diagnosed or treated patients from any analyses and only 3 (3.4%) from main analyses. In 3 studies that reported the number of patients excluded due to current treatment, the number of excluded patients was more than twice the number of newly identified depression cases. None of 5 meta-analyses identified the inclusion of currently diagnosed and treated patients as a potential source of bias.

integrity of the data and the accuracy of the data analysis.

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Conclusions

The inclusion of currently diagnosed and treated patients in studies of depression screening tool accuracy is a problem that limits the applicability of research findings for actual clinical practice. Studies are needed that evaluate the diagnostic accuracy of depression screening tools among only untreated patients who would potentially be screened in practice.

Introduction

Major depression is present in 5–10% of primary care patients, including 10–20% of patients with chronic medical conditions [1, 2]. Effective treatments are available, but approximately half of depressed patients go unrecognized [3]. At the same time, overdiagnosis and overtreatment are common [4, 5]. Among older primary care patients in the United States (US), for example, fewer than 20% of those diagnosed with depression by a physician or prescribed antidepressant medication meet major depression diagnostic criteria [6].

The vast majority of depression care is provided outside of psychiatric settings [7], and depression screening has been proposed as a way to improve identification and management of depression in primary [1, 8] and specialty care settings [9–15]. Depression screening guidelines and policies vary substantially, however. The US Preventive Services Task Force recommends depression screening in primary care settings with integrated, collaborative depression care systems [1]. Accreditation for many healthcare providers in the US requires documentation of depression screening [16], and depression screening is a required component of Medicare's Annual Wellness Visit [17]. In the United Kingdom (UK), on the other hand, neither the National Institute for Health and Care Excellence [2] nor the UK National Screening Committee [18] recommend routine depression screening. The UK Quality and Outcome Framework incentivized routine depression screening in primary care from 2006 to 2013, but discontinued the program due to disappointing outcomes [8, 19]. In Canada, depression screening was previously recommended in primary care, but in 2013 the Canadian Task Force on Preventative Health Care recommended against it [20]. In their recommendation, the Canadian Task Force raised the concern that existing research may exaggerate the diagnostic accuracy of depression screening tools [21].

For depression screening to improve upon usual care, screening tools must accurately identify patients who are not currently in treatment or seeking treatment and whose depression would not otherwise be recognized by a healthcare provider [20–22]. A 2011 study, however, reported that only 4% of primary studies included in 17 systematic reviews on depression screening tool accuracy appropriately excluded patients currently diagnosed or being treated for depression [21]. Since screening is done to identify previously unrecognized cases, including potentially large numbers of patients already being treated would exaggerate estimates of the accuracy of screening tools and the yield of new cases from screening [21].

It is not known whether more recently published studies have excluded currently diagnosed and treated patients in order to generate results that are more applicable for clinical practice. The objectives of the present study were to investigate (1) the proportion of primary studies of depression screening tool accuracy that were recently published in journals listed in MEDLINE, which appropriately excluded patients with current depression diagnoses or treatment at the time of study enrolment; and (2) whether recent meta-analyses identified the failure to exclude currently diagnosed and treated patients from primary studies as a potential source of bias.

Methods

Article Selection

Our objective was not to conduct a systematic review of screening tool accuracy. Rather, it was to evaluate inclusion and exclusion criteria in studies likely to influence future research methods, policy and practice. A recent study found that restricting a search to only MEDLINE for studies of diagnostic test accuracy did not influence summary estimates in meta-analyses [23]. Consistent with this, studies of depression screening tool accuracy that were published in journals not listed in MEDLINE would not be likely to substantively influence future research methods, policy, or practice. Thus, we limited our search to MEDLINE. We searched MEDLINE (PubMed interface) on March 27, 2015 for primary studies and meta-analyses published in 2013 or later that evaluated the diagnostic accuracy of depression screening using the search terms (depress* AND sensitivity AND specificity), restricted to title or abstract. We included studies published in 2013 or later to obtain recent studies that reflect current practices, which were published long enough after the 2011 review on this topic [21] to incorporate recommendations.

Eligible primary studies were published in any language and reported the accuracy of one or more depression screening tools compared to a diagnosis of depression based on clinician interview or a validated diagnostic interview. Studies were excluded if the diagnostic reference standard was based on a chart diagnosis or a score above a threshold on another self-report measure or rating scale. Studies that included only patients in mental health treatment were also excluded since screening is not meant to be applied to patients already receiving treatment.

Eligible meta-analyses: (1) included a systematic review of the literature using at least one electronic database; (2) statistically combined results from ≥ 2 primary studies; and (3) reported measures of diagnostic accuracy (e.g., sensitivity, specificity) for one or more depression screening tools compared to depression diagnoses. We excluded systematic reviews without meta-analyses because commonly used screening tools are more likely to be included in meta-analyses. Publications that included meta-analyses of the diagnostic accuracy of screening tools for depression, as well as for other disorders, were included if results were presented separately for depression.

Citations were uploaded directly from PubMed into the systematic review manager DistillerSR (Evidence Partners, Ottawa, Canada), which was used for all coding procedures, including tracking the review process and data extraction. Two investigators independently reviewed primary studies for eligibility. If either reviewer deemed a study potentially eligible based on title and abstract review, full text review was conducted. Disagreements between reviewers after full-text review were resolved by consensus.

Data Extraction and Classification

One investigator extracted data from each included study with independent validation by a second reviewer. For each primary study, we extracted the screening tool(s) evaluated, reference standard, study population, number of patients, number of depression cases, and whether the study excluded patients currently diagnosed or treated for depression. Primary studies were classified as having excluded patients with current depression diagnosis or treatment if the study authors specifically indicated this in the exclusion criteria. Studies were classified as having included currently diagnosed or treated patients if the study did not specifically indicate that such patients were excluded. For each meta-analysis, we extracted author, publication year, journal, and 2014 journal impact factor. For publications that included meta-analyses of

diagnostic accuracy and other measurement characteristics (e.g., reliability) only diagnostic accuracy results were extracted. For each meta-analysis, investigators recorded whether the authors identified the inclusion of currently diagnosed or treated patients in primary studies as a possible source of bias.

Results

Article Selection

The database search yielded 501 unique titles and abstracts. Of these, 374 were excluded after title and abstract review and 33 after full-text review because they did not report results from a primary study or meta-analysis that evaluated the diagnostic accuracy of a depression screening tool, leaving 89 eligible primary studies and 5 eligible meta-analyses (Fig 1). The 89 primary studies included sample sizes from 34 to 42,676 (median = 224) and number of depression cases from 5 to 3,115 (median = 37). The majority of studies were from Europe (28%), Asia (24%) or North America (19%). Primary study characteristics are shown in S1 Appendix. Characteristics of included meta-analyses are shown in Table 1.

Exclusion of Currently Diagnosed and Treated Patients. Only 5 of 89 primary studies (5.6%) excluded patients with a current diagnosis or currently being treated for depression at the time of study enrolment from any analyses [24–28], and only 3 (3.4%) excluded these patients from the main study analyses [24, 25, 26].

There were 3 studies that reported the number of patients excluded for current depression diagnosis or treatment [24–26]. In a study of coronary heart disease patients [24], 65 of 803 (8.1%) otherwise eligible patients were excluded due to current depression diagnosis or treatment. Of the remaining 730 patients (after removal of 8 patients with missing data), 32 (4.4%) were newly diagnosed with a depressive disorder. In a second study, of women with breast or gynaecological cancer [25], 28 of 100 women recruited (28.0%) were excluded due to existing

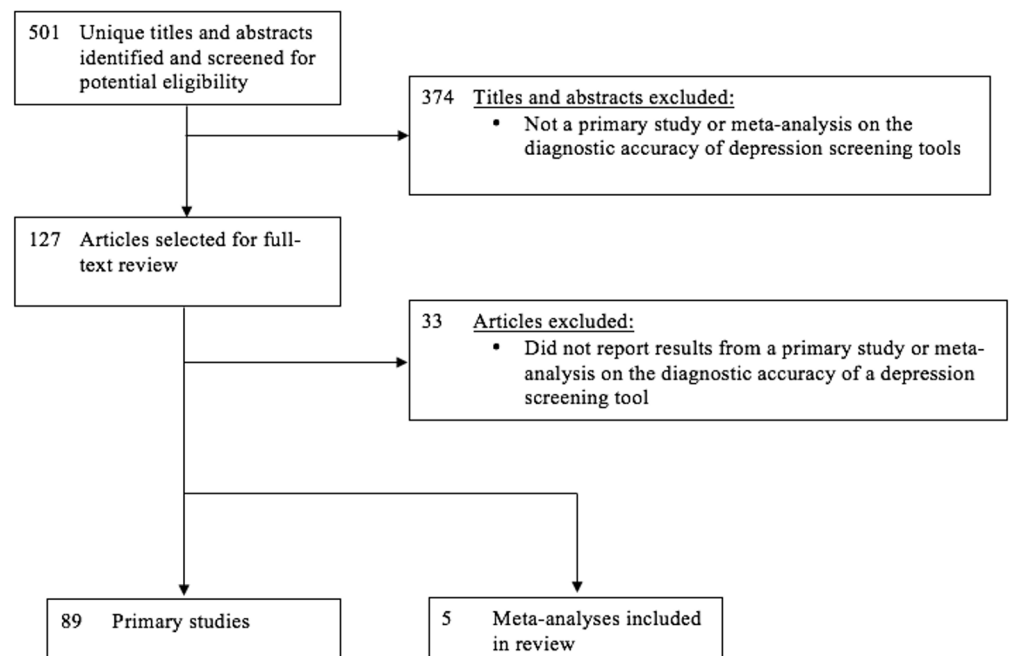


Fig 1. Flow Diagram of Selection of Primary Studies and Meta-analyses that Evaluated the Diagnostic Accuracy of Depression Screening Tools.

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Table 1. Characteristics of Included Meta-Analyses.

First Author, Year of Publication	Journal (2014 Impact Factor)	Focus of Meta-Analysis	Screening Tool(s) Meta-Analyzed	Range of Years of Publication of Included Primary Studies
Manea, 2015	Gen Hosp Psychiatry (2.6)	PHQ-9 algorithm scoring in any setting	PHQ-9	2001–2013
Stockings, 2015	J Affect Disord (3.4)	Screening in children and adolescents	BDI, CESD, CDI	1984–2012
Meader, 2014	J Neurol Neurosurg Psychiatry (6.8)	Screening tools in poststroke patients	BDI or BDI-II, CESD, GDS-15, HADS-D, HADS-T, PHQ-2, PHQ-9	1988–2012
Tsai, 2014	JAIDS (4.6)	Screening tools in HIV-positive adults in Africa	CESD	2008–2012
Tsai, 2013	PLoS One (3.2)	Screening tools in pregnancy or postpartum in Africa	EPDS	1998–2011

BDI = Beck Depression Inventory; CDI = Children’s Depression Inventory; CESD = Center for Epidemiologic Studies Depression Scale; EPDS = Edinburgh Postnatal Depression Scale; GDS = Geriatric Depression Scale; HADS-D = Hospital Anxiety and Depression Scale—depression subscale; HADS-T = Hospital Anxiety and Depression Scale—total score; PHQ-2 = Patient Health Questionnaire-2; PHQ-9 = Patient Health Questionnaire-9.

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treatment, and 13 of 72 untreated patients (18.1%) were newly diagnosed with a depressive disorder. The third study enrolled 152 Canadian patients with multiple sclerosis [26]. There were 20 patients diagnosed with major depression, but 15 were already being treated for depression at the time of study enrolment.

None of the 5 meta-analyses identified the inclusion of patients currently diagnosed or currently treated for depression in primary studies as a potential source of bias.

Discussion

The main finding of this study was that fewer than 6% of primary studies on the diagnostic accuracy of depression screening tools published since 2013 excluded patients with a current diagnosis or treatment for depression. Only 3% of studies excluded these patients from main study analyses. None of 5 included meta-analyses identified the inclusion of currently diagnosed and treated patients as a potential source of bias. These results are similar to findings from a 2011 study [21], which first identified this problem. In that study, only 8 of 197 (4%) primary studies in 17 systematic reviews appropriately excluded already diagnosed and treated patients, and none of the systematic reviews mentioned this problem as a potential source of bias.

It is not known to what extent including currently diagnosed and treated patients in primary studies exaggerates the yield of new depression cases and estimates of accuracy compared to what would occur in practice. A previous study [21] estimated that in a primary care population with 10% major depression prevalence, if half of depressed patients were already receiving treatment [3], then properly excluding already diagnosed and treated patients from screening accuracy studies would reduce the positive predictive value (proportion of positive screens that are true cases), from 27% to 14%, even if sensitivity were only exaggerated by 10%.

We identified only 3 studies [25, 26, 29], although none in primary care settings, that have analysed depression screening tool accuracy with and without patients currently diagnosed or receiving treatment, including 2 primary studies from the present study [25, 26]. One study [25], which included 100 female cancer patients (26 with depressive disorders), evaluated the diagnostic accuracy of the Centre for Epidemiological Studies Depression Scale and Hospital Anxiety and Depression Scale. For both screening tools, sensitivity and positive predictive

value were reduced by approximately 10% when already-treated patients were excluded. In a second study [29], which involved 113 women with breast cancer, excluding already-treated patients did not change sensitivity, but reduced positive predictive value from 21% to 7%. A third study [26] reported data on 152 multiple sclerosis patients, and 15 of the 20 patients diagnosed with depression in the study were receiving treatment for depression at the time of study enrolment. These studies all involved very small numbers of untreated patients with major depression. Nonetheless, results from these studies are generally consistent with prior estimates [22] and suggest that inclusion of currently diagnosed and treated patients may substantially exaggerate estimates of both the accuracy of depression screening tools and the number of patients who would be newly identified as depressed compared to clinical practice, where only previously unidentified, non-treated patients are screened.

In clinical practice, depression symptom questionnaires, or screening tools, are used by healthcare providers for a number of purposes, including screening to detect previously unidentified cases, tracking treatment progress, or detecting relapse, for instance. For the purpose of screening, however, they are only useful to the extent that they distinguish between disordered and non-disordered states that are not otherwise identified [30]. The 3 primary studies that reported the number of patients who were excluded due to existing depression treatment at the time of study enrolment [24–26] found that more than twice as many patients were excluded for this reason than the number of new cases identified with a screening tool. Thus, it is likely that many of the 94% of primary studies that did not exclude these patients also included large numbers of already-treated patients. This conclusion would be consistent with the high rates of existing depression treatment in the general population and among patients in medical settings. A recent study, for instance, reported that 7% of 26,800 randomly sampled Europeans from 27 countries had used antidepressants in the last 12 months [31]. A US general population survey found a 10% prevalence of current antidepressant use among adults and reported that this was long-term use (at least 24 months) in two-thirds of cases [32]. A systematic review of antidepressants among acute coronary syndrome (ACS) patients found that 10–15% of patients assessed between 2000 and 2005 were prescribed or using antidepressants within 12 months of the index ACS [33]. Similarly, administrative data from Ontario, Canada showed that the rate of antidepressant prescriptions within 6 months of an acute myocardial infarction doubled from 8% in 1993 to 16% in 2002 among patients age 65 and older [34].

Systematic reviews on the effectiveness of depression screening have differed in the studies they included and the conclusions drawn. A systematic review done in conjunction with the 2013 Canadian Task Force on Preventive Health Care depression screening guideline [20] did not identify any eligible randomized controlled trials (RCTs) [35]. A 2008 Cochrane systematic review included 5 RCTs that met some criteria for a depression screening trial and reported that depression screening did not reduce depressive symptoms [36]. In contrast, a systematic review done as part of the 2009 US Preventive Services Task Force guideline [1] included 9 RCTs and concluded that depression screening benefitted patients when provided in the context of staff-assisted collaborative care [37]. That review has been criticized, however, because the main trials used to support the claim that screening benefitted patients were trials of collaborative depression treatment that required a diagnosis of depression to enrol [8, 38]. None of the trials in the Cochrane review or the US Preventive Services Task Force review randomized patients prior to screening, excluded currently treated patients, and provided similar depression treatment to patients identified as depressed through screening and patients identified through usual care [8, 38]. The results of the present study emphasize that it should not be assumed that depression screening programs would accurately identify and successfully treat otherwise unrecognized patients without evidence from a properly designed, well-conducted randomized controlled trial to demonstrate this.

A possible limitation of the present study was that we searched only the MEDLINE database for eligible studies. However, including only MEDLINE for searches of studies of diagnostic test accuracy have been shown to not influence summary estimates in meta-analyses [23]. Thus, it is not likely that our main results would have changed if other databases had been searched. An additional limitation is that only a few studies with a small number of depression cases have presented information on how accuracy estimates are influenced by the inclusion versus exclusion of already diagnosed and treated patients. Thus, we could not determine with precision the effect of inappropriate inclusion of currently diagnosed and treated patients on accuracy estimates. However, many studies from other areas of research have reported that the inclusion of established cases among examined cohorts inflates assessments of diagnostic test accuracy [39]. Individual patient data meta-analysis is an approach that may be able to provide stable estimates of diagnostic accuracy parameters by excluding already treated patients in studies of depression screening tool accuracy [40]. A final limitation, although unlikely, is the possibility that already diagnosed and treated patients could have been excluded from primary studies, but that authors of the primary studies did not report this as an exclusion criterion.

In summary, we found that fewer than 6% of primary studies on the diagnostic accuracy of depression screening tools published since 2013 appropriately excluded patients currently diagnosed or undergoing treatment for depression and that recent meta-analyses have neglected this issue as a potential source of bias. Existing evidence on the accuracy and case yield of depression screening tools may substantially overestimate their utility in clinical practice. Well-designed studies that exclude patients currently diagnosed or treated for depression are needed to generate realistic estimates of accuracy that reflect what would be achieved in clinical practice. Although depression symptom questionnaires are used for a variety of purposes, including follow-up assessment of patients receiving treatment, studies that seek to evaluate their accuracy for identifying patients with previously unrecognized depression must exclude these patients.

Supporting Information

S1 Appendix. Primary Studies of the Diagnostic Accuracy of Depression Screening Tools.

Characteristics of included primary studies, including first author and year published, journal, country, population, number of participants, number of depression cases, diagnostic criterion, screening tool, and inclusion or exclusion of currently diagnosed and treated patients. (DOCX)

S1 Checklist. PRISMA Checklist. Table that indicates where in manuscript all elements of the PRISMA Checklist can be found.

(DOC)

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Author Contributions

Conceived and designed the experiments: DBR BDT. Analyzed the data: DBR BDT. Contributed reagents/materials/analysis tools: DBR BDT. Wrote the paper: DBR BDT.

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