Rapid Screening for Depression and Emotional Distress in Routine Cancer Care: Local Implementation and Meta-Analysis

M.D. Thesis

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Dr Alex J Mitchell **ajm80@le.ac.uk**

Honorary Senior Lecturer in Psycho-oncology, Department of Cancer & Molecular Medicine,

University of Leicester LE51WW

0.0 Preface

Abstract

Objectives.

To quantitatively summarize, in a meta-analysis, the existing literature concerning the effect of rapid screening for depression / distress in cancer settings and to examine the benefits of rapid screening for emotional distress in local cancer patients.

Methods.

For the meta-analysis, a search and critical appraisal was made of observational studies and interventional implementation trials studies to August 2012. After excluding quality of life studies, 29 publications were located, involving a total of 15,176 unique cancer patients.

In the primary local implementation study using a sequential cohort design, 50 chemotherapy nurses and treatment radiographers were asked to implement a screening programme for distress/depression/unmet needs as part of routine care and record their feedback before and after application of the distress thermometer (DT) and emotion thermometer (ET) screens. Data were available on 539 clinician-patient assessments involving 379 patients.

Results.

In the meta-analysis, six observational studies found that the proportion of cancer patients who received psychosocial care following a positive distress screen was 30.0% (95% CI = 19.6% to 41.3%). Screening increased psychosocial care by 2.8 fold and psychosocial referrals by 2.7 fold, a significant effect ($p<0.05$). Nine implementation studies (sequential cohort and RCTs) found that psychosocial referrals increased by 3.0 fold in cancer patients who were screened vs not screened. Screening with feedback enhanced referrals by only 12% over usual care ($p = 0.03$).

In the local screening study 56% of patients reported a significant emotional problem and 39% scored high for distress. Without screening, cancer clinicians' detection sensitivity was only 11.1% for distress and 6.8% for depression. After screening clinicians' sensitivity did not significantly improve but specificity increased by 6% for anxiety and 17.5% for any mood problem. Cohen's kappa agreement improved from poor to fair when looking for distress. Across all screening applications, clinicians felt screening was not useful in 35.9% of applications and on multivariate analysis three variables were associated with high staff satisfaction with screening, namely receipt of training, talking with the patient about psychosocial issues and improved detection of psychological problems.

Conclusions.

Screening for distress/depression in cancer settings is likely to increase recognition and quality of psychosocial care but only if barriers are addressed.

Acknowledgements

Many thanks to the staff and patients of University Hospitals of Leicester who took part in this study. Special thanks to Karen Lord, Senior Nurse Specialist, Chemotherapy Department and to Jo Slattery, Senior Treatment Radiographer, Radiotherapy Department and to Lorraine Grainger, Senior Chemotherapy Nurse Specialist, Chemotherapy Department; all at University Hospitals of Leicester NHS Trust, Leicester, LE1 5WW. Thank to Amy Waller (Calgary) for contributing to a draft version of Table 1.7.3 (unmet needs tools).

Thanks to my main supervisor Professor Paul Symonds for support and encouragement. Thanks also to the authors of primary screening studies who responded to email requests for information.

Copyright Declaration

Publications arising from this thesis (see appendix 4)

Reviews

1. Carlson LE, Waller A, Mitchell AJ. Screening for distress and unmet needs in patients with cancer: review and recommendations. J Clin Oncol. 2012;30(11):1160-77.

2. Mitchell AJ. Screening for Cancer-Related Distress: When is Implementation Successful and When is it Unsuccessful? Acta Oncologica 2013;52(2):216-24.

Meta-analyses

3. Mitchell AJ, Meader N, Davies E, Clover K, Carter GL, Loscalzo MJ, Linden W, Grassi L, Johansen C, Carlson LE, Zabora J. Meta-analysis of screening and case finding tools for depression in cancer: Evidence based recommendations for clinical practice on behalf of the Depression in Cancer Care consensus group. J Affect Disord. J Affect Disord. 2012;140(2):149-60.

4. Mitchell AJ, Newton L, Vanderpuye W. Does Screening for Distress Influence the Quality of Psychosocial Care in Cancer? Meta-analysis of Observational and Interventional Studies. Journal of Clinical Oncology (submitted)

Primary Data

5. Mitchell AJ, Lord K, Slattery J, Grainger L, Symonds P. How feasible is implementation of distress screening by cancer clinicians in routine clinical care? Cancer. Cancer. 2012 Dec 15;118(24):6260-9.

Statistics of Thesis

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Figures	33
Tables	14

Common Abbreviations

AngT -	Anger thermometer
AnxT -	Anxiety thermometer
BDI -	Beck Depression Inventory
BDI -	Beck Depression Inventory
BSI-18 -	Brief Symptom Inventory
CaNDI -	Cancer Needs Distress Inventory
CAPHS -	Consumer Assessment of Healthcare Providers and Systems Clinician and Group
CHALS -	Canada Health and Activity Limitation Survey
CARES -	Cancer Rehabilitation Evaluation System
CaSUN -	Cancer Survivors Unmet Needs measure
CCM -	Cancer Care Monitor
CES-D -	Centers for Epidemiological Studies Depression Scale
CNQ-	Cancer Needs Questionnaire
COOP-	Dartmouth Primary Care Cooperative Information Health Assessment
DepT -	Depression thermometer
DSM-IV	Diagnostic and statistical manual of mental disorders 4th edition
DT -	Distress Thermometer
EPDS -	Edinburgh Postnatal Depression Scale
EQ5D-	Euroquol instrument
ET -	Emotion thermometers
FACT-G -	Functional Assessment of Cancer Therapy- General
FLIC-	Functional Living Index-Cancer
GHQ-	General Health Questionnaire
HADS-	Hospital Anxiety and Depression Scale
Help T -	Help thermometer

HRQL-	Health-related Quality of Life
IT -	Impact Thermometer
KPS -	Karnofsky Performance Status
NA-ACP -	Needs Assessment of Advanced Cancer Patients
NEQ -	Needs Evaluation Questionnaire
NPV -	Negative predictive value
PCNA -	Prostate Cancer Needs Assessment
PCNQ -	Prostate Cancer Needs Questionnaire
PDIS -	Patient-Doctor Interaction Scale
PHQ-9 -	Patient Health questionnaire
PNAT -	Patient Needs Assessment Tool
POMS-	Profile of Mood States
PPV -	Positive predictive value
PROMS -	Patient reported outcomes measures
PSQ III -	Medical Outcomes Study Patient Satisfaction Questionnaire-III
PSSCAN -	Psychosocial Screen for Cancer Patients
QoL-	Quality of Life
SCNS -	Supportive Cancer Needs Survey
SF-36 -	Medical Outcomes Study 36-Item Short Form Health Survey
SNST -	Supportive Needs Screening Tool
SPARC -	Sheffield Profile for Assessment and Referral to Care
SPEED -	Screen for Palliative and End-of-Life Care Needs in the ED
SPHERE-Short-	Somatic and Psychological Health Report Short form
SSQ-	Social Support Questionnaire
WONCA-	World Organization Project of National Colleges and Academics

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1.0 Introduction

1.0 Introduction

1.1 Importance of Psychological Wellbeing in Cancer

Cancer is a very common experience with a lifetime incidence of 38-41% according to recent UK and US data.[1] 5% of people develop two independent cancers in their lifetime.[1] In high income countries cancer survival has improved over the last 30 years, with average 10 year survival being 46% compared with 24% in the early 1980s.[2] Improvements in survival shift the emphasis from incidence to prevalence and from diagnosis to rehabilitation. There are approximately 2 million cancer survivors in the UK today and approximately 25 million worldwide, a prevalence figure of almost 4% which is about three times the annual incidence rate.[3] In those aged 65 years it is estimated that more than 13% of the population are cancer survivors.[3] Almost 50% of patients with cancer also have another chronic medical condition. Only 64% of cancer patients actually die from cancer, 36% die from a separate medical condition.[4] Cancer is a feared diagnosis associated with marked mobility. In population surveys in the US and UK, cancer is the most feared of common medical disorders and of individual cancers, brain tumours are those the public is most afraid of.[5 6] In a UK survey of 780 cancer survivors and 2740 controls, cancer survivors were significantly more likely to report being in average or poor general health (47% of cancer survivors vs 17% of healthy participants). They reported finding performing physical activities very difficult (16 vs 3%), and had poor emotional well-being (23 vs 18%) and poor cognitive functioning (2.3 vs 1.5%).[7] In addition, cancer survivors' health more commonly prevented them from working (19% vs 5%), and they also consulted more health services in the past 12 months (4.2% vs 1%). In one recent survey, one third of British long term cancer survivors had current unmet needs.[8] This survivorship landscape sets the scene for the importance of psychological wellbeing in cancer.

The World Health Organization (WHO) defined health as "a complete state of physical, mental and social well-being, and not merely the absence of disease or infirmity."[9] Bircher defined health as "a dynamic state of well-being characterized by a physical and mental potential, which satisfies the demands of life commensurate with age, culture, and personal responsibility."[10] Health therefore encompasses physical and mental wellbeing. Mental wellbeing is closely affiliated with the concept of quality of life, together with an absence of current mental health problems and significant emotional distress. Both distress and depression are important not just for mental health professionals but also for cancer clinicians. The presence of distress

is linked with reduced health related quality of life,[11] poor satisfaction with medical care[12] and possibly reduced cancer survival.[13] Depression itself is one of the strongest determinants of health related quality of life and it also influences participation in treatment.[14 15] A meta-analysis of 25 observational studies showed a 39% higher all-cause mortality rate in cancer patients diagnosed with major or minor depression (95% CI, 1.10-1.89).[16] An important question, particularly in relation to distress, is when does an emotional disorder become serious enough to be clinically important? This is unresolved, but from the clinician's perspective, distress does appear as a clinical significance criterion for depression and anxiety disorders in the Diagnostic and statistical manual of mental disorders 4th edition (DSM-IV).[17] From the patient's perspective, a significant emotional disorder may simply be any distress issue where individuals want help for that problem.

Unfortunately there appears to be a serious gap in the provision of psychosocial care. Clear evidence shows that mental health problems are overlooked by busy cancer professionals in palliative and non-palliative settings who rely on their own unassisted clinical judgment. [18 19] Only the minority (less than a third) of patients recall being asked about emotions, worry or mood changes.[20 21 22] About half of the medical notes of patients have no evidence of having received any assessment for psychosocial wellbeing.[23] Using observed clinical interviews, emotional issues are typically not emphasised during medical consultations. [24 25] This low awareness of psychosocial concerns leaves many cancer patients with unmet psychosocial needs. [26 27 28 29 30] To address this gap in psychosocial care several organizations have recommended (but not yet mandated) screening for emotional complications of cancer. [31 32 33 34] However, screening and many other aspects of psychosocial care have not become part of routine (figure 1.1a). In the US, only 51% of organizations (43% of comprehensive centers, 67% of community-based practices and 19% of patient service organizations) surveyed in 2009 / 2010 conducted routine psychosocial screening for new patients.[35] Open-ended interviews were the most common approach with a distress screener used in 72%, 68%, and 42% of organizations, respectively. [35] In a national UK survey of cancer clinicians only 25% routinely used some form of assessment for distress or depression.[36 37] Yet failures in screening and detection are only part of the reason underlying unmet psychosocial needs. Many patients with mental health concerns are not offered appropriate treatment whilst in cancer settings. Hewitt and Rowland (2002) demonstrated a 12 month service use of only 34.6% in 4878 cancer patients vs 32.7% in 90,737 non-cancer patients (Fig 1.1).[38]

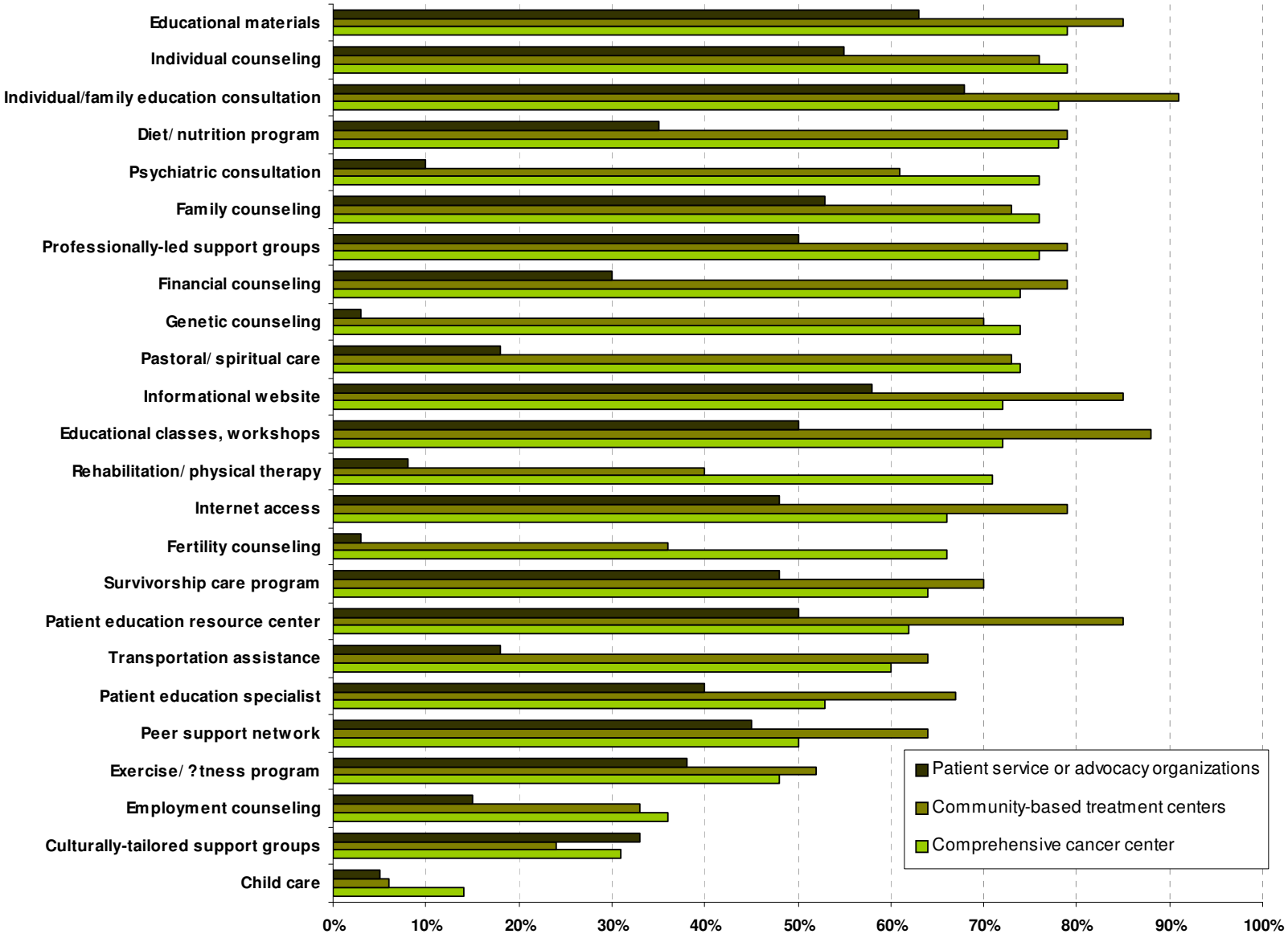


Figure 1.1a - Provision of psychosocial services in the Unites States (data from Deshields et al 2012).

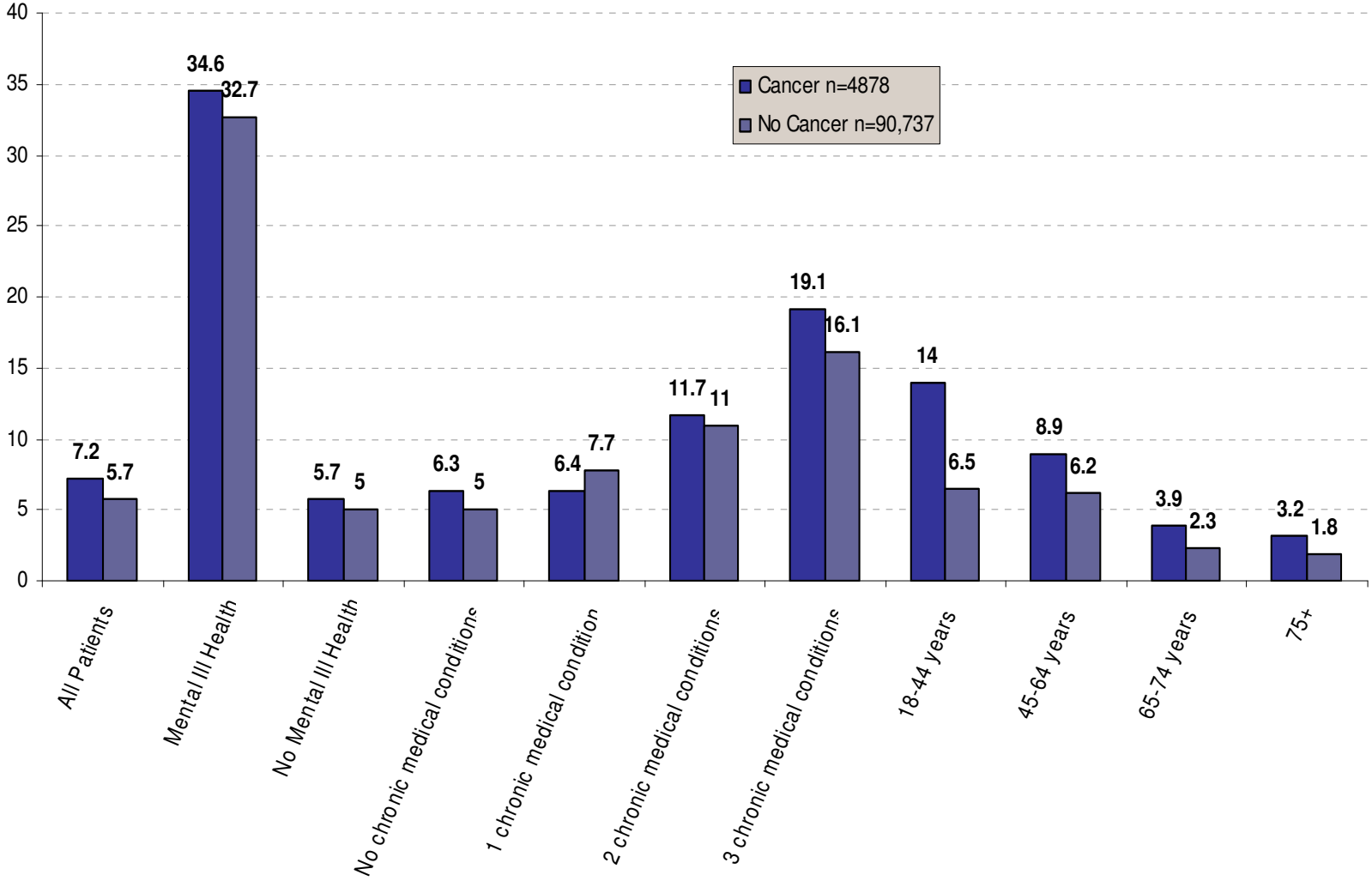


Figure 1.1b - 12 month psychosocial service use in cancer / non-cancer patients with mental health complications (data from Hewitt and Rowland, 2002)

1.2 Definition and Diagnosis of Depression

1.2.1 ICD10 & DSM-IV

Depression refers to the clinical syndrome of depression as exemplified by the criteria listed in the International Classification of Diseases (ICD10) and the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV).[17] The World Health Organization (WHO) introduced mental disorders in the sixth revision of the International Classification of Diseases (ICD-6) in 1948.[39] The American Psychiatric Association Committee on Nomenclature and Statistics published the first edition of the Diagnostic and Statistical Manual: Mental Disorders (DSM-I) in 1952.[40] New diagnostic classification systems: DSM-V and ICD-11 are due in 2013. Each major diagnostic system is overlapping but not identical, yielding different definition of cases and thus different prevalence rates.[41] In ICD10 the core symptoms of depression include decreased energy or increased fatigability in addition to low mood and loss of interest. Further, only 4 symptoms are required for a mild episode and six (five in early versions) symptoms quality as moderate depressive episode (see table 1.2.1). The most commonly applied criteria in research and in clinical practice are those for a current episode of major depression (also called major depressive disorder, MDD) as set out in DSM-IV.[17] This diagnosis requires five of nine qualifying symptoms, together with a minimum duration of two weeks and clinical significance defined by concomitant distress or impaired daily function (table 1.2.1). Strictly symptoms cannot be due to "the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (e.g., hypothyroidism)" but it unclear how to ascertain this aetiological contribution. Uncertainty also exists regarding less common forms of depression, not meeting full criteria for MDD. These include minor depression, dysthymia, adjustment disorder with predominant depression and a research category of brief reactive depression. The criteria for minor depression are identical to major depression but require only 2 symptoms. Dysthymia requires 3 symptoms with a chronic course lasting at least 2 years. All of these categories attempt to define patients who do not fulfil criteria for major depression but have troubling symptoms, nonetheless. These together with major depression may be termed "clinical depression". Patients with at least two symptoms but not fulfilling criteria for major or minor depression have been termed subsyndromal depression.[42] The non-major depressions are more common in most studies than major depression and still linked with considerable burden.[43 44]

The criterion reference (or gold standard) for a diagnosis of clinical depression is an approved structured or semi-structured interview conducted by a trained clinician or researcher. Fully structured and semi-structured interviews are not generally used in routine clinical care as they require 20-60 minutes to complete. Nevertheless, they are useful for research purposes in order to clarify the best estimates of depression in cancer patients. The most popular method is the Structured Clinical Interview for DSM (SCID).[45] Other examples include the Composite International Diagnostic Interview (CIDI)[46] and the Mini-International Neuropsychiatric Interview (MINI).[47]

1.2.2 Criteria for Comorbid Depression in Cancer Settings

It is uncertain if the symptoms suggested by ICD10 and DSM-IV are applicable to medically ill patients or whether adaptations are necessary. DSM-IV criteria for MDD comprise four somatic symptoms and five psychological symptoms.[17] In the Rhode Island MIDAS project Zimmerman and colleagues (2006) conducted an in-depth analysis of symptoms for MDD by asking trained raters to administer a semi- structured interview to 1523 psychiatric outpatients and then analysing an 17-item bank of possible symptoms of depression. [48] The authors found that the ranked order of diagnostic weight (by individual item) for DSM-IV membership on logistic regression was depressed mood > anhedonia > sleep disturbance > concentration/indecision > worthlessness/excessive guilt > loss of energy > appetite/weight disturbance > psychomotor change > death/suicidal thoughts. Based on a series of psychometric analyses in psychiatric settings they developed an alternative set of diagnostic criteria for MDD that did not include somatic symptoms but nonetheless demonstrated a high level of concordance with the current DSM-IV definition. The Zimmerman et al (2006) study did not aim to answer which symptoms occur in depressed patients seen in medical settings. Given the physical burden of cancer there is much debate about the appropriate criteria for depression in cancer settings.[49 50 51 52] The key question is whether the conventional somatic symptoms listed in DSM-IV lack specificity when detecting comorbid depression due to their high occurrence in those with physical illness who were not depressed. Also would adaptation of the criteria for major depression result in a prevalence rate appreciably different from the 94 studies employing conventional criteria (Fig 1.2.2)?

Table 1.2.1. Criteria for Common Psychiatric Complications of Cancer

	Symptoms	**Clinical Significance**	**Duration**
ICD-10 Depressive Episode	Requires two of the first three symptoms (depressed mood, loss of interest in everyday activities, reduction in energy) plus at least two of the remaining seven symptoms (minimum of four symptoms)	At least some difficulty in continuing with ordinary work and social activities	2 weeks (unless symptoms are unusually severe or of rapid onset).
DSM-IV Major Depressive Disorder	Requires five or more out of nine symptoms with at least at least one from the first two (depressed mood and loss of interest).	These symptoms cause clinically important distress OR impair work, social or personal functioning.	2 weeks
DSM-IV Minor Depressive Disorder	Requires two to four out of nine symptoms with at least at least one from the first two (depressed mood and loss of interest).	These symptoms cause clinically important distress OR impair work, social or personal functioning.	2 weeks
DSM-IV Adjustment disorder	Requires the development of emotional or behavioral symptoms in response to an identifiable stressor(s) occurring within 3 months of the onset of the stressor(s). Once the stressor has terminated, the symptoms do not persist for more than an additional 6 months.	These symptoms cause marked distress that is in excess of what would be expected from exposure to the stressor OR significant impairment in social or occupational (academic) functioning	Acute: if the disturbance lasts less than 6 months Chronic: if the disturbance lasts for 6 months
DSM-IV Dysthymic disorder	Three symptoms - persistently low mood +two (or more) of the following six symptoms: (1) poor appetite or overeating (2) Insomnia or hypersomnia (3) low energy or fatigue (4) low self-esteem (5) poor concentration or difficulty making decisions (6) feelings of hopelessness	The symptoms cause clinically significant distress OR impairment in social, occupational, or other important areas of functioning.	Requires depressed mood for most of the day, for most days (by subjective account or observation) for at least 2 years

Two groups have proposed changing the DSM-IV criteria to adjust for undue (or possibly unknown) influence of somatic symptoms in cancer. Chochinov et al (1994) examined the merits of the Endicott method of replacing specific somatic symptoms (change in weight or in appetite, sleep disturbance, loss of energy and reduced concentration) with non-somatic alternatives (depressed appearance, social withdrawal, brooding, self-pity or pessimism and lack of reactivity). [53] The authors found little effect of this substitution in 130 patients receiving palliative care; although the inclusion of somatic symptoms in the diagnostic criteria increased the prevalence of depression when these symptoms were used in conjunction with a so called low-threshold approach. Rayner et al (2011)[54] tried using the Zimmerman et al[55] proposal of excluding the somatic symptoms of sleep, fatigue, appetite and psychomotor change from the list of qualifying symptoms and then requiring only 3 of 5 remaining psychological symptoms, rather than the original 5 of 9. The authors found that these psychological symptoms resulted in a decrease in prevalence of depression from 19.3% to 15%, hinting at a possible 4% correction rate or perhaps error rate in a palliative setting. Looking at this area afresh it is well known that when compared with health controls, individuals with cancer have a higher level of most of the conventional somatic symptoms.[56] However, individuals with uncomplicated primary depression also have a high rate of somatic symptoms.[57] An appreciable difference in endorsement of any symptom in depressed vs non-depressed will still allow this symptom to be used diagnostically, even if the base rate is elevated. Only a handful of studies have looked at symptom profiles of depressed and nondepressed patients with cancer. In a mixed sample of 121 hospitalized patients with breast, oesophageal and head and neck cancer, Chen and Chang (2004) used the Hospital Anxiety and Depression Scale (HADS) depression subscale at a score ≥11 to classify 30 patients as depressed and 91 as nondepressed. [57] Depressed patients showed a significantly higher occurrence (vs nondepressed patients) of the following symptoms: insomnia (83% versus 62%), pain (83% versus 55%), anorexia (63% versus 42%), fatigue (67% versus 32%) and wound/pressure sores (30% versus 13%). In a sample of 300 palliative patients Rayner et al (2011) found that sleep disturbance, poor appetite and fatigue had some discriminatory value (notably high negative predictive value) but that the optimal single symptom was low mood measured against their modified definition of major depression.[54] Recently, Mitchell et al (2012) approached 279 patients up to three times within 9 months of first presentation with a diagnosis of cancer, and collected data following a total of 558 contacts using the PHQ9 and HADS-D scales. [58]

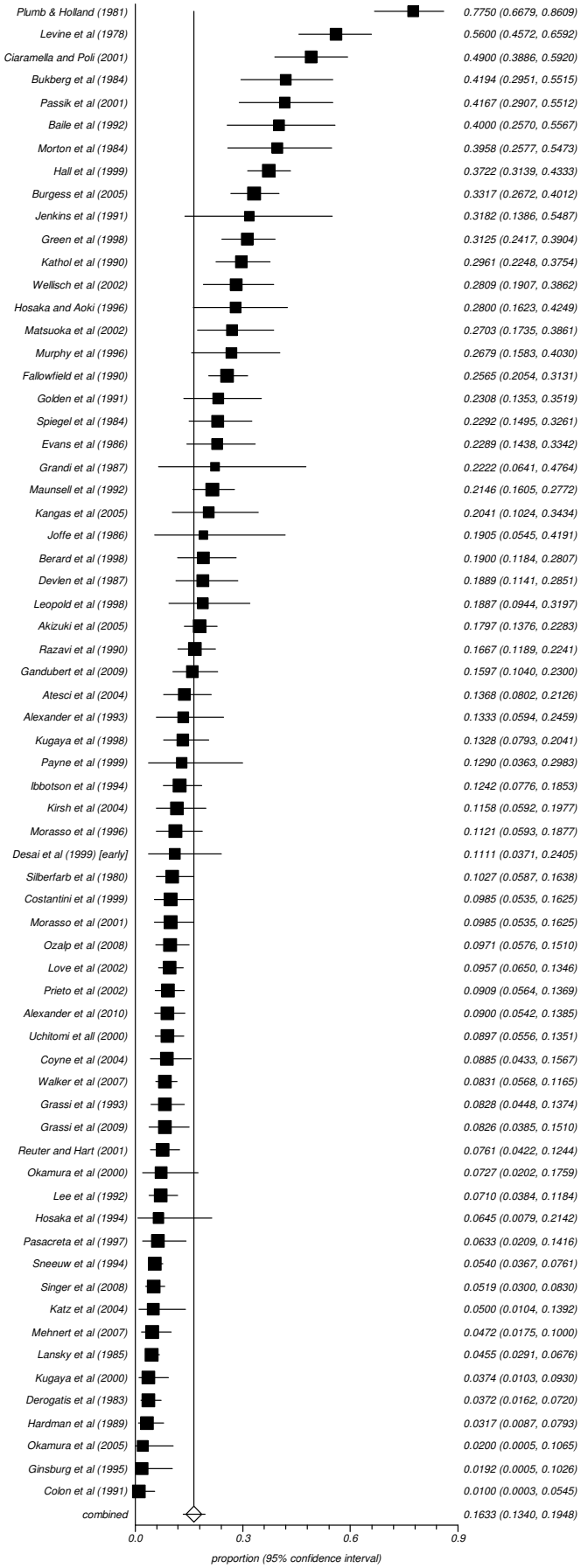


Fig 1.2.2 – Prevalence of Interview defined depression (Proportion meta-analysis from Mitchell et al, 2011 [65])

76 contacts (31%) were in a palliative stage. All symptoms of depression were significantly more common in depressed versus non-depressed cancer patients regardless of stage. Both somatic and non-somatic symptoms were valuable (including but not limited to the PHQ2 stem questions). Only low energy was poorly discriminating which may suggest that the standard ICD10 criteria may not be optimal. In a subset of patients treated without curative intent feeling bad about yourself and moving or speaking slowly were less influential replaced by poor appetite/overeating and feeling tired or having little energy. Given the paucity of data, it is not clear to what extent these findings are related to sampling (or lack of sampling) patients in later palliative stages of illness who are likely to suffer more extensive underling somatic symptoms.[59] The current convention, therefore, remains to diagnose MDD according to the listed criteria.

1.3 Definition and Diagnosis of Distress

A recent direction is to use simpler, patient defined terms to identify emotional complications rather than psychopathological ones. Hence "distress" has been proposed as a concise user-friendly concept that could be considered "a sixth vital sign" in medical settings. [60] [61] Watson and Clark proposed a second-order, nonspecific factor reflecting high levels of "general distress" common to both depression and anxiety.[62] Distress is the experience of significant emotional upset arising from various physical and psychiatric conditions.[63] [64] In a cancer context, distress has been defined by National Comprehensive Cancer Network (NCCN) as 'A multifactorial unpleasant emotional experience of a psychological (cognitive, behavioural, emotional), social, and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms and its treatment'.[32] Distress should be considered a treatable complication of cancer that can present at any stage in the cancer pathway. Distress is not a specific category in DSM-IV or ICD10 but appears as a qualifier (also known as clinical significance criteria) to notate a disorder as clinically important. Distress is a generic lay term, without a succinct medical definition that is generally understood without explanation in most cultures. The lack of a clear definition can be problematic for research but an advantage for everyday use by patients and staff. Distress is essentially a broad symptom not a disorder but it is sometimes linked with the psychiatric category of "adjustment disorder". Adjustment disorder itself lacks specific symptom criteria but was revised in DSM-III and again in DSM-IV to describe a reaction which occurs within three months (ICD 10 uses one a month window) of an identifiable stressor and consists of mild symptoms of depression, anxiety or trauma stress. Adjustment disorder encompasses symptoms of depression and anxiety and occurs in about one in five cancer patients acutely. [65]

Accumulating evidence suggests that the presence of distress is associated with reduced health-related quality of life,[11] poor satisfaction with medical care[12] and possibly reduced survival after cancer.[13] It is not yet clear, however, to what extent distress adversely influences outcomes once psychiatric disorders are accounted for. Unfortunately, interventions for distress and related emotional disorders have failed to show any benefit on survival as a whole implying distress is linked with mortality through confounding factors.[66] [67]

1.4 Prevalence of Emotional Complications of Cancer

1.4.1 Depression

One early meta-analysis by Van't Spijker et al (1997) located 50 studies of psychological and psychiatric problems using a variety of self-report scales but included only 8 involving formal interview.[18] Depression in cancer has been compared with other medical groups in at least two studies and the relative risk of depression in cancer exceeded depression in stroke, diabetes and heart disease.[5 6] Mitchell and colleagues recently conducted an meta-analysis of the point prevalence of depression after cancer.[65] In oncology and haematology settings, largely involving early stage cancers, across 70 studies and 10,071 individuals living in 14 countries, the prevalence of depression was 16.3% (95% CI = 13.4% to 19.5%) (fig 1.2.2) although for DSM major depression it was 15% (95% CI = 12.2% to 17.7%) and for minor depression it was 20% (95% CI = 9.1% to 31.9%). In this study, combination diagnoses were common. For example, depression or adjustment disorder occurred in 32.0% and any mood disorder (which includes anxiety) occurred in 38.2%. There were few consistent correlates of depression but in non-palliative settings, lower rates of depression were found in more recent, high quality publications.

There has been considerable interest in the prevalence of depression in people with advanced cancer. Early reviews of depression in palliative setting hinted at prevalence rates of between 1% and 69%.[15] Many authors have stated that depression is a more common problem in palliative settings and propose demographic (age, gender) and disease based (tumour stage, tumour type) risk factors. Although there is an assumption that depression must be higher in palliative settings, this did not prove to be the case in the meta-analytic review by Mitchell et al (2011). In palliative settings and advanced cancer 24 studies involving 4007 individuals living in 7 countries found a pooled prevalence of DSM or ICD defined depression of 16.5% (95% CI = 13.1% to 20.3%) and it was 14% (95% CI = 11.1% to 17.9%) for DSM defined major depression. The rate for adjustment disorder alone was 15% (10.1% to 21.6%). A combination of depression or adjustment disorder occurred in about 25%and any type of mood disorder in about 30%.

This meta-analysis did not have sufficient power to examine the effect of time since diagnosis. Therefore it was not clear whether the prevalence of depression is appreciably different in long-term survivors compared to the general population. Large scale general population surveys suggest that the 30-day

prevalence of depression is approximately 5% and the 12 month prevalence about 9% in the general population.[68] Several well powered studies have attempted to compare cancer rates with the general population. Rasic et al (2008) found that a diagnosis of cancer was significantly associated with 12 month prevalence of major depression (15.5% vs 5.4%) in those 15-54 years old. [69] Dalton et al (2009) found a relative risk for depression of 1.16 to 3.08 in the first year after a cancer, a risk which appeared to be elevated through 10 years of follow-up.[70] Mitchell et al (2012 in submission) recently pooled data from 13 studies examining the prevalence of depression in long-term cancer survivors compared with comparable data gathered from healthy controls. In absolute terms, the prevalence of depression was 14.2% (95% CI = 10.3% to 18.6%) in a pooled sample of 33,373 cancer survivors 2 years of more post-diagnosis compared with 11.4% (95% CI = 9.5% to 13.5%) in 171,469 people without cancer. The random effects pooled relative risk (rr) was 1.16 (95% CI = 0.98 to 1.36) indicating a trend towards (Chi^2 3.2, p = 0.08) higher rates of depression in long-term cancer survivors patients than healthy controls.

1.4.2 Distress

Estimates regarding the prevalence of distress have been informed by early studies using the Brief Symptom Inventory (BSI), Hospital Depression and Anxiety Scale (HADS) and recent research involving the Distress Thermometer (DT). Distress is not a formal syndrome is DSM-IV or ICD10 but the category of adjustment disorder is often considered the interview-based equivalent of distress. Pooled BSI data from two studies involving 7272 patients illustrates that approximately 4 in 10 cancer patients report significant distress (fig 1.4.2a).[71 72] Cancer type alone appears to have a modest effect on distress and indeed on QoL.[73] The HADS total score (HADS-T) has been used in at least 16 studies in cancer settings and from these the proportion of cancer patients scoring above the utilized cut-off was 37% (it was 46% at a cut off of ≥ 9). However, this figure has been criticized as more equivalent to “depression or anxiety” than “any significant distress”.[74] It is not clear if the HADS is an appropriate instrument for the identification of general emotional distress. The DT has been used in more than 100 studies in cancer but only twelve (one unpublished) have reported the frequency of scorers at each point from zero to ten.[37 75 76 77 78 79 80 81 82 83 154]

From these, the proportion of cancer patients scoring 4 or above was 42% (see figure 1.4.2b).

As mentioned, adjustment disorder can be considered to be the interview-based equivalent of distress. Our group recently completed a meta-analysis of the point prevalence of adjustment disorder after cancer, identifying 28 studies.[65] In oncology and haematology settings, largely involving early stage cancers, adjustment disorder was found in about 20% (95% CI = 14.5% to 24.8%) and in palliative settings and advanced cancer adjustment disorder was present in 15% (10.1% to 21.6%).

Whilst studies of prevalence are helpful, clinicians want to know who is at particular risk of distress following cancer. Individuals with certain cancers such as lung, brain and pancreatic cancer are more likely to be distressed but differences by cancer type are generally modest. Much more powerful predictors of distress include low quality of life, disability (eg low Karnofsky performance scores), ongoing unmet needs.[72] [84]

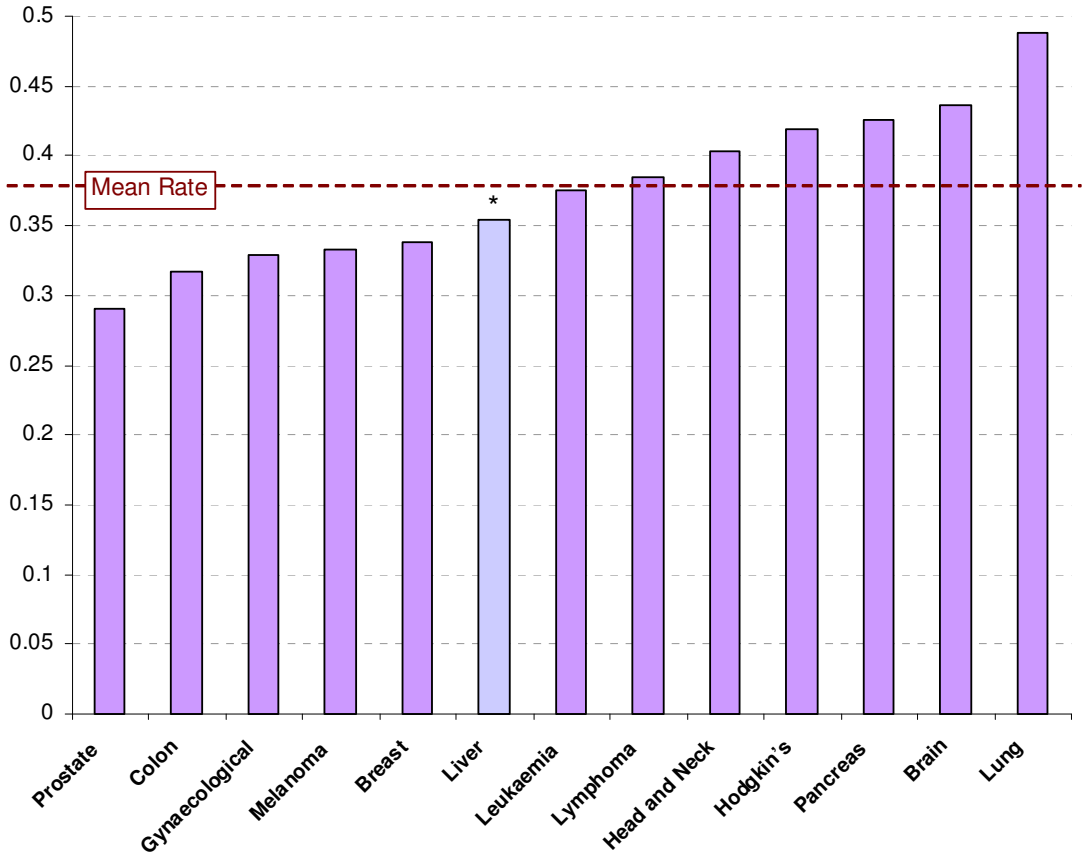


Figure 1.4.2a Mean rate of distress using BSI - data from Carlson LE et al. British Journal of Cancer 90, 2297 – 2304 and Zabora J et al Psycho-Oncol 2001; 10: 19 – 28. * = data from Zabora et al only.

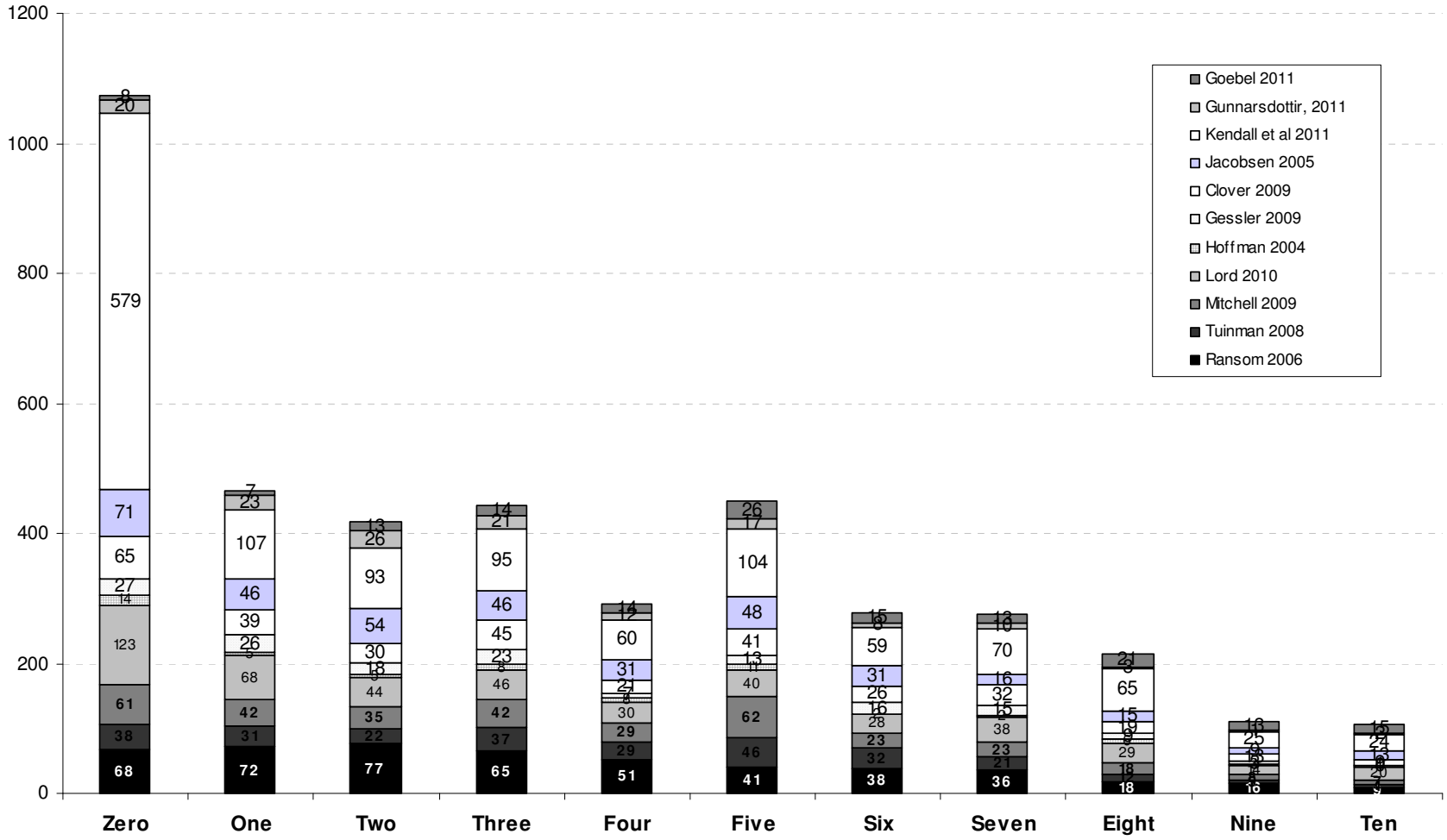


Figure 1.4.2b Mean rate of distress using DT. Original figure from multiple sources

1.5 Unmet needs in Patients with Cancer

Unmet needs are problems or concerns, usually arising from the current illness, that warrant medical attention. Unmet needs are most commonly defined by the patient or patient's caregiver. Sometimes the term "meetable unmet needs" is preferred to clarify those needs where clinicians have a responsibility. This term was first coined by Mitchell et al at the International Psychooncology Society World Congress, 2010.[85] Cancer patients report high levels of unmet needs in multiple areas including informational needs,[26 86] psychological needs,[87 88] practical assistance,[89 90]and personal needs and intimacy issues.[91 92] Patient concerns, when voiced, can often be assumed to be unmet, but in the best studies patients are specifically asked if these needs are current, unaddressed and whether professional help is actually wanted. Multiple small studies have looked at unmet needs in selected cancer samples but there have been few genuinely large studies encompassing psychosocial needs.[27 93 94] A brief review of the literature reveals the following studies, each with over 400 cancer patients beginning in 1977 when the American cancer society documented 28% of 810 cancer patients had unmet needs.[95] In 1992 the Canadian Cancer Society surveyed 2000 patients but reported no specific proportions.[96] In 2000 Sanson-Fisher et al surveyed 888 patients with mixed cancers and found 30-40% with psychosocial needs.[26] Also in 2000 Tamburini et al surveyed 423 patients with mixed cancers and found 11-38% with psychosocial needs.[97] In 2004 Davis et al surveyed 544 patients with breast cancer and found 31% with informational needs and 15% with psychosocial needs [98] In 2011 Lam et al, asked 640 Hong Kong Chinese and German Caucasian women with breast cancer to complete the 34 item Supportive Care Needs Survey Short Form (SCNS-SF). Only 11% of the participants reported not needing help for any of the 34 items. Hong Kong Chinese women appeared to prioritize information needs, whereas German Caucasian women appeared prioritize physical and psychological support.[99] In 2012, Holm et al conducted a large study in 3000 cancer patients and found 30.6% had unmet psychosocial needs 14 months following a cancer diagnosis.[30] White et al (2012) surveyed 829 Australian patients using the Supportive Care Needs Survey (SCNS-LF59). 40% of the sample had fear of cancer returning and the top three concerns were all psychological.[100] Choi et al (2012) asked 2661 cancer patients from 10 cancer centres about unmet needs using the Comprehensive Need Assessment Tool in Cancer. 54% had psychological needs, 39% social support needs with needs correlated with time since diagnosis.[101]

Longitudinal studies suggest that needs probably diminish over time, yet residual unmet needs in cancer survivors are not uncommon.[102 103] For example, McDowell et al (2010) asked patients at a regional cancer treatment centre in Australia to complete the Supportive Care Needs Survey (SCNS) at recruitment (n=439) and then at six months follow-up (n=396). Moderate to high unmet needs were reported by 58% of patients at baseline and 47% of patients at six months follow-up. Having unmet needs at baseline was the strongest predictor of unmet needs at six months and greater depression and greater distress at baseline was associated with higher physical/daily living domain at six months follow-up. Barg et al (2006) examined long-term unmet psychosocial needs in 614 American cancer survivors who returned usable questionnaires.[104] 64.9% had at least 1 unmet need, almost half (48.3%) reported 3 needs and remarkably 23.4% reported 11 unmet needs. The highest rate were needs in the emotional (38.7%) and physical (37.5%) domains and at the symptom level the most commonly reported concerns were ''tiring easily'' (24.6%), ''feeling very nervous or afraid'' (22.1%), ''feeling down or depressed'' (23.1%), ''difficulty with memory or concentration'' (19.6%) and ''difficulty sleeping'' (18.3%) (figure 1.5). One recent British study offered a rare large scale comparison of 780 cancer survivors, 1372 individuals with a non-cancer chronic condition and 2740 individuals without a previous cancer diagnosis or chronic condition. Thirteen measures of health and well-being were constructed from answers to 25 survey items covering physical, psychological and social dimensions of health and well-being.[7] Cancer survivors were significantly more likely to report poor health outcomes across all 13 measures than those with no history of cancer or a chronic condition. The adjusted odds ratios for cancer survivors with no chronic conditions compared with healthy participants ranged from 1.37 for emotional well-being to 3.34 for number of health professionals consulted in the last 12 months. Unaddressed, such needs are associated with distress, anxiety and poorer quality of life (QoL) among patients.[29 105] Although the literature on unmet needs varies according to the definition and type of need, it is clear that many, perhaps most patients have unmet needs that warrant medical attention at all times following a cancer diagnosis. Where medical input is ongoing for the cited needs it must be concluded that the medical management is not entirely effective. These patients could be defined as having *refractory meetable unmet needs*. Where medical input is absent for the cited needs these patients could be said to have *unaddressed meetable unmet needs*.

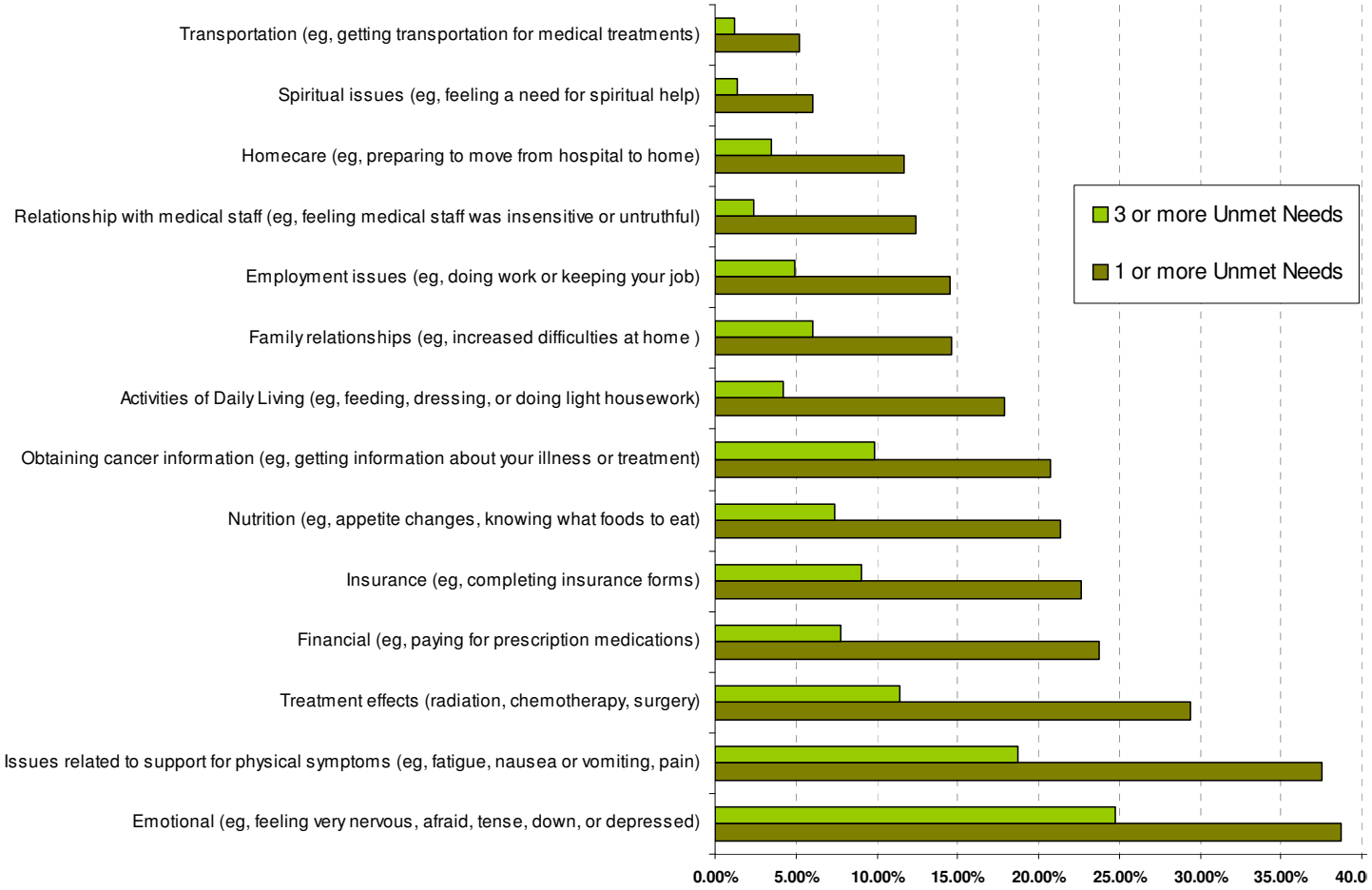


Figure 1.5 Rate of unmet need in US cancer survivors (data from Barg et al Cancer 2007 110(3):631-9)

1.6 Clinical Recognition of Emotional Complications of Cancer

Several informative studies have examined rates of routine clinical enquiry regarding psychological issues as well as subsequent recognition. Surveys find that many cancer clinicians do not routinely ask about psychosocial issues, preferring to rely on patients mentioning a problem first.[36] Less than 15% use a screening instrument, instead using their own clinical judgement.[36 106] Observed interview studies regarding distress and health related quality of life (HRQoL) appear to confirm that clinicians typically mention psychological issues in approximately 15% (range 10% - 40%) of consultations. [24 25 107 108] Interestingly patients, not clinicians, initiate many of these discussions[24 108 109] as medical clinicians (physicians) often gravitate towards physical symptoms and medical issues.[24 109 110] Oncologists often feel more able to help with physical rather than psychological concerns but may overestimate their attention to emotional issues by about 20%.[111 112 113 114] Therefore patients may be reluctant to mention psychosocial issues.[115 116 117] The main barriers to thorough assessment and formal screening at the clinician level appear to be perceived lack of time, lack of training and low personal skills or confidence about diagnosis and availability of specialist mental health services in many centres.[19 36 117 271]

Given that cancer clinicians typically use their own clinical judgement to diagnose depression, how accurate is that professional judgement? There have been several studies examining the unassisted ability of cancer clinicians to identify depression or distress but only a minority have measured detection sensitivity as well as detection specificity (that is the ability to rule-in and rule-out cases).[18 118 119] Sollner et al (2001) examined the accuracy of eight oncologists who had evaluated 298 cancer patients.[18] Against moderate or severe distress on the HADS-T (a 12v13 cut-off), oncologists' sensitivity was 80% but their specificity was only 33%. Using a HADS-T at a cut-off 18 (representing severe distress), sensitivity was only 37% and specificity increased to 88%. This study suggested that oncologists are likely to identify only a minority of those with severe distress but appears to contradict many detection studies in primary care whereby detection sensitivity improves for more severe types of distress and depression.[120] Fallowfield's group compared cancer clinicians' ratings of patients using visual analogue scales with an independent patient reported GHQ-12 score (at a cut-off ≥4).[121] In this high prevalence sample, detection sensitivity was only 29%. Mitchell and colleagues looked identification of distress by chemotherapy cancer nurses using distress defined by the DT in 400 patients (Mitchell et al, 2011).[37] Nurse practitioners had a detection sensitivity of

50% and specificity 80%. Interestingly there was higher sensitivity but lower specificity in those clinicians with high self-rated confidence. It is rarely appreciated that modest specificity can translate into a significant number of false positive errors. Assuming distress is present in 40% of cancer patients, clinicians would probably miss 20 patients (false negatives) and misidentify 12 patients (false positives) for every 100 people seen in routine cancer care. Thus the decision and action that follows initial judgement is a critical step in clinical diagnoses as well as in screening. The rate of false positives increases further when clinicians are under study (Hawthorne effect)[122] and indeed in any situation where the prevalence of depression is low. There are many possible reasons for diagnostic error including both patient and provider factors. For example, not all patients want to talk about their emotional problems and many may not mention key psychological terms early in the consultation.[123] Clinician related factors linked with low detection include the willingness to look for emotional problems, clinical confidence, clinical communication skills and consultation time. Shared factors include confidence/trust between patients and clinician, and belief that help is available and likely to be acceptable and effective.

1.7 Tools to Identify Emotional Complications of Cancer

1.7.1. Tools to rapidly identify depression

This has been a very active area of research. Numerous tools for depression have been developed varying from 1 item to 90 items.[124] Currently there are at least 50 depression scales on the market but only a selection offer rapid assessment in an ultra-short format (table 1.7.1). Numerous tools have varying degrees of accuracy, acceptability and evidence base.[124] A growing number have been tested in medical settings such as oncology and palliative care. The complexity of a tool is governed not simply by the item count but moreover its completion time and the complexity of scoring. Tools can be divided into self-report (including the special type utilizing computerized delivery) and clinician administered (usually structured verbal scales).[125] Consider the stem "how depressed are you?" could be asked by a clinician, computer or in written form and responses collected on a variety of scales. Rarely have the same stems been tested head-to-head using different methods of delivery.[126]

The best-known conventional self-report mood scale in oncology and palliative settings is the Hospital Anxiety and Depression Scale (HADS).[127] This is a 14 item scale (HADS-T) subdivided into two subscales for depression (HADS-D) and anxiety (HADS-A). Two recent reviews found that the HADS could not be recommended as a case-finding (diagnostic) instrument but may be suitable as an initial screening tool.[74 126] In addition the HADS is probably too long for routine use, at least in paper and pencil format, although it has been successfully implemented by computerized waiting room touch screen in some well resourced areas.[128 129] The accuracy of the HADS-T/HADS-D using sensitivity and specificity is approximately 80% sensitivity and 80% specificity. A sensitivity of 80% and a specificity of 80% could be considered to be a minimum for screening diagnostic accuracy but in clinical practice this will depend on prevalence and the implications of diagnostic errors. Given the fairly extensive research experience with the HADS, the HADS may serve as a useful reference point in the development of rapid screening alternatives. [74] In short, new tools should aim to be more accurate and more acceptable than the HADS.

Screening tools for depression in cancer settings have been comprehensively reviewed (see table 1.7.1). [130] Abbreviated versions of many mood scales have been published using factor analysis or Rasch analysis. An important caveat is that often the abbreviated version is untested in an independent sample making interpretation difficult. Simple structured verbal methods are perhaps the simplest and quickest of all screening modalities and these can be memorized by clinicians (eg, asking the patient “are you depressed?” or “how distressed have you been in the previous week?”).[131] A meta-analysis of verbal stem questions against interview defined depression found that the single ‘depression’ question has a sensitivity of 72% and specificity of 83%; slightly inferior to the ‘loss-of-interest’ question which had a sensitivity 83% and specificity of 86%.[132] Despite the low sensitivity, negative predictive value (NPV) is reasonably well maintained allowing the “are you depressed” question to be used as an initial first step. That said combining the two key questions (low mood and low interest where only one positive answer is required) had a sensitivity of 91% and specificity of 86%. These simple stem questions are one of many possible screening options for depression. Recently the DT from the NCCN (National Comprehensive Cancer Network) has become popular due to its simplicity or scoring, ability to be understood and royalty free distribution. The DT is intended for identification of broadly defined distress but has been tested against depression. In a comprehensive review of the accuracy of the DT, Mitchell et al found it to have a sensitivity (Se) of 80.9%

and a specificity (Sp) of 60.2%, positive predictive value (PPV) of 32.8 and negative predictive value (NPV) of 92.9%) for depression, a Se of 77.3% and Sp 56.6% (PPV of 55.2% and NPV of 80.25%) for anxiety and a Se of 77.1% and Sp 66.1% (PPV 55.6% and NPV 84.0%) for broadly defined distress.[133]

Many other depression screens have been tested in cancer, albeit in single studies. According to the Depression in Cancer Consensus Group, as of 2012, there were 63 diagnostic validity studies involving 19 tools designed to help clinicians identify depression in cancer settings.[131] However, only 8 tools had reasonable data gathered from independent replication. These tools included the Beck Depression Inventory (BDI),[134] BDI fast screen,[135] DT (applied to depression),[143] Edinburgh Postnatal Depression Scale (EPDS),[136] Patient Health questionnaire (PHQ-9),[137] PHQ-2,[138] the structured two stem questions ('low mood' and 'loss of interest')[139] and the Centers for Epidemiological Studies Depression Scale (CES-D).[140] After pooling the results for each scale the Depression in Cancer Consensus Group concluded that for screening two stem questions had level 1b evidence (with high acceptability) and the BDI-II had level 2c evidence (but with modest acceptability) (see primary publication for explanation of levels of evidence). For the purposes of depression case-finding then one stem question, two stem questions and the BDI-II all had level 2 evidence. In pragmatic terms the authors estimated that for every 100 people screened in a non-palliative setting, under ideal conditions the BDI-II would accurately detect 17 cases, missing 2 and correctly re-assure 70, with 11 falsely identified as cases. This real world estimate can be compared with the estimate of clinician's judgement namely 20 false negatives and 12 false positives for every 100 patients seen. Therefore assuming these results extrapolate to other centres, and that prevalence rates remain comparable, the BDI would appear to improve upon the clinicians' judgement alone by reducing false negatives by about 80% but without any appreciable effect on false positives. This can be considered the potential added value of the scale above routine clinical care, but as this is hypothetical, implementation studies are needed for confirmation (see section 1.8.2). A statistical summary of the performance of current depression screening tools in cancer, measured against an interview standard is presented in table 1.7.2.

Table 1.7.1 - Rapid Psychometric Instruments for Distress or Depression

Items	Scale	Abbreviation	Primary Focus	Diagnostic Validity Study in Cancer?	Replication Study in Cancer	Implementation Studies?**
14	Hospital Anxiety and Depression scale	HADS-T	Distress	Yes	Yes	Yes
13	Beck Depression Inventory -Short form *	BDI-SF	Depression	Yes	No	Yes
13	Psychological Distress Inventory	PDI	Distress	Yes	No	No
12	General Health Questionnaire-12 *	GHQ-12	Distress	Yes	No	Yes
11	Bech-Rafaelsen Melancholia Scale	MES	Depression	No	No	No
10	Edinburgh Postnatal Depression Scale	EPDS (original)	Depression	Yes	Yes	No
10	Montgomery Asberg Depression Rating Scale	MADRS (original)	Depression	No	No	No
10	Zung Self-Rating Depression Scale –short *	SDS-10	Depression	No	No	No
10	Psychological Screen for Cancer (Part C)	PSSCAN Part C	Depression/Anxiety	Yes	No	Yes
10	Center for Epidemiologic Studies Depression Scale 10 *	CES-D 10	Depression	No	No	No
9	Patient Health Questionnaire 9	PHQ9	Depression	No	No	No
9	Hornheide Short Form *	Hornheide Short Form	Depression	Yes	No	No
8	Medical Outcomes Scale 8	MOS-8	Depression	No	No	No
8	Even Briefer Assessment Scale for Depression *	EBAS-Dep	Depression	No	No	No
8	Edinburgh Postnatal Depression Scale 8 *	EPDS-8	Depression	No	No	No
8	Patient Health Questionnaire 8 *	PHQ-8	Depression	No	Yes	No
7	Hospital Anxiety and Depression scale - Depression	HADS-D	Depression	Yes	Yes	Yes
7	Hamilton Depression Scale-7 *	HAM-D-7	Depression	No	No	No
7	Beck Depression Inventory 7 *	BDI-7	Depression	No	No	No
7	Duke Anxiety-Depression Scale	DADS-7	Depression	No	No	No
7	Edinburgh Postnatal Depression Scale - depression items	EPDS-7	Depression	No	No	No
7	Hornheide Screening Instrument *	HSI	Depression	Yes	No	No
6	Brief Edinburgh Postnatal Depression Scale *	BEDS	Depression	Yes	No	No
6	Hamilton Depression Scale -6 *	HAM-D-6	Depression	No	No	No
6	Center for Epidemiologic Studies Depression Scale -6 *	CES-D-6	Depression	No	No	No
5	Edinburgh Postnatal Depression Scale -5 *	EPDS-5	Depression	No	No	No
5	WHO Mood scale	WHO-5	Multiple domain	No	No	No
5	Geriatric Depression Scale 5 *	GDS-5	Depression	No	No	No
5	Emotion Thermometers	Emotion Thermometers	Multiple domain	Yes	No	Yes
4	Brief Case find for Depression	BCFD	Depression	Yes	No	No
3	Patient Health Questionnaire 2+help question	PHQ2+help question	Depression	Yes	No	No
3	Edinburgh Postnatal Depression Scale – anxiety items	EPDS-3	Depression	No	No	No
2	Patient Health Questionnaire 2	PHQ2	Depression	Yes	No	No
2	Any two verbal questions	Whooley questions	Depression	Yes	Yes	No
2	DT and Impact Thermometer (combined)	DT/IT	Distress	Yes	No	No
2	Beck Depression Inventory 2 *	BDI-2	Depression	No	No	No
1	Patient Health Questionnaire Q1	PHQ Q1	Depression	Yes	No	No
1	Patient Health Questionnaire Q2	PHQ Q2	Depression	Yes	No	No
1	Any single verbal item	Any single verbal item	Depression	Yes	Yes	No
1	Distress thermometer	Distress thermometer	Distress	Yes	Yes	Yes
1	Impact thermometer	Impact thermometer	Distress	Yes	No	Yes
1	Help thermometer	Help thermometer	Desire for Help	Yes	No	Yes

** See table 1.8.2 for detail of implementation studies

1.7.2 Tools to rapidly identify distress

Diagnostic validity tools for cancer distress have been under-investigated primarily because of the difficulty agreeing on an appropriate criterion reference (gold standard). Issues with longer questionnaires led several groups to re-examine visual-analogue scales that had been introduced in the 1970s for evaluation of mood, suicidal thoughts, pain and quality of life.[141] In 1997 Chochinov and colleagues examined a VAS from ‘‘worst possible mood’’ ‘to ‘best possible mood’ [142] but in 1998 the Distress Thermometer (DT) was formally introduced.[143] The DT has done much to revitalize interest from cancer clinicians looking for a rapid method of screening for emotional complications of cancer without recourse to complex scoring or algorithms (see table 1.7.1). The DT was developed by a panel of 23 health professionals and a patient representative working in collaboration with the National Comprehensive Cancer Network (NCCN) and is currently royalty free (NCCN, 2007).[32] The DT is a simple pencil and paper measure consisting of a 0 to10 scale anchored at zero “No Distress” and at 10 with “Extreme Distress.” Patients are asked to answer the question “How distressed have you been during the past week on a scale of 0 to 10?”. A revised cut-off of 4 or above is recommended (in 2006 the NCCN recommended cut was ≥5) as significant but generally mild distress, whereas 6 denotes moderate distress and 8 or higher denotes severe distress. Thus a score of 0, 1, 2 or 3 is under threshold. The main caveats are that the DT linear scale is subjective in interpretation, distress might not be a universal cultural concept and also that the DT performs best in relation to distress, but modestly regarding anxiety and depression (see 1.7.1). An important addition to the thermometer is a problem checklist that highlights potential unmet needs for a patient that may be linked with perceived distress (see 1.5). Diagnostic validity studies of the DT against an interview based standard suggest that the DT has reasonable sensitivity but lower than ideal specificity. In the real world assuming a 40% prevalence of distress then clinicians relying on the DT (at ≥4) would miss 9 patients and misidentify 20 patients for every 100 people seen in routine care. This represents a modest gain compared with clinicians using their own unassisted judgement. Further, this high false positive rate is why all patients who screen positive on the DT require a second-step assessment.

Table 1.7.2 – Performance of Rapid Psychometric Instruments for Distress or Depression

(adapted from J Affect Disord. 2012 May 24)

	Acceptability of tool	Weighted Sensitivity	Weighted Specificity	Case-Finding Clinical Utility*	Screening Clinical Utility*	Number of Studies
Distress @ 40%						
HADS-T (14 items)	Low-Moderate	70.4% (95% CI = 56.1% to 82.9%)	80.6% (95% CI = 72.8% to 87.4%)	Average	Good	13
Distress thermometer (1 item)	High	78.5% (95% CI = 69.8% to 86.1%)	67.4% (95% CI = 60.1% to 74.3%)	Poor	Average	4
Single Verbal Question (1 item)	High	67.3% (95% CI = 51.0% to 81.6%)	78.9% (95% CI = 58.3% to 93.7%)	Poor	Average	4
Depression @ 15%						
1Q (1 item)	High	68.3% (95% CI = 52.9% to 81.8%)	88.1% (95% CI = 80.4% to 94.1%)	Poor	Excellent	9
2Q (2 items)	High	95.6% (95% CI = 88.9 to 99.3%)	88.9% (95% CI = 79.0% to 96.0%)	Average	Excellent	4
DT (1 item)	High	81.8% (95% CI = 0.768 to 0.865)	70.9% (95% CI = 63.7% to 77.6%)	Poor	Good	5
EPDS (10 items)	Moderate	66.9% (95% CI = 51.7% to 80.4%)	84.5 % (95% CI = 78.3% to 89.9%)	Poor	Good	4
HADS-A (7 items)	Moderate	77.1% (95% CI = 0.689 to 0.844)	84.2% (95% CI = 72.1% to 93.4%)	Poor	Good	4
HADS-D (7 items)	Moderate	66.6% (95% CI = 54.5% to 77.7%)	83.4% (95% CI = 75.6% to 89.9%)	Poor	Good	18
HADS-T (14 items	Low-Moderate	76.4% (95% CI = 69.9% to 82.2%)	79.4% (95% CI = 59.9% to 93.5%)	Poor	Good	8

* Calculated from clinical utility index (see 2.5.8 for explanation) assuming 40% prevalence of distress and 15% prevalence of depression

Several variations on the DT have been published as possible improvements on the original DT. In a Japanese study on 275 cancer patients, the authors suggested an "Impact Thermometer" where the question is worded "What is the impact of illness to you").[144] Akizuki and colleagues showed that the Impact thermometer had added value over the DT alone. Gil and colleagues used a "mood thermometer" (MT) in a multicenter study carried out in Italy, Portugal, Spain, and Switzerland, based on a convenience sample of 312 cancer outpatients who completed the DT and MT.[145] Against the HADS total score, the area under the curve (AUC) was 0.77 for the DT and 0.83 for the MT, a non-significant trend in favour of the MT. Notably, the DT correlated more significantly with HADS anxiety (r=0.50) than depression (r=0.40) whereas the MT correlated significantly both with HADS depression (r=0.61) and HADS anxiety (r=0.56). Baken et al (2008) also examined the merits of the Impact Thermometer.[146] Onelov and co-workers (2007) used two unique, seven point visual-analogue scales for anxiety and depression amongst 3030 patients who were also asked to complete the Centre for Epidemiological Studies Depression Scale (CES-D) and Spielberger's State-Trait Anxiety Inventory (STAI-T).[147] The visual-analogue scales were accompanied by the questions "Have you been depressed during the previous six months?" and "Have you experienced anxiety during the previous six months?" A cut-off point of 2 vs 3 on the visual-analogue-depression subscale gave a sensitivity of 77% and specificity of 77% (PPV 51%, NPV 91%). For the visual-analogue-anxiety subscale, the sensitivity and specificity were 52% and 87% respectively (PPV 64%, NPV 80%). Recently several other new variants on the thermometer format have also been developed. Lees and Lloyd-Williams (1999) tested a VAS anchored with a sad face and happy face.[148] The authors reported a high correlation with the HADS-T but did not report sensitivity or specificity. Mitchell and colleagues (2009) developed and validated a five item Emotion Thermometer designed to measure multi-domain emotional complications of cancer. It had good validity against DSM-IV defined depression and HADS total scores in early cancer.[149] Of course, some longer conventional question based scales also have been developed. The Psychological Distress Inventory (PDI) is a 13-item scale first proposed to measure distress in breast cancer patients. It was tested against a structured clinical interview as the criterion and a cut-off of 28 or 29 is considered clinically significant.[150] One immediate difficulty when evaluating distress tools is that, the gold standard for distress is itself undefined. A close approximation might be any psychiatric disorder on full semi-structured interview, and a weaker approximation would be anxiety or depression in any combination. The latter is typically generated

by studies relying on the HADS as a comparison tool. Bearing in mind this limitation, Mitchell (2010) reviewed the tools proposed for distress against an interview-based gold standard.[151] Mitchell (2010) found 45 potentially useful short and ultra-short tools. However, when studies were limited to those tested against distress defined by semi-structured interview only six methods had received a validation attempt. These were the HADS (13 studies), the DT (4 studies), a single verbal question (4 studies), the Psychological Distress Inventory (1 study), combined DT & Impact thermometer (1 study) and combined two verbal questions (1 study). A comparison of these six approaches side-by-side suggested that for screening all tools had approximately the same accuracy. Therefore it is likely that informed choice of a short/ultra-short screening tool for distress will be one that depends more on acceptability, cost (or cost-effectiveness), availability and local preferences rather than accuracy. A statistical summary of the performance of current distress screening tools in cancer, measured against an interview standard is presented in table 1.7.2.

1.7.3 Tools to identify Unmet Needs

Unmet needs, like distress and depression can easily be overlooked in clinical practice. In a recent study of 97 Korean oncologists' assessments of 495 patients using the Comprehensive Needs Assessment Tool for Cancer Patients, physicians systematically underestimated patient needs and patient-physician concordance was poor, with weighted kappa statistics ranging from 0.04 to 0.15 for individual items.[152] Although needs may be identified through patients' spontaneous reports during consultations, patients vary in their ability and willingness to volunteer information just as clinicians vary in their ability to elicit information.[153] Further, needs in some domains such as side-effects, cognitive symptoms, psychosexual issues, may be less discuss than others. Therefore systematic approaches to eliciting unmet needs may be helpful. A number of tools have been developed to identify unmet needs but many are very long taking at least 15 minutes and consisting of as many as 132 items (in the case of the Needs Assessment of Advanced Cancer Patients) , 135 items (Prostate Cancer Needs Assessment) and 138 items (Problems and Needs in Palliative Care). For the purposes of this thesis I was interested in tools taking less than 15 minutes with fewer than 40 items. An extensive search of the literature highlighted 17 brief unmet needs scales focussing on the needs of cancer patients (table 1.7.3). Of these the "problem list" is a list of 33-35 items included with the original DT. It aims to address practical, family/social, emotional, spiritual, and physical problems. The domains in the Problem List were not designed to function as an independent scale. However, the 5 domains may

represent a multi-dimensional assessment of overall distress. An early validation study on the DT's Problem list suggested good internal consistency (Cronbach α = 0.81).[77] A second study also reported internal consistency of 0.81 as a whole but also on each subscale, namely physical (α = 0.92), emotional (α = 0.88), practical (α = 0.42) family (α = 0.59), and spiritual subscales (α = 0.31). Other groups have attempted to correlate DT score with the frequency of each of the items on the problem list.[154] [155] [156] Several groups have reported how much distress each problem list item is associated with.[77] [157] Yet despite these studies full psychometric examination of the NCCN Problem list remains lacking.

Table 1.7.3 shows that tools have been subjected to variable degrees of psychometric examination.[158] The most common strategy for establishing content validity of needs assessment measures was through expert opinion alone. Evidence of validity and reliability varied considerably between tools. In terms of construct validity, most tools relied primarily on factor analysis and correlations with existing measures. Evidence of predictive validity has been provided for the 39 item CaNDI and the longer CCM. Evidence of reliability was more complete, generally utilising internal consistency (Cronbach's α >0.70 for acceptable reliability) and inter-item and item-total correlations. Others methods included inter-rater reliability; alternate forms reliability; and test-retest reliability. No reliability data were available for the SPEED, see table 1.7.3.

Some evidence suggest that supplementing standardized distress screening tools with needs assessment tools may have the potential to enhance the ability of clinicians to identify and manage patient's concerns (see 1.8.4 for detailed evidence).[159] While distress screening tools can detect the presence of distress in patients, needs assessment tools provide a more comprehensive assessment of concerns. However, further evidence of psychometric quality is needed, particularly evidence of test-retest reliability, predictive validity, responsiveness and clinical utility of these tools. Fundamentally the ability of needs tools to improve patient outcomes/PROs in implementations trials remains relatively untested.

Table 1.7.3 – Tools to rapidly identify unmet needs

Instrument / Items / Main study	Tool purpose and population	Question format and administration	Content Validity	Construct Validity	Reliability
NEST (13 items) Needs near the end-of-life scale Emanuel et al. (2000)[160]	To identify the subjective experiences and overall care of people at the end of life Tested with 988 patients Time 1 and 650 at Time 2 (4-6 months later)	Self-report or health professional Interview Financial, Access to care, Social connection, Caregiving needs, Psychological distress, Spirituality Sense of purpose, Patient-clinician relationship, Clinician communication, Personal acceptance 0 'None' to 10 'a great deal'	Literature review Focus groups and interviews with patients, caregivers and health professionals Pilot test Clinical opinion	Exploratory factor analysis 12 factors (55% of variance); 8 met criteria (46% of variance)	8 factors baseline α =0.63 to 0.85 Follow-up 7 factors α =0.64 to 0.89 Correlations between dimensions low at Time 1 and 2.
SPEED (13 items) Screen for Palliative and End-of-Life Care Needs in the Emergency Department Instrument Richards et al (2011)[161]	Palliative care symptom assessment tool designed for use in the emergency department 49 patients	Self-report Domains: Physical, Spiritual, Social, Therapeutic, Psychological 10-point Likert scale	Expert opinion Consensus From 3011 items from 86 validated tools selected 107 items most similar to 13 SPEED items. Combined into 120 item tool.	13 SPEED items with 107 validated items all α>0.70 α =0.716 to 0.991 <u>Corrected item correlation</u> r=.326 to 0.970 (no single items predictor of overall needs)	Not reported

3LNQ (16 items) Three-Levels-of-Needs Questionnaire Johnsen et al (2011)[162]	Assesses unmet need and desire for help using 3 approaches: problem intensity, problem burden, and felt need. Supplement for EORTC QLQ 74 advanced cancer (Stage 3 or 4)	Self-report 11 EORTC QLQ-C30 items plus sexuality, feeling burden and loneliness. Assesses in past week using 4 point scale ranging from 'Not at all' to 'Very much'	Literature review Based on EORTC QLQ-C30	Not reported	<u>Agreement between two clinicians</u> 93% (67%-100%) k= 0.91 (0.38-1.00) <u>Agreement between patients and clinician ratings</u> Intensity: 81% (58%-86%); k= 0.73 (0.62-0.78). Burden: 70% (r50%-90%); k=0.63 (0.26-0.77). Felt need: 65% (53%-91%); k=0.26 (0.05-0.83).
PNAT (16 items) Patient Needs Assessment Tool Coyle et al (1996)[163]	To screen people with cancer for potential physical and psychosocial concerns	Completed by health professional - structured interview 16 items Physical, Psychological, Social 5 point Likert 'No impairment' to 'severe impairment'.	Literature review Clinical opinion	Physical domain correlated with KPS Psychological domain correlated with GAIS, Memorial Pain Assessment Scale, BDI and BSI Social domain correlated with Interpersonal Support Evaluation List	ICC=0.85 to 0.94 <u>Inter-rater reliability</u> Concordance coefficient range .73 to .87 Spearman r=.59 to .98 (average .85)

Custom "Problems checklist" (16 items) Wright et al (2001)[164]	To assess the prevalence and severity of psychosocial problems experienced by cancer patients Tested in 505 oncology patients	Self-report Questionnaire Domains: Daily living, Relationships, Emotions Economics Five response options 0 'No difficulty' to 3 'Severe difficulty'; ("Does not apply to me" category added)	Literature review Focus groups and interviews with patients, caregivers and health professionals Clinical opinion	Factor analysis 4 factors 64% of variance. Males reported >scores (economic/relationship) Older reported < scores on all scales (-.148 to -.305) Higher HADS-A > problems (r=.295 to .575) Higher HADS-D > problems (r= .226 to .521) Higher HADS-T > problems (r= .312 to .601)	α = 0.70 to 0.82 Inter-item correlation >0.30 except 2 items <u>Item to total correlation:</u> Daily living r=.57 to .73 Relationships r=.42 to .63 Economics r=.54 Emotions r=.54 to .63
NAT: PD-C (18 items) Needs Assessment Tool: Progressive Disease-Cancer (previously Palliative Care Needs Assessment Tool (PC-NAT)) <u>Study 1:</u> Waller et al. (2008)[165] <u>Study 2:</u> Waller et al (2010)[166] <u>Study 3:</u> Waller et al (2011)[167]	To assess the needs of advanced cancer patients and caregivers in generalist and specialist settings <u>Study 1:</u> 103 health professionals completed tool using three simulated consultations <u>Study 2:</u> 11 clinicians completed 2 tools on 50 advanced cancer patients in clinical setting <u>Study 3:</u> Evaluation over 18 months with 195 patients	Health professional completed (in consultation with patient) Domains: Section 1: 3 items Section 2: Patient wellbeing Section 3: Ability of caregiver/family to care for patients Section 4: Caregiver/Family wellbeing Section 1: yes/no Section 2-4: Level concern: 'none' to 'significant' Action taken: 'directly managed' to 'referral'	*<u>Study 1:</u>* Focus groups with health professionals Literature review Expert opinion and consensus *<u>Study 2:</u>* Staff survey – acceptable, comprehensive, feasible	<u>Study 2:</u> PCPSS: Presence need k=0.24 to 0.48; Severity need k=0.25-0.47 Agreement 49%-65% AKPS vs NAT:PD-C daily living item r=-0.84; lower AKPS had higher needs. RUG-ADL vs NAT:PD-C daily living item r=0.74; higher RUG-ADL had higher needs <u>Study 3:</u> *Consistency with SCNS over time:* Physical: k=0.38 (69% agreement) Psychological: k=0.42 (71% agreement) Information: k= 0.86 (87% agreement) Spirituality: k=0.74 (93% agreement)	<u>Study 1:</u> *<u>Inter rater reliability:</u>* Presence need: 92% k>0.20; 91% k>0.40 (0.01-1.00) Agreement 47%-100%. Severity need: 73% k>0.20; 43% k>0.40 (0.01-1.00) Agreement 27%-100%. <u>Study 2:</u> *<u>Inter rater reliability:</u>* Severity need: 100% k>0.20; 66% k>0.40 (0.22-0.76) Agreement 52%-88%

NEQ (23 items) Needs Evaluation Questionnaire <u>Study 1:</u> Tamburini et al (2000)[97] <u>Study 2:</u> Annunziata et al. (2009)[168] Duration: 5mins	To identify the needs and desire for help of people with cancer who are hospitalised <u>Study 1:</u> 30 patients (item identification) 101 (acceptability) 423 (construct validity) 60 (item content) 88 (test-retest) <u>Study 2:</u> 534 hospitalized cancer patients	Self-completed Domains: Physical, psychological, Social Spiritual, Information, Financial Yes/No response scale	*<u>Study 1:</u>* Semi-structured interviews with 30 patients 60 patients pilot test	<u>Study 1:</u> Confirmatory factor analysis (factors confirmed only in part) <u>Study 2:</u> EFA – five factors CFA confirmed the EFA structure ($\chi 2$ = 254.23, p<0.005; all >0.38) CFA better than uni-dimensional ($\chi 2$=91.36, p<0.001); difference in CFIs >0.01.	<u>Study 1:</u> α =0.69 to 0.81
CaTS (25 items) Cancer Treatment Survey Schofield et al (2010)[169]	To measure patients preparation for starting chemotherapy and radiation therapy and desire for help 192 breast, lymphoma and colon patients	Self-report 2 domains: Sensory/ psychological Procedural 5 point Likert scale (in last month): 1 'strongly disagree' to 5 'strongly agree'.	Expert consensus Literature review for pool of items Pilot tested with 10 patients	Principal component factor analysis (CFA): 2 factors (67.9% variance) <u>Discriminative validity:</u> Younger patients' greater procedural concerns. No difference in scores by gender or disease status. <u>Divergent validity:</u> *<u>Sensory items:</u>* HADS anxiety r=.26 HADS total r=.24. *<u>Procedural items:</u>* HADS anxiety r=.15; HADS total r=.13 (ns)	α = both >0.90 Sensory α =0.96 Procedural α =0.97 <u>Inter-item correlations:</u> All r>0.30 Sensory items: r=.47 to .92) Procedural items: r=.51 to .86.

CPILS (31 items) Cancer Problems in Living Scale Zhao et al (2009)[170]	An inventory of problems commonly faced by those diagnosed with cancer. Tested with 5155 cancer patients	Self-report Domains: Physical distress, emotional distress, employment / financial problems, fear of recurrence 3 point Likert scale: 0 'Not a problem' to 2 'Severe problem'.	Patient interviews Patient surveys Clinical opinion	Exploratory Factor analysis 4 factors <u>Convergent validity:</u> Physical correlated with RSCL-M (r=.50) and SF-36 (r= -.31 to -.45) Emotional correlated with POMS-SF (r=.27 to .38) and SF-36 (r= -.18 to -.31) <u>Divergent validity:</u> Financial subscale had low correlation with other measures (r=.00 to .15) Fear of recurrence had low correlations with other measures (r=-.01 to .12)	All α >0.70 Physical α =0.84 Emotional α =0.87 Financial α =0.78 Fear of recurrence α =0.84.
CNQ-SF (32 items) Cancer Needs Questionnaire Short Form <u>Study 1</u> Cossich et al (2004)[171] Time taken: 20 min	Assessing the needs and desire for help of patients with cancer in an ambulatory care setting. Tested with 450 patients	Self-report -point Likert scale 1 'No need/Not applicable' to 5 ' High need' Domains: Psychological Health information; Physical and daily living Patient care and support Interpersonal communication	From original CNQ	Factor analysis 5 factors (68% of variance) <u>Correlated with:</u> EORTC QLQC-30 Beck Depression Inventory (short-form) <u>Contrasting groups validity</u> <u>*Psychological:*</u> female, advanced poorer physical functioning, undergoing treatment higher needs. Information: younger had higher needs Physical: advanced and poorer functioning higher needs.	α =0.77 to 0.99.
DT Problem list (33 items)	checklist for problems experienced at any stage of cancer	Self-report checklist (tickbox) Domains: Practical problems, Family problems Emotional Problems, spiritual/religious concerns, Other	Not reported	Not reported	α =0.81

PNPC-sv (33 items) Problems and Needs in Palliative Care Short Version (PNPC-sv) Osse et al. (2007)[172] Time taken: 5-10 minutes	Shortened checklist for problems experienced in palliative care and desire for help. For metastatic patients Tested with 94 patients	Self-completed with 2 questions for each item: - Is this a problem? (Yes/No) - Do you want attention? Yes/More, As much as now, No Domains: Physical/daily living, autonomy, psychological, social, spiritual, Information, financial	Selected from original PNPC <u>Item response frequency:</u> All problem items reported as problems for at least one in four patients; range 40-92%. All need for care items reported as problems by 14-56% patients.	<u>Original PNPC:</u> Spearman's rho all >0.80 <u>Convergent validity with EORTC QLQ-C30 & COOP WONCA:</u> *<u>Problem aspect:</u>* 10/14 domains >0.40 (0.27-0.76). *<u>Need for care:</u>* 10/14 domains >0.40 (0.27-0.65) Social issues and physical symptoms lowest correlation.	<u>Problems aspect</u>: 6/8 domains α = >0.70 (0.61-0.86) <u>Need for care:</u> 8/8 domains α =>0.70 (0.70-0.86)
PNAS (34 items) Psychosocial needs assessment survey Moadel et al (2006)[173]	Used to assess the psychosocial needs and desire for help of patients. 248 oncology outpatients	Self-completed 4 point scale: 'Yes'/'Yes but not now'/'No'/'Does not apply' Domains: Informational, Practical, Supportive Spiritual	Literature review Clinical opinion	Not reported	<u>Kuder-Richardson 20 statistic:</u> Information: 0.90 Practical: 0.86 Supportive: 0.83 Spiritual: 0.90 Subscale correlations: r=.57 to .82

SCNS-SF34 (34 items) Supportive Care Needs Survey Short Form <u>Study 1</u> Boyes et al. (2010) [174] <u>Study 2</u> Schofield et al (2011)[175] duration: 10mins	To develop and validate a short version of the Supportive Care Needs Survey (SCNS) <u>Study 1</u> 1138 mixed cancer <u>Study 2</u> 332 prostate cancer patients	Self-completed 5-point Likert scale Questionnaire Domains: Physical and daily living, Psychological, Health system and information, Sexuality, Patient care and support	<u>Study 1</u> Selected from original SCNS 20 items factor loading >0.70 6 items: item-to-total correlation > domain cut-point & factor loading 0.51–0.69. 4 items factor loading 0.64–0.74 and clinically important 4 items clinically important	<u>Study 1</u> Confirmatory factor analysis (CFA) of five factors (73% of the total variance) <u>*Known-groups validity:*</u> remission vs no remission patient using summated domain mean score. Patients not in remission had higher scores. <u>*Convergent validity:*</u> Correlated with DT r= .56 HADS anxiety r= .48 HADS depression r= .48; QLQ-C30 global r= -.51 <u>Study 2:</u> Exploratory factor analysis 5 factors. 4/5 factors identical to Study 1. <u>*Convergent*</u> HADS-A r=.35 to .67 HADS-D r=.29 to .54 EPIC-26 hormonal scale r= -.27 to -.57 <u>*Divergent*</u> EPIC-26 urinary, bowel and sexuality r= -.11 to -.35	<u>Study 1</u> All α>0.70 (α=0.86 to 0.96) Item-to-total score correlation coefficients r>0.55 <u>*Sensitivity with original SCNS*</u> k= 0.88 to 1.00 <u>Study 2</u> All α>0.70 (α=0.82 to 0.96) Item-to-total score correlation coefficients r>0.52

CARES-SF (38 items) Cancer Rehabilitation Evaluation System Short Form <u>Study 1</u> Schag et al. (1991)[176] <u>Study 2</u> te Velde et al (1996)[177] duration: 11mins	To identify the physical and psychosocial issues affecting cancer patients; and in the clinical version, desire for help <u>Study 1:</u> 120 lung, colorectal, prostate (test-retest reliability and validity) 479 patients (factor analysis) 1047 patients (normative data) 109 breast patients (responsiveness) <u>Study 2:</u> 485 Dutch patients before treatment T1), one month later (T2), then 3 months (T3).	Self-administered 5-point Likert scale: 0 'Does not apply' to 4 'Applies very much' 5 domains: Physical, Psychological, Medical interaction, Marital,Sexual Also Global CARES score	<u>Study 1:</u> From original CARES by experts Principal components analysis 5 factors. <u>Study 2:</u> Factor analysis 5 factors. Multi-trait scaling analysis: Item-rest correlations r> 0.40 except the Physical scale at T2 and Medical Interaction scale at T2 and T3	<u>Study 1</u> Factor analysis 5 factors <u>*Correlated with:*</u> CARES: r=.90 to .98 FLIC: r=.-.36 to -.72 DAS: r=.03 to .56 KPS: r=-.01 to -.68. SCL-90: r=.26 to .74 <u>Study 2</u> <u>*Known groups validity:*</u> Time 1: metastatic and lower KPS reported > needs Time 2: chemo > needs than radiation patients Time 3: metastatic with tumour progression > needs than metastatic stable tumour.	<u>Study 1 (3 samples):</u> Physical: α =0.83-0.85 Psychological: α =0.82-0.85 Medical: α =0.60-0.67 Sexuality: α =0.67-0.72 Marital: α =0.67-0.78 <u>Study 2:</u> α >0.70 criterion for the Physical, Psychosocial, and Global scales all time; medical interaction at T2 and T3.

CCM (38 items) Cancer Care Monitor <u>Study 1</u> Fortner et al (2003)[178] <u>Study 2</u> Fortner et al (2006) [179] Time taken: 20 minutes for paper version, 13 minutes for computer version	Screen high frequency cancer-related symptoms and assess overall symptom severity and QoL. <u>Study 1</u> Tested with 3 samples cancer patients <u>Study 2:</u> 40 female and 20 male patients	Self-report 10-point Likert scale Past week: 0 'not bad' to 10 'bad as possible'. Domains: Physical symptoms, Treatment side effect , acute distress , despair impaired ambulation ,impaired performance Summed score: QoL index <u>Study 2</u> Tested 19 symptoms and treatment effects with additional 23 items. Compared patients vs nurse ratings on CCM	Clinical opinion Patient review	<u>Study 1:</u> Factor analysis 6 factors 60% variance <u>*Convergent/Divergent:*</u> 6 CCM subscales & QoL index correlated with BSI, SF-36, LSI, MSAS and SWLS. <u>*Known groups validity*</u>: QoL index, impaired ambulation and performance lower for better ECOG status. More psychological problems had higher acute distress & despair. <u>Study 2</u> <u>*Presence need:*</u> 98% k>0.40 (0.26-1.00). <u>*Severity need:*</u> 75% k>0.50 (0.10-0.96). Ratings differed significantly for 4 items. <u>*Sensitivity*</u> 75% >0.80 (0.44-1.00) <u>*Specificity*</u> 75% >0.80 (0.40-1.00) <u>*PPV*</u> 75% >0.66 (0.44-1.00); <u>*NPV*</u> 75% >0.90 (0.40-1.00) <u>*Youden's index*</u> 75% >0.67 (0.31-1.00)	<u>Study 1</u> All α >0.70 (α = 0.80 to 0.89); QoL index α = 0.84. <u>Inter-item correlations</u> r=.26 to .69 <u>Alternate forms</u> (n=38) Reliability paper vs computer High Pearson product r=.83 to .98

NA-ALCP (38 items) Needs Assessment for Advanced Lung Cancer Patients Schofield et al (2011)[169]	Assess the needs and desire for help of people with advanced lung cancer 108 advanced lung patients	Self completed 4-point Likert scale (during last 4 months) Domains: Daily living, symptom, psychological social,spiritual, financial, medical communication & information	Adapted from 132 item NA-ACP Pilot test and interviews (n=10 patients)	All NA-ALCP subscales correlations with EORTC QLQC-30 satisfactory except spiritual. <u>Convergent/divergent</u> With EORTC QLQC-30. HADS and BDT: 11 predictions supported (convergent r= .13 to .27; divergent r= .45 to .71), 4 predictions inconclusive, 7 predictions contradictory	α =0.71 to 0.95 (six of seven acceptable – excluding spiritual domain α =0.57)
CaNDI (39 items) Cancer Needs Distress Inventory Lowery et al (2011)[180]	Needs-based measure of cancer-related distress assesses unmet need and desire for help 100 mixed cancer	Self-report likert scale of 1 'Not a problem', to 5 'Very severe problem' including desire for help/discussion with health professionals Domains: Depression, Anxiety, Emotional, Social, Health care, Practical Physical	Literature review Derived from pool of items of concerns of cancer patients at Johns Hopkins Medical Center used in clinical assessment; also revised in 2005 at the Moores Cancer Center based on the bio-psychosocial Model	<u>Spearman's r total score:</u> HADS-T r= .65 FACT-G r= -.77 BSI r= -.58 PDS: r= -.18 <u>Spearman's r CaNDI anxiety and depression:</u> BSI anxiety: r=.75, BSI dep: r=.70 <u>Sensitivity and specificity:</u> CaNDI Dep vs HADS-D≥8: AUC=0.84, sensitivity 0.83, specificity 0.84, PPV=37.50 CaNDI Anx vs HADS-A≥8: AUC=0.83, sensitivity 0.80, specificity 0.75, PPV=36.67	All α >0.70 Time 1: 0.91 for full and retest Time 2: 0.92 for retest sample

Table adapted from Carlson LE, Waller A, Mitchell AJ. J Clin Oncol. 2012 Apr 10;30(11):1160-77.

1.8 Screening Implementation for Emotional Complications of Cancer

1.8.1 Design of Screening Implementation Studies

Screening implementation is the process whereby a screening method is developed, applied and tested. This is illustrated in table 1.8.1. Diagnostic accuracy studies demonstrate the potential accuracy of the tool under optimal conditions when compared to a criterion reference (gold standard). Even in a representative sample, the diagnostic accuracy of a tool (eg 80% sensitivity, 80% specificity) doesn't mean that it will be valuable in clinical practice. To test this possibility implementation studies are required.

Implementation studies can be comparative or non-comparative (observational). Observational studies are not without value. For example, the effect of screening on quality of care (process measures) or patient reported outcomes can be monitored using current or historical data. Observational studies may reveal how well screening is working, but will not reveal how much care improves using screening compared with usual care (typically diagnosis using clinical judgement). For this, an interventional screening study is required. These can be randomized or non-randomized. In the typical randomized study, two equivalent groups of clinicians, or in the case of "cluster randomization" two centres, are randomized to have either access to screening vs no access to screening. A variant on this design is to randomize two groups to have either access to *results* of screening or screening without feedback of the *results* of screening. In the latter studies it is feedback of results that are randomized not screening itself. Theoretically this may help distinguish which effects are related to application of the screener and which to the receipt of screening results. Application of the screener, even without results could theoretically influence the interaction of clinicians and patients perhaps by improving communication, focussing on unmet needs and clarifying what help is desired. Receipt of screening results would focus on the severity of the distress/depression at the time of screening and perhaps quantify the unmet needs, if that was part of screening. The screening application can be conducted by a third party or by computer whilst results are shown to the clinician. This is a time-saving option that should be ideally compared to screening conducted fully by frontline clinicians.

The next methodological question is what outcome is most relevant? Historically the main outcome of interest has been patient wellbeing (also known as patient reported outcomes measures or PROMS). This

could be (change in) patient quality of life, distress, depression or other mood complication. Clearly in a screening intervention study where distress is subject to natural change demonstrating added value in the screening arm may be difficult. As a result the comparator is an important methodological considerations. Demonstrating differential improvement in wellbeing compared with a control (treatment as usual) arm typically requires a large sample size. Whilst patient wellbeing is a certainly key outcome, a second outcome of interest is acceptability of the screening programme to patients and clinicians. This can be measured by satisfaction scores or by proxy measures such as uptake and participation. Unfortunately, acceptability is often overlooked in screening studies. A third outcome is clinician behaviour, for example the number of accurate diagnoses recorded, or quality of doctor-patient communication. A related variable is proportion of consultations where treatment is initiated or referrals and help are given; both of which can be considered markers of quality of care. These are sometimes called process measures but these can influence outcomes. For example, Carlson et al (2010) found that the best predictor of decreased anxiety and depression was receipt of referral to psychosocial services.[181] If a screening study shows benefits in quality of care or clinician behaviour but not patient wellbeing this may suggest there are significant barriers to care downstream of the screening process. If a screening study shows no benefits in quality of care or clinician behaviour and none in patient wellbeing then this may suggest that screening did not influence the process of care. If a screening study shows benefits in patient wellbeing in both arms, this may suggest that screening was not the rate limiting factor in determining quality of care in that centre and that the resources allocated to screened and unscreened patients are helpful.

Table 1.8.1 Design and Evaluation of Screening Studies

Stage	Type	Purpose	Description
Pre-clinical	Development	Development of the proposed tool or test	Here the aim is to develop a screening method that is likely to help in the detection of the underlying disorder, either in a specific setting or in all setting. Issues of acceptability of the tool to both patients and staff must be considered in order for implementation to be successful.
Phase I_screen	Diagnostic validity	Early diagnostic validity testing in a selected sample and refinement of tool	The aim is to evaluate the early design of the screening method against a known (ideally accurate) standard known as the criterion reference. In early testing the tool may be refined, selecting most useful aspects and deleting redundant aspects in order to make the tool as efficient (brief) as possible whilst retaining its value.
Phase II_screen	Diagnostic validity	Diagnostic validity in a representative sample	The aim is to assess the refined tool against a criterion (gold standard) in a real world sample where the comparator subjects may comprise several competing condition which may otherwise cause difficulty regarding differential diagnosis.
Phase III_screen	Implementation	Sequential cohort before vs after screening tool	This is an important step in which the tool is evaluated clinically in one group with access to the new method compared to a second group (ideally selected in a randomized fashion) who make assessments without the tool.
Phase III_screen	Implementation	Screening RCT; clinicians using vs not using a screening tool	This is an important step in which the tool is evaluated clinically in one group with access to the new method compared to a second group (ideally selected in a randomized fashion) who make assessments without the tool.
Phase III_screen	Implementation	Screening feedback RCT; clinicians using vs not using a results of screening tool	This is an important step in which the tool is evaluated clinically in one group with access to the new method compared to a second group (ideally selected in a randomized fashion) who make assessments without the tool.
Phase IV_screen	Audit	Observational screening study using real-world outcomes	In this last step the screening tool /method is introduced clinically but monitored to discover the effect on important patient outcomes such as new identifications, new cases treated and new cases entering remission.

1.8.2 Summary of Depression Screening Implementation Studies

To date only five Implementation studies have tested the merits of depression screening in cancer settings or measured the effect of broad psychosocial screening on depression outcomes. These are summarized in table 1.8.2 and described as follows.

Maunsell et al, (1996) conducted the first randomized study of its kind, involving 251 breast patients randomized to a telephone screening using the GHQ-20 every 28 days (n=123) or basic psychosocial care only (n=127).[182] Patients scoring ≥5 on the GHQ were referred to a social worker. Distress decreased over time in both groups with little to differentiate between groups and no additional benefit of screening. It is possible that screening was not successful because of the high quality of usual care in addressing psychosocial needs, a lesson for future studies.

McLachlan et al (2001) conducted a 2 arm feedback vs no feedback RCT involving quality of life, depression and unmet needs in 450 people with cancer.[183] Patients completed self-reported questionnaires via a touch-screen computer and for the intervention group, a computer-generated one-page summary of the questionnaire results was made available immediately for consideration during the consultation with the doctor. In the intervention arm a nurse was also present during this consultation and formulated an individualized management plan based on the issues raised in the summary report and pre-specified expert psychosocial guidelines. Six months after randomization there were no significant differences between the two arms overall but for a subgroup of patients who were at least moderately depressed at baseline, there was a significantly greater reduction in depression for the intervention arm. This again provides a valuable lesson that screening / interventions most benefit those with most distress at baseline and that screening with resources is likely to be more effective than screening alone.

Boyes and colleagues in Australia (2006) asked 95 patients to complete a computerized screen assessing their psychosocial well-being while waiting to see the oncologist during each visit.[184] Alternate consenting patients were assigned to an active group with feedback and a control group without feedback. Thus the study was not randomized. Responses (including the HADS scores) were placed in each patient's file for oncologist's attention. At subsequent visits there was no effect on levels of anxiety, depression and perceived needs among those who received the intervention, but only three intervention patients reported

that their oncologist discussed the feedback report with them. Nevertheless, acceptability of the screening seemed high.

Rosenbloom and colleagues (2007) randomly assigned 213 patients with metastatic breast, lung or colorectal cancer to feedback or no feedback following screening with the Functional Assessment of Cancer Therapy- General (FACT-G).[185] The main intervention group received structured interview by the treating nurse. The authors looked at 3 and 6 month outcomes in QoL, mood (profile of mood states, POMS-17) and satisfaction. Halfway through physicians switched arms, reducing the likelihood of confounding. No significant differences were found between study conditions in HRQoL or satisfaction.

Macvean et al (2007) undertook an RCT of a telephone based volunteer led screening and support (Pathfinder Program).[186] The sample size was modest, 52 colorectal cancer patients recruited via a state-based cancer registry and only 18 in the intervention arm and 34 in usual care. They were assessed using quality of life, unmet needs and depression measures at baseline and 3months follow-up. Results showed that HADS-D scores and supportive care needs for groups decreased at follow-up a non-significantly greater decrease in the intervention group than the usual care but there was a significantly greater decrease in depression at 6 months in patients depressed at baseline.

Table 1.8.2 Summary of Distress and Depression Screening Implementation Studies

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
Randomized							
Maunsell et al (1996)[182] Canada	2 arm screen vs no screen RCT Both groups: Basic psychosocial care (ie contact with social worker at initial treatment). Follow-up telephone interviews 3 and 12 months later Intervention: telephone screening using GHQ-20 every 28 days (12 calls). Patients scoring GHQ≥5 referred to social worker Control: No telephone screening	251 breast patients Intervention n=123; control n=127	Primary outcome: Distress: PSI Secondary outcome: Overall Health Perception Usual activities: CHALS Depression/Anxiety: DIS Social support: SSQ Stressful life events: LES	Primary outcome: Distress decreased over time (both groups) Secondary outcomes: No between group differences in distress, physical health, usual activities, return to work, marital satisfaction, use of other psychosocial services or medical consultations	No	No	Not studied
Sarna (1998) [188] United States	2 arm feedback vs no feedback RCT Both groups: seen by research assistants using SDS, HADS, KPS. Intervention: Feedback to nursing team Control: No Feedback	48 newly diagnoses patients with advanced lung cancer	Primary outcome: Symptoms Distress: SDS measured monthly for 6 months	Primary outcome: Feedback was associated with better SDS scores with time, most apparent at 6months. Significant in multivariate model.	Yes	Yes	Not studied

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
McLachlan et al (2001)[183] Australia	2 arm feedback vs no feedback RCT (allocation: 2: 1 intervention: control) Both groups: Completed measures using touch-screen computer prior to consultation at baseline, 2 and 6 months Intervention: results summary available to doctor and coordination nurse during consultation. Individualized management plan based on scores and predefined guidelines developed for patients Control: usual clinical encounter; information not available to clinicians	450 cancer outpatient; Intervention n=296; control n=154 2 and 6 month outcomes	Primary outcome: CNQ-SF (psychological and information needs) Secondary outcomes: Other needs: CNQ-SF QoL: EORTC QLQ-C30 Depression: BDI-SF 6 month only: Satisfaction with medical staff, information provision, overall satisfaction	Primary outcome: No between group difference in changes in psychological / information needs Secondary outcomes: No difference in changes in other needs between two groups. *Intervention:* greater decrease in depression at 6 months (in patients depressed at baseline). No between group differences in changes in satisfaction with care	Partial (in depressed patients).	Yes (in depressed only)	Not studied

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
Velikova et al (2004) [189] UK	3 arm feedback vs no feedback vs no screen RCT (allocation ratio: 2:1:1 in favour of intervention group and stratified by cancer site) Intervention (I): completion of touch-screen screening measure (EORTC QLQ-C30; HADS); with feedback of results to physicians Attention control (AC): completion of screening measure (EORTC QLQ-C30; HADS) touch-screen computer; no feedback provided to physicians Control: no touch-screen measurement of HRQOL before clinic encounters All groups: Followed up for 6 months	286 patients Intervention n=144; AC n=70; control n=72	Primary outcomes QoL: FACT-G Secondary outcomes: Audio-taped consultations content of any QOL issues included in EORTC QLQ-C30.	Primary outcome: Intervention and AC groups higher QoL than control group (no difference between intervention and AC) Proportion patients with clinically meaningful improvement in FACT-G greater in intervention group Secondary outcomes: EORTC symptoms higher in intervention group; no difference in number other symptoms discussed; several patient reported outcomes improved. Physician satisfaction also reported	Yes	Yes	Mixed

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
Rosenbloom et al (2007)[185] USA	3 arm feedback vs no feedback RCT; stratified by diagnosis, all groups completed questionnaires prior to regular consultation Structured interview and discussion (SID): interviewed by nurse after questionnaire completed (baseline, 1, 2 months) Assessment control (AC): QoL results presented to nurse at baseline, 1, 2 months and patients followed up at 1, 2, 3 and 6 months. Full control (FC): No feedback to nurses or interview. Followed up at 3 and 6 months.	213 patients with advanced breast, lung or colorectal, regional or distant spread, receiving chemotherapy	Screening measure: QoL: FACT-G (baseline and follow-up for SID & AC; 6 month only for FC) Primary outcomes: All time point (all groups) QoL: FLIC Mood: POMS-17 Satisfaction: PSQ-III. Secondary outcomes: Treatment: 5 items completed by nurse	Primary outcomes: Satisfaction and QoL did not change; no differences across groups in changes in QoL or satisfaction over time (FLIC or PSQ-III). Secondary outcomes: No statistically significant differences across groups in changes in clinical treatment changes	No	No	Not studied

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
Macvean et al (2007)[186] Australia	RCT of telephone based volunteer led screening and support (Pathfinder Program) Baseline and 3months follow up	52 colorectal cancer patients recruited via a state-based cancer registry 18 intervention 34 usual care 62% of the sample was male and the mean age was 64 years.	SCNS HADS-D	The decrease in average number of needs from baseline to 3-month follow-up was greater for intervention than for control participants	HADS-D scores and supportive care needs for groups decreased at Time 2 and, although the decrease was greater for the intervention group than the usual care group, the group by time interaction was not significant	Yes (depression)	High

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
Carlson et al (2010)[181] Canada	3 arm feedback vs no feedback RCT (allocation ratio of 1:1:1) All groups: Completed measures via computerized kiosk prior to consultation 3 month follow-up via email or telephone by a research assistant. Minimal screening: DT only. No feedback Full screen: DT and PSSCAN Part C; received personalized report and summary on EMR Full screening & triage: DT; PSSCAN Part C; received personalized phone call within 3 days. Detailed triage algorithm followed to discuss referral options with the patient	585 breast and 549 lung patients Minimal screen n=365; full screen n=391, screening with triage n=378	Primary outcome: Distress: DT Secondary outcomes: Anxiety and Depression: PSSCAN Part C (completed by minimal screening group at 3 month follow-up only).	Primary outcome: marginally significant differences between triage and minimal screen groups *Lung only:* 20% fewer in triage group reported continued high distress at follow-up compared to other groups *Breast only:* full screening and triage groups had lower distress at follow-up than minimal screening Secondary outcomes: No between group differences in anxiety or depression; best predictor of decreased anxiety and depression was referral to psychosocial services	Yes (in breast and lung cancer)	No	High

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
Carlson et al (2012) [190] Canada	2 arm feedback vs personalized feedback RCT: (allocation ratio of 1:1) Both groups: Completed DT, FT, PT, SSCAN Part C, service use prior to consultation Followed up at 3, 6 and 12 months Computerized: received a printout summary of concerns and instructions on how to access appropriate services Personalized: received brief computer printout summary of concerns and contacted by screening team within 3 days. Detailed triage algorithm followed to discuss **referral** options	3133 patients Computerized n=1531; personalized n=1602	Primary outcome measures: Distress: DT Fatigue: FT Pain: PT; Anxiety & Depression: PSSCAN Part C Secondary outcomes measure: Services accessed since last screening	Primary outcomes: Significant decreases in all outcomes over time in both groups; however no differences between groups Secondary outcome: Personalized triage group and patients with higher symptom burden more likely to access services. Access related to greater decrease in distress, anxiety and depression	No	Yes	High

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
Braeken et al (2011)[191] Germany	2 arm screen vs no screen RCT: (allocation ratio of 1:1) <u>Intervention:</u> Radiotherapists were asked to apply SIPP screening and indicate whether patients were offered an appointment with a psychosocial care provider. Radiotherapists were trained in using and interpreting the SIPP, including interpretation of scores and the type of potential psychosocial problems and the need for psychosocial care during a one-hour training session. <u>Control</u>: Treatment as usual	Of 1123 eligible patients (age over 18 years; patients without metastases; and able to provide written informed consent.) 555 refused. 268 cancer patients; 263 completed the SIPP screening at baseline. 300 were in the radiotherapists control arm and 268 in the radiotherapists screening arm	Patients randomized to receive SIPP screening. SIPP comprised 24 items taking 5.3mins and assesses physical and psychological complaints	48.7% (n=146) of the con- trol group patients and 42.9% (n=115) of the screened group patients reported their satisfaction with patient–physician communication to be 'very good' 69/300 controls and 58/268 screened patients received a referral, although 19 and 13, respectively had previously been in receipt of care. 63.6% (21/33) who screening positive accepted psychosocial care. Patients were positive about the content of the SIPP. Clinician's views were mixed.	No intervention effect on overall psychological distress and HRQoL at 3 or 12mo. No effect on communication, no effect on referrals. Early referral to the social workers had favourable short-term effects on some aspects of patients' health-related outcomes.	No	Mixed

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
Hollingworth et al (2012)[192] UK	2 arm screen vs no screen RCT: (allocation ratio of 1:1) Intervention group: completed the DT & problem list, rating distress and discussing sources of distress with a trained radiographer/nurse. Psychological distress (POMS-SF) and disease specific quality of life (EORTC-QLQ C30) were measured at baseline, 1 and 6 months. Control: Treatment as usual	220 patients (49% breast, 27% urological, 24% other cancer sites) were randomised. 107/112 randomised to the DT&PL completed it, taking about 25 minutes.	Distress Thermometer Psychological distress (POMS-SF) and disease specific quality of life (EORTC-QLQ C30) were measured at baseline, 1 and 6 months	POMS-SF and EORTC scores in both arms deteriorated at 1 month then improved at 6 months, particularly in the fatigue subscale. There was no evidence that patients randomised to the DT&PL had better POMS-SF (mean post-treatment difference 0.58 but non-significant), EORTC (0.88; but non-significant) or subscale scores compared to control.	No	No	High
Non-randomized							
Pruyn et al (2004)[187]	Non-randomized side-by-side comparison of screen vs no screen in two hospitals	105 in intervention and 124 in control group	Communication Referral Custom screening checklist	23/105 screening consultations vs 20/124 discussed emotional problems 73/105 vs 20/124 discussions initiated by clinician 11% vs 2% received a referral	Yes	Not studied	Screening acceptable to 77% of patients

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
Boyes et al, (2006)[184] Australia	Alternate feedback vs no feedback (allocation: alternate consenting patients assigned to groups via computer). Both groups: Patients completed computerized screening measure (SCNS, HADS, physical symptoms) prior to consultation. Assessed at 1st visit and 3 following consecutive visits. Intervention: Feedback report of summary scores and strategies for managing issues was printed and placed in patient file for discussion in consultation with oncologist. Control: No results made available to oncologist.	95 cancer patients Intervention n=42, control n=38	Primary outcomes: Physical symptoms Anxiety/Depression: HADS Secondary outcomes: Needs: SCNS Acceptability: survey administered to patients and oncologists	Primary outcomes: No significant differences between the groups in changes in anxiety, depression Intervention patients reporting physical symptoms at visit 1 less likely to report at visit 3. Secondary outcome: No significant differences between the groups in the proportion of patients reporting any moderate/high unmet needs. Patients: Easy, acceptable and willing to complete at each visit Oncologists: 2/4 reported discussing feedback sheet with patients, 3/4 reviewed at beginning of consultation, easy to understand, adequate content	No	No	Yes

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
Bramsen et al (2008)[193] Netherlands	Sequential cohort design screening vs usual care Both Groups: At baseline and 4 weeks following discharge, the usual care and screening groups completed mental health and quality of life questionnaires. Intervention: Patients received an information leaflet and visit from a psychologist or a social worker visited the patient to determine if (s)he wished to talk with a member of the psychosocial team. If so, a semi-structured interview was conducted Control: Treatment as usual	Newly admitted to the oncology department of an academic hospital were assigned to a usual care group (n=50) or a screening group (n=79). A retrospective, medical records group (n=89) was also included.	EORTC quality of life questionnaire (QLQ-C30, version 3.0) The General Health Questionnaire (GHQ-12) Impact of Event Scale (IES) Uptake of care	51% indicated that they wished to speak with a psychosocial worker and 33% had psychosocial care arranged Referral for psychosocial care: 24% in the screening group 18% in the medical records group 8% in the usual care group Change from baseline to follow-up on the QLQ-C30 'pain', 'physical functioning', and 'role functioning' scales. Favoured screening (The usual care group reported decreases) the screening group scored significantly better on the GHQ-12 positive mental health scale	Yes	Partial	Not studied

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
Thewes et al (2009) [194] Australia	Sequential pre-screen/post-screen cohort study (sequentially recruited first into control group, then into screened group). Both groups: Followed up 6 months later Screened: Completed DT, SPHERE-Short prior to consultation /chemotherapy education session; nurses encouraged to assess problems and explore interest in receiving **referral** to psychosocial staff Control: Questionnaire (SPHERE-Short) completed prior to consultation or chemotherapy education session	83 newly diagnosed patients with malignant disease Screened n=43, control n=40	Primary outcomes: Referrals: Medical record Distress: SPHERE-Short Secondary outcomes: Needs: SCNS-SF	Primary outcome: 44% scored DT≥ 5; of these, 10 (53%) were referred to a social worker or psychologist No significant difference in PSYCH-6 between cohorts in % who where cases Secondary outcomes: Time to referral shorter in screened cohort (5 vs 14 days) Screened cohort reported higher unmet information, psychological and daily living needs at 6 months	Partial (in referral delay)	No	Yes

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
Shimizu et al (2010) [195] Japan	Retrospective cohort analysis (patients treated during the program-period vs historical control data gathered during the usual care-period) Intervention group: two week recruitment period; received 3 stage DISPAC program. Stage 1: complete DIT and submit to physician; Stage 2: physician review DIT and recommended **referral** to psycho-oncology service if > cut-off. If accepted **referral**; Stage 3: seen by psychiatrist, psychologist or nurse specialist and diagnostic interview conducted Control: two week recruitment period; received standard care (**referral** based on clinical acumen)	Control n=574; and intervention n=491	Primary outcome: Referrals: Medical record audit of patients referred to psycho-oncology and treated for major depressive or adjustment disorder (AD) Proportion patients who accepted referrals Secondary outcomes: Distress ad impact: DIT Screening rates: Medical record audit of % screened, time taken for nurse to instruct patient on DIT	Primary outcome: Significantly more patients referred during intervention (5.3%) than usual care (0.3%). Of high distressed 93% referred to service; 25% accepted. Secondary outcome: DIT higher in patients who accepted referrals; 92% completed DIT in intervention cohort; 37% reported high distress.	Partial (in referral)	No/Unknown	Not studied

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
Ito et al (2011) [197] Japan	Retrospective cohort analysis (patients treated during NASPRP program-period vs historical control data) <u>Intervention group:</u> provided with information on psychiatric service and screened using DIT by pharmacists while providing routine instructions on chemotherapy regimens. Administered during 2nd visit for each patient beginning new chemotherapy regimen. <u>Control group:</u> received standard care	Patients beginning chemotherapy during 6 month period Usual care n=478, intervention n=520	<u>Primary outcomes:</u> Medical record audit of proportion of patients referred to Psychiatric Service and treated for major depressive or AD Days from the first chemotherapy to the first visit to Psychiatric Service <u>Secondary outcome:</u> Screening rates: Medical record audit of proportion patients screened	<u>Primary outcomes:</u> No difference in proportion referred (1% usual care vs 2.7% intervention); or proportion patients referred who did not fit DSM-IV criteria Fewer days between treatment and visit psychiatric service for intervention (12.9 vs 55.6 days). <u>Secondary outcomes:</u> 76% screened at first visit; positive screening rate of 29%; 72% screened at second visit; positive screening rate 22%.	Partial (in referral delay)	No	Not studied

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
Grassi et al (2011) [196] Italy	Retrospective cohort analysis (patients treated during intervention period vs historical control) Screened: 1 year recruitment period and screened with DT and PL immediately; clinicians also received an educational intervention Control: Usual care and referrals to POS based on clinical acumen. Once referred patients screened with DT and PL.	newly diagnosed patients Usual care n=153 and Screened n=583	Primary outcome: Referrals Secondary outcomes: Distress: DT Problems: PL	Primary outcome: *Control group:* 153/2268 (6.1%) were referred to psycho-oncology; 31.4% of referred DT<4 (non-case) when assessed by psycho-oncology *Screened group*: 544/1107 screened; 52.2% DT≥4 and 284 (25.7%) referred to psycho-oncology. Secondary outcome: *Screened:* referred patients higher DT, pain, sleep and sexual problems; DT cases reported more family, practical, emotional and physical problems than non-cases *Control:* DT cases reported more emotional and physical problems than non-cases	Partial (in referral)	No	Not studied

From a narrative perspective these five studies appear to be somewhat disappointing regarding any positive effects of depression screening on patient wellbeing. Whilst some secondary outcomes have been positive, screening for depression in cancer settings has not yet proven successful during implementation.

1.8.3 Summary of Distress Screening Implementation Studies

To date, 14 Implementation studies have tested the merits of screening for distress in cancer settings. These are listed in table 1.8.2 and are described as follows.

Maunsell et al (1996) conducted the first randomized study of its kind, involving 251 breast patients randomized to a telephone screening using the GHQ-20 every 28 days (n=123) or basic psychosocial care only (n=127).[182] Patients scoring ≥5 on the GHQ were referred to a social worker. Distress decreased over time in both groups with little to differentiate between groups and no additional benefit of screening. It is possible that screening was not successful because of the high quality of usual care in addressing psychosocial needs, a lesson for future studies.

Sarna (1998) conducted a trial whereby the results of screening with the Symptom Distress Scale (SDS), HADS and Karnofsky Performance Status (KPS) were fed back or not fed back to clinical nurses according to randomization.[188] The sample was 48 patients within three months of a diagnosis of advanced lung cancer. Over 6 months of follow up 'symptom distress' in the feedback group declined but in the no feedback group it increased and the difference was statistically significant by 6 months. In this study resources were similar in both groups suggesting feedback of screening results was the main influence.

McLachlan et al (2001) conducted a 2 arm feedback vs no feedback RCT involving quality of life, depression and unmet needs in 450 people with cancer.[183] Patients completed self-reported questionnaires via a touch-screen computer and for the intervention group, a computer-generated one-page summary of the questionnaire results was made available immediately for consideration during the consultation with the doctor. In the intervention arm a nurse was also present during this consultation and formulated an individualized management plan based on the issues raised in the summary report and pre-specified expert psychosocial guidelines. Six months after randomization there were no significant differences between the two arms overall but for a subgroup of patients who were at least moderately depressed at baseline, there was a significantly greater reduction in depression for the intervention arm. This again provides a valuable

lesson that screening / interventions most benefit those with most distress at baseline and that screening with resources is likely to be more effective than screening alone.

Velikova and colleagues in Leeds (2004) recruited 28 oncologists treating 286 cancer patients and randomly assigned them to an intervention group who underwent screening along with feedback or screening alone (called attention-control) or a no screening condition.[189] The questionnaires used were the EORTC QLQ-C30 and touch-screen version of HADS. A positive effect on emotional well-being was seen in the intervention with feedback vs control group but there was little to differentiate intervention and the screening-only attention-control. More frequent discussion of chronic non-specific symptoms was found in the intervention group (without prolonging encounters), there was no detectable effect on patient management. Clinician satisfaction was also monitored prospectively. Physicians found the HRQoL information clinically "very useful/quite useful" in 43% of encounters, but "little use" in 21%, and "not useful" (or missing response) in 9%. They felt that the HRQoL screening data provided additional information in 33% of cases and identified problems for discussion in 27% but felt it contributed to patient management in only 11% of encounters.

Carlson et al. (2010) examined the effect of screening on the level of psychological distress in lung and breast cancer patients randomized to minimal screening (screening but no feedback), full screening (screening with feedback) and screening with feedback and optional triage and referral.[181] This study therefore had no null-screening arm. The questionnaires used were the EORTC QLQ-C30 and a touch-screen version of the HADS administered to over 1000 patients: 365 in minimal screen, 391 in full screen and 378 in screening with triage. Results differed by cancer type. In lung cancer patients receiving full triage, 20% fewer reported continued high distress at follow-up compared to other groups. In breast cancer the full screening and triage groups both had lower distress at follow-up than minimal screening. A positive effect on emotional well-being was seen in the intervention vs control group but there was little to differentiate intervention and the screening-only attention-control. Although more frequent discussion of chronic non-specific symptoms was found in the intervention group (without prolonging encounters), there was no detectable effect on patient management.

Carlson et al in Calgary Canada (2012) also conducted a large scale 2-arm RCT of computerized screening vs personalized screening.[190] The computerized arm comprised a printout summary of concerns and instructions on how to access appropriate services. Personalized screening consisted of computerized

screening plus personal contact within 3 days. This was effectively screening with follow-up vs screening alone. The screened group received the PSSCAN and distress thermometer. There were no significant differences in HRQoL and treatment satisfaction outcomes between any groups at 3 and 6 months, although high baseline scores may have made improvements difficult to produce. There was a significant difference in access to services as 3 and 12 months, however.

Braeken et al (2011) conducted an innovative study using radiotherapists who were asked to apply a 24-item Screening Inventory of Psychosocial Problems (SIPP) and indicate whether patients were offered an appointment with a psychosocial care provider.[191] Results were compared with treatment-as-usual. Radiotherapists were trained in using and interpreting the SIPP, including interpretation of scores and the type of potential psychosocial problems and the need for psychosocial care during a one-hour training session. At baseline, 263 patients completed the SIPP screening and 250 completed repeat SIPP screening and outcome measures at end of their radiotherapy treatment. While results have just been reported, there was no overall benefit in patient wellbeing and although referrals improved the effect was not significant. Acceptability to radiotherapists was mixed.

Hollingworth and colleagues in the UK (2012) used the DT and associated problem list to rate distress and discuss sources of distress as applied by a trained radiographer/nurse and compared this with treatment as usual.[192] Psychological distress (POMS-SF) and disease specific quality of life (EORTC-QLQ C30) were measured at baseline, 1 and 6 months. 220 patients (49% breast, 27% urological, 24% other cancer sites) were randomised with 107/112 in the DT arm. Both groups improved by 6 months and there was no evidence that patients randomised to the screening condition had better outcomes.

As mentioned above, Pruyn et al (2004) conducted a non-randomized side-by-side comparison of screening vs no screening in two hospitals.[187] There were 105 in intervention hospital under study and 124 in control hospital. The authors found nonsignificant benefits of screening for distress on referrals and communication. Remarkably duration of consultations decreased with screening. Screening was modestly acceptable to 77% of patients. In 23/105 of screened consultations there was a discussion of emotional problems vs 20/124 of non-screened consultations.

Bramsen et al (2008) studied 50 newly admitted patients given usual care and 79 screened with the EORTC QLQ-C30, General Health Questionnaire (GHQ-12) and Impact of Event Scale (IES).[193] They also studied a retrospective medical records group (n=89). Referral and access to psychosocial care was the main

outcome. Psychosocial care was received by 24% in the screening group, 18% in the medical records group and only 8% in the usual care group. Further, subscales on both the QLQ-C30 and the GHQ-12 significantly favoured screening over usual care.

Thewes et al (2009) allocated newly diagnosed patients with malignant disease to screening (n=43) with the DT and short Somatic and Psychological Health Report Short form (SPHERE) prior to a chemotherapy education session and in high scorers nurses were encouraged to assess and manage distress.[194] 40 historical patients followed up prior to screening acted as controls. At six months participants in the screened cohort reported significantly higher levels of overall unmet needs, psychological needs, information needs and physical and daily living needs compared with the unscreened cohort. This might be because screening identified a more unwell cohort or because screening was not linked with successful treatment. In fact, of those scoring ≥ 5 on the DT, only 10 (53%) were referred to a social worker or psychologist. There was a trend (non-significant) towards lower SPHERE cases in unscreened patients vs screened (24% vs 35%, p = 0.282). Referral delay was shorter in the screened cohort (5 vs 14 days). Acceptability to patients was generally high, as 86% did not believe that the screening questions were too personal or upsetting.

Shimizu et al (2010) used retrospective cohort analysis of 491 patients treated during the program-period vs 574 historical control data gathered during the usual care-period.[195] There were significant decreases in all distress-related outcomes over time in both groups but no differences between groups. Nevertheless, patients in the personalized triage group and patients with higher symptom burden were more likely to access services, which was subsequently related to greater decreases in distress, anxiety and depression.

Grassi et al (2011) used a retrospective cohort analysis of 583 patients treated during the intervention period compared with 153 historical controls.[196] Screened patients received the DT and associated problem list. Screening increased referrals to a specialist psycho-oncology service from 6.1% to 25.7%. Patients who screened positive and were referred to services had higher distress scores, suggesting the programme focussed attention on those with more emotional needs.

Ito et al (2011) conducted a retrospective cohort analysis of patients treated during NASPRP program-period against historical control data.[197] The intervention group were provided with information on psychiatric service and screened using DIT by pharmacists while providing routine instructions on chemotherapy regimens. The control group received standard care. Patients were screening at the

beginning chemotherapy during 6 month period ands the sample size was good (usual care n=478, intervention n=520). Results showed no difference in proportion referred (1% usual care vs 2.7% intervention); or proportion patients referred who did not fit DSM-IV criteria but there was an improvement in referral delay.

From a narrative perspective these 14 studies appear to present a mixed picture regarding any positive effects of distress screening on patient wellbeing. Results seemed to support some benefit of distress screening on process measures and quality of care but little effect on detections. Results concerning overall patient wellbeing are mixed but the most successful studies appear to be those where screening was tied with a clear treatment or follow-up. Stand alone screening, and screening without feedback does not appear to be successful.

1.8.4 Summary of Unmet Needs Screening Implementation Studies

To date nine Implementation studies have tested the merits of screening for unmet needs or unmet needs as an outcome of broad psychosocial screening in cancer settings. These are as shown in table 1.8.4. Eight studies screened for mixed unmet needs but Kristeller et al (2005) screened for only spiritual needs.[199]

As discussed above in section 1.8.2, McLachlan et al (2001) conducted a 2 arm feedback vs no feedback RCT involving quality of life, depression and unmet needs in 450 people with cancer. [183] The unmet needs tool was the CNQ-SF for psychological and information needs. Patients completed self-reported questionnaires via a touch-screen computer and for the intervention group, a computer-generated one-page summary of the questionnaire results was made available immediately for consideration during the consultation with the doctor. In the intervention arm a nurse was also present during this consultation and formulated an individualized management plan based on the issues raised in the summary report and pre-specified expert psychosocial guidelines. Six months after randomization there were no significant differences between the two arms overall but for a subgroup of patients who were at least moderately depressed at baseline, there was a significantly greater reduction in depression for the intervention arm.

Girgis and colleagues (2009) conducted a 3-arm RCT involving usual care, a telephone caseworkers and an oncologist/general practitioner alone.[198] Telephone caseworker were trained in the use of an unmet needs list modified from the cancer helpline database. 356 breast and colorectal were assessed at baseline, 3

months and 6 months. Results showed that patients with a telephone caseworker were more likely to discuss anxiety (P =.01) and unmet psychological needs (P =.01), whereas Oncologists/GPs were more likely to discuss unmet patient care/support needs. Patients with a telephone caseworker were more likely to have referrals recommended, in particular for unmet psychological needs and also were more likely to strongly agree that study participation had made discussions with their health care practitioners easier.

Macvean et al (2007) undertook an RCT of a telephone based volunteer led screening and support project (Pathfinder Program) in 52 colorectal cancer patients recruited via a state-based cancer registry.[186] Only 18 were in the intervention arm and 34 in usual care. They were assessed using quality of life, unmet needs (using the SCNS) and depression measures at baseline and 3months follow-up. Results showed that HADS-D scores and supportive care needs for groups decreased at follow-up a non-significantly greater decrease in the intervention group than the usual care but there was a significantly greater decrease in depression at 6 months in patients depressed at baseline.

Kristeller et al (2005) allocated 118 alternate patients to discussion of spiritual needs during consultation and compared this with usual care. Patients had mixed cancer diagnosesm51.7% diagnosed within 2 years of diagnosis. Four oncologists rated themselves as comfortable during the inquiry with 85% of patients and 76% of patients felt the inquiry was "somewhat" to "very" useful. At 3 weeks, the intervention group had greater reductions in depressive symptoms ($p < .01$), more improvement in QoL ($p < .05$), and an improved sense of interpersonal caring from their physician ($p < .05$) relative to control patients.

Boyes and colleagues (2006) asked 95 Australian patients to complete a computerized screen assessing their psychosocial well-being while waiting to see the oncologist during each visit. Patients completed computerized screening measure (SCNS, HADS, physical symptoms) prior to consultation and were assessed at 1st visit and 3rd following consecutive visits. Alternate consenting patients were assigned to an active group with feedback and a control group without feedback. Thus the study was not randomized. Responses (including the HADS scores) were placed in each patient's file for oncologist's attention. At subsequent visits there was no effect on levels of anxiety, depression and perceived needs among those who received the intervention, but only three intervention patients reported that their oncologist discussed the feedback report with them. Nevertheless, acceptability of the screening seemed high.

As mentioned in 1.8.3, Thewes et al (2009) allocated newly diagnosed patients with malignant disease to screening (n=43) with the DT and SPHERE prior to a chemotherapy education session and nurses were

Table 1.8.4 Unmet Needs Screening Implementation Studies

Author	Study Design	Sample	Measures	Results	Screening Beneficial?	PROs Improved?	Acceptability of Screening?
Randomized Studies							
McLachlan et al (2001)[183] Australia	2 arm feedback vs no feedback RCT (allocation: 2: 1 intervention: control) Both groups: Completed measures using touch-screen computer prior to consultation at baseline, 2 and 6 months Intervention: results summary available to doctor and coordination nurse during consultation. Individualized management plan based on scores and predefined guidelines developed for patients Control: usual clinical encounter; information not available to clinicians	450 cancer outpatient; Intervention n=296; control n=154 2 and 6 month outcomes	Primary outcome: CNQ-SF (psychological and information needs) Secondary outcomes: Other needs: CNQ-SF QoL: EORTC QLQ-C30 Depression: BDI-SF 6 month only: Satisfaction with medical staff, information provision, overall satisfaction	Primary outcome: No between group difference in changes in psychological / information needs Secondary outcomes: No difference in changes in other needs between two groups. *Intervention:* greater decrease in depression at 6 months (in patients depressed at baseline). No between group differences in changes in satisfaction with care	Partial (in depressed patients).	Yes (in depressed only)	Not studied

Girgis et al (2009)[198] Australia	3 arm RCT RCT of usual care (n=117): a telephone caseworker (n=120) model and an oncologist/general practitioner (O/GP; n=119) model.	356 Breast and colorectal assessed at baseline, 3 months and 6 months	HADS-D / HADS-A EORTC QLQ-C30	TCW group were more likely to have their issues discussed than were those in the O/GP group (P .0001). TCW were more likely to discuss anxiety (P .01) and unmet psychological needs (P .01), whereas O/GPs were more likely to discuss unmet patient care/support needs (P .02;). TCW participants were more likely to have referrals recommended (P .0001), in particular for unmet psychological needs TCW participants were more likely to strongly agree that study participation had made discussions with their health care practitioners easier	Partial (in communication and action)	No	High
Macvean et al (2007) [186] Australia	RCT of telephone based volunteer led screening and support (Pathfinder Program) Baseline and 3months follow-up	52 colorectal cancer patients recruited via a state-based cancer registry 18 intervention 34 usual care 62% of the sample was male and the mean age was 64 years.	SCNS HADS-D	The decrease in average number of needs from baseline to 3-month follow-up was greater for intervention than for control participants HADS-D scores and supportive care needs for groups decreased at Time 2 and, although the decrease was greater for the intervention group than the usual care group, the group by time interaction was not significant	Yes but not significant	Yes (depression)	Good

Hollingworth et al (2012)192 UK	2 arm screen vs no screen RCT: (allocation ratio of 1:1) <u>Intervention group</u>: completed the DT & problem list, rating distress and discussing sources of distress with a trained radiographer/nurse. Psychological distress (POMS-SF) and disease specific quality of life (EORTC-QLQ C30) were measured at baseline, 1 and 6 months. <u>Control</u>: Treatment as usual	220 patients (49% breast, 27% urological, 24% other cancer sites) were randomised. 107/112 randomised to the DT&PL completed it, taking about 25 minutes.	Distress Thermometer Psychological distress (POMS-SF) and disease specific quality of life (EORTC-QLQ C30) were measured at baseline, 1 and 6 months	POMS-SF and EORTC scores in both arms deteriorated at 1 month then improved at 6 months, particularly in the fatigue subscale. There was no evidence that patients randomised to the DT&PL had better POMS-SF (mean post-treatment difference 0.58 but non-significant), EORTC (0.88; but non-significant) or subscale scores compared to control.	No	No	High
Non-randomized Studies							
Boyes et al, (2006) Australia	Alternate feedback vs no feedback (allocation: alternate consenting patients assigned to groups via computer). <u>Both groups:</u> Patients completed computerized screening measure (SCNS, HADS, physical symptoms) prior to consultation. Assessed at 1st visit and 3 following consecutive visits. <u>Intervention:</u> Feedback report of summary scores and strategies for managing issues was printed and placed in patient file for discussion in consultation with oncologist. <u>Control:</u> No results made available to oncologist.	95 cancer patients Intervention n=42, control n=38	<u>Primary outcomes:</u> Physical symptoms Anxiety/Depression: HADS <u>Secondary outcomes:</u> Needs: SCNS Acceptability: survey administered to patients and oncologists	<u>Primary outcomes:</u> No significant differences between the groups in changes in anxiety, depression Intervention patients reporting physical symptoms at visit 1 less likely to report at visit 3. <u>Secondary outcome:</u> No significant differences between the groups in the proportion of patients reporting any moderate/high unmet needs. Patients: Easy, acceptable and willing to complete at each visit Oncologists: 2/4 reported discussing feedback sheet with patients, 3/4 reviewed at beginning of consultation, easy to understand, adequate content	No	No	Yes

Kristeller et al (2005)[199] United States	Alternate allocation to discussion of spiritual needs during consultation vs usual care	118 consecutive patients of four oncologist-haematologists (55.1% female, 91.5% Caucasian) with mixed diagnoses, duration (51.7% diagnosed within 2 years) and prognosis	FACT-G QOL and FACIT-Sp (Spiritual Well-Being) Scales; BSI Depression Scale; the PCAS Interpersonal and Communication scales; and ratings of acceptability.	Satisfaction: Oncologists rated themselves as comfortable during the inquiry with 85% of patients. Of patients, 76% felt the inquiry was "somewhat" to "very" useful. PROMs At 3 weeks, the intervention group had greater reductions in depressive symptoms ($p < .01$), more improvement in QOL ($F = 4.04$, $p < .05$), and an improved sense of interpersonal caring from their physician ($p < .05$) relative to control patients. Improvement on Functional Well-being was accounted for primarily by patients lower on baseline spiritual well-being	Yes	Yes	High
Thewes et al (2009) [194] Australia	Sequential pre-screen/post-screen cohort study (sequentially recruited first into control group, then into screened group). <u>Both groups:</u> Followed up 6 months later <u>Screened:</u> Completed DT, SPHERE-Short prior to consultation /chemotherapy education session; nurses encouraged to assess problems and explore interest in receiving referral to psychosocial staff <u>Control:</u> Questionnaire (SPHERE-Short) completed prior to consultation or chemotherapy education session	83 newly diagnosed patients with malignant disease Screened n=43, control n=40	<u>Primary outcomes:</u> Referrals: Medical record Distress: SPHERE-Short <u>Secondary outcomes:</u> Needs: SCNS-SF	<u>Primary outcome:</u> 44% scored DT≥ 5; of these, 10 (53%) were referred to a social worker or psychologist No significant difference in PSYCH-6 between cohorts in % who where cases <u>Secondary outcomes:</u> Time to referral shorter in screened cohort (5 vs 14 days) Screened cohort reported higher unmet information, psychological and daily living needs at 6 months	Partial (in referral delay)	No	Yes

Scandrett et al (2010)[200] USA	Non-randomized alternatve allocation (quasi random) Screened: NEST13+ by face-to-face interview on admission Control: 12 questions about satisfaction with care	451 cancer inpatients aged 56 years 45% female	NEST13+ Needs of a social nature; Existential concerns; Symptoms; and Therapeutic interaction instrument	Significantly more needs were documented among intervention subjects than baseline or control subjects in seven content areas. Significantly more orders placed by clinicians in NEST vs controls in all content areas except for spirituality and patient physician communication Significant improvement made in dimensions of physical health (71% versus 59%, p<0.05), mental health (49% versus 29%, p<0.001), and information (23% versus 11%, p¼0.01). Overall quality of care was similar	Partial	Yes (in physical health, mental health and information)	NR
Grassi et al (2011)[196] Italy	Retrospective cohort analysis (patients treated during intervention period vs historical control) Screened: 1 year recruitment period and screened with DT and PL immediately; clinicians also received an educational intervention Control: Usual care and referrals to POS based on clinical acumen. Once referred patients screened with DT and PL.	newly diagnosed patients Usual care n=153 and Screened n=583	Primary outcome: Referrals Secondary outcomes: Distress: DT Problems: PL	Primary outcome: *Control group:* 153/2268 (6.1%) were referred to psycho-oncology; 31.4% of referred DT<4 (non-case) when assessed by psycho-oncology *Screened group*: 544/1107 screened; 52.2% DT≥4 and 284 (25.7%) referred to psycho-oncology. Secondary outcome: *Screened:* referred patients higher DT, pain, sleep and sexual problems; DT cases reported more family, practical, emotional and physical problems than non-cases *Control:* DT cases reported more emotional and physical problems than non-cases	Partial (in referral)	No	Not studied

encouraged to assess and manage distress in high scorers.[194] Unmet needs using the SCNS-SF were used as a secondary outcome measure. 40 historical patients followed up prior to screening acted as controls. At six months participants in the screened cohort reported significantly higher levels of overall unmet needs, psychological needs, information needs and physical and daily living needs compared with the unscreened cohort. There was a trend (non-significant) towards lower SPHERE cases in unscreened patients vs screened (24% vs 35%, p = 0.282). Referral delay was shorter in the screened cohort (5 vs 14 days). Acceptability to patients was generally high, as 86% did not believe that the screening questions were too personal or upsetting. Scandrett et al used a non-randomized alternative allocation design using the NEST13+ by face-to-face interview on admission to hospital vs 12 control questions about satisfaction with care. 451 cancer inpatients participated and significantly more needs were documented among intervention subjects than baseline or control subjects in seven content areas. Also significantly more orders were placed by clinicians in NEST vs controls in all content areas except for spirituality and patient physician communication. Overall there was a significant improvement made in dimensions of physical health (71% versus 59%, $p<0.05$), mental health (49% versus 29%, $p<0.001$), and information (23% versus 11%, $p=0.01$) but overall quality of care was similar in both groups.

Only two studies have used the NCCN problem list. As mentioned above, Grassi et al (2011) used the DT and associated problem list in a retrospective cohort of 583 patients treated during the intervention period compared with 153 historical controls.[196] Screening increased referrals to a specialist psycho-oncology service from 6.1% to 25.7%. Hollingworth et al (2012) used the DT and associated problem list to rate distress and discuss sources of distress as applied by a trained radiographer/nurse and compared this with treatment as usual.[192] Both groups improved by 6 months and there was no evidence that patients randomised to the screening condition had better outcomes.

Overall, these nine studies that included either unmet needs as a screener (screening test) or used unmet needs as a screening target in an implementation design suggest a modest positive effect on patient wellbeing. However, the data are difficult to fully interpret because only four studies focussed on unmet needs as a screening test.[192 196 198 200] Unmet needs are an under-investigated method of screening for emotional wellbeing which potentially have high acceptability. Future studies may be able to compare screening with and without assessment of unmet needs but nevertheless unmet needs have high face validity.

2.0 Methods

2.0 Methods

2.1 Rationale of the Clinical Study

Chemotherapy nurses routinely explain complex treatments (including possible side effects), administer chemotherapy, give information and deliver face-to-face support. Treatment radiographers routinely undertake treatment planning, administer treatment, give information and also deliver face-to-face support. They are key non-medical frontline cancer clinicians who regularly see patients many times during the course of treatment. Yet clinicians are unsure how to detect distress and depression and related emotional concerns. Cancer clinicians in Leicester do not currently use any screening instruments and are not certain how to help patients once a psychosocial concern is identified. No funding was available for computerized waiting room screening.

2.2 Study aims

Objective I - To examine the local implementation of a screening programme for distress / depression

Objective II – To undertake a meta-analysis of all implementation studies of screening for distress / depression in cancer settings using a) observational studies (b) interventional studies

2.3 Timeline / Approval

The data collection phase of primary local study was conducted in Leicester Royal Infirmary between 2008 and 2010 and the meta-analysis was conducted between 2011 and 2012. As the screening project was already planned for clinical implementation and no randomized component was required the clinical project was designated as an audit. The project was then ethically approved by UHL department of cancer studies as an audit of clinical practice (see appendix 3) according to local departmental policy.

2.4 Methods of Meta-analysis

2.4.1 Search and Appraisal Methodology

A critical appraisal protocol was agreed as adaptation of the PRISMA standard – a standard proposed to rate reviews and meta-analyses.[19] A systematic search was conducted using Pubmed/Medline, Google Scholar and Web of Science (ISI) database from inception to August 2012. Where necessary, study authors were contacted directly for primary data (see acknowledgements). A four point quality rating and a three point bias risk was applied to each study, a method adapted from a previous publication.[65] The quality rating score evaluated study sample size, study design, study attrition, measurement methods and method of dealing with possible confounders with the following scale: 1 = low quality, 2 = low-medium quality, 3 = medium-high quality, 4 = high quality. The risk of bias rating score evaluated possible bias in assessments of age, gender, setting, cancer type and cancer stage with the following score: 1 = high bias risk, 2 = medium bias risk, 3 = low bias risk.

2.4.2 Inclusion and Exclusions

Studies were included that examined screening for distress or depression as a primary target in the context of an implementation study. The main outcome variable was quality of psychosocial care, defined as receipt of psychosocial care, receipt of referral for psychosocial care and communication regarding an emotional or psychosocial issue. Several studies were excluded which did not randomize or evaluate the effect screening itself; that is they did not include a screening and a no screening condition but randomized only the treatment or follow-up that followed screening.[128 198 201 202 203 204 205 206 207] Data from multiple publications on the same sample was excluded if no additional data were reported in subsidiary studies.[208] Studies were also excluded from meta-analysis if without adequate data, for example, those in which no raw numbers were presented (or calculable). [209]

2.4.3 Statistical Analysis For Meta-Analysis

Primary data were extracted as raw numbers or calculated from data provided in the primary papers or by the authors. Weighted proportion meta-analysis was used to adjust for study size using the DerSimonian–Laird model to allow for heterogeneity inclusion in the analysis. Mantel-Haenszel pooled risk ratios were estimated, with a chi-square test for heterogeneity (I_2) used to assess between-study differences in effect. Random-effects models were fitted if there was heterogeneity and risk ratios are presented as a forest plot. The forest plot shows study-specific risk ratios (and their 95% CIs) and the relative weighted contribution of each study, as well as the risk ratio estimate pooled across all studies. StatsDirect 2.7.7 was used to make

forest plots. StatsDirect uses a line to represent the confidence interval of an effect (e.g. odds ratio) estimate. The effect estimate is marked with a solid black square. The size of the square represents the weight that the corresponding study exerts in the meta-analysis; this is the Mantel-Haenszel weight. The pooled estimate is marked with an unfilled diamond that has an ascending dotted line from its upper point. Confidence intervals of pooled estimates are displayed as a horizontal line through the diamond.

DerSimonian-Laird random effects meta-analysis using StatsDirect 2.7.7 was the preferred method of choice. Heterogeneity (I^2) was formally tested using the following thresholds ≥80% = moderate ≥90% = high and also tested for publication bias, using Egger method.[210] A technical validation of meta-analysis has been provided by StatsDirect (Fig. 2.4.3). StatsDirect first transforms proportions into a quantity (the Freeman-Tukey variant of the arcsine square root transformed proportion)[211] suitable for the usual fixed and random effects summaries.[212] The pooled proportion is calculated as the back-transform of the weighted mean of the transformed proportions, using inverse arcsine variance weights for the fixed effects model and DerSimonian-Laird (1986) weights for the random effects model: - where p hat is the fixed effects pooled proportion, x is the Freeman-Tukey transformed proportion, w is the inverse variance weight for the transformed proportion, q is the Cochran q statistic, tau squared is the moment-based estimate of the between-studies variance, w underscore r is the DerSimonian-Laird weight, and p hat underscore r is the random effects estimate of the pooled proportion.[212]

$$\hat{p} = \sin^2\left[\hat{x}/2\right]$$

$$\hat{x} = \frac{\sum (xw)}{\sum w}$$

$$x = \arcsin\left[\sqrt{r/(n+1)}\right] + \arcsin\left[\sqrt{(r+1)/(n+1)}\right]$$

$$se_x = \sqrt{1/(n+1)}$$

$$w = \frac{1}{se_x^{\,2}}$$

$$q = \sum w(x - \hat{x})^2$$

$$\tau^2 = \frac{\left[q - (k-1)\right]\sum w}{1 - \sum w^2}$$

$$w_r = \frac{1}{\tau^2 + (1/w)}$$

$$\hat{p}_r = \sin^2\left[\hat{x}_r\right]$$

$$\hat{x}_r = \frac{\sum (xw_r)}{\sum w_r}$$

Fig. 2.4.3. StatsDirect Validation Equation

2.5 Methods of Local Clinical Study

2.5.1 Background Definitions of Screening and Case-Finding

Screening can be defined pragmatically as "the application of a diagnostic test or clinical assessment in order to optimally rule-out those without the disorder with minimal false negatives (missed cases)".[37 213] When conducted systematically in routine practice the benefits can be measured by the negative predictive value (NPV).[214] Screening is often performed in a large population as the first of several diagnostic steps. The main objective of screening is to rule out those without the condition of interest with minimal false negatives. In screening programmes those who screen negative may not receive any further follow-up therefore a high NPV is critical. The related procedure of case-finding can be defined as "the application of a diagnostic test or clinical assessment in order to optimally identify those with the disorder with minimal false positives (misidentifications)". Case finding is often performed as a second step in a selected population at high risk for the condition following initial screening in order to confirm the presence of a treatable emotional disorder. In epidemiological terms this is often called *case-finding* and is crudely measured by the positive predictive value (PPV) (Mitchell, 2008).[214] An ideal diagnostic method would have high rule-in and rule-out accuracy with minimal false positives and false negatives. Diagnostic accuracy studies demonstrate the potential accuracy of the tool under optimal conditions. It is useful to understand that no test can offer 100% accuracy and as such, on a linear scale, a compromise between sensitivity and specificity may be achieved. Varying sensitivity or varying specificity have different effects on false positive or false negative errors as can be seen from a plot of post-test probabilities tests with a variety of accuracies (figure 2.5.1). This is a plot of all PPVs and NPVs across varying prevalence values assuming a fixed sensitivity and specificity. As sensitivity and specificity usually are stable in the same sample, the plot of conditional probabilities graphics shows how sensitivity and specificity would affect real world diagnoses. For screening (which is only the first step) then higher sensitivities are preferred as these will favour the negative predictive value. Contrary to diagnostic validity studies, implementation studies are conducted in clinical settings and without a criterion reference. Implementation studies are fundamentally designed to answer the question how does a test change clinical practice and patient care?

Screening can be conducted in a number of strategic ways.

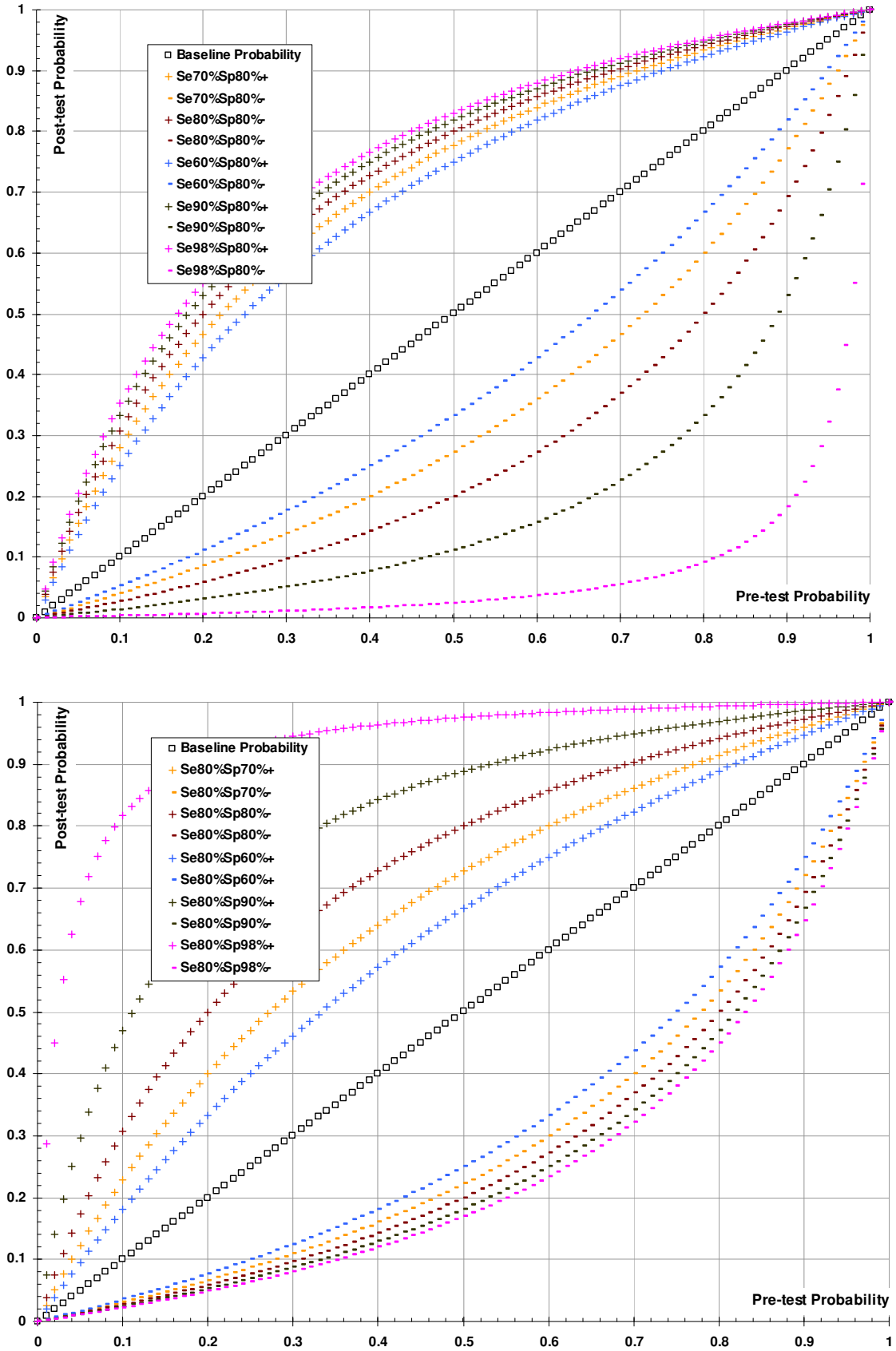


Figure 2.5.1 Conditional Probability Plots with varying sensitivity or specificity

These can be defined as follows (table 2.5.1)

Universal screening	Unselected application to all consecutive patients
Parsimonious screening	Selected application in certain demographic groups (eg all men)
Indicated screening	Selected application following clinical suspicion
Random screening	Random screening to sample a proportion of attendees
Systematic screening	Organized application to all patients fulfilling a criteria (eg all inpatients)
Routine screening	Application to all patients, who are willing and able to consent, seen in clinical practice by a clinician without special assistance

Table 2.5.1 – Subtypes of Screening

2.5.2 Setting of the Clinical Study

Between October 2008 and September 2010, all local nurses and treatment radiographers/radiation technologists working in the chemotherapy suite and radiotherapy department at the cancer centre of Leicester Royal Infirmary were approached. 50 cancer clinicians agreed to participate and were involved in the implementation of paper and pencil based screening. The Leicester cancer centre received about 3500 new cancer cases per year from Leicester city, Leicestershire and Rutland. Our study involved front-line cancer clinicians, comprising 20 chemotherapy nurses and 30 treatment radiographers who all volunteered to take part in the study. The mean age of chemotherapy nurses was 45.5 years and the mean age of treatment radiographers was 52.3 years (range 22-63 years). 47 were female clinicians and 3 were males.

2.5.3 Development of the Screening Tool

After considering many options and ruling out many due to low acceptability and /or high cost we attempted to adapt the Distress Thermometer (DT) into a viable local screener. The DT is probably the best known single item measure consisting of a line with a 0-10 scale anchored at the zero point with 'No Distress' and at scale point ten with 'Extreme Distress'. Patients are given the instruction "How distressed have you been during the past week on a scale of 0 to 10?" The recommended ≥4 cut-off was tested locally in a separate validation study.[32] However as discussed above (1.7.2) the DT performs best in relation to distress but underperforms in relation to specific emotional concerns such as depression and anxiety.

Therefore using the existing literature and building on the success of the DT, I designed a new five dimensional tool called the Emotion Thermometers (ET). This is a combination of five visual analogue scales in the form of four predictor domains (distress, anxiety, depression, anger) and one outcome domain (need for help) (see Fig 2.5.3). Each domain is rated on an 11 point (0 to 10) Likert scale in a visual thermometer format.

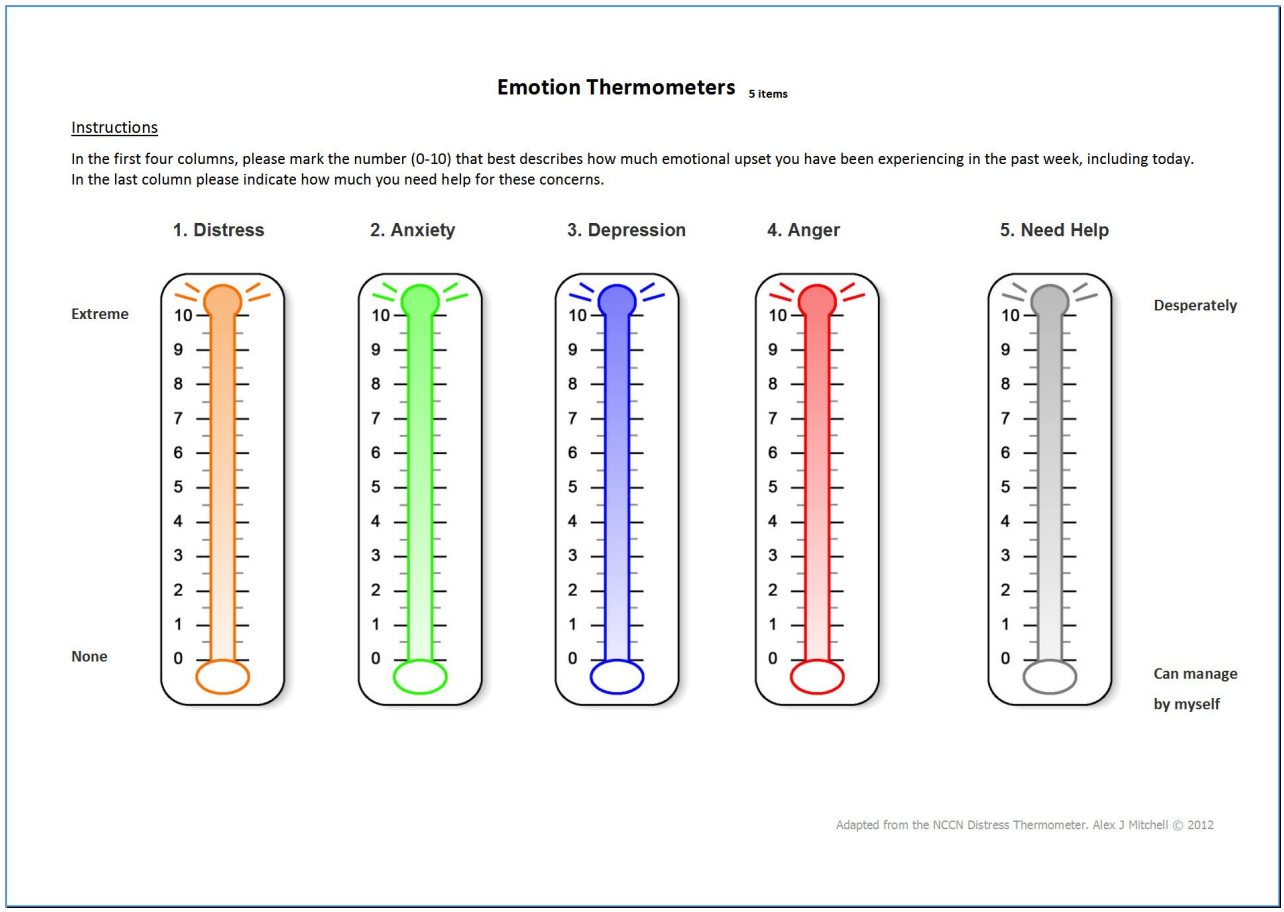


Figure 2.5.3 Emotion Thermometers tool

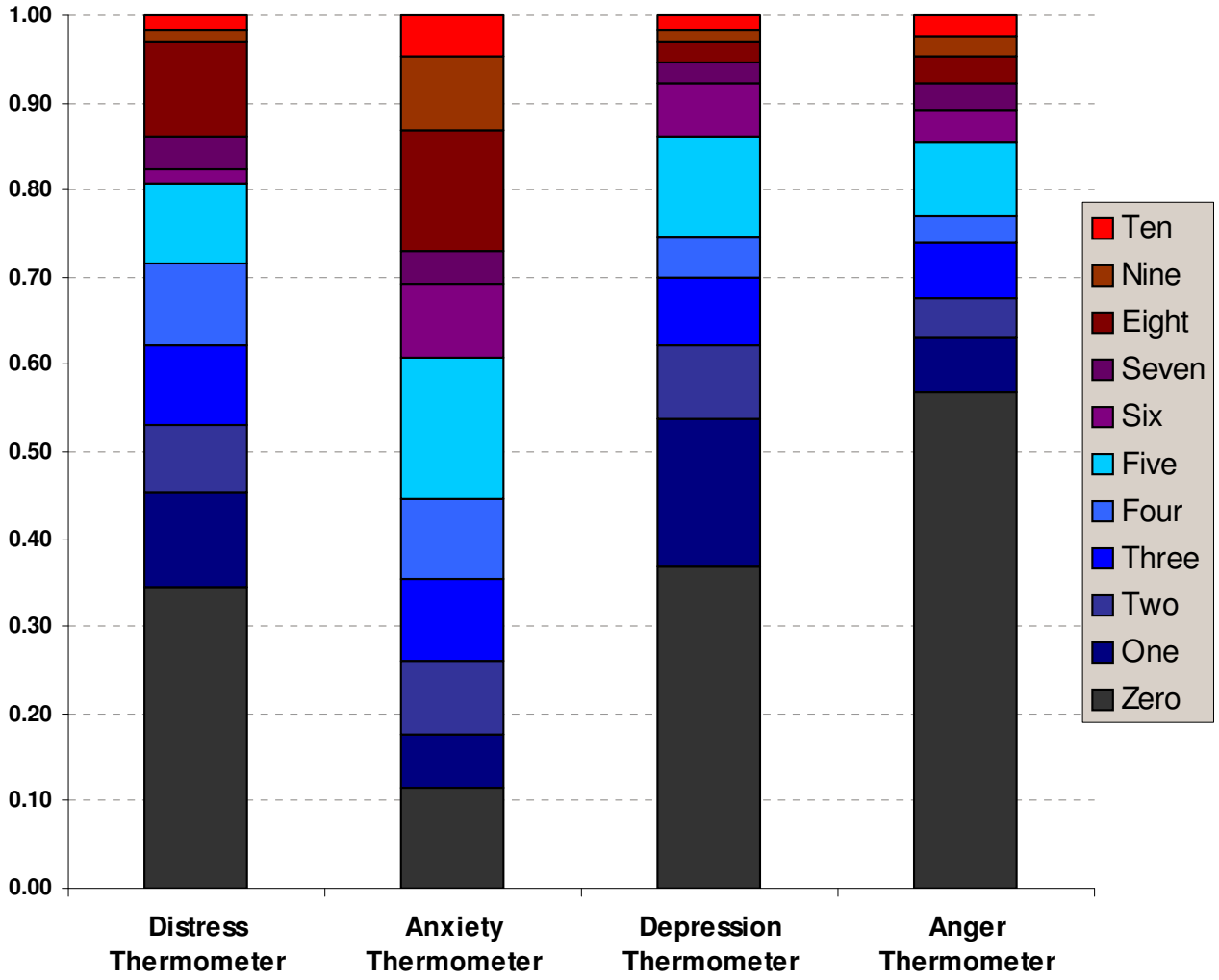


Figure 2.5.3b – Frequency of responses to ET using pilot data

Thus the tool can be considered to be a multidomain adaptation of DT, with revised scoring (half-marks), colour coding and duration (one week). It includes a Depression Thermometer (DepT), an Anxiety Thermometer (AnxT) and an Anger Thermometer (AngT). In a pilot evaluation in the Leicester Cancer Centre, we found that the tool takes about 45 seconds to complete (compared to about 20 seconds for the DT) and was no less acceptable than the DT alone.

2.5.4 Preliminary Pilot Validation of the Screening Tool

Preliminary validation was undertaken in pilot work, in terms of the ET's ability to accurately rule-in or rule-out distress, depression or anxiety.[149] The cut point of the ET was calculated using receiver operator characteristic (ROC) curves (figure 2.5.4) and also for convenience a set cut-off of ≥4 on all thermometers. In an earlier pilot validation study we established validation against distress using the HADS total score. Validation of anxiety was achieved using the HADS anxiety subscale (cut-off ≥8). Validation of depression was achieved using the HADS depression subscale (cut-off ≥8) and using DSM-IV criteria for major depression applied using the Patient Health Questionnaire (PHQ-9). Out of all those with an emotional complication, 93.3% would be recognised using the AnxT alone, compared with 54.4% who would be recognised using the DT alone.

Using pilot data it was found that against the total HADS score (cut-off 14v15), the optimal thermometer was the AngT (sensitivity 89% specificity 46%). Against HADS Anxiety scale (cut-off 7v8) the optimal thermometer was AnxT (sensitivity 92% specificity 61%) and against the HADS depression scale (cut-off 7v8), the optimal thermometer was the DepT (sensitivity 60% specificity 78%). Finally, against a DSM-IV based diagnosis of MDD, the optimal thermometer was the DepT (sensitivity 80% specificity 79%). Thus each thermometer appears to has face validity and internal consistency (data not shown) and diagnostic validity against an appropriate target.

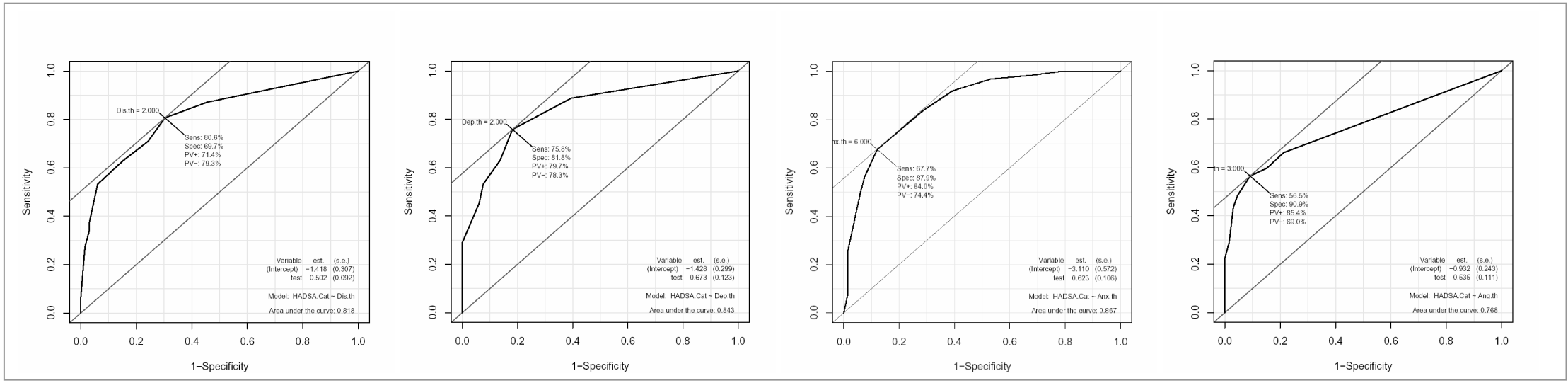


Figure 2.5.4a. Receiver Operator Curves of Emotion Thermometer Domains Against HADS-A (DT;DepT;AnxT;AngT) from Psychooncology. 2010 Feb;19(2):125-33.[149]

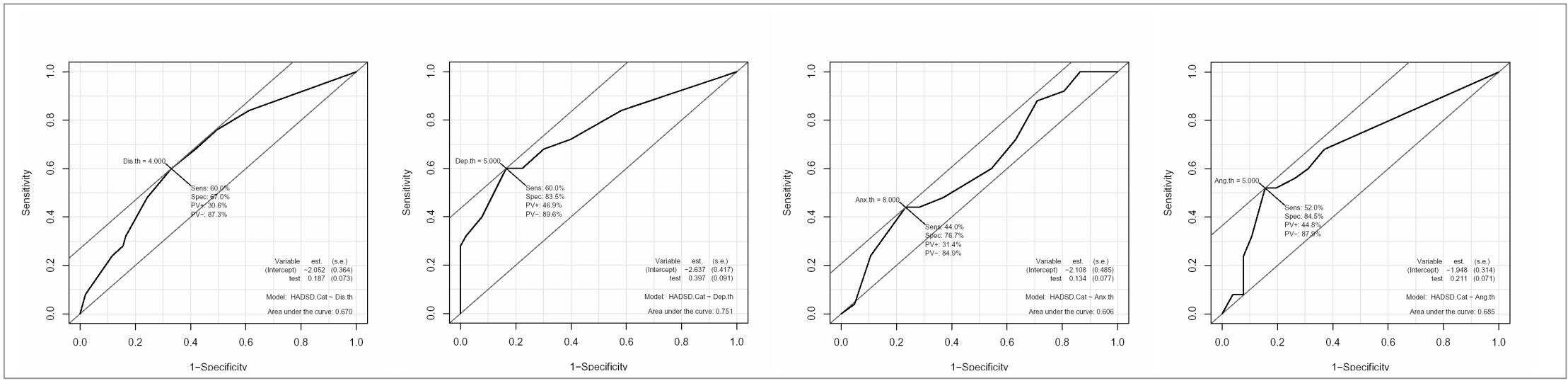


Figure 2.5.4b. Receiver Operator Curves of Emotion Thermometer Domains Against HADS-D (DT;DepT;AnxT;AngT) from Psychooncology. 2010 Feb;19(2):125-33.[149]

2.5.5 Pilot Implementation of the Screening Programme

All cancer clinicians in this study used the DT and/or Emotion thermometers (ET) screener integrated into a screening programme that included assessment of unmet needs and clinician therapeutic response (see appendix 1). Screening implementation was test as a pilot in 2009 (n=86) using community cancer nurses and later, in the main study, as part of routine clinical care starting in April 2009 for 9 months in the chemotherapy suite and September 2010 for 6 months at the radiotherapy assessment centre. No researchers assisted cancer staff in completing the screens in the pilot or main study. The original screener, when considered as a package (screening programme) included a custom list of unmet needs elicited by checklist or free text. In total the screening programme took cancer clinicians about 4 minutes to complete but, as a result of feedback in the pilot, this was streamlined following clinician feedback to a version taking approximately 3 minutes. All staff were offered a one hour induction training session with the recommendation to attend up to four further hourly sessions of support during the implementation phase. Training covered common emotional complications, how to screen and management of distress and related emotional issues. Communication training was available separately. Uptake of the training package was incomplete with less than a quarter of cancer staff taking up training opportunities but we have no outcome data on these training and support sessions.

During this pilot phase and screening phase staff had access to usual care which included expert psycho-oncology referral. Even in the context of systematic screening cancer clinicians were permitted to use their own clinical judgement about the appropriateness of screening on a case-by-case basis for example by not screening when patients were too unwell or uncooperative.

2.5.6 Administration of the Screening Programme

All local cancer clinicians were invited to use the screener as part of routine care. Staff themselves utilised the screen on each clinical contact without automated help, and without assistance from administrative or research staff. Staff were asked to screen all consecutive patients unless there was a clinical reason to avoid screening. Reasons for non-completion included the patient being unable or unwilling to complete the screen. Staff themselves administered the screener during their own clinical assessments, typically during initial assessment (treatment planning) or during the early stages of treatment. Cancer clinicians were encouraged to screen at least once per patient, with the maximum frequency dictated by clinical

judgement. Screening was conducted regardless of patient gender, ethnicity or stage using informal verbal translation if required (as many of our Gujarti speakers cannot read printed Gujarti). Staff filled in a survey concerning their diagnostic judgement, clinical care offered and their opinion on the possible benefits of screening immediately after completion of screening with the patient, that is after each application of screening (appendix 2)

2.5.7 Outcome Measurement

Recognition of Emotional Problems

Health professionals were asked to evaluate patients clinically and, if appropriate, diagnose distress and related emotional problems on a prospective (case-by-case) basis. Previous studies have found that clinicians might suspect that a patient has a broadly defined emotional complication but may be unable or unwilling to diagnose a specific disorder. [215] Therefore we asked clinicians to identify distress or any mental health complication, as well as specific emotional complications. Soon after clinicians completed their clinical evaluation, patients were asked to complete the self-rated DT/ET tool. Cancer staff used results clinicially but returned summary data (appendix 2). Data were collected by mail or by fax. Every effort was made to ensure that initial (baseline) clinicians' opinions were obtained without recourse to the DT scores or indeed any other mood ratings. However, as rating were not made at separate points in time blinding cannot be guaranteed. An attempt was made to collect data on diagnoses routinely made by cancer clinicians in day-to-day practice in a sample greater than 500 (500 patient clinician screening interactions).

Acceptability of Screening

We rated clinician satisfaction with several short quantitative and qualitative questions regarding the success of screening and the burden of screening, applied prospectively after each consultation. Cancer staff could therefore evaluate their opinion regarding appropriateness of the tool across all types of clinical encounter. Several variables were measured that could influence the success (or otherwise) of screening. These included the following clinician baseline measures: clinical rating of practicality of the screening programme; clinician self-rated confidence; clinician receipt of psychosocial training. We also asked about the following clinician reported outcome measures: perception of improved clinician-patient communication; improved detection of psychosocial problems; propensity of the clinician to act therapeutically (help offered), and change in clinical opinion following screening (Appendix 2). Several

patient reported measures were reported: distress, anger, depression, anxiety and desire for help. We examined rates of global satisfaction and predictions of satisfaction with screening using logistic regression. Finally, feedback was collected using free text boxes on the screening form and asked a random split-half subset of 25 cancer clinicians about their experiences with screening in more detail namely the effect on communication, recognition of emotional problems and practicality of the screen.

Unmet Needs

Two methods were used to elicit unmet needs: checklist and free text self report. The checklist approach was an adaptation of the NCCN's DT problem list, originally a 33 item list of possible patient concerns. This was adapted locally into a 26 item list on the basic of pilot data on 86 patient-clinicians consultation in the community. The 26 items were in four categories: practical concerns, personal concerns, emotional concerns and physical concerns. The full list was as follows. Worry about cancer, sleep problems, nervousness/anxiety, fatigue/exhaustion, eating/weight, memory/concentration, appearance, family issues, depression/hopelessness, self-esteem/confidence, breathing, headaches/pain, toileting, loss of independence, anger/irritability, problems with medication, finances/bills, sexual/intimacy issues, self-care, odd experiences, nausea, loss of role, pain, issues with health staff, lack of information, spiritual issues
The free text self-report method allowed patients to indicate their most pressing concerns without prompting, other than by ranking the concerns as most pressing, second most pressing and third most pressing. For analysis the most pressing concerns were allocated a score of 3 = most pressing, 2 = second most pressing and 1 = third most pressing.

Clinician Response Post-Screen

Responses cancer clinicians made following a positive and negative screen were collected. Possible actions included face-to-face help, referral, advice, information, no help needed and help declined. This was collected by clinician self-report (see appendix 2).

2.5.8 Statistical Analysis of the Clinical Study

The methodology to evaluate screening studies has been published elsewhere.[214] Briefly, attempts to separate those with a condition from those without on the basis of a test or clinical method are usually represented by the 2x2 table which generates sensitivity (Se), specificity (Sp), positive predictive value (PPV)

and negative predictive value (NPV).[216] Sensitivity and specificity were based on clinician judgement vs patient self-reported emotional disorder.

Performance of most tests vary with the baseline prevalence of the condition. For example, it is hard to detect cases when such cases are very rare.[217] Rule in and rule out accuracy should be considered independent variables although a test may perform well in both directions. Rule-in accuracy is best measured by the PPV but a high Sp also implies few false positives and hence any positive screen will suggest a true case. [218] Rule-out accuracy is best measured by the NPV where the denominator is all who test negative but again if the Se is high there will be few false negatives and hence any negative implies a true non-case (box 2).[218] The likelihood ratio (LR+) = sensitivity / (1-specificity) and likelihood ratio (LR-) = (1-sensitivity) / specificity, clinical utility indices and fraction correct (TP+TN/all cases) were also calculated. In addition the clinical utility index (UI) was used as a method which generates a quantitative interpretation of diagnostic accuracy.[219 220] Clinical utility may be more important to clinicians than validity.[221] The UI takes into account both discriminatory ability and occurrence for case-finding (UI+) and screening (UI-) such that the positive utility index (UI+) = sensitivity x positive predictive value and the negative utility index (UI-) = specificity x negative predictive value.

Where necessary univariate logistic regression, multivariate regression and chi-squared test in StatsDirect 2.7.7.were used. StatsDirect calculates the probability associated with a chi-square random variable with n degrees of freedom. Further agreement analysis was conducted using Cohen's kappa. In broad terms a kappa below 0.2 indicates poor agreement, 0.2 to 0.4 fair agreement, 0.4 to 0.6 moderate agreement, 0.6-0.8 good agreement and a kappa above 0.8 indicates very good agreement beyond chance.[222]

3.0 Results

3.0 Results

3.1 Results of Local Screening Study

3.1.1 Demographics / Uptake / Distress

851 patient interactions (consultations) were assessed by 50 chemotherapy nurses and treatment radiographers. Of these, clinical staff returned information on 539 assessments (60.2%) involving 379 patients. We had no further information on patient ratings or clinicians' opinions of those without returned data. We estimate that 160 (42.2%) patients received two screening consultation and 219 patients received one consultation. There was incomplete data on 21 consultations and missing data after 4 consultations. 382 consultations were conducted in chemotherapy setting and 136 in radiotherapy. A patient recruitment overview is shown in figure 3.1.1. Demographic characteristics of the 379 patients are shown in table 3.1.1. 15.5% had late stage cancer (as defined by the clinical staff as patients receiving palliative treatment) and the remainder early or an intermediate stage. The most common cancer type was breast cancer (46.9%) followed by colorectal cancer (12.4%). Less common cancers included lung cancer and bladder cancer. Female patients accounted for almost three quarters of individuals under study. In the total sample 56% of patients reported a significant problem in at least one emotion domain and 39% scored high on distress. We considered this sample fairly representative of the wider population seen in the Leicester Cancer Centre with the exception of the female preponderance (75%) in an early stage.

Total Consultations	539
Total sample (unique patients)	379
Advanced/Palliative stage	15.5%
Female	74.7%
Mean Age	63.3 years
Age Range	33.0 - 83.9 years
Chemotherapy setting	65.7%
Breast cancer	46.9%
Lung cancer	6.7%
Prostate cancer	7.2%
Colorectal cancer	12.4%
Bladder cancer	1.4%
High distress (DT ≥ 3)	39.3%

Table 3.1.1 Demographics of the screened sample

3.1.2 Baseline Recognition of Emotional Problems

Data were available on 514 baseline clinician-patient assessments from the chemotherapy and radiotherapy departments. Using clinician judgement prior to screening, cancer clinicians had difficulty with the terms depression, anger and even distress. They preferred to use broadly defined mental health problems/mood problems or preferred the term anxiety. Staff used the terms depression, anger and distress on only 5, 2 and 22 of 514 screening encounters, respectively. This was reflected in their diagnostic sensitivity. Sensitivity at baseline (before screening) was 11.1% for distress, 6.8% for depression and 2.9% for anger. Their detection sensitivity was 43% for anxiety and also 43% for any mood problem. PPV was also poor, for example, PPV was 77% in relation to anxiety. Thus, cancer clinicians would identify less than half of patients reporting significant anxiety, and of those suspected to be anxious, about a quarter would not have anxiety. This suggests that cancer staff are not reliably able to diagnose emotional problems without the aid of screening. Conversely, specificity was often high and when combined with reasonable NPV, clinicians may be considered to have good rule-out performance for depression and anger (but not distress, anxiety or any emotional problem). Agreement analysis conducted using Cohen's kappa is shown in table 3.2.2. The optimal agreement between patients and cancer clinicians at baseline was with any mood problem (kappa = 0.31) and next anxiety (kappa =0.27) both suggesting fair agreement. The remaining domains showed poor agreement between patients and clinicians.

Table 3.1.2 – Diagnostic Agreement of Clinicians and Patients by Cohen's Kappa

Test	Kappa (95% CI)	Kappa Qualitative	Z score (p value)
BEFORE SCREENING			
Recognition of ANY Mood Problem	0.31 (0.23 to 0.38)	Fair	8.33 (P < 0.0001)
Recognition of Distress	0.11 (0.06 to 0.16)	Poor	4.55 (P < 0.0001)
Recognition of Anxiety	0.27 (0.17 to 0.37)	Fair	5.17 (P < 0.0001)
Recognition of Depression	0.09 (0.03 to 0.15)	Poor	3.11 (p = 0.0009)
Recognition of Anger	0.04 (0.01 to 0.07)	Poor	1.69 (p = 0.0448)
AFTER SCREENING			
Recognition of ANY Mood Problem	0.33 (0.25 to 0.40)	Fair	8.45 (P < 0.0001)
Recognition of Distress	0.26 (0.18 to 0.33)	Fair	6.62 (P < 0.0001)
Recognition of Anxiety	0.23 (0.13 to 0.32)	Fair	4.56 (P < 0.0001)
Recognition of Depression	0.14 (0.07 to 0.20)	Poor	4.19 (P < 0.0001)
Recognition of Anger	0.17 (0.09 to 0.24)	Poor	4.47 (P < 0.0001)

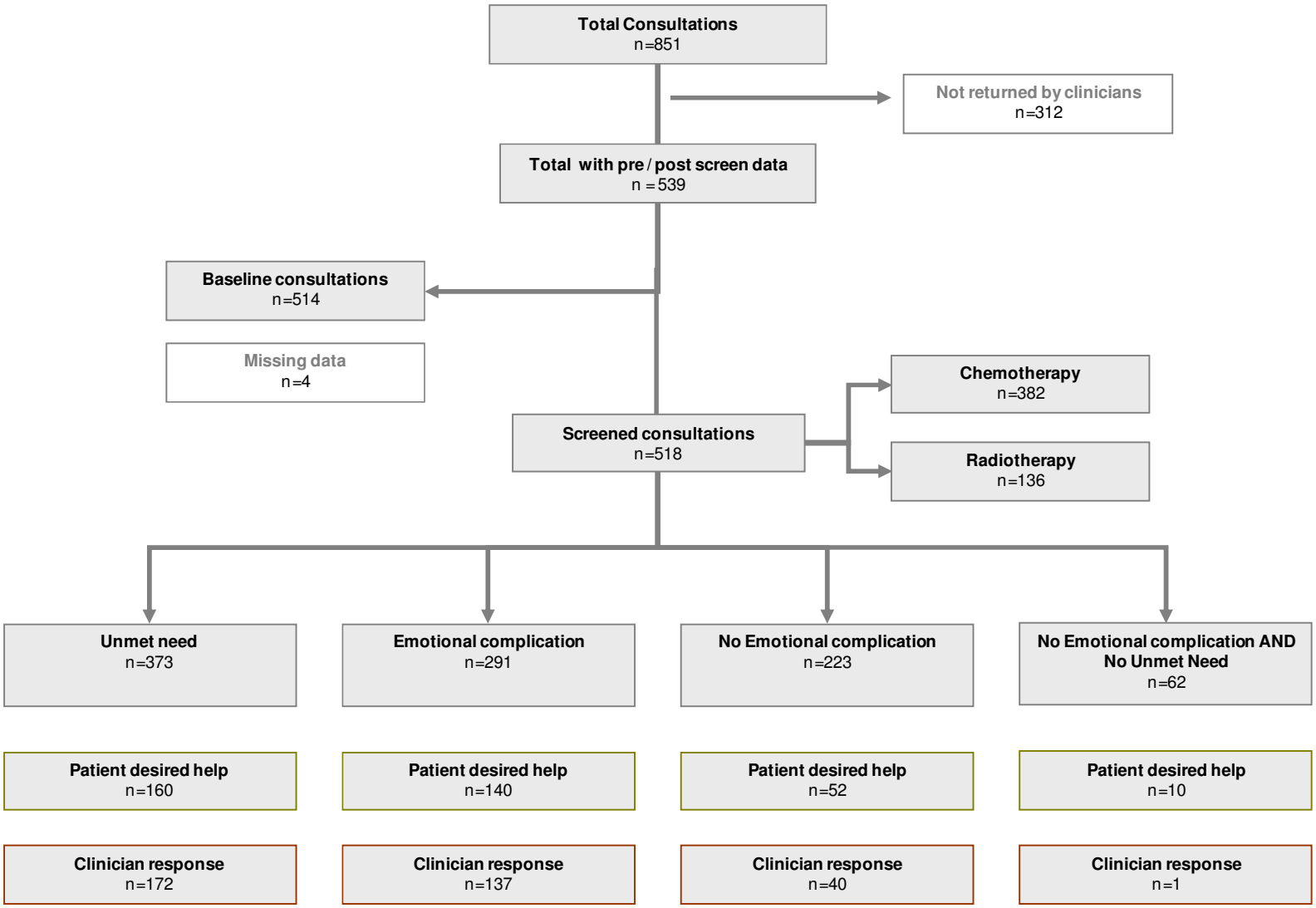


Figure 3.1.1 – Patient recruitment and retention

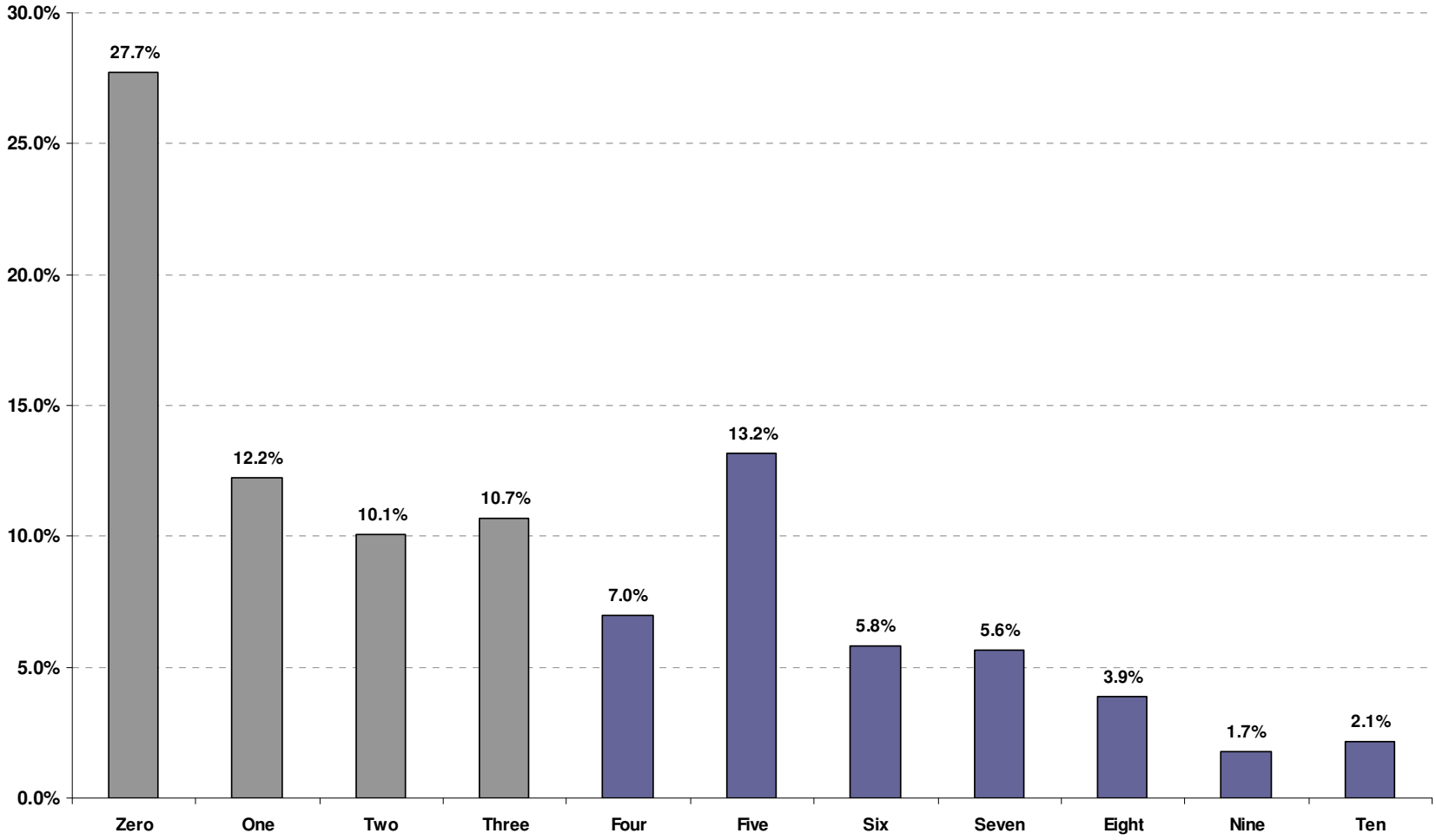


Figure 3.1.1 – Distribution of distress scores on the DT (purple indicates > 3)

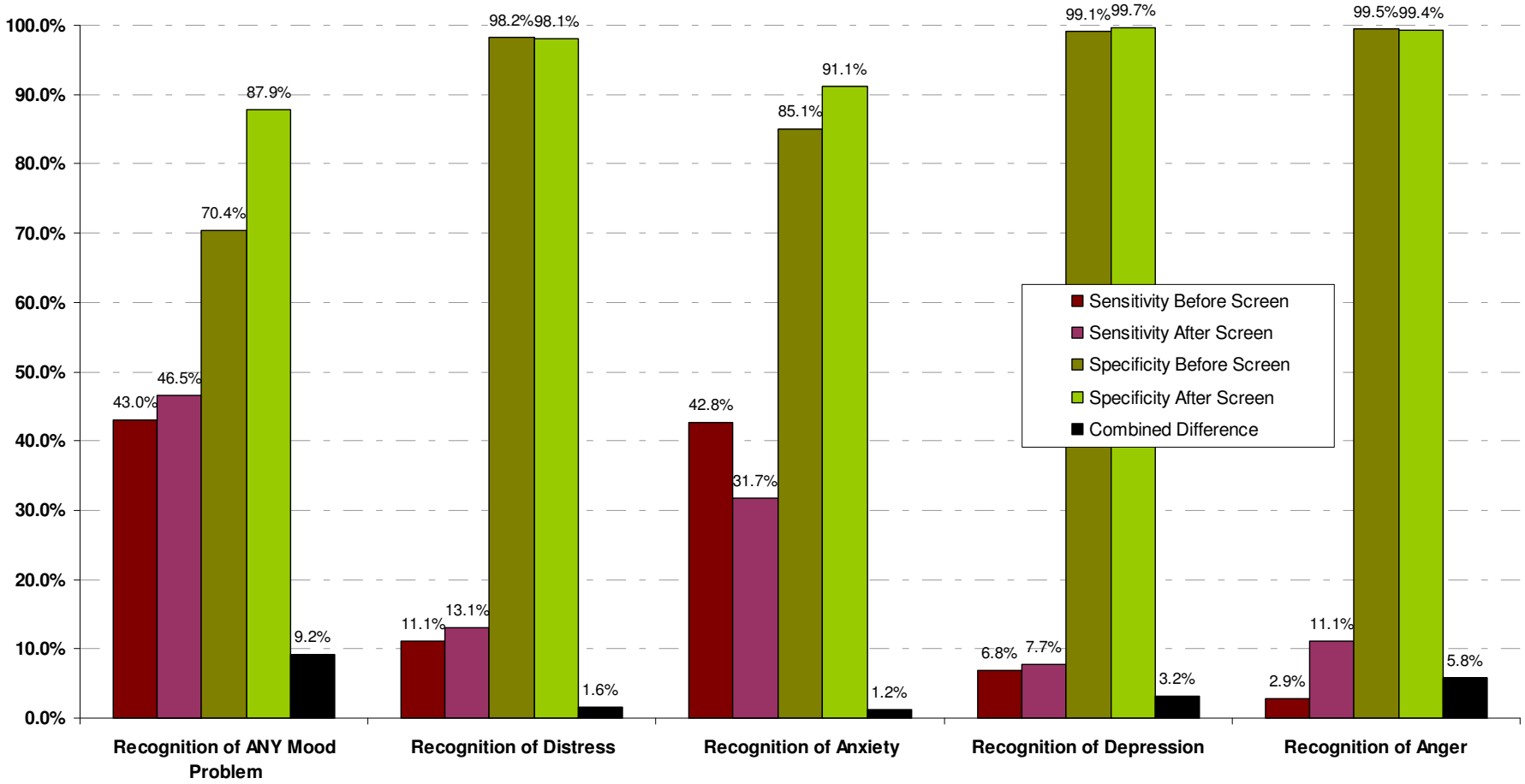


Figure 3.1.3 – Pre/post screen recognition of mood domains by sensitivity and specificity

Table 3.1.3 – Diagnostic agreement between clinician and patient before and after screening

Test	Patient Reported Problem	Detected by Clinician	Sensitivity	False Negatives	No Patient Reported Problem	True Negatives	Specificity	False Positives	PPV	NPV	Utility (+) [Se x PPV]	Utility (-) [Sp x NPV]	likelihood ratio (LR+)	likelihood ratio (LR-)	Fraction Correct
BEFORE SCREENING															
Recognition of ANY Mood Problem	302	130	43.0%	172	216	152	70.4%	64	67.0%	46.9%	0.288	0.330	1.453	0.809	54.4%
Recognition of Distress	198	22	11.1%	176	284	279	98.2%	5	81.5%	61.3%	0.091	0.602	6.311	0.905	62.4%
Recognition of Anxiety	159	68	42.8%	91	134	114	85.1%	20	77.3%	55.6%	0.330	0.473	2.865	0.673	62.1%
Recognition of Depression	73	5	6.8%	68	215	213	99.1%	2	71.4%	75.8%	0.049	0.751	7.363	0.940	75.7%
Recognition of Anger	70	2	2.9%	68	214	213	99.5%	1	66.7%	75.8%	0.019	0.754	6.114	0.976	75.7%
AFTER SCREENING															
Recognition of ANY Mood Problem	301	140	46.5%	161	214	188	87.9%	26	84.3%	53.9%	0.392	0.473	3.828	0.609	63.7%
Recognition of Distress	206	27	13.1%	179	309	303	98.1%	6	81.8%	62.9%	0.107	0.616	6.750	0.886	64.1%
Recognition of Anxiety	189	60	31.7%	129	214	195	91.1%	19	75.9%	60.2%	0.241	0.548	3.576	0.749	63.3%
Recognition of Depression	91	7	7.7%	84	311	310	99.7%	1	87.5%	78.7%	0.067	0.784	23.923	0.926	78.9%
Recognition of Anger	81	9	11.1%	72	319	317	99.4%	2	81.8%	81.5%	0.091	0.810	17.722	0.894	81.5%

For explanation of calculation see section 2.5.8

3.1.3 Post-Screen Recognition of Emotional Problems

Data were available on 518 clinician-patient assessments from the chemotherapy and radiotherapy departments following feedback of screening results to cancer clinicians. Clinicians' diagnostic sensitivity was only slightly improved with screening and only in certain domains. Sensitivity with screening was 13.1% for distress, 7.7%% for depression, 11.1% for anger, 31.7% for anxiety and 46.5% for any mood problem (see table 3.1.3). Thus diagnostic sensitivity improved by 8% for detection of anger but actually deteriorated in relation to anxiety (-11%). Chi² analysis suggested that these changes were both statistically significant at p=0.05 and p=0.03. Overall, recognition of any mood problem improved by a non-significant 3.5%. Conversely, specificity showed larger improvements at least in relation to anxiety and any mood problem. Detection specificity increased by 6% for anxiety (not significant) but 17.5% for any mood problem (p<0.001). Combining sensitivity and specificity in the fraction correct (also known as total correct) showed an overall accuracy of 54.4% before screening and 63.7% after screening, an improvement of 9%. Post-screening agreement analysis conducted using Cohen's kappa is shown in table 3.1.2. Fair agreement between patients and clinicians was achieved with mood problem (kappa = 0.33) and next anxiety (kappa =0.23) and distress (kappa =0.26). However depression and anger remained with poor agreement between patients and clinicians.

3.1.4 Post-Screen Recognition of Graded Emotional Distress

Given the interest in emotional distress, a more detailed analysis was performed of recognition of patient reported distress, graded by severity according to the DT score. Results are shown in table 3.1.4. Cancer staff showed increasing diagnostic sensitivity with increasing severity of distress, from 40%-50% at a score of 4, 5 and 6 to 60%-80% at scores of 8,9,10. The maximum accuracy was achieved in patients scoring 10/10 on the DT with the benefit of screening scores. Those cancer clinicians who scored patients as significantly distressed but whose patients self-reported low distress (<4 on the DT) can be considered a false positives. A patient who scores zero on the DT is almost certainly a false positive in this case. The false positive rate was 8% before screening and 12.6% after screening for patients scoring zero on the DT. Thus screening did not help at a DT score of zero. An interesting observation from this table (3.1.4) is that clinicians admitted to being unsure in 23% of assessments without the aid of screening, and 15% with the aid of screening. On Chi^2 this was a highly significant reduction ($Chi^2 = 8.6$ $p = 0.003$).

	Pre-screening			Post-screening		
	Judgement = Distressed	Judgement = Uncertain	Judgement = Non-distressed	Judgement = Distressed	Judgement = Uncertain	Judgement = Non-distressed
Below Threshold on DT						
DT Zero	8.4	16.8	74.8	12.6	9.1	78.3
DT One	12.7	30.2	57.1	19.4	16.1	64.5
DT Two	27.5	23.5	49.0	14.0	8.0	78.0
DT Three	27.3	23.6	49.1	27.3	14.5	58.2
Above Threshold on DT						
DT Four	43.2	18.9	37.8	44.4	11.1	44.4
DT Five	39.7	19.1	41.2	50.0	7.4	42.6
DT Six	36.7	33.3	30.0	46.7	6.7	46.7
DT Seven	58.6	20.7	20.7	69.0	6.9	24.1
DT Eight	75.0	10.0	15.0	65.0	5.0	30.0
DT Nine	66.7	22.2	11.1	66.7	22.2	11.1
DT Ten	72.7	9.1	18.2	80.0	0.0	20.0

Table 3.1.4 – Diagnostic Agreement between Clinician and Patient before and after screening

3.1.5 Patient Reported Unmet Needs

Two methods were used to elicit unmet needs: checklist and free-text self report (see 2.5.7). Of the 26 items in the checklist "worry about cancer" was the most commonly reported concern with 36.8% of consulting patients endorsing this option. Of those with distress (≥ 3 on the DT) 62% of patients had worry about cancer. The next most common concerns were sleep problems (26.5%), anxiety (23.5%), fatigue (23.5%), eating/weight (19.1%) and memory/concentrations (12.5%) (see figure 3.1.5). By category, the most commonly endorsed domains were 1. emotional concerns 2. physical concerns 3 personal concerns and 4. practical concerns. The average number of concerns per patient was 2.9 and 72% of patients endorsed at least one individual checklist concern/unmet need. 46.7% reported 3 or more needs and 13.9% more than 5 concurrent needs.

When examined by severity, focussing on the most pressing three concerns, anxiety/cancer worries were present in 36.3% of patients, much more than any other concern (figure 3.1.5b). Cancer worries were also present in 57% of those with significant distress (≥ 3 on the DT). Cancer worries were not more common in 76 patients treated with palliative intent (32.9%) than 438 remaining patients (38.1%). Although there were only 12 patients labelled by their cancer clinicians as having metastases, their rate of cancer worry was also no higher (25%). The second most common category was "no pressing problems" recorded by 28.3% of the sample, illustrating that 71.7% did record a pressing concern. Next were family concerns, appearance issues, appetite/weight problems and loss of independence/role. When ranked only by most pressing concern, then out of those with any concern (71.7%) the most pressing top four single concerns were anxiety/cancer worries (24.2%), family concerns (9.0%), loss of independence/role (7.5%) and changes in appearance (7.4%) (see Figure 3.1.5c).

When checklist and free-text self report concerns were combined, then concerns were reported in 374/462 (80.9%) of consultations. After 50 consultations cancer staff assessed the needs to not warrant medical attention; that is they endorsed "no action needed" (see appendix 1). Therefore, it is logical to suggest that patients had meetable unmet needs after 70.1% of consultations.

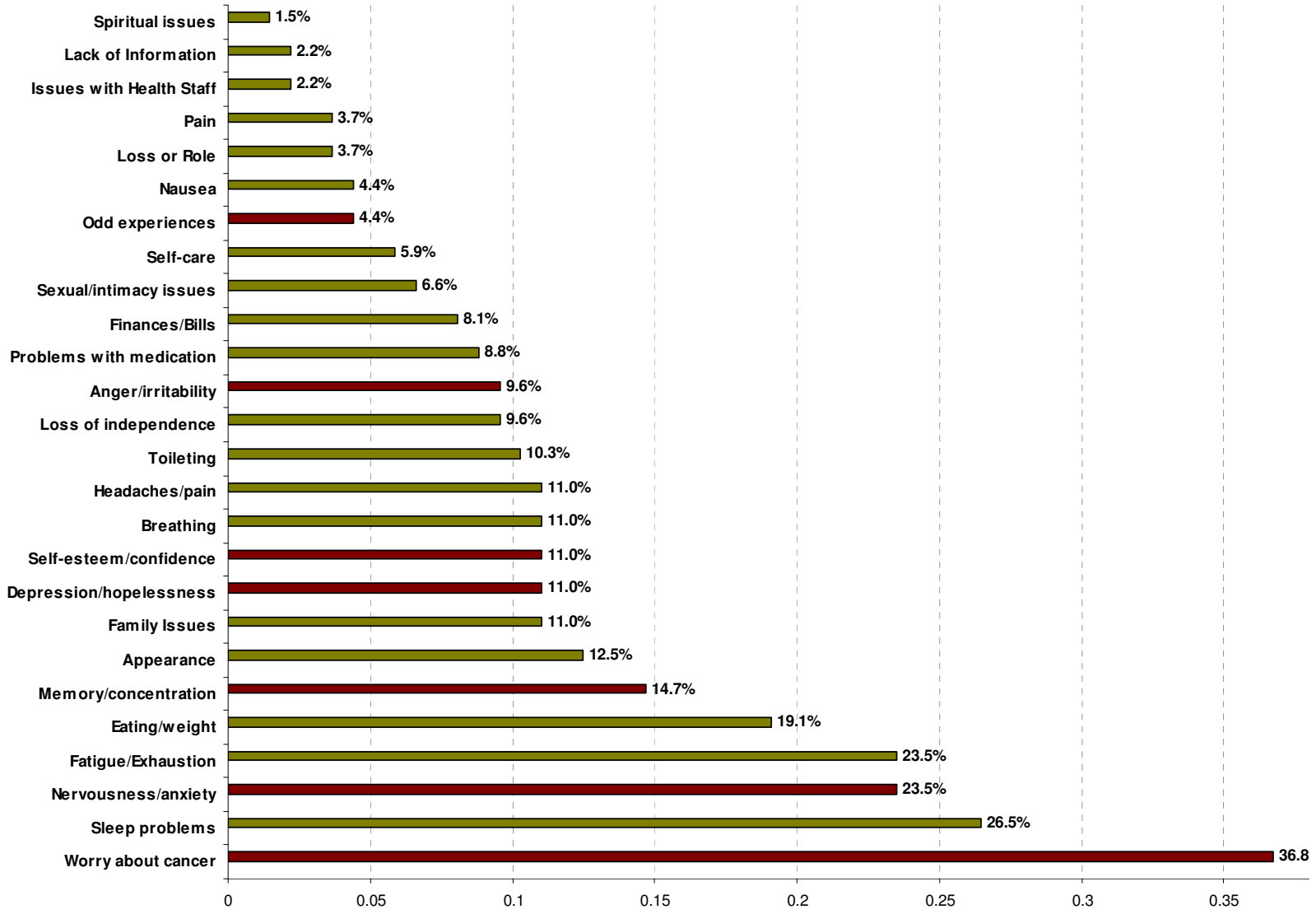


Figure 3.1.5a – Unmet Needs/Patient Concerns by Checklist Self-Report (red represents emotional domain)

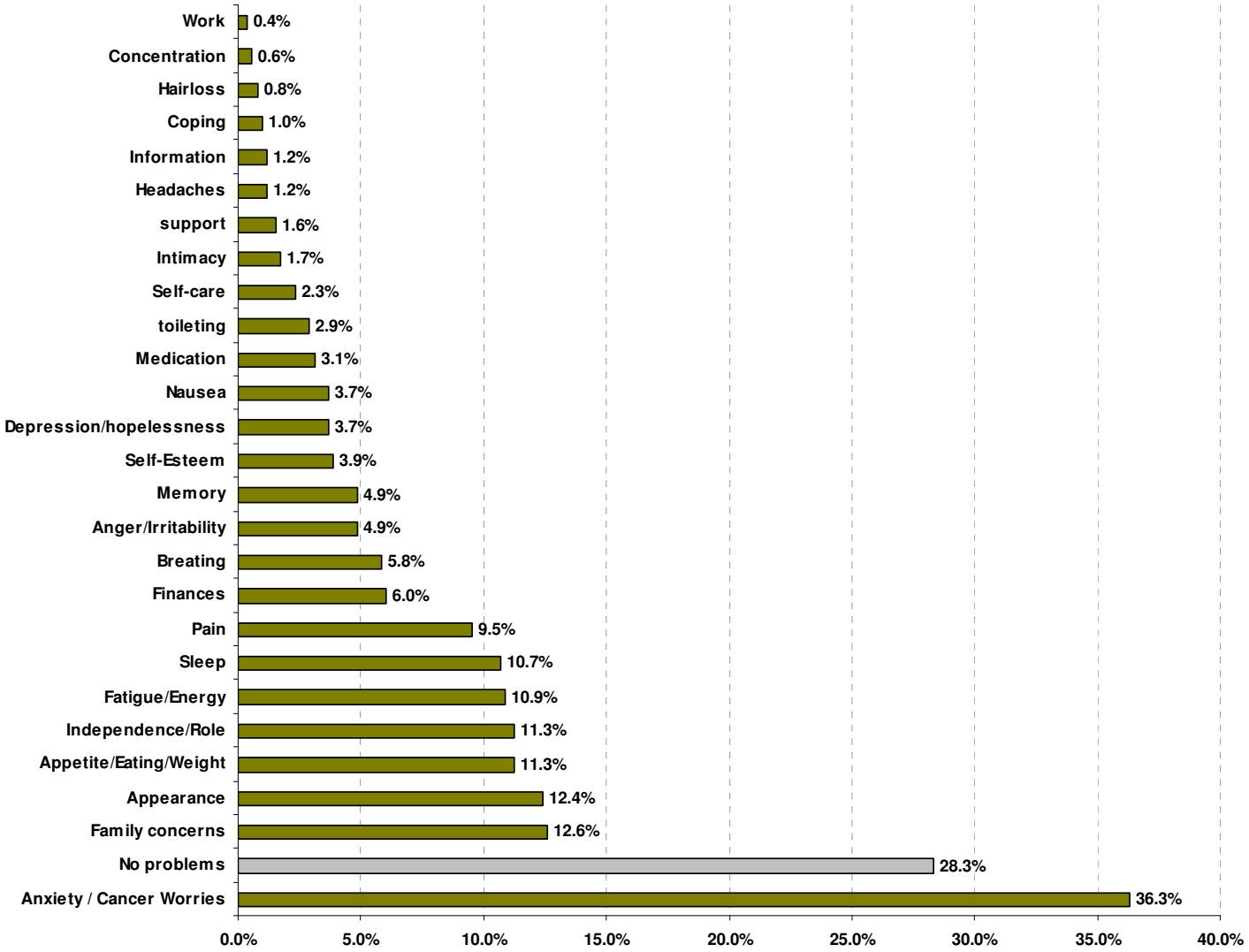


Figure 3.1.5b – Unmet Needs/Patient Concerns by Severity of Free Text Self-Report ("most pressing")

3.1.6 Acceptability of screening

Clinician Rating of Global Satisfaction

Across all screening applications, cancer clinicians felt screening was useful in 43.0% of assessments, but not useful in 35.9% and they were unsure or neutral in 21.1%. The application of the screening programme assisted staff in changing their clinical opinion in 41.9% of assessments. Most commonly this was clarification of baseline uncertainty (50.9%) but also included revaluation of an initially null assessment (i.e. the patient appears non-distressed) (26.0%) or revaluation of a positive assessment (23.1%) (i.e. the patient appears distressed).

Clinician Rating of Clinical Benefits

In a sub-sample of 267 with complete data, on 51.0% of occasions cancer clinicians felt that the screening programme helped improve clinical communication. On 40.6% of occasions clinicians felt that the screening programme helped with recognition of distress, anxiety or depression (in 18.9% they expressed no opinion). Cancer clinicians felt that the simple paper and pencil screening programme was practical for routine use in 45.3% of applications, but impractical in 37.5% (on 17.2% of occasions staff expressed no opinion).

Chemotherapy vs Radiographers Feedback of Acceptability

Chemotherapy nurses rated the screener useful on 42.9% of assessments, not useful in 43.4% and were uncertain or had no opinion in the remaining 13.7%. Radiographers rated the screening programme useful in 43.0% of assessment, not useful in 21.5% and were unsure on 35.4% of occasions. Although rating of chemotherapy nurses and radiographers were similar, the difference in those rating “not useful” was significant ($Chi^2 = 17.3$; $p<0.001$). Chemotherapy nurses appeared to have more difficulty accommodating screening into busy initial assessments although both groups found screening challenging when patient turnover was high.

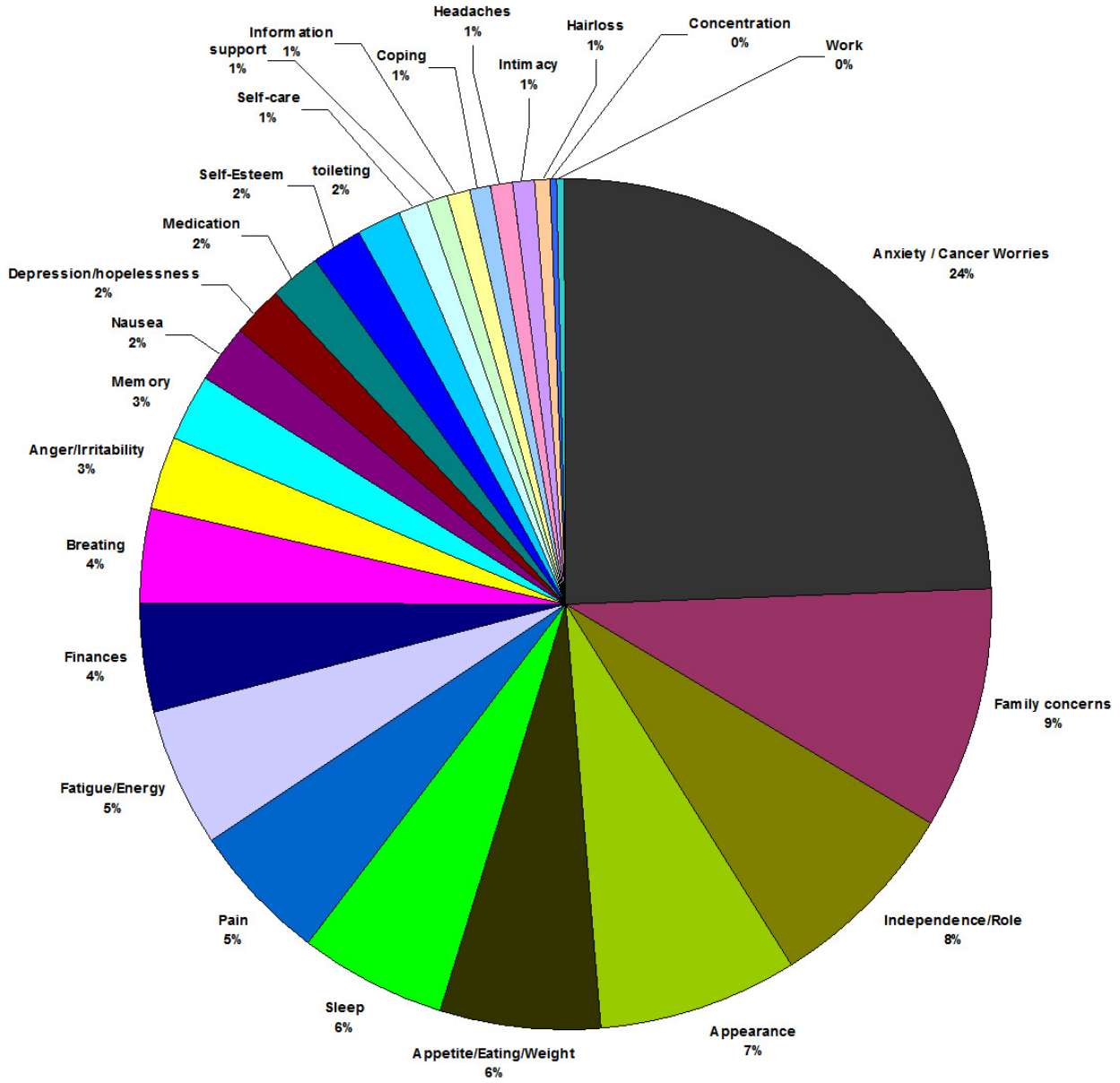


Figure 3.1.5c – Unmet needs by most pressing concern out of those patients with a concern.

3.1.8. Predictors of Favourable Staff Perceptions of Screening

On univariate logistic regression the following variables were significantly associated with a favourable staff perception of screening: clinicians rating the instrument as practical ($p<0.0001$), low clinician confidence ($p<0.001$) and high patient rated anxiety ($p =0.02$). Two outcome variables were linked with staff satisfaction with screening: talking with the patient about psychosocial issues ($p<0.0001$), and a change in clinical opinion ($p<0.0001$). On multivariate analysis three variables were associated with high staff satisfaction with screening, namely receipt of training ($p<0.0001$), talking with the patient about psychosocial issues ($p<0.0001$) and improved detection of psychological problems such as depression / anxiety ($p<0.0001$). On univariate chi squared analysis, cancer clinicians who rated the programme as useful were twice as likely to change their clinical opinion following screening ($chi^2 = 15.9$, $p< 0.0001$).

3.1.9 Clinician Response to Screening Results

Out of 518 patients screened for emotional complications of cancer, 291 (56.2%) reported a significant problem on one of the emotion thermometers (using a cut-off score of 4 or higher). Of these, cancer clinicians helped on 137 occasions (47.1%). Interestingly, clinicians also helped 40 of 223 (17.9%) without a significant emotional problem. Of those where any action was taken, a referral to specialist service was made on 41 (29.9%) of occasions (14.1% of those with any emotional concern).

Out of all patients assessed 373 reported a unmet need/concern. Of these, staff helped on 172 occasions (46.1%). Yet 35 had no meetable needs (“no action needed”) and 24 declined help. Removing these, the best estimate is that clinicians helped during 172/304 (56.6%) of consultations for those with meetable unmet needs, not declining help.

Out of all patients assessed 257 reported a significant emotional complications and also a problem list concern. After removing those with no meetable needs (“no action needed”) and those who declined help, Cancer clinicians helped 60.9% of the remaining patients. In the subsample of patients with emotional complications and a problem list concern whom were correctly recognised by clinicians as having an emotional problem, they helped 72% (who did not themselves decline).

It is interesting to ask whether failure to help patients who screen positive may be due to patients declining help. Using patients self-report on the help thermometer, desire for help was stratified into no helped wanted (HelpT = 0); a little help wanted (HelpT =1-3) and help definitely wanted (HelpT >3). From 209 consultations where patients screened positive for "any emotional problem" (defined as a >3 score on the depression, anxiety, distress or anger thermometers) and with help data, 69 patients said no help was wanted, 79 a little help wanted and 61 help definitely wanted. Within this sample, intervention was given according to the following table (table 3.1.9a).

Using Chi^2 there was a significant difference between offers of intervention in those who wanted a little help vs definite help ($Chi^2 = 14.6$, $p = 0.0001$) and between those who didn't want help vs those wanting definite help ($Chi^2 = 17.6$ $P < 0.0001$).

Predictors of clinicians willingness to give an intervention was further investigated with logistic regression using clinicians' action as a predictor vs emotional domains. All emotion domains significantly predicted whether cancer clinicians took an action when entered on their own. However, the predominant effect was for anxiety which was the only significant factor on a logistic model with all emotional concerns entered simultaneously.

On conditional logistic regression (forward) using cancer clinicians' action as a predictor, when desire for help and all emotional problems were entered, the predominant effect was patients' desire for help; here the effect of anxiety became of borderline significance. This suggests that the main influence on clinicians' action is patients' own desire to be helped.

Using logistic regression using any unmet need as a predictor and clinicians response as the dependent variable, the only unmet need significantly linked with a clinician's response was cancer worry (p=0.03) (table 3.19c)

	No Help Wanted	A Little Help Wanted	Helped definitely Wanted
Intervention given	13	18	37
No intervention given	56	61	24
total	69	79	61

Table 3.1.9a 3x2 table stratifying desire for help with clinicians' intervention response in those with an emotional complication

Distress Score	b1 = 0.028755	z = 0.38897	p = 0.6973
Anxiety	b2 = 0.129312	z = 2.161608	p = 0.0306
Depression	b3 = 0.047633	z = 0.671553	p = 0.5019
Anger	b4 = 0.002232	z = 0.04299	p = 0.9657

Table 3.1.9b Predictors of clinicians willingness to give an intervention

	z =	P =
Anger/Irritability	-0.01	0.99
Anxiety	-0.08	0.94
Appearance	-0.06	0.96
Appetite/Weight	-0.08	0.94
Breathing	-0.12	0.91
Cancer worry	**2.15**	**0.03**
Concentration	-0.06	0.96
Coping	0.00	1.00
depression	-0.03	0.97
Distress	-0.11	0.91
Family	0.00	1.00
Fatigue/Energy	0.01	0.99
toileting	0.03	0.98
Finances	-0.04	0.97
Hairloss	0.13	0.90
Headaches	0.10	0.92
Information	-0.06	0.95
Independence/Role	-0.07	0.94
Medication	-0.02	0.98
Memory	0.00	1.00
Intimacy	0.03	0.98
Nausea	-0.13	0.89
Pain	-0.10	0.92
Sleep	-0.04	0.97
support	0.04	0.97
Self-Esteem	0.06	0.95
Self-care	-0.03	0.98
Work	0.03	0.98
Any Problem	0.14	0.89

Table 3.1.9c Unmet need predictors of clinicians willingness to give an intervention

3.1.10 Patients' Desire for Psychosocial Help

418 patients reported data on their desire for help on a linear scale (0-10). 215 (51.9%) did not want help and 48.1% did. 77 (18.4%) patients wanted significant help at the current time judging by a score of 4 or more. There was a relationship between patients' desire for help and their experience of emotional complications. For example, only 24.2% of those not desiring help had a significant emotional complication but more than 80% of those scoring 7 of more on the helpT had one. Similarly, there was a relationship between patients' desire for help and clinicians action as discussed above. This relationship is illustrated in figure 3.1.10.

On multiple regression, distress on the DT was the variable significantly most associated with desire for help but many other variables were also influential. In an earlier study using the HADS, a path analysis suggested variables most associated with desire for help were: 1. distress (DT = SMW 0.271) and 2. anxiety (HADS-A= 0.225) and depression (HADS-D = 0.122).[223] However even collectively variables explained only 42% of variance in desire for help (see figure 4.3.8 in discussion).

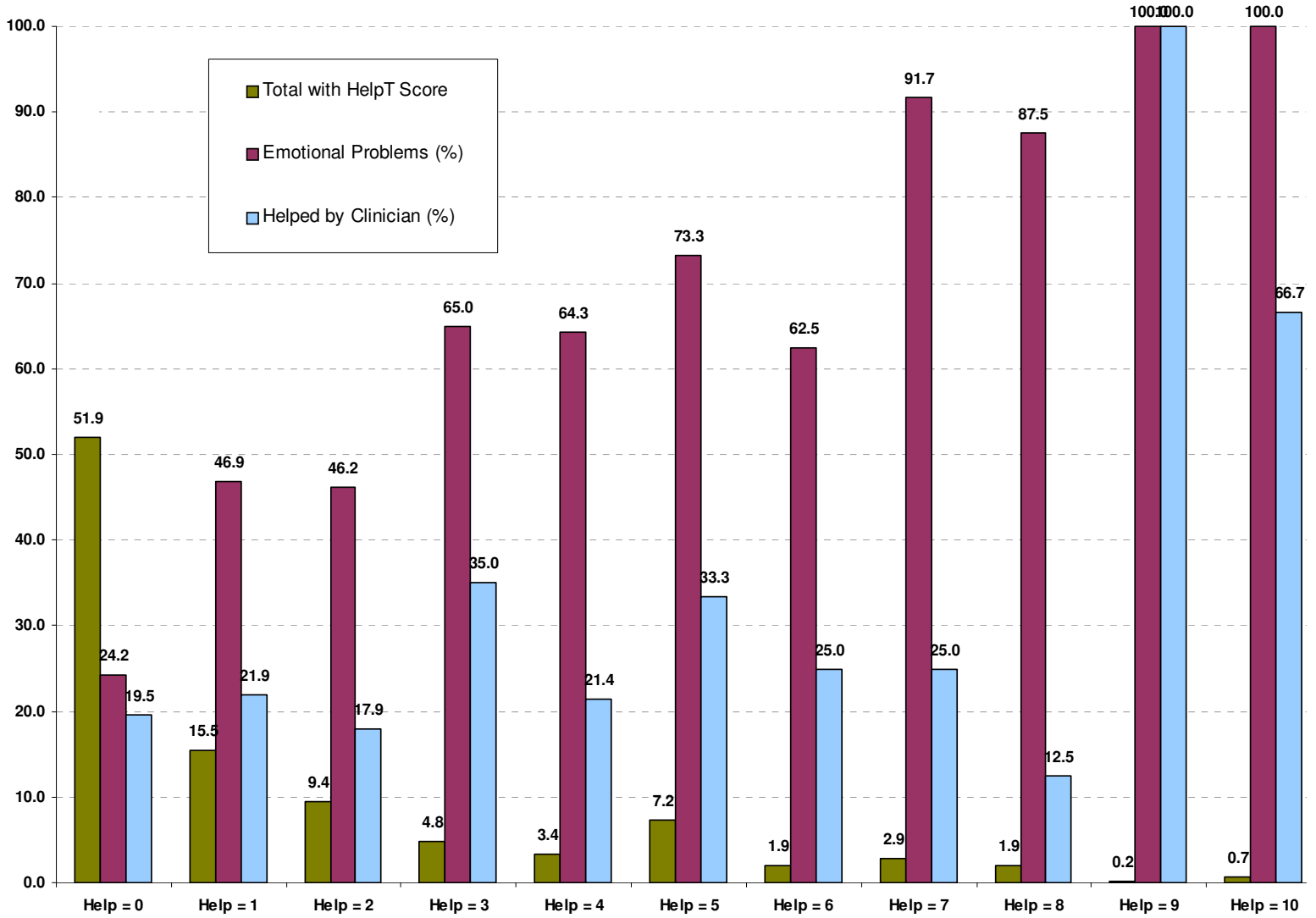


Figure 3.1.10 Frequency of scores on help thermometer (0-10) and percentage with emotional complications / percentage helped by their clinician.

3.2 Results of Recognition Screening Implementation Meta-analysis

3.2.1 Search Results

From a total of 291 studies retrieved from a total of three searches, we identified twelve randomized trials of the effect of screening for psychological distress/QoL.[185 187 181 182 183 189 188 192 191 224 225 226] A further eight non-randomized studies measured changes in distress or related outcomes before and after screening without randomization.[184 194 195 197 196 193 227 228] The following nine studies used screening without comparative samples (they were one-sided observational studies).[118 229 230 231 232 233 234 235 236] Studies of broadly defined unmet needs without a psychosocial focus were not included.[237] Unfortunately many of these highlighted studies did not contain data that could be extracted. After exclusions, six publications were found that measured receipt of psychosocial care and six publications were found that measured receipt of psychosocial referral following screening using observational (non-comparative) methodology. Any interventional study with no screening (as opposed to no feedback after screening) in the comparator arm could be legitimately combined with observational studies. As this current Leicester study is currently unpublished I combined it with the observational studies as a failsafe procedure. 13 interventional implementation studies were identified that included extractable data. These include 7 interventional implementation studies that measured receipt of psychosocial referral in a sequential cohort design, that is before and after the introduction of distress screening and 2 randomized controlled screening trials; a total of 9 distress implementation studies.

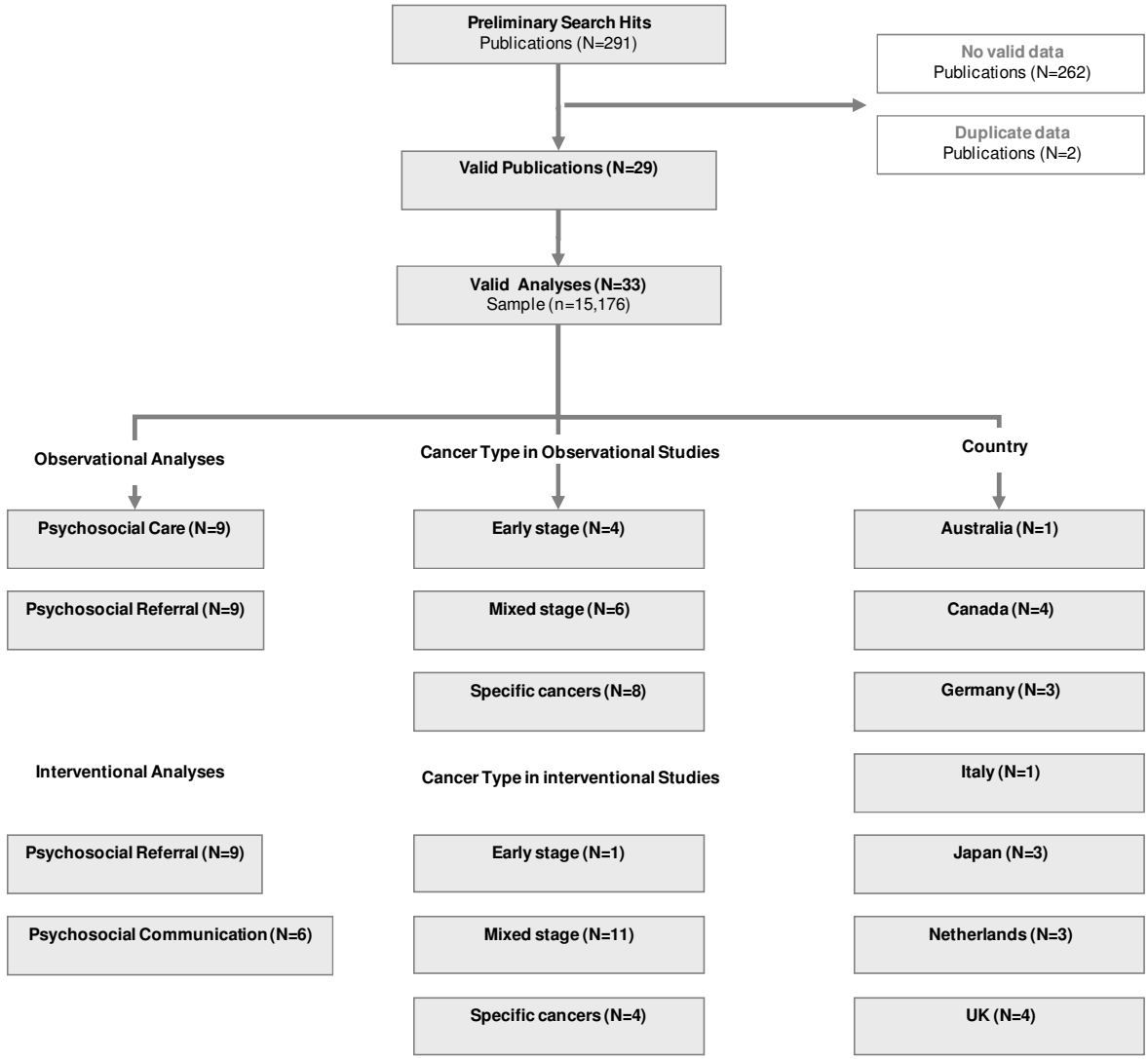


Figure 3.2.1 – Search results overview of observational and interventional implementation studies

3.2.2 Receipt of Psychosocial Care in Observational Screening Studies

Nine observational screening analyses (in five publications plus this primary Leicester study) measured receipt of psychosocial care following screening. The total sample was 1802 patients with cancer. 6 of 9 studies reported on receipt of care in those that screened positive for emotional distress and 3 studies reported on receipt of care in those who screened negative for emotional distress (as well as in the total sample screened).

In patients screening positive for emotional distress, heterogeneity was high I^2 = 93.3% (95% CI = 88.8% to 95.5%) but there was no publication bias (Harbord = -2.11, 92.5% CI = -14.12 to 9.90, p = 0.69. After adjustment, on random effects meta-analysis, the proportion of cancer patients who received psychosocial help following a positive screen was 30.0% (95% CI = 19.6% to 41.3%) (figure 3.2.2).

In patients screening negative for emotional distress, heterogeneity was high I^2 = 88.9% (95% CI = 59.3% to 94.6%) but there was no publication bias (Harbord bias = 14.7; 92.5% CI = -146.1 to 175.6; p= 0.58). On random effects meta-analysis, the proportion of screen negative cancer patients who received psychosocial help was 10.9% (95% CI = 8.4% to 13.6%). This represents a 2.8 relative risk improvement (95% CI = 1.95 to 4.07) and a pooled risk difference of 22.2% (95% CI = 10.4% to 33.9%, Chi^2 92.4, p < 0.0001). In all (unselected) cancer patients subjected to screening (positive and negative screens) the proportion who received psychosocial help was 23.7% (95% CI = 10.2% to 40.6%).

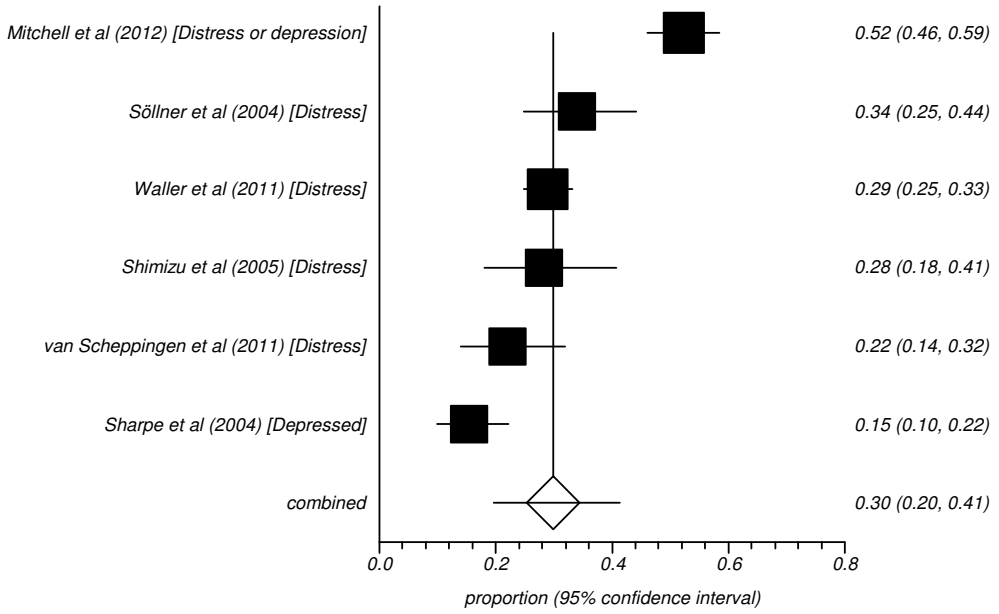


Figure 3.2.2. Receipt of Psychosocial Care in Observational Screening Studies - meta-analysis

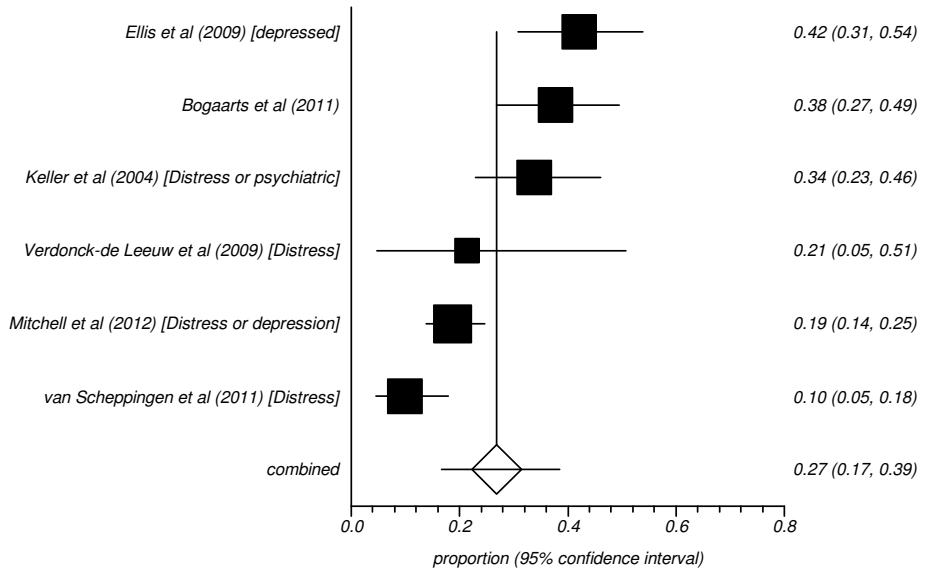


Figure 3.2.3 Receipt of Psychosocial Referral in Observational Screening Studies – meta-analysis

3.2.3 Receipt of Psychosocial Referral in Observational Screening Studies

Nine observational screening studies (in six publications) measured receipt of psychosocial referral following screening. The total sample was 1441 unique patients with cancer. 6 of 9 studies reported on referrals in those that screened positive for emotional distress and three studies reported on referrals in those who screened negative for emotional distress (as well as total sample screened).

In patients who screened positive for emotional distress, heterogeneity was high I^2 = 86.9% (95% CI = 71.6% to 92.2%) but there was no publication bias (Harbord bias = 2.50; 92.5% CI = -5.96 to 10.97; p = 0.52). On random effects meta-analysis, the proportion of cancer patients who received psychosocial referral following a positive distress screen was 26.9% (95% CI = 16.7% to 38.5%) (figure 3.2.3). The proportion of screen negative cancer patients who received a psychosocial referral was 9.6% (95% CI = 0.02% to 33.3%). The difference in referral between screen positive patient and screen negative patients was significant with a relative risk of 2.7 (95% CI = 1.04 to 7.01, Chi^2 4.16, p= 0.04), and a risk difference of 11.0% (95% CI = 6.3% to 15.7%, Chi^2= 21.0, p < 0.0001). In all cancer patients subjected to screening (positive and negative screens) the proportion who received psychosocial referral was 14.6% (95% CI = 2.5% to 34.5%).

3.2.4 Effect of Distress Screening on Receipt of Psychosocial Referral in Implementation Studies

Nine implementation studies measured receipt of psychosocial referral using either a sequential cohort design (n=6 non-randomized trials) or in clinicians/patients randomized to screen or no screen (n=3 randomized trials). The total sample size was 10,185 unique cancer patients. Note that the non-randomized trials were generally similar in design, focussing on distress, although one study examined QoL without distress (Hilarius et al, 2008).[228] The randomized trials differed in design, one randomizing patients to screen vs no-screen[191] and two randomizing patients to either screening without feedback/follow-up and screen with feedback and/or follow-up.[181 232] Considering the nine implementation studies together, heterogeneity was high (95% CI = 94.3% to 96.8%), with no publication bias (Harbord bias = -2.77; CI = -12.64 to 7.09; p = 0.57). The relative risk of receiving a psychosocial referral was 2.96 (95% CI = 1.47 to 5.96; Chi^2 = 9.24, p< 0.01) in cancer patients who were screened vs not screened (note that this analysis includes Carlson et al (2010) whose control arm comprised patients screened without feedback of results to

clinicians). The pooled risk difference was 11.7% (95% CI = 1.1% to 22.4%, $Chi^2 = 4.64$, p = 0.03) meaning that screening with feedback significantly enhanced referrals by about 12% over usual care. These results are illustrated in figure 3.2.4.

Moderator Analysis

After excluding the three studies mentioned above which could be considered atypical on methodological grounds, the adjusted relative risk of referral with screening was 3.78 (95% CI = 1.64 to 8.72; $Chi^2 = 9.77$, p = 0.001) with a risk difference of 13.1% (95% CI = 0.0 to 27.2%), an effect on the borderline of significance (p = 0.06).

Predictors of Referral in Implementation Studies

On meta-regression none of the following were significant predictors of referral: training clinicians, collaborative psychiatric care, repeated screening, audit of clinician satisfaction, screening by front-line staff, screening for unmet needs, screening for QoL, screening for distress or mandatory follow up.

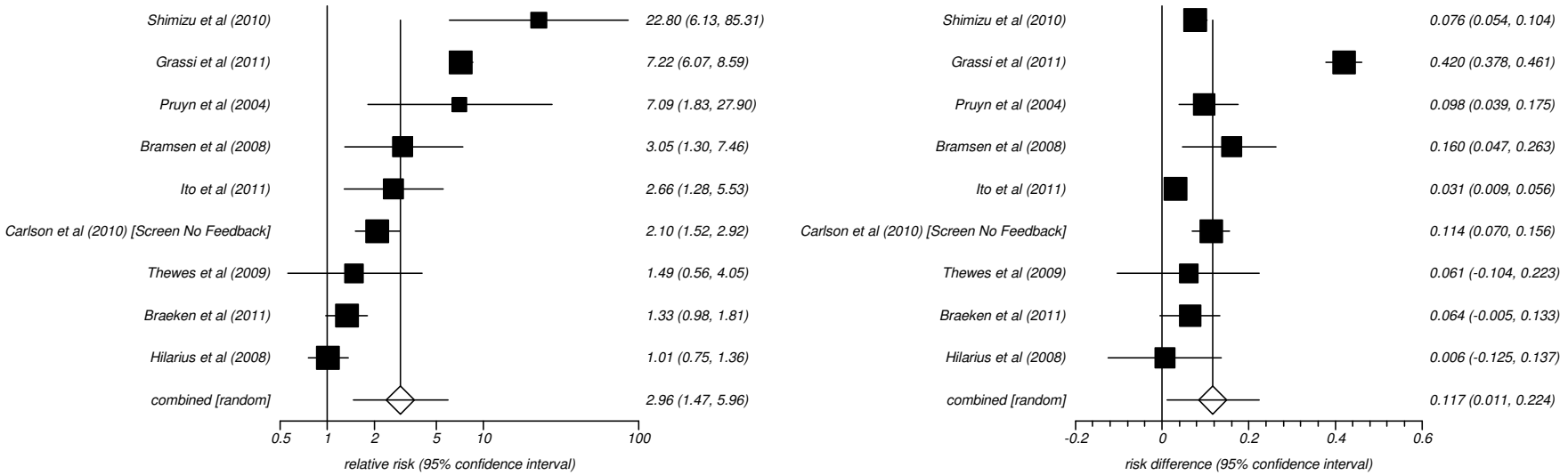


Figure 3.2.4 Relative Risk and Risk Difference Meta-Analyses: Implementation of Distress Screening on Referrals

4.0 Discussion

4.0 Discussion

Psychosocial complications of cancer are becoming more important as the burden of cancer increases. Epidemiological burden is related to the number of people living with that condition. Survival following cancer has been improving over the last 20 years due to improvements in diagnosis and targeted treatments. As a result, cancer is increasingly conceptualized as both an acute and a chronic disease in which about 70% of all patients live for at least 5 years past a diagnosis.[238 239] GLOBOCAN has examined the future incidence of cancer and projects that by 2030 there will be over 21 million new cases diagnosed annually worldwide.[240] Prevalence estimates suggest that by that time there will be at least 20 million people living with cancer in the US and perhaps 50 million worldwide.[241] Of these at least 30% will have unmet psychosocial needs (see 1.5), 15% major depression, 40% a clinical mood disorder (see 1.4.1) and 40% general emotional distress (see 1.4.2). Given the low recognition of emotional complications using clinical judgement alone (see 1.6) many organizations have asked whether screening for distress or depression in cancer settings is worthwhile?

4.1 Guidelines on Screening

Details of how and how often to screen are disputed and subject to much local variation. Screening implementation in most centres has been most influenced by local opinion rather than evidence. According to the National Comprehensive Cancer Network (NCCN), distress should be recognized and monitored through regular and repeated screening and treated promptly at all stages of disease.[242] A 2002 US National Institutes of Health (NIH) Conference Statement called for the routine use of screening tools to identify untreated depression among cancer patients.[243] The 2004 guidelines from the UK National Institute for Clinical Excellence (NICE)[244] recommended screening for psychological distress including depression in cancer patients. The Cancer Journey Action Group (CJAG) of the Canadian Partnership Against Cancer (CPAC) recommends that patients be screened routinely at critical time points during the cancer continuum.[245] A 2007 report from the Institute of Medicine (IOM) recommended screening for psychological distress in cancer settings.[31] However, none of these important consensus statements were able offer thorough evidence based advice regarding which tool to use and its likely added value in clinical

practice. Such evidence has been accumulating rapidly and can be divided into diagnostic valid studies (how accurate is the screening tool) and implementation studies (how well does screening work in practice). The aim of screening is fundamentally to facilitate effective and efficient treatment by focussing on people who would most benefit from a proven intervention. Yet in order to justify the time and effort required, screening must be more worthwhile than not screening (treatment-as-usual). This thesis sets out the evidence from a new local study and from the worldwide literature on this question.

4.2 Uptake of Screening

There has been a great deal of work concerning tool accuracy in diagnostic validity studies although most have concentrated on depression per se.[124 133 246] Our group has published a meta-analysis on depression tools[130] and a meta-analysis on distress tools.[151] This body of work has been largely successful in that numerous "validated" tools are available and offer to potentially improve upon the clinician's unassisted judgement. However, adoption of these tools into clinical practice has been largely unsuccessful in terms of reach (very few centres) or effect (proven added value over an above clinical routine).[247 248] A national survey of US oncologists conducted in 2007 found that 65.0% reported screening patients for distress routinely, but only 14.3% used a screening instrument.[106] Out of 84 Canadian cancer institutions surveyed in 2008 only 36.5% routinely screened patients for emotional distress at the time of admission.[248] In a national UK survey of cancer cancer clinicians only 25% routinely used some form of assessment for distress or depression.[36] In short, there is no country that has mandated routine screening but this is only problematic if screening is beneficial with few risks, burden or hazards.

4.3 Discussion of the Local Study (Part I)

4.3.1 Discussion of the Sample

In the local screening study 851 patient interactions (consultations) were assessed by 50 chemotherapy nurses and treatment radiographers. Of these, clinical staff returned information on 539 assessments (60.2%) involving 379 patients. This suggests that screening cannot be entirely universal as up to 40% of patients may be unwilling or unable to complete the screening questions. However, this proportion will be

reduced if clinicians and caregivers help with questionnaire completion. In the published literature (see 1.4.1 and 1.4.2) 40-50% of patients report emotional complications. In this local Leicester study 56% of patients report a significant emotional problem and 39% scored high for distress (using the NCCN cut-off of >3). Thus four in ten patients had distress (point prevalence self-report estimate) and another 17% of the sample had a significant emotional complication in the domains of anger, anxiety or depression that could not be adequately captured by the DT alone. This suggests caution should be exercised if relying upon single-domain screening tests. Our sample was mostly female (75%) seen in chemotherapy or radiotherapy with curative treatment intent (85%). Breast cancer was the most common diagnosis. The sample was ethnically diverse but unfortunately we did not collect adequate data on cultural and ethnic differences.

4.3.2 Discussion of the Development of the Screening Tool

Many previous tools have been developed to aid the detection of depression or distress but most have been too long for routine use. [36 49] In response, simple verbal and visual-analogue methods of assessing depression, anxiety or distress have been developed, either as part of a symptom checklist (exemplified by the Edmonton Symptom Assessment method)[249 250] or by focussing on distress or mood alone.[132 143 251] The DT is probably best known and is a single item self-report 0-10 scale. Patients are given the instruction "How distressed have you been during the past week on a scale of 0 to 10?" In 1998 the DT represented an extremely important advance in screening in that is was highly acceptable to both patients and health professionals, simple to score and easy to interpret. Yet evidence showed that it performs best in relation to distress, but modestly regarding anxiety and depression (see section 1.7.2). In a comprehensive review of the accuracy of the DT, it was found to have a specificity of only 60.2% and a PPV of only 32.8 for identification of depression.[133] Specificity was not much better for identification of distress (66.1%) with a PPV of 55.6%. For this reason a multidimensional approach was preferred in this primary Leicester study, utilising a similar design to the DT, previously validated locally.

The ET differs from the DT in the following ways. It is colour coded with specific domains for anxiety, depression and anger. It also includes desire for psychosocial help. It included half-marks (between each whole number). The screening tool was then embedded in a screening programme. The screening programme was a simple paper and pencil screener incorporating three major components: 1. assessment of emotional distress 2. unmet needs checklist and 3. clinicians' response (see appendix 1). The ET typically

takes less than one minute to complete and the screening programme less than 3 minutes. The paper and pencil screener was delivered by clinical nurse specialists in chemotherapy and treatment radiographers, that is front-line cancer clinicians. They were not assisted, therefore, this screening study can be considered a test of screening in routine clinical care.

Previously, it was reported that the ET domains had potential superiority over the DT alone when looking for specific emotional complications. For detection of broadly defined distress, the AngT was promising and may be better than the DT alone, although a combination of items may be preferable. For detection of anxiety, the AnxT was somewhat more accurate than the DT. For all types of depression, the optimal method was the DepT. In a clinical setting where the prevalence of major depression was 20%, use of the DT alone would correctly identify 14 out of 20 depressed cases, missing 6 and correctly rule-out 56 non-cases, with false positives in 24 non-cases. On the other hand use of the DepT (at 3v4) would correctly identify an additional 1.5 cases and correctly rule out an additional 7 cases. Clinicians using the DT to rule-in and rule-out major depression would be correct about 71% (fraction correct at DT 3v4) of the time but this could be improved to 88.5% using the DepT at a cut-off of 5v6. In the implementation study, no gold standard was used therefore verification of this diagnostic validity data was not possible. The ET is currently available to clinicians royalty free.

4.3.3 Discussion of Baseline Results

Results of the baseline cancer clinicians' judgement indicated that the clinical judgement of frontline cancer clinicians is unlikely to be sufficient for detection of distress, anxiety, anger, depression or broadly defined any mood problem. Without screening, clinicians' detection sensitivity was only 11.1% for distress and 6.8% for depression. Detection of anxiety and any mood problem were somewhat better at 42.8% and 43.0%, respectively. However, in no domain could clinicians' judgement be considered satisfactory. It is possible that clinicians' accuracy could be improved further by further training and support, without screening but we previously found such training poorly attended. Thus, correcting errors in cancer clinicians' baseline judgement is a great challenge with no easily available solution.

There have been several previous studies examining the unassisted ability of cancer clinicians to identify depression or distress in cancer settings, but rarely any concerning anxiety and none regarding anger. Anger is not necessarily an insignificant problem. 60.3% of those scoring ≥ 3 on anger, also scored ≥ 3 on distress.

Anger appears to be linked with stronger imperative to act than depression or anxiety.[252] From this study 73% of those with the symptom of significant anger would consider some form of psychosocial help. Five previous studies have examined the success of cancer clinicians in looking for depression. Passik et al (1988) used the Zung depression scale (cut off > 49) to identify 173 depressed cancer patients and 560 non-depressed patients. 12 oncologists managed a detection sensitivity of 43.7% and specificity of 79%.[119] False positive and false negative errors were seen, as clinicians underestimated severity of depression in 284 and overestimated severity of depression in 164. Hardman et al (1989) used a psychiatric interview to define clinical depression in a sample of 99 patients rated by doctors and 301 ratings by nurses. Oncologists identified 10/25 cases (40% detection sensitivity) and 68/74 non-cases (91.9% detection specificity).[253] Nurses identified 37/71 cases (52% detection sensitivity) and 178/230 non-cases (77.4% detection specificity). Overall nurses were accurate in 71.% of their assessments (fraction correct statistic). McDonald and colleagues (1999) asked 40 oncology clinic nurses from Indiana to evaluate depression in 1,109 patients who also completed the Zung Self-Rating Scale (ZSDS).[254] Sensitivity was 42.1% and specificity 81.2%. Singer et al (2007) used structured clinical psychiatric interview for DSM-IV (SCID) to diagnose major and minor depression in 28 patients of whom 15 were correctly identified by oncologists (sensitivity = 53.6%; specificity not reported).[255] By comparison oncology nurses in the study by Singer et al 2007) had a sensitivity of 67.8%. Our detection sensitivity of 6.8% was the lowest ever recorded but might reflect our self-report method of elucidating depression. In this Leicester study the cancer clinicians' detection specificity was 99.1%. As sensitivity and specificity are interdependent according to the threshold for diagnosis, it is often more meaningful to examine total correctly identified (fraction correct). The total correctly identified by clinicians in this study was 75.7% vs 71.4% in the only comparable study by Hardman et al (1989). How do these results compare to the accuracy of nurses working in other medical settings? Mitchell and Kakkadasam (2011) conducted a meta-analysis of nurses ability to detect depression including 7 studies involving hospital nurses.[256] Hospital nurses managed 43.1% sensitivity and 79.6% specificity. A comparison of these results is illustrated in figure 4.3..3 From this figure it appears nurses and treatment radiographers in Leicester had a relatively high PPV (low false positives) but low NPV (high rate of false negatives), implying a high threshold for diagnosis depression.

Regarding distress, five studies have examined cancer clinicians' ability to identify distress, three using the HADS-T, one using the GHQ12 and one using the DT. In the first study by Sollner et al (2001) eight oncologists evaluated 298 cancer patients. Against moderate or severe distress on the HADS-T (a 12v13 cut-off), oncologists' sensitivity was 80% but their specificity was only 33%. Keller et al conducted the only study of cancer nurses ability to detect distress using the HADS-T (>15).[118] Using a five point recognition scale, nurses were able to spot 72.1% of distress and 56.6% of non-distressed patients (60.6% fraction correct). Okuyama et al (2009) asked lung cancer specialists to identify 17 of 60 lung cancer patients who were distress on the HADS-T (>19). They managed to identify 29.4% with a specificity of 74.4%.[257] Fallowfield's group compared cancer clinicians' ratings of patients using visual analogue scales with an independent patient reported GHQ-12 score (at a cut-off ≥4). In this high prevalence sample, detection sensitivity was only 29% and specificity 84.8%.[121] In this Leicester study our cancer clinicians correctly identified only 11% of distress, much lower than expected with 98% specificity. Thus they seemed to have too high threshold for diagnosing distress. They managed to identify 43% of any mood problems. Only one previous study in the literature has looked at recognition against the DT. Trask et al (2002) found that clinicians had 60% sensitivity and 84% specificity against a score of ≥4 on the DT. In this Leicester study, clinicians recognized more severe forms of distress. Other work, particularly in primary care has highlighted that many clinicians struggle to diagnose mild mental health conditions with significant false positives (and to a lesser extent false negatives).[258 259] In the MAGPIE primary care study, Bushnell et al (2004) found that 38% of those with distress were not recognised. Reasons for error were not categorising psychological issues as clinically significant (23.4%), recognising clinical significance but not ascribing a particular diagnosis (7.1%) and making an incorrect diagnosis (7.7%).[260] In a cancer context, Martensson et al (2008) collected nurses' opinions of 90 patients who completed HADS, the Cancer Behaviour Inventory (CBI) and the Functional Assessment of Chronic Illness Therapy- Spiritual Well-being (FACIT-Sp). Nurses systematically overestimated patients' emotional distress and underestimated patients' coping resources and quality of life and the percentages of agreement were between 36% and 60%.[261] Thus, both false positive and false negative errors are possible depending on context. When a condition is rare false positives are more likely, as they are when clinicians have a low threshold for diagnosis, are over-confident or over-vigilant.

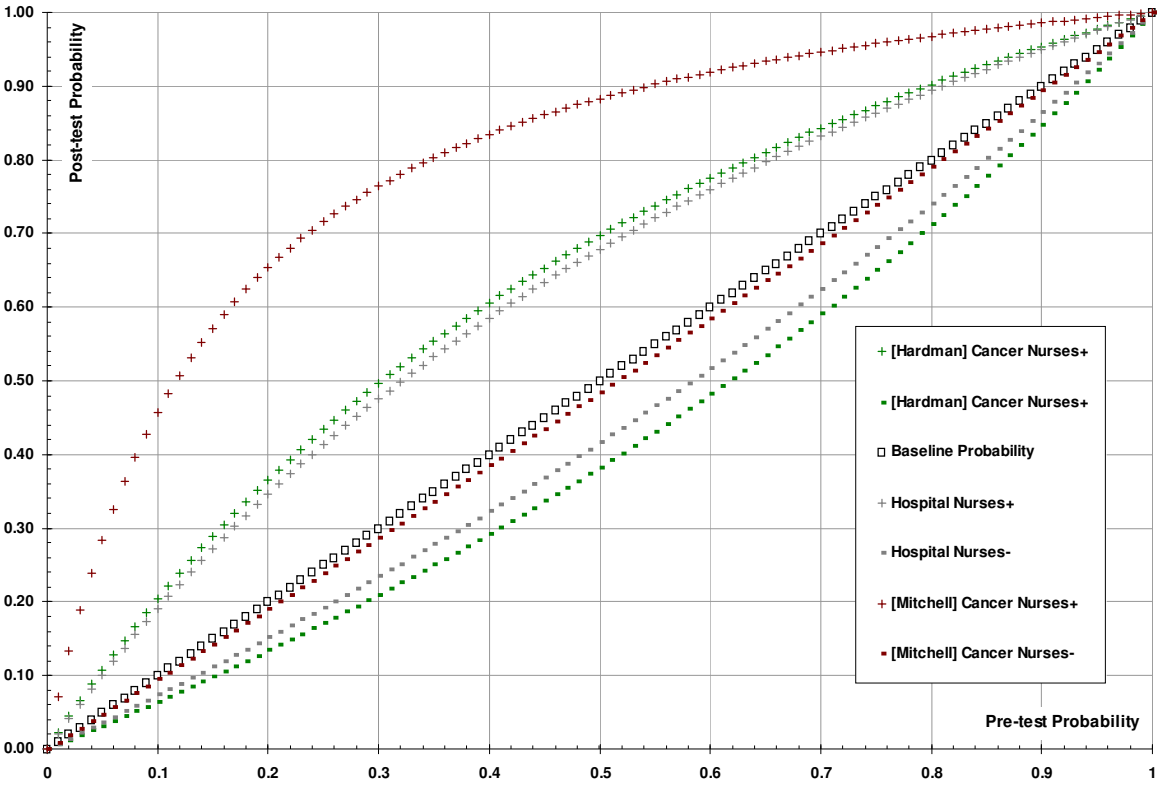


Figure 4.3.3 Comparison of detection of depression by nursing staff in Hardman et al vs Mitchell et al (2011) vs this study

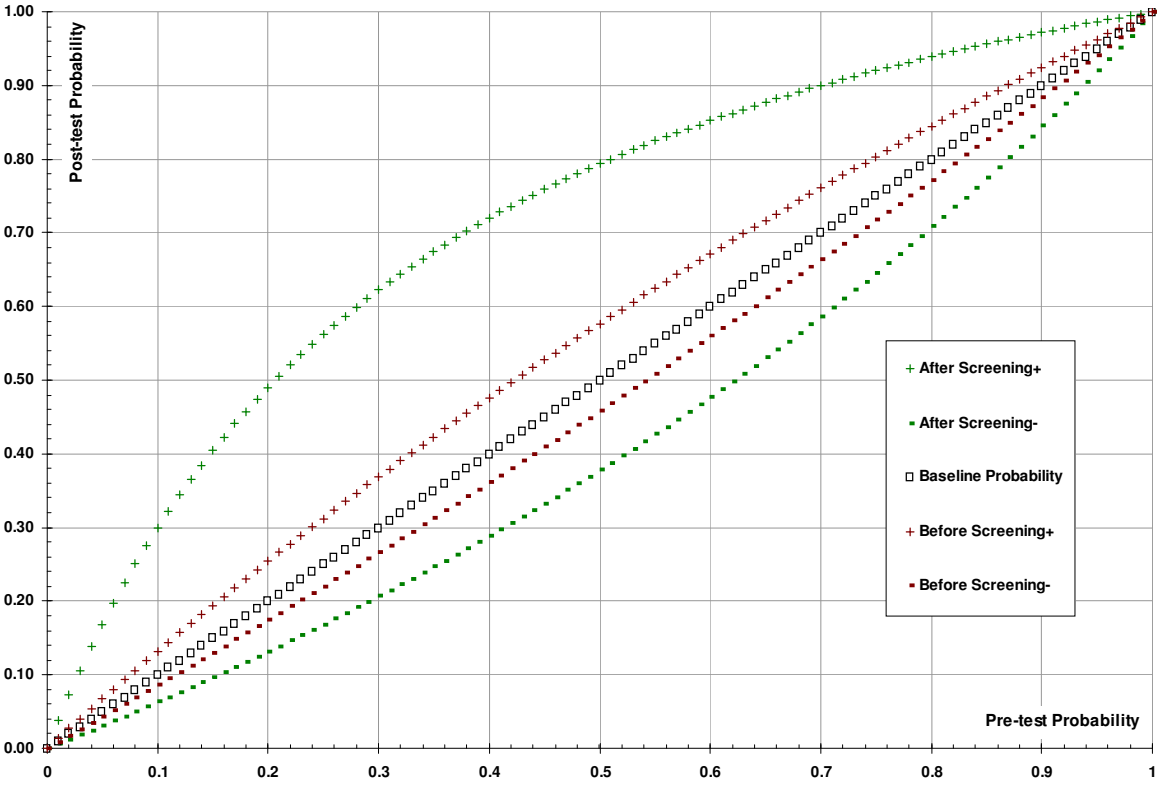


Figure 4.3.4 The effect of screening on 'any mood problem' using a plot of conditional probabilities.

4.3.4 Discussion of Post-Screen Results

Results of the effect of screening on change in detection of mood disorder were disappointing (see fig 3.1.3). After application of screening, cancer clinicians sensitivity for any mood problem did not significantly improve (+3.5% in absolute terms). That said, specificity increased by 6% for anxiety and 17.5% for any mood problem. The latter was statistically significant. However, diagnostic sensitivity improved by 8% for detection of anger but actually deteriorated in relation to anxiety (-11%), both of which were modestly significant. Combining sensitivity and specificity in the fraction correct (also known as total correct) showed an overall accuracy of 54.4% before screening and 63.7% after screening, an improvement of 9%. Thus in terms of effect on clinicians' diagnoses, screening can be seen to modestly influence diagnosis, with perhaps more of an effect on specificity than sensitivity. This effect is illustrated in a comparison of before vs after screening on 'any mood problem' using a plot of conditional probabilities (see 2.5.1 for explanation of conditional probability plot). From figure 4.3.4 we can see that PPVs are improved with screening, but nevertheless are unlikely to reach satisfactory levels except at very high prevalence levels. A clinical interpretation of this finding is that, even with the aid of screening, achieving a 90% correct identification rate of distressed patients (90% PPV) will only be achievable in a very high risk sample where 7 out of 10 people with cancer are distressed.

An alternative method of understanding diagnostic accuracy is to use Cohen's kappa. Using kappa scores there was generally low agreement between clinicians and patients at baseline, rating as "fair" or "poor" according to conventional thresholds. The optimal agreement between patients and clinicians at baseline was with any mood problem (kappa = 0.31) and next anxiety (kappa =0.27). With the aid of screening there was a slight improvement, namely "fair agreement" between patients and clinicians was achieved with mood problem (kappa = 0.33) as well as with anxiety (kappa =0.23) and distress (kappa =0.26). However, agreement regarding depression and anger remained poor between patients and clinicians. Clearly these kappa values are far from high, but not dramatically different than found in previous studies of agreement of patients vs physicians regarding physical symptoms or functional status.[262 263 264] Low agreement is generally present for physicians vs patients (rather than nurses opinions) and for symptoms that cannot be observed directly (eg vomiting and diarrhoea).[265 266]

Given the interest in emotional distress, a more detailed analysis of recognition of patient reported distress, graded by severity according to the DT score and incorporating clinician uncertainty was undertaken. Detailed findings are shown figure 4.3.5. Clinicians showed increasing diagnostic sensitivity with increasing severity of distress up to a maximum of approximately 80% in the most distressed patients. Cancer clinicians admitted to being "unsure" in 23% of assessments without the aid of screening, but only 15% with the aid of screening (a highly significant reduction $Chi^2 = 8.6$ $p = 0.003$). This finding suggests that screening informs clinicians' judgement. In clinical practice many assessments may end in uncertainty, and errors are more likely when clinicians feel obliged to make a decision at first assessment. Re-assessment, even with a short delay of days or weeks, is likely to substantially improve clinical judgement. This has been demonstrated in primary care, where two assessments improved GPs diagnostic accuracy by over 15%.[267]

4.3.5 Discussion of Unmet Needs Results

When checklist and free-text self report concerns were combined, concerns were reported in 80.9% of consultations but needs did always warrant medical attention. After unmeetable needs were removed, meetable unmet needs occurred after remarkable 70.1% of consultations.

Using a 26 item checklist clarified that "worry about cancer" was the most common concern with 36.8% of patients endorsing this option. Patient concerns were associated with levels of emotional complications. For example, of those with distress (≥ 3 on the DT) 62% of patients had worry about cancer compared with 30.3% of those with low DT scores (this is a highly significance difference $Chi^2 = 8.6$ $p = 0.003$). Anxiety (23.5%), fatigue (23.5%) and memory / concentration (12.5%) were common emotional concerns (see figure 3.1.5). However, cancer worries were not more common in patients treated with palliative intent (32.9%) than 438 remaining patients (38.1%) and although there were only 12 patients with metastases, their rate of cancer worry was also no higher (25%).

By category, the most commonly endorsed domain was emotional concerns. Remarkably the average number of concerns per patient was 2.9 and 72% of patients endorsed at least one checklist concern/unmet need after a consultation. When ranked only by most pressing concern, then out of those with any concern (71.7%) the most pressing top four single concerns were anxiety/cancer worries (24.2%), family concerns (9.0%), loss of independence/role (7.5%) and changes in appearance (7.4%). That said a common category was "no pressing problems" recorded by 28.3% of the sample. This highlights that although

concerns/unmet needs are common, they are not invariable and about 30% do not recall having current unmet needs.

These findings seem to parallel some but not all previous studies. This Leicester sample is one of the largest in the literature of unmet needs although several larger studies also exist. Perhaps the most comparable is the British study by Elliott et al (2011) who offered a large scale comparison of 780 cancer survivors using 25 survey items covering physical, psychological and social dimensions of health and well-being. Our results indicating that more than 70% have meetable concerns/unmet needs (as well as 46.7% having 3 or more needs and 13.9% having 6 or more concurrent needs), parallels Barg et al (2006) who examined long-term unmet psychosocial needs in 614 American cancer survivors. Barg et al found that 64.9% had at least 1 unmet need, and 48.3% reported 3 or more needs.[104] Similar to these Leicester results, the highest rate of needs/concerns was need in the emotional (38.7%) and physical (37.5%) domains.

Although the literature on unmet needs varies according to the definition of need, this study confirms what others have found fairly consistently. Most patients in cancer treatment have unmet needs that warrant medical attention. The most common type of unmet needs are generally psychosocial and the most common single need is worry about cancer/ worry about cancer returning which is estimated to be present in 30-40% of patients. This need was the only one significantly linked with clinicians willingness to give an intervention (see table 3.1.9c).

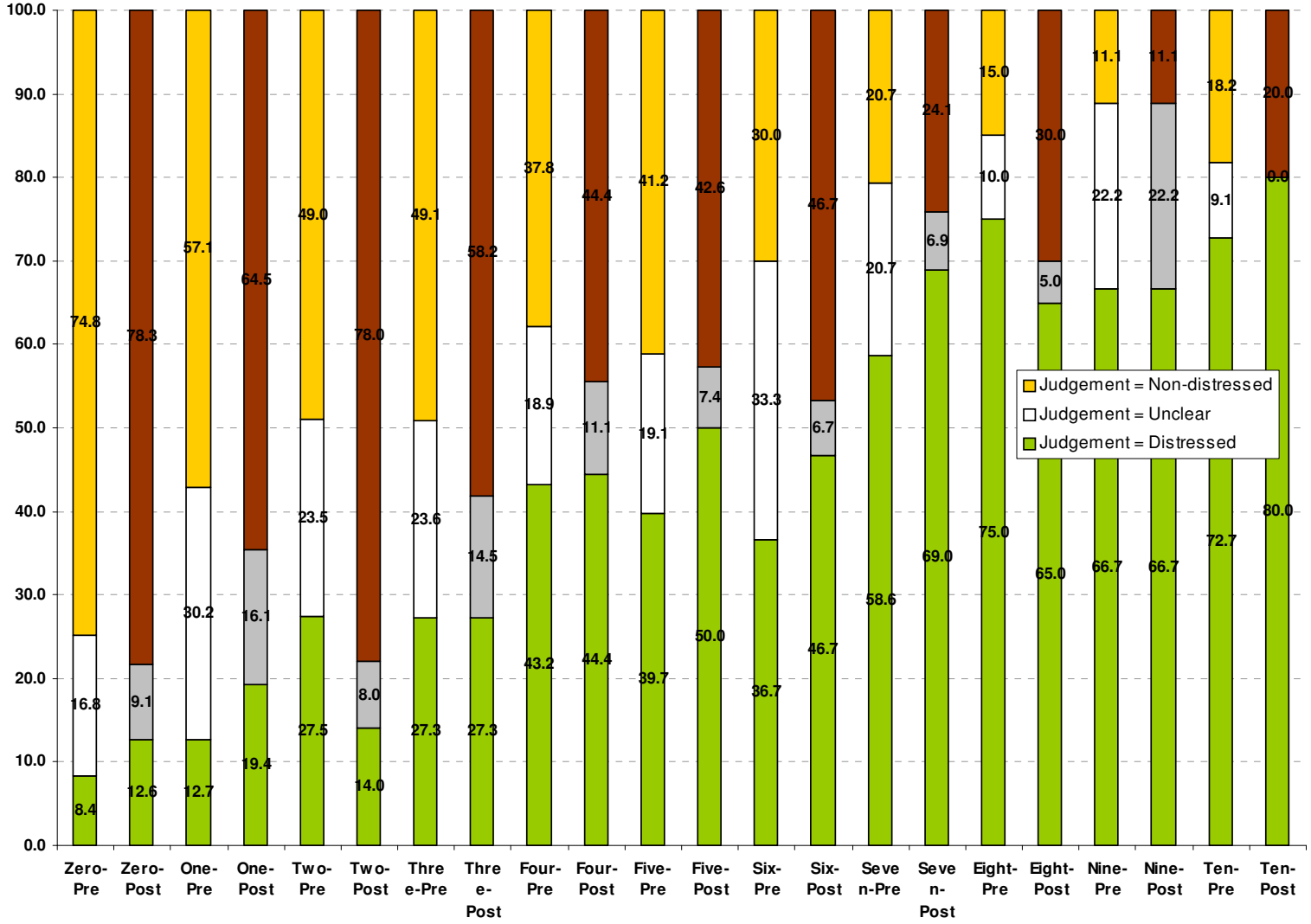


Figure 4.3.5 – Pre/Post Screen Recognition of Graded Emotional Distress according to DT scores from 0-10.

4.3.6 Discussion of Acceptability of Screening

A fundamental issue for a successful screening programme is long-term acceptability. That includes acceptability to both clinicians and patients Programmes appear to show enhanced acceptability when assisted by dedicated funded researchers but maintaining this in the clinical environment is extremely difficult. Indeed it is not certain whether systematic screening can actually be accomplished in busy clinical environments. In this study, acceptability to patients was not asked directly but may be inferred by the uptake of screening in actual practice. An attempt was made to record 851 patient-clinician interactions but of these 539 assessments (60.2%) were completed and returned. No information is available on patients who were screened but no feedback received (see appendix 2) and no further information is available on clinicians' opinions of patients not screened. It is unlikely that many patients were screened but results not returned because the feedback form was an integral part of the screener. This implies that screening was not acceptable or not possible for 40% of clinician-patient interactions in clinical practice.
Acceptability to clinicians was tested indirectly (by uptake) but also by questionnaire. Across all screening applications, clinicians felt screening was useful in 43.0% of assessments, but not useful in 35.9% and they were unsure or neutral in 21.1%. Clinicians felt that the simple paper and pencil screening programme was practical for routine use in 45.3% of applications, but impractical in 37.5% (on 17.2% of occasions clinicians expressed no opinion). Thus, clinicians often found the simple screening programme simple and useful but sometimes found it burdensome. This effect should not underestimated as perceived burden of screening is very likely to increase with time. Acceptability can be considered the rate limiting step behind the adoption of screening into clinical practice. Interestingly, chemotherapy nurses appeared to have more difficulty accommodating screening into busy initial assessments although both groups found screening challenging when patient turnover was high.

The causes of our initial non-completion rate of 40% are multifactorial. It includes patients who declined, patients who were unable to participate, clinicians who declined to apply screening and clinicians who failed to return the feedback scores. Several studies have reported that under optimal conditions and with the assistance of screening coordinators and research affiliates, it is possible to screen large numbers of patients with few refusals.[195 197 225] Here, screening was conducted by front-line busy clinicians who had no

additional time to conduct assessments. Anecdotally, they reported difficulty when screening generated detailed discussion of psychosocial complications in the normal clinic or radiotherapy setting. Clinicians may also struggle to interpret screening scores and complexities in scoring or interpretation lengthen screening and reduce acceptability.

Previous work asking clinicians to apply screening have found mixed acceptability. When measured, most researcher find that screening generally increase the length of consultations with clinicians (Pruyn et al, 2004 was an exception).[187] Our local Leicester showed that this largely occurs from two mechanisms. The first is the direct effect of spending time applying and interpreting the screener, and the second is the indirect effect of spending more time on psychosocial issues during the consultation. Most clinicians object to the first type of delay. Some but not all object to the second type of delay. The second type of delay is inherent in conducting a thorough patient centred consultation. Some previous data on acceptability was gathered by Carlson et al who was able to accrue 89% of all eligible patients in screening over an 18 month period. Shimizu et al similarly accrued 92% of cancer patients in a general oncology practice and Ito et al recruited 76% of eligible chemotherapy patients. In Leeds, UK doctors found QoL screening at least 'quite useful' in 43% of encounters but 'somewhat useful' in 28% and 'little use' in 30%.[189 209] Two past studies involving radiographers are particularly informative for the current work. In a German study Braeken et al found that reception by frontline radiotherapists to screening also mixed.[191] Similar results were reported by Dinkel et al in a non-randomized study of screening by frontline radiographers who also found mixed acceptability to clinicians.[268] Moreover, Dinkel et al found acceptability was a clear barrier to implementation success. Only 16% of patients said that their clinicians were aware of patients' screening results and only 7% recalled any discussion of screening results. Indeed only 36% felt their clinicians had an increased emotional awareness as a result of screening.

What options are there to increase the acceptability of screening? First, tools can be simplified and screening programmes streamlined. For widespread clinical use tools that take less than 2 minutes to apply are usually preferred, especially when trained mental health specialists are not available.[19 269] Popular ultra-short tools for screening such as the DT and ET are easy to understand and acceptable to most patients. Yet some patient groups may struggle with completion, particularly those with visual problems, severe fatigue

or cognitive impairment. Language and cultural barriers must also be considered. A brief alternative to visual-analogue methods is simple verbal query, although surprisingly no studies have been conducted to validate it against distress in cancer patients. The second method to increase acceptability is to increase the yield of meaningful screening, usually by targeting high-risk groups. Targeted screening of pre-selected high risk groups may include those troubling physical complications or those people whose family members ask for help. Targeted screening is theoretically more efficient than systematic screening because the prevalence of the condition under study is higher and hence fewer screens are needed for each identified case. In addition, psychosocial treatment is more successful when the baseline severity is high. [270] However targeted screening has the risk of immediately overlooking many occupying low risk but with unmet needs. A third method of increasing acceptability of screening is to remove responsibility from clinicians for application of the screener, and move the screening into the waiting room, reception desk or online. This is process used during computerized screening. Computerized screening can incorporate all the elements discussed here namely emotional distress, unmet needs and clinicians' response but requires funding to support and maintain the programme.[271]

In this study predictors of a favourable clinician perception of screening were analysed. On univariate logistic regression the following variables were significantly associated with a favourable staff perception of screening: clinicians rating the instrument as practical ($p<0.0001$), low clinician confidence ($p<0.001$) and high patient rated anxiety ($p =0.02$). This suggests that clinicians with high confidence do not particularly like systematic screening and prefer their own clinical judgement but clinicians with low confidence may see screening as an asset. Clinicians also favour screening when the screening process is seen as simple and easy to accommodate into clinical practice, but also one that is meaningful and associated with useful outcomes. In fact two outcome variables were linked with staff satisfaction with screening: talking with the patient about psychosocial issues ($p<0.0001$), and a change in clinical opinion ($p<0.0001$). Clinicians who liked screening were more likely to use it to help with clinical practice. In fact, clinicians who rated the programme as useful were twice as likely to change their clinical opinion following screening ($chi^2 = 15.9$, $p< 0.0001$) and (on multivariate analysis) clinicians with high satisfaction had improved detection of depression / anxiety ($p<0.0001$).

4.3.7 Discussion of Clinicians' Response to Local Screening Results

Once screening has been conducted, the clinicians response to a high, low or ambiguous score is a critical factor in determining whether patients benefit. This question addresses the quality of care that follows screening. In a more recent study involving 214 cancer patients in Florida there was no evidence of an action being taken in 42% of patients those with unmet psychosocial needs.[23] This question links the local Leicester study and the meta-analysis conducted in the second part of this thesis. As such the background literature and further implications are discussed in section 4.5 and 4.8 below.

Out of 518 patient consultations when emotional complications of cancer were assessed, a significant problem on one of the emotion thermometers (using a cut-off score of 4 or higher) was reported on 291 (56%) of occasions. Of these consultations generating high scores, clinicians helped on 137 occasions (47.1%). Interestingly, clinicians also helped 40 of 223 (17.9%) without a significant emotional problem. Of those where any action was taken, a referral to specialist service was made for 14.1% of those with any emotional concern. At face value this suggests front-line cancer clinicians are not responding adequately to a person who screens positive. There could be several explanations. The most obvious is that patients didn't warrant an intervention at that time. Yet we encouraged clinicians to report when "no action was necessary". This absence of response in about 52% of consultations cannot be fully explained by clinicians deciding clinically no action was necessary despite a high score (in other words interpreting the screening score as a false positive). Other possible predictors of clinicians' willingness to intervene were patients' own desire for help, the degree of emotional distress and also cancer worries specifically. Using Chi^2 there was a significant difference between offers of intervention in those who wanted a little help / no help vs those wanting definite help. Emotional distress was also influential but it was patient anxiety that best predicted clinicians' response (vs other emotional domains). However, on conditional logistic regression (forward) when desire for help and all emotional problems were entered, the predominant effect was patients' own desire for help. This suggests that the main influence on clinicians' action is in fact patients' own desire to be helped. Presumably clinicians are asking about patients desire for help and responding accordingly in many cases. However the match between patients' wish to be helped and clinicians' response is not perfect. The 2x3 table 3.1.9a shows that clinicians offer to help in 61% (37/61) of situations where there is both an emotional complication and strong desire for help but only 19% (13/69) where there is an

emotional complication but no patient desire for help. It is notable that clinicians fail to help in about 40% of occasions when there is an emotional complication and desire for help, this is discussed further below. It is also notable that clinicians "over-rule" patients on 20% of occasions when patients do not want help but clinicians respond in any case. In these cases the clinician intervention is likely to be simple supportive care. This shows that clinical judgement can, on occasions, disagree with patient self-perception. It is not clear however what is the outcome of such initially 'unwanted' interventions is.

Clinicians who had high satisfaction with the screening programme tended to have been those in receipt of training ($p<0.0001$). They also tended to talk more with the patient about psychosocial issues ($p<0.0001$) and have improved detection of psychological problems such as depression / anxiety ($p<0.0001$). On univariate chi squared analysis, clinicians who rated the programme as useful were twice as likely to change their clinical opinion following screening ($chi^2 = 15.9$, $p< 0.0001$). Previously, Braeken et al found that radiotherapists who considered their screening instrument used were more likely to discuss psychosocial complaints ($P =0.01$) and sexual problems ($p<0.01$) with their patients.[191] This creates something of a paradox for screening. Skilled interested individuals may not benefit as much from screening (or indeed training) because they may have accurate routine clinical judgement but if they do use screening then patients appear to benefit. Uninterested individuals are often those who do not use screening (and do not attend training) and they may have inferior clinical judgement. Of clinicians who do use screening, those that feel it is useful are likely to gain most benefits. This can be called the *screening paradox*: uninterested individuals will not use screening, interested individuals may not need to screen. In this study only a minority of clinicians attended training, therefore results mostly reflect relatively untrained frontline clinicians. For organizations, the lesson here is to involve clinicians in the design and implementation of screening, support them whilst screening and amend screening according to their feedback. Screening should be considered to be only one component of holistic psychosocial care. Clinicians need support not just in screening but in managing the detected complications. Support and training packages for common emotional complications are available and to some extent have been evaluated.[128 272 273 274 275 276]

4.3.8 Discussion of Patient's Desire for Psychosocial Help

As discussed above (4.3.7) patients' desire for help is influential in influencing clinicians' actions. What is the description of desire for help in the whole sample? 418 patients reported data on their desire for help on a linear scale (Help thermometer, 0-10). 51.9% did not want help at the time of assessment and 48.1% did (HelpT > 0). 77 (18.4%) patients wanted significant help at the current time (HelpT > 3).

Many variables appear to contribute to patients' desire for help. In an earlier study using the HADS, path analysis variables most associated with desire for help were: 1. distress, 2. anxiety and depression. However even collectively variables explained only 42% of variance in desire for help (see figure 4.3.8).[223]

4.4 Discussion of Recognition Screening Implementation Meta-analysis (Part II)

A meta-analysis of 29 screening studies involving a total of 15,176 cancer patients was conducted and completed focussing on two key quality of care outcomes: receipt of psychosocial care and receipt of psychosocial referral. Several methodological limitations were apparent in the meta-analysis. First although the total sample size was large, individually studies were of modest size and there were significant methodological differences between the studies and their results leading to high heterogeneity scores. A complicating limitation is that many studies did not adequately define usual care and hence the effectiveness of usual care varied considerably. For example, some services had pre-existing psychosocial oncology services, some relied upon referral to specialist mental health. A further limitation is that only relatively narrow outcomes could be combined across studies, with little data on PROMs and other important domains.

From six observational studies, the proportion of cancer patients who received psychosocial help following a positive screen was 30.0% (95% CI = 19.6% to 41.3%). It is not clear if this is markedly different from the rates of receipt of care in routine clinical practice without screening. For example, a study of breast cancer patients seen across 101 hospitals in Germany found 32.5% of patients received care from a psycho-oncology service during 2005.[277] In an audit of medical records of 1660 patients seen in Florida cancer centres, Jacobsen et al (2010) found that only 52% contained evidence of an assessment of psychosocial wellbeing.[23] Yet it is clear from this meta-analysis that patients with a positive screen certainly receive more psychosocial help than those who screen negative, although this difference (22.2%) was less than expected. Note the same results were found in our local data (see 3.1.9). Similar results were found in the meta-

analysis of psychosocial referrals. Across all qualifying studies, the proportion of cancer patients who received a psychosocial referral following a positive distress screen was 26.9% (95% CI = 16.7% to 38.5%). From one perspective this means that screening for distress and related disorders is unlikely to over-burden specialist services, but then only a minority of screen positive patients appear to be offered help. It is important to acknowledge that the provision of psychosocial help and offer of referral were overlapping but non-identical datasets. Of the papers reviewed here, only Van Scheppingen 2012[233] looked at different types of help. Further, it is possible that observational screening studies tend to underestimate psychosocial help by not taking into account informal supportive help given by frontline cancer clinicians at the point of contact with patients.

Perhaps the key finding from this meta-analysis concerns the effect of screening upon quality of care in high quality implementation studies. Nine implementation studies measured receipt of psychosocial referral using either a sequential cohort design (n=6 non-randomized trials) or in clinicians/patients randomized to screen or no screen (n=3 randomized trials). From these, although the relative risk of receiving a psychosocial referral was about three fold in cancer patients who were screened vs not screened, in absolute terms screening with feedback only enhanced referrals by about 12% over usual care. Thus, screening for distress does appear to significantly improve the proportion of patients who receive a psychosocial referral but is limited by a very low base rate of referrals.

Given the current controversy regarding routine screening, how can these findings be interpreted? Given the evidence available to date, screening appears to significantly improve quality of care in specific areas but the magnitude of this effect is disappointing and limited by the barriers to care demonstrated in the observational studies. Only 30% of patients who screen positive for distress receive recorded timely and appropriate care. Thus the benefit of screening is effectively capped by the rate limiting step of poor aftercare. A meta-regression of predictors of screening success was unable to identify any strong predictors of success but this may have been limited by overall sample size.

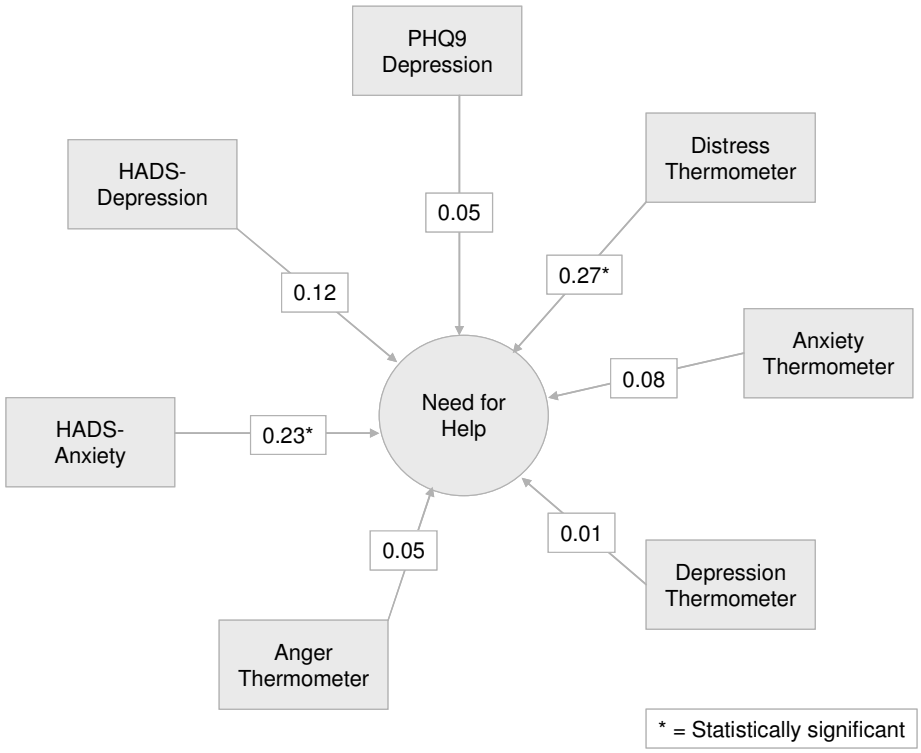


Figure 4.3.8 Predictors of desire for help from Baker-Glenn et al (2011)

4.5 Lessons for Distress Screening Implementation

As discussed in section 1.8 and elsewhere there have been a large number of psychosocial screening studies in cancer settings which can be divided by target condition into distress, depression, unmet needs and (not considered here) quality of life.[63 246 278] At the current time there are at least twelve randomized trials that have examined screening for psychological problems (or wellbeing) divided in 6 concerning emotional complications and 6 involving QoL and 1 that studied both domains.[185 191 181 182 183 189 188 192 190 225 226 224] A further nine non-randomized studies tested changes in psychological problems / QoL before and after screening without randomization (including this one).[184 193 194 195 197 196 193 227 228] Nine studies included unmet needs but only four studies focussed on unmet needs as a screening test (rather than target of improvement).[192 196 198 200] The remainder utilized unmet needs only as a screening target.

There have been several valuable lessons from previous work. Maunsell et al conducted an early screening RCT involving 251 breast cancer patients.[182] Both groups received basic psychosocial care and follow-up telephone interviews 3 and 12 months later, but the intervention group also received telephone screening using the GHQ20 every 28 days (a total of 12 calls). Patients scoring ≥5 on the GHQ were referred to a social worker. Results showed that distress decreased over time in both groups with little to differentiate between groups and no additional benefit of screening. The lesson here was that if the treatment-as-usual arm does particularly well, then screening has little to offer. Velikova et al (2004) studied 28 oncologists treating 286 cancer patients, who were randomly assigned to an intervention group who underwent screening along with feedback of results to physicians, a screen-only group who completed questionnaires without feedback and a control group with no screening at all.[189 209] The questionnaires used were the EORTC QLQ-C30 and a touch-screen version of HADS. A positive effect on emotional well-being was seen in the intervention vs control group but there was little to differentiate intervention and the screening-only no feedback group. Carlson et al. (2010) examined the effect of screening on the level of psychological distress in lung and breast cancer patients randomized to minimal screening (again, no feedback), full screening (with feedback) or screening with optional triage and referral.[181] This was one of the largest studies to date with over 1000 patients, 365 in minimal screen, 391 in full screen and 378 in screening with triage. Results differed by cancer type. In lung cancer patients receiving full triage continued high distress at follow-up was reduced by 20% compared to other groups. In breast cancer the full screening and triage groups both had

lower distress at follow-up than minimal screening. The lesson here are that screening with feedback is unlikely to be identical to screening without feedback. Similarly screening with follow-up is different to screening alone. In general the process of screening tends to help communication but feedback of clear results has potential to influence clinicians' decisions and follow-up is probably what most influences patient management. Several new studies have now re-looked at screening with the simple DT with or without additional QoL ratings. Recently Hollingworth et al (2012) used the DT and problem list to rate distress and discuss its sources as applied by a trained radiographer/nurse and compared this with treatment-as-usual.[192] Psychological distress (POMS-SF) and disease specific quality of life (EORTC-QLQ C30) were measured at baseline, 1 and 6 months. 220 patients were randomised with 107/112 in the DT arm. Both groups improved by 6 months and there was no evidence that patients randomised to the screening condition had better outcomes.

Summarizing the rather complex results so far, across all implementation studies published to date, do these modest but statistically significant effects of screening on quality of care translate into meaningful clinical improvements to patient wellbeing? This is a question that has been addressed elsewhere.[279] There have been 13 RCTs and 10 non-randomized trials of screening for distress/QoL that measured patient wellbeing. Of the RCTs, 5 of 13 reported added benefits on patient wellbeing compared with unscreened patients. [183 186 188 189 226] However, only 2 of 10 non-randomized sequential cohort screening studies reported added benefits on patient wellbeing.[193 227] Benefits appeared to be more significant in those depressed at baseline,[183] those followed frequently[188] or given linked input for unmet needs[226] and possibly in lung cancer.[181 225] Looking at the design of these implementation studies, six were randomized application of the screening tool itself whilst the remainder randomized feedback of the results. Overall, four studies and this local Leicester study reported screening helped with patient-clinician communication.[189 224 227 228] Four studies noted a benefit on referral rates or referral delay.[194 195 196 197] However, even with screening, referral rates did not exceed 25% thereby allaying concerns that screening would lead to an excess of referrals to specialist services.

Regarding overall effect on wellbeing the results from this meta-analysis we suggest that screening without feedback is unlikely to be effective.[183 225 225] Screening with feedback may be successful or unsuccessful but is almost certainly dependant of what follows screening. [184 185 224] Screening with mandatory follow-up is

likely to be beneficial compared with no screening (and treatment as usual). Indeed, Kornblith et al (2006) showed that screening with monthly telephone follow-up significantly reduced distress, anxiety and depression and enhanced referrals compared with screening without follow-up.[207] Several other trials have compared screening allied with a randomized treatment/follow-up to screening with treatment as usual. These "enhanced screening" studies have generally shown beneficial PROMs.[201 202 204 205 206 207] It is apparent that screening with mandatory follow-up (in high scorers) and treatment ("enhanced screening") is also likely to have added value compared with screening and treatment as usual.

4.6 Addressing Criticisms of Screening

Critics of screening usually voice several important concerns that are worth considering here. The first caution is that screening should apply only to those not already currently recognized as depressed/distressed and in receipt of treatment.[23] This is a fair comment but this number of previously recognized patients in current need of treatment is probably lower than expected, in part because psychosocial needs of patients are often overlooked routinely. Braeken et al (2011) found that of those who received a referral in their screening RCT only 22% of referred screened patients were previously identified, and 29% of non-screened referred patients were also previously identified. In other words the yield of screening or looking without screening was modestly reduced in both screened and non-screened arms by taking into account previous care. The second caution from critics is that those who screen positive often don't accept the treatment that is offered.23 This is a very real barrier to receipt of care. Carlson et al (2012) found that over 12 months follow up after screening only 20% received services in the screen + triage arm compared with 15% in the screen alone arm. This criticism is discussed in 4.6 but definitely should be considered. In fact screening without clarifying who wants to receive an intervention is probably not a very efficient strategy. The third caution is that the same treatment and care resources should be available to both groups (screened and not-screened) to effectively isolate the effect of screening. In fact, this has been extensively studied in the so called feedback implementation studies which compared screening with vs without feedback of results. In both arms care is typically treatment-as-usual. From 8 feedback vs no-feedback implementation studies, 6 have found superiority of screening in a primary or secondary outcomes, and 2 have found no effect. However there is more subtly to this point than initially

appears. In particularly is screening the best method with which to decide upon the allocation of resources? Further, should resources be withheld from screen negative patients who still desire psychosocial help? The fourth caution from some critics is that screening "as a routine" may be inefficient given that many people have very mild complications. This caution is difficult to confirm or refute as it rests on whether mildly distressed patients are correctly identified, and also worth identifying. Most patients have mild to moderate distress, not severe distress. At low levels there are more sufferers but they are harder to correctly identify and they respond to relatively simple interventions. [280 281] At more severe levels of distress/depression sufferers are easier to identify but they represent a rarefied group. An alternative to systematic routine screening is targeted screening of pre-selected high risk groups, such as those with troubling physical complication or those people whose family members ask for help. Targeted screening is theoretically more efficient than systematic screening because fewer screens are needed to identify each case and psychosocial treatment is more successful when the baseline severity is high. However targeted screening has the risk of immediately overlooking many individuals with unmet needs despite apparent low risk. Both screening and clinical judgment are more accurate when focusing on more severe cases. The fifth caution is that screening can be resource intensive and can be a burden to staff and patients. As shown here, this is a valid concern as screening is indeed typically perceived as a burden to frontline cancer clinicians. The time taken for completion, scoring and interpretation varies but is rarely completely burden free.[167] Yet the key question is whether the burden of screening is worth the effort in terms of clinical benefits. Any intervention pharmacological or psychological is a burden compared with nothing at all but the burden is worthwhile if the intervention brings about some longer term gains. Thus this caution is partially upheld, whilst acceptability of screening is generally good, when conducted by front line clinicians it is often perceived as burdensome. This is somewhat alleviated when screening is brief, has tangible benefits, associated with resources and staff support. Also use of waiting room screening and computerized touch screen terminals can be helpful. Finally some have queried whether screening with mandatory follow-up / targeted resources would be superior to non-screen diagnosis as usual but with mandatory follow-up / equivalent resources. This requires further study but may depend on the nature of the resources themselves. For example, guidelines alone are probably not effective,[282 283] communication skills training probably benefits clinicians but not patients.[284 285]

4.7 Methodological strengths and limitations

This is one of the first studies to systematically collect front line cancer clinicians' opinions on the value of routine screening for distress. This is one of the first studies to compare chemotherapy nurses with treatment radiographers. This is the first study to systematically collect multi-domains of emotional distress, along with desire for help, clinician response and unmet needs/concerns. This is the first study to analyze recognition of anger in a cancer setting and one of very few to do the same for anxiety. This is one of the largest studies of desire for help and one of the largest studies of clinician response. Another strength of the study is that we collected data prospectively based on the actual implementation of a rapid paper and pencil based screening programme. Paper and pencil based testing was favored over computerized methods mainly because of lack of resources. Data were gathered per clinician-patients interaction rather than by hypothetical survey. Thus an individual clinician could report satisfaction with screening following some consultations but dissatisfaction in others. This may be stronger methodologically than grouping clinicians' feedback into one category. Regarding the meta-analysis, this is the first meta-analysis to examine the merits of screening for distress in a cancer setting.

There are several limitations to this primary local Leicester study. First, no validated structured or semi-structured interview was conducted for validation purposes. This was intentional because this is not a validation study and such methods are typically unacceptable to front line clinicians. Second, we relied upon the clinicians own reports and patient self-report for all data. This could introduce errors, although medical notes, and databases are also subject to errors. Third, the design of the screening study was not randomized. Clinicians were asked to give their clinical judgment before screening and shortly after screening. This method has been called a sequential cohort design. An RCT would have the advantage of randomized uncontrolled and unknown factors. In the sequential cohort study, the clinicians effectively acted as their own comparator. That said, the method is reliant upon accurate self-report by clinicians. It was also reliant upon returns of the screening data (see appendix 2). As mentioned above clinical staff returned information on 539 assessments (60.2%) involving 379 patients. There was no way to compare the returned sample with the non-returned sample. Fourth, the screening method (DT/ET) was previously validated in our centre but many other alternative choices are available (see 1.7). All tools are a

compromise of accuracy and acceptability and it is doubtful that choice of tool itself was a major limiting factor. Indeed the ultra-short method was chosen at the request of front-line staff in a pilot study of 86 consultations conducted by community cancer nurses (data not shown). Fifth, we may have underestimated clinicians action following screening (provision of psychosocial help) by not taking into account informal supportive care. This level of care was not reported back on the feedback of screening (appendix 2) to a satisfactory degree. Sixth, the study was unfunded which limited any screener that could have been used away from high resource options. However a simple screener used by cancer clinicians arguably gives a better insight into the real-world feasibility of screening for many centres that lack availability of dedicated screening researchers or administrators. Seventh, we did not collect patient opinions on the acceptability of screening, future studies may be able to shed more light on this issue. Eighth, a further limitation is that patients were not followed-up to ascertain which improved as a result of screening. In short true patient reported outcomes regarding wellbeing were not collected. Instead satisfaction, detection data and process measures were collected. Ninth, the sample was not entirely representative of unselected cancer patients in Leicester, specifically there was a preponderance of female patients (75%) in an early stage. Additionally, we had limited data on cultural background. The somewhat atypical sample was reflective of patients willing and able to participate in distress screening.

4.8 Recommendations for the future

With increases in the incidence and prevalence of cancer, psychosocial complications are more important than ever. Yet the psychological care of cancer patient remains suboptimal in recognition, diagnosis, treatment and follow-up. This was recognized in the 2007 report from the Institute of Medicine "Cancer care for the whole patient: meeting psychosocial health needs." [31] Screening is one possible way to improve quality of care, but it cannot work in isolation. Further, the evaluation of evidence regarding screening for distress should be no different to the evaluation of any other screening target such as screening for prostate cancer or cervical cancer. Screening has been suggested to improve patient outcomes in depression presenting in primary care, but positive benefits have been disputed.[286 288] The same argument for and against screening has played out in cardiovascular settings.[287] Fortunately, we have the opportunity to learn lessons from the extensive literature screening for depression in primary care and other medical

areas and avoid making the same mistakes again. [288] One lesson is that it appears that the key barriers that prevent screening being effective include the same barriers that prevent the delivery of high quality psychosocial care in general, namely, availability of a range of suitable treatments, availability of suitably prepared (skilled, trained, motivated) front line cancer clinicians as well as the availability of psychologists, psychiatrists and other experts in psychosocial care. Barriers can be further divided into clinician and organizational barriers. At the clinician level the main barriers to screening are mainly lack of time, lack of training and low personal skills or confidence.[19 36 271] At the organizational level, barriers include lack of administrative and clinical resources, lack of dedicated funding and the absence of a screening strategy.[33] Previous screening specific barriers namely, availability of suitable tools and uncertainty about the screening target have largely been addressed. In my opinion an appropriate screening tool must be short enough to be acceptable to clinicians (if involved) and patients and caregivers (if involved) but as accurate as possible. Also the target should be multi-domain and broad covering the wide ranging causes of distress, not purely clinical depression or even clinical anxiety, worthy though these targets are. At the same time screening for quality of life alone and indeed screening for distress alone may be too broad unless an effort is made also to identify unmet needs and/or clarify patients' desire for help. Innovative projects show that multi-domain screening is possible in clinical settings.[289] Overall screening success may be determined by two key factors: acceptability of screening programme as a whole and availability of appropriate resources for aftercare. Acceptability applies to the screening programme and to linked treatment options. Availability of appropriate resources applies to patients who screen positive, but possibly those who screen negative but raise clinicians' concerns and/or desire help by self-report.

When evaluating screening for distress, the ideal comparison is with treatment as usual. Yet treatment as usual is by no means uniform. Treatment as usual may be high quality or low quality, high resource or low resource. It is very likely that routine screening would fail to show benefits when compared to a cohort subject to high quality non-screened diagnoses in a centre with excellent choice of patient friendly resources. However, this scenario is not common and almost all major centres show considerable variability in psychosocial care.[23] The introduction of screening reduces that variability at the point of diagnosis, but if treatment is not offered then screening is fruitless. In short there is no point identifying a condition that cannot be ameliorated in some way as this raises unnecessary alarm and introduces stigma for little or no tangible benefit. For this reason the challenge for organizations and cancer centres who are considering

screening for distress is to ensure effective treatment follows accurate diagnosis. When we evaluate screening studies, we are most interested in added value, that is, the additional merit of screening that would not otherwise be achieved by routine clinical judgement. Approximately 20-30% of people with unmet psychosocial needs will have already been recognized and treated at any one point in time but this leaves 70-80% who have not.[38]

Previous work has largely focussed on the development and diagnostic validity testing of tools for measuring cancer-related distress. This has been partly successful in that many brief, broad screening tools have been subject to validation. Yet it is also partly unsuccessful in that no tool is sufficiently broad to encompass all emotional problems and unmet needs whilst at the same time sufficiently accurate to point towards clinical disorders without the need for an expert opinion. It is worth reflecting that this is similar to the process whereby expert clinicians learn to apply skills after years of training and does not rest on one question but many questions in a complex algorithm. It is unlikely one simple tool will ever be a proxy of expert judgement. The best alternative is still relatively unexplored, that is computer adaptive testing. Computer adaptive testing aims to follow an algorithm in order to elicit the most valuable information with the least burden. An example is the Patient-Reported Outcomes Measurement Information System (PROMIS), a large scale US National Institutes of Health initiative. PROMIS based instruments are available in as item banks for use in computer-adaptive testing.[290 291] An attempt to generate a valid item bank for emotional distress has been reported.[292] The PROMIS cooperative group found an initial bank of 1,404 items from 305 instruments. After qualitative item analysis final banks of 28, 29, and 29 items were calibrated for depression, anxiety, and anger were tested in a calibration sample included nearly 15,000 respondents. respectively, using item response theory. Test information curves showed that the PROMIS item banks provided more information than conventional measures in a range of severity from approximately −1 to +3 standard deviations (with higher scores indicating greater distress). Short forms consisting of seven to eight items provided information comparable to legacy measures containing more items. Yet there is an alternative; before computer adaptive testing becomes widely available, simple questionnaire based adaptive testing is possible in the form of screening algorithms.

Despite strong recommendations of many professional societies and accreditation agencies to begin screening, valid cautions against premature adoption of screening exist. Many of these criticisms have been

addressed (see 4.6) whilst others remain under study. Previously, it was reasonable to assert that there was a lack of evidence regarding distress screening but with many implementation studies this position is no longer tenable with one exception. The exception being screening implementation trials in advanced cancer and palliative settings. Only three implementation studies have examined screening patients with advanced cancer with mixed results; namely Sarna (1998),[188] Rosenbloom et al (2007),[185] Detmar et al (2002).[224] Whilst the evidence base is mixed, lessons have been learned from negative studies which failed to find any positive effect. The main lesson is that screening is insufficient on its own, without feedback of results, without follow-up care and without appropriate support and treatment for the identified condition/concerns.

All health care providers who are considering screening must also consider barriers to psychosocial care and ideally audit the success of screening locally and indeed audit quality of care overall. At the clinician level, the main barriers to implementation of screening are time, training and confidence. Awareness of the importance of psychosocial complications is also important. At the organizational level, the main barrier to successful implementation is availability of appropriate aftercare. Hewitt and Rowland (2002) demonstrated that if all cancer survivors with mental health problems who needed but could not access mental health services due to cost had received such care, mental health service use would have increased from 7.2% to 11.7%.[38] Organizations must therefore invest in valuable psychological, psychiatric, nursing, rehabilitation and social services that assist cancer patients psychosocial wellbeing following a diagnosis or recurrence, regardless of their stage of disease.

5.0 Appendices

5.0 Appendices

Appendix 1 – Clinician Screener (including Emotion thermometers)

UHL Chemotherapy Emotion Quick Screen

1. PATIENT DETAILS

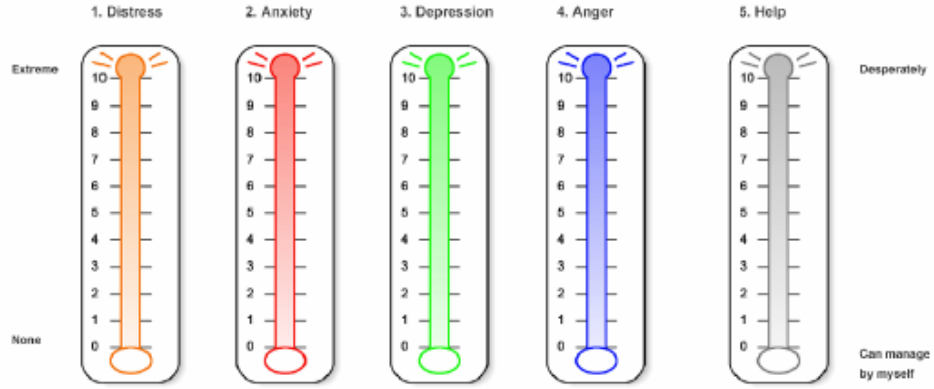
Name (or addressograph) *Addressograph*

Ward/Dept _____

2. EMOTION THERMOMETERS

Instructions

In the first four columns, please mark the number (0-10) that best describes how much emotional upset you have been experiencing in the past week including today. In the final column please indicate how much you need help for these concerns.



3. CONCERNS CHECKLIST

Instructions

Please ask the patient to tick any of the following that has been a cause of distress over the past week, including today. Also ask for the most pressing concerns.

Practical Concerns	Personal Concerns	Emotional Concerns	Physical Concerns
❑ Family Issues	❑ Appearance	❑ Anger / irritability	❑ Breathing
❑ Issues with Health Staff	❑ Self-care	❑ Nervousness / anxiety	❑ Eating / weight
❑ Finances / Bills	❑ Loss of Independence	❑ Depression / hopelessness	❑ Toileting
❑ Lack of Information	❑ Loss or Role	❑ Worry about cancer	❑ Fatigue/Exhaustion
❑ Problems with medication	❑ Sexual/Intimacy Issues	❑ Odd experiences	❑ Sleep problems
	❑ Spiritual issues	❑ Memory / concentration	❑ Nausea
❑ Others		❑ Self-esteem / confidence	❑ Headaches
_____			❑ Pain
_____			
	(1st) Most Pressing _____	**(2nd) Most Pressing** _____	**(3rd) Most Pressing** _____

4. ACTION TAKEN FOR EACH CONCERN

❑ No action	❑ No action	❑ No action
❑ Declined Help	❑ Declined Help	❑ Declined Help
❑ Help Given	❑ Help Given	❑ Help Given
❑ Referral	❑ Referral	❑ Referral
❑ Other (state)	❑ Other (state)	❑ Other (state)

Clinician _____ **Designation** _____ **Specialty** _____ **Date**_____

Please file with additional information in notes & return the feedback form overleaf

Appendix 2 – Clinician Screener feedback form

UHL Radiotherapy Emotion Quick Screen — Feedback Form

INSTRUCTIONS

We would be grateful if you can fill in this form after ***each application (for each patient)*** of the Quick Screen, so that we can evaluate its success. Please return a copy for all patients not just those with high scores. For queries ring 0116 225 6218

PATIENT RESULTS

Ethnicity Patient Age _____ M / F Cancer Type (if known) _____

White ☐ Indian / Asian ☐ Adjuvant ☐ Neo-adj ☐ Curative ☐ Palliative ☐
Afro-Caribbean ☐ Unknown / Other ☐ _____

Score on the Emotion Thermometers Distress ☐ Anxiety ☐ Depression ☐ Anger ☐

Score on the Impact Thermometers Help ☐ Duration ☐ Burden ☐

What were the three most pressing concerns? (1)_____ (2)_____ (3)_____ OR **None** ☐

What was your clinical impression **BEFORE** using this screening tool? (tick any that apply)

Distressed ☐ Depressed ☐ Anxious ☐ Angry ☐ Unsure ☐ Well ☐ Other _____

What is your clinical impression now **AFTER** reading the screening scores above? (tick any that apply)

Distressed ☐ Depressed ☐ Anxious ☐ Angry ☐ Unsure ☐ Well ☐ Other _____

PLEASE GIVE US YOUR FEEDBACK

Did the Quick Screen tool.....

(1) Facilitate communication on this occasion?	Yes ☐	No ☐	Not sure ☐
(2) Help elicit patient concerns?	Yes ☐	No ☐	Not sure ☐
(3) Improve your ability to recognize emotional problems?	Yes ☐	No ☐	Not sure ☐
(4) Improve your ability to deal with patient concerns?	Yes ☐	No ☐	Not sure ☐
(5) Take too long in this setting?	Yes ☐	No ☐	Not sure ☐

OVERALL

(6) Was the screening tool useful on this occasion?	Yes ☐	No ☐	Not sure ☐

ACTION TAKEN FOR EACH CONERN

(1)	(2)	(3)	(4) N/A
❑ No action taken	❑ No action taken	❑ No action taken	
❑ No action needed	❑ No action needed	❑ No action needed	
❑ Declined Help	❑ Declined Help	❑ Declined Help	❑ There were no concerns
❑ Help Given	❑ Help Given	❑ Help Given	
❑ Referral	❑ Referral	❑ Referral	
❑ Other (state)	❑ Other (state)	❑ Other (state)	

Clinician Name _____ **Specialty** Chemo Onc Surg Haem Radiother

Date _____ **Please return to coordinator (FAO Alex Mitchell)**

Appendix 3 – Approval for Study

University of Leicester

Professor R P Symonds
Professor of Clinical Oncology
Tel 0116 258 6294
Fax 0116 258 7599
Email rps8@le.ac.uk

College of Medicine,
Biological Sciences and Psychology
Department of Cancer Studies
and Molecular Medicine
2nd Floor · Osborne Building
Leicester Royal Infirmary
Leicester LE1 5WW
UK

Head of Department
Professor W P Steward

T +44 (0)116 258 7597
F +44 (0)116 258 7599
E wps1@le.ac.uk

15 April 2013

Dr Alex Mitchell
Consultant Liaison Psychiatrist
Department of Liaison Psychiatry
Daisy Peak Building
Towers Hospital
Leicester
LE5 0TD

Dear Dr Mitchell

MD Thesis – Rapid Screening for Depression and Emotional Distress in Routine Cancer Care

This note is to confirm that your audit of the screening programme for distress/depression had been approved as an audit of clinical practice. Following a peer review visit we were requested to investigate screening for distress, especially in the chemotherapy suite. Your study was discussed and approved by the radiotherapy manager (Mrs Ghislaine Boyd) and the nurse in charge of the chemotherapy suite (Mrs Lorraine Granger).

I also presented your audit at a consultant's meeting and the consultants in the oncology department approved the study.

Yours sincerely

RPS

Professor R P Symonds TD, MD, FRCP, FRCR
Professor of Clinical Oncology
University of Leicester
Honorary Consultant Oncologist
University Hospitals of Leicester NHS Trust

Appendix 4 – Copies of Related Published Papers (full text on request)

Published Ahead of Print on March 12, 2012 as 10.1200/JCO.2011.39.5509
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JOURNAL OF CLINICAL ONCOLOGY

REVIEW ARTICLE

Screening for Distress and Unmet Needs in Patients With Cancer: Review and Recommendations

Linda E. Carlson, Amy Waller, and Alex J. Mitchell

Linda E. Carlson, Tom Baker Cancer Centre; Linda E. Carlson and Amy Waller, University of Calgary, Calgary, Alberta, Canada; and Alex J. Mitchell, Leicestershire Partnership Trust and University of Leicester, Leicester, United Kingdom.

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Corresponding author: Linda E. Carlson, PhD, Department of Psychosocial Resources, Holy Cross Site, 2202 2nd St SW, Calgary, Alberta, Canada T2S 3C1; e-mail: l.carlson@ucalgary.ca.

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A B S T R A C T

Purpose
This review summarizes the need for and process of screening for distress and assessing unmet needs of patients with cancer as well as the possible benefits of implementing screening.

Methods
Three areas of the relevant literature were reviewed and summarized using structured literature searches: psychometric properties of commonly used distress screening tools, psychometric properties of relevant unmet needs assessment tools, and implementation of distress screening programs that assessed patient-reported outcomes (PROs).

Results
Distress and unmet needs are common problems in cancer settings, and programs that routinely screen for and treat distress are feasible, particularly when staff are supported and links with specialist psychosocial services exist. Many distress screening and unmet need tools have been subject to preliminary validation, but few have been compared head to head in independent centers and in different stages of cancer. Research investigating the overall effectiveness of screening for distress in terms of improved recognition and treatment of distress and associated problems is not yet conclusive, but screening seems to improve communication between patients and clinicians and may enhance psychosocial referrals. Direct effects on quality of life are uncertain, but screening may help improve discussion of quality-of-life issues.

Conclusion
Involving all stakeholders and frontline clinicians when planning screening for distress programs is recommended. Training frontline staff to deliver screening programs is crucial, and continuing to rigorously evaluate outcomes, including PROs, process of care, referrals, and economic costs and benefits is essential.

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WHAT IS SCREENING FOR DISTRESS?

The National Comprehensive Cancer Network Distress Management Guidelines Panel defines distress as "a multifactoral unpleasant emotional experience of a psychological (cognitive, behavioral, emotional), social, and/or spiritual nature that may interfere with the ability to cope with cancer, its physical symptoms and its treatment. Distress extends along a continuum, ranging from common normal feelings of vulnerability, sadness, and fears, to problems that can become disabling such as depression, anxiety, panic, social isolation and spiritual crisis."[1(p6)] In this framework, distress related to cancer diagnosis and treatment is explicitly tied to a number of common practical, physical, and psychologic problems. Elevated levels of distress have been linked with reduced health-related quality of life (QoL),[2] poor satisfaction with medical care,[3] and possibly reduced survival,[4,5] although this mortality effect may be confined to later stages.[6]

Distress is not a precise clinical term that appears in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, which is used to assign formal psychiatric diagnoses, but it is part of the clinical significance criterion that is a qualifier for several mood disorders, including major depression and adjustment disorder. One reason for its adoption in cancer care is that the term distress is often more useful for cancer clinicians than psychiatric terms such as anxiety or depression. It is easily understood by the lay person and does not carry the stigma often associated with diagnostic labels and terms such as psychiatric, psychosocial, and emotional problems. It is usually well understood by non–mental-health clinicians, facilitating quick assessment with simple verbal enquiry or patient self-report.

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6.0 Bibliography

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Original Article

How Feasible Is Implementation of Distress Screening by Cancer Clinicians in Routine Clinical Care?

Alex J. Mitchell, MD[1]; Karen Lord, RGN[2]; Jo Slattery, DCR(T)[3]; Lorraine Grainger, BSc[2]; and Paul Symonds, MD[1]

BACKGROUND: There is considerable uncertainty regarding the acceptability of routine distress screening. **METHODS:** In an unfunded implementation study, the authors asked 50 clinicians (chemotherapy nurses and treatment radiographers/radiation technologists) to implement a screening program for distress as part of routine care and to record their feedback after each clinical encounter. In total, 379 patients were screened using a simple paper-and-pencil versions of distress thermometer and the emotion thermometer (ET). **RESULTS:** Across all screening applications, clinicians believed that screening was useful during 43% of assessments and was not useful during 35.9% of assessments, and they were unsure or neutral in 21.1% of assessments. The application of the screening program assisted staff in changing their clinical opinion after 41.9% of assessments, and clinicians believed that the screening program helped with communication in >50% of assessments. However, 37.5% believed that screening was impractical for routine use, and more chemotherapy nurses than radiographers rated the screening program as "not useful." On multivariate analysis, 3 variables were associated with high staff satisfaction with screening, namely, receipt of prior training, talking with the patient about psychosocial issues, and improved detection of psychological problems. A favorable perception of screening also was linked to a change in clinical opinion. **CONCLUSIONS:** Opinions of cancer clinicians regarding routine distress screening were mixed: Approximately 33% considered screening not useful/impractical, whereas >50%n believed promoted good communication and/or helped with recognition. Clinicians who were more positive about screening gained greater benefits from screening in terms of communication and recognition. ***Cancer* 2012;000:000–000.** © *2012 American Cancer Society.*

KEYWORDS: distress, depression, screening, satisfaction, implementation, cancer, diagnosis.

INTRODUCTION

Distress is a common complication of cancer, occurring in approximately 4 in 10 cancer patients who undergo cross-sectional assessment.[1-3] Depression with or without adjustment disorder occurs in approximately 3 of 10 patients.[4] Distress, depression, and anxiety are important not just for mental health professionals but also for cancer clinicians. The presence of distress is linked with reduced health-related quality of life,[5] poor satisfaction with medical care,[6] and possibly reduced survival.[7] Although distress is poorly operationalized, a working definition has been offered by the National Comprehensive Cancer Network (NCCN).[8] Distress should be considered a treatable complication of cancer that can present at any stage in the cancer pathway.[9] Previously, several groups reported that the ability of cancer clinicians to detect patient-rated distress is modest to low when unaided.[9-13] Indeed, only a minority of clinicians ask about emotional problems systematically, many preferring to rely on patients mentioning a problem first.[14] Less than 15% use a screening instrument, and most prefer their own clinical judgement.[14,15] Observed interview studies confirm that emotional issues are discussed in approximately 15% to 40% of consultations.[16-18] It is noteworthy that patients, not clinicians, initiate these discussions in most instances.[18,19] The main barriers to a thorough psychosocial assessment appear to be perceived lack of time, lack of training and low personal skills or confidence about diagnosis and availability of mental health services,[14,20] and, in some cases, over confidence about personal skills.[21,22]

Given this context, several national guidelines recommend screening to enhance the ability of clinicians to detect emotional problems.[23-25] Provisional evidence appears to provide some support for screening programmes regarding added value to clinicians.[26-28] Yet, in clinical practice, the uptake of screening often is suboptimal, and this can be perceived as a marker for difficulties patients and clinicians have with any particular screening approach.[29-31] The success of screening will be limited if uptake is insufficient. To date, randomized trials of screening have provided only mixed support for improved recognition of patients' emotional problems, and data on long-term patient reported benefits are

Corresponding author: Alex J. Mitchell, MD, Department of Psycho-oncology, Towers Hospital, Leicestershire Partnership NHS Trust, Leicester LE50TD; Fax: (011) 62956673; ajm80@le.ac.uk

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[1]Department of Cancer Studies and Molecular Medicine, University of Leicester, Leicester, United Kingdom; [2]Chemotherapy Department, University Hospitals of Leicester National Health Service Trust, Leicester, United Kingdom; [3]Radiotherapy Department, University Hospitals of Leicester National Health Service Trust, Leicester, United Kingdom

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lacking. In contrast, a positive impact on communication between patients and their medical teams has been observed.[31-33] Against this, the potential hazards of screening have recently been acknowledged.[34] The main issues are that it may be inappropriate to reveal unmet needs without a clear therapeutic strategy, there is a potential issue of making a diagnosis where none exists (false-positive), and there also is a question of whether frontline cancer clinicians can use systematic screening as part of routine care.[35]

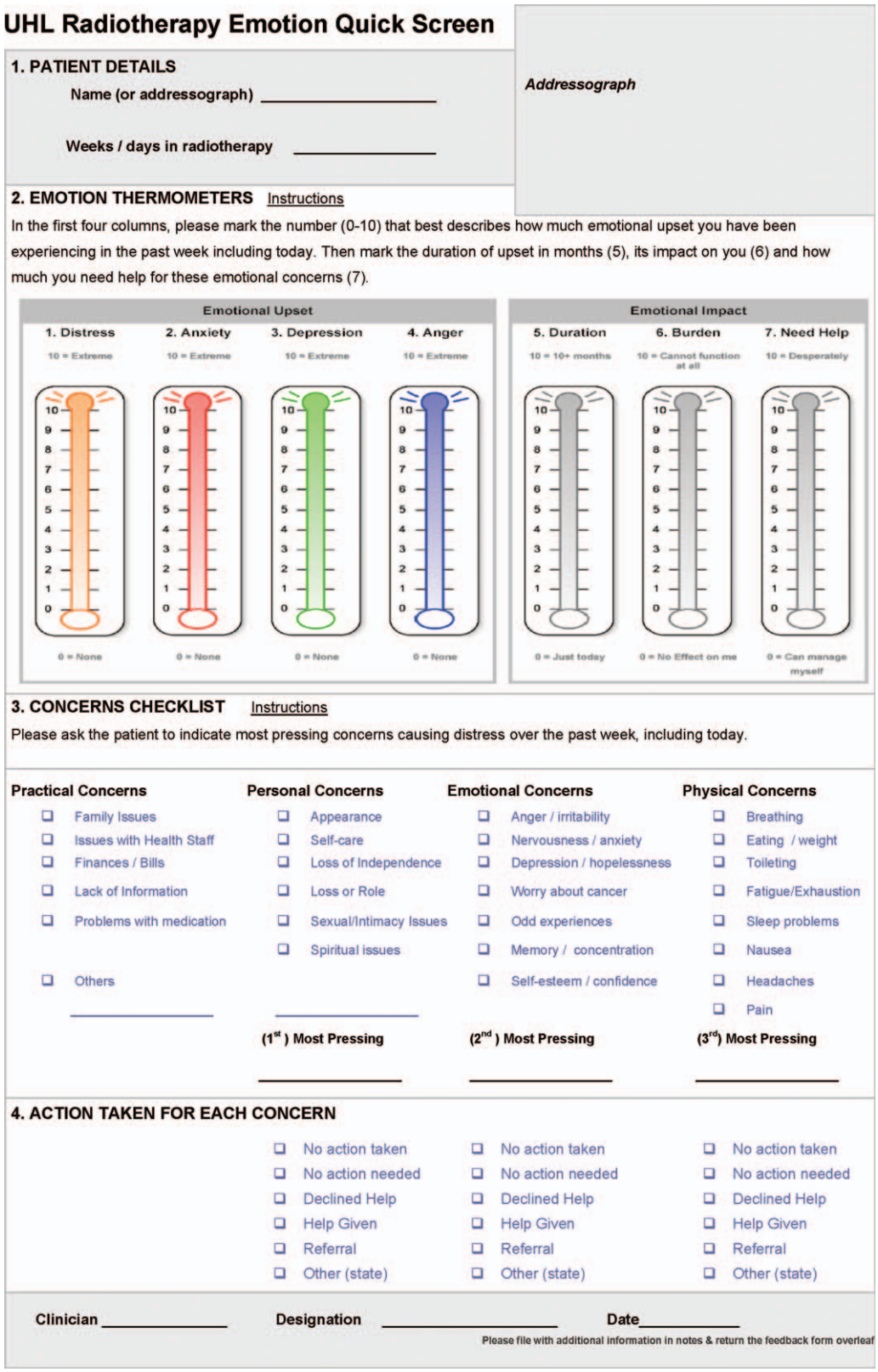
The potential for screening to be adopted and to change practice can be measured by patient-reported outcomes, such as change in newly initiated treatment and referrals.[36] Another simple method is to survey clinicians and or patients about its merits. This can be done hypothetically, asking about screening in general or prospectively by eliciting feedback about a particular screening program. In 1 example of the former strategy, Mitchell et al[14] surveyed 226 United Kingdom cancer health professionals and observed that only 6% screened using a formal questionnaire, the majority preferring their own clinical judgment. Pirl et al[15] also surveyed 448 oncologists about distress screening. Two-thirds reported screening patients for distress routinely, but only 14.3% used a screening instrument. Predictors of screening patients for distress included availability of mental health services, knowledge of NCCN guidelines, experience, lack of time, uncertainty about identifying distress, and being a women practitioner. Recently, Absolom et al[37] interviewed 23 United Kingdom health professionals and reported that experience with screening tools was limited and that the respondents expressed several reservations about routine implementation. A significant weakness of these surveys is that they ask about theoretical, self-reported practice. This method tends to overestimate actual performance.[38,39] We suggest that feedback on the views of health care professionals currently participating in screening programs would be valuable. In oncology, we were able to identify only 4 studies that reported clinicians' opinions or feedback concerning the value of screening.[40-43] Two studies reported effects on communication. A study by Lynch et al indicated that outpatient clinic staff believed screening helped them talk to patients about their concerns before their consultation with the physician.[42] Recently, Dinkel et al reported that 36% of cancer clinicians believed screening helped them become more attentive to emotional concerns.[43] Although there is a paucity of studies in cancer settings, staff surveys from other areas are informative. In the context of postnatal depression and primary care depression screening, clinicians generally supported screening and believed that screening enhanced detection.[44-46] However, staff also can report that screening is burdensome and time-consuming.[47,48] In a cardiovascular setting, Sowden et al[49] screened 3504 patients with the 2-item Patient Health Questionnaire (PHQ-2) followed by the PHQ-9 administered by a social worker. Nurses reported high satisfaction with the screening process, and they believed that screening was a useful addition to patient care and that it helped the patient receive better treatment of depression. In primary care, Bermejo et al investigated at attitudes to screening with the PHQ-9.[50] Patients rated the usefulness of the instrument more positively than general practitioners (GPs): Indeed, 62.5% of the GPs believed that the questionnaire was too long, and 75% thought it was impractical compared with only 25% of patients.

In 2009, we introduced a screening program into routine oncology practice involving chemotherapy and radiotherapy departments (see Fig. 1). Chemotherapy nurses routinely explain complex treatments (including possible side effects), administer chemotherapy, give information, and deliver face-to-face support. Similarly, radiographers routinely undertake treatment planning, administer treatment, give information, and also deliver face-to-face support. They are key nonmedical, frontline cancer clinicians who regularly see patients many times during the course of treatment. Our objective was to examine clinician satisfaction regarding the benefits of routine screening during routine implementation in a clinical setting. Our secondary objective was to examine clinician opinion on the merits of screening their communication with patients and distress management.

MATERIALS AND METHODS

Setting

We approached all local nurses and treatment radiographers/radiation technologists working in the chemotherapy suite and radiotherapy department at the Cancer Center of Leicester Royal Infirmary, a busy United Kingdom teaching hospital. Fifty clinicians agreed to participate and were involved in the implementation of paper-and-pencil based screening. The Cancer Center has approximately 3500 new cases per year. Our study involved front-line cancer clinicians, comprising 20 chemotherapy nurses and 30 treatment radiographers, all of whom volunteered to take part in the study, although 66% of screening was undertaken by the chemotherapy nurses. The mean age of chemotherapy nurses was 45.5 years, and the mean age of treatment radiographers was 52.3 years (age range, 22-63 years). Forty-seven clinicians were women, and 3 were men.



UHL Radiotherapy Emotion Quick Screen

1. PATIENT DETAILS

Name (or addressograph) _____

Weeks / days in radiotherapy _____

Addressograph

2. EMOTION THERMOMETERS Instructions

In the first four columns, please mark the number (0-10) that best describes how much emotional upset you have been experiencing in the past week including today. Then mark the duration of upset in months (5), its impact on you (6) and how much you need help for these emotional concerns (7).

Emotional Upset

1. Distress — 10 = Extreme — 0 = None
2. Anxiety — 10 = Extreme — 0 = None
3. Depression — 10 = Extreme — 0 = None
4. Anger — 10 = Extreme — 0 = None

Emotional Impact

5. Duration — 10 = 10+ months — 0 = Just today
6. Burden — 10 = Cannot function at all — 0 = No Effect on me
7. Need Help — 10 = Desperately — 0 = Can manage myself

3. CONCERNS CHECKLIST Instructions

Please ask the patient to indicate most pressing concerns causing distress over the past week, including today.

Practical Concerns	Personal Concerns	Emotional Concerns	Physical Concerns
❑ Family Issues	❑ Appearance	❑ Anger / irritability	❑ Breathing
❑ Issues with Health Staff	❑ Self-care	❑ Nervousness / anxiety	❑ Eating / weight
❑ Finances / Bills	❑ Loss of Independence	❑ Depression / hopelessness	❑ Toileting
❑ Lack of Information	❑ Loss or Role	❑ Worry about cancer	❑ Fatigue/Exhaustion
❑ Problems with medication	❑ Sexual/Intimacy Issues	❑ Odd experiences	❑ Sleep problems
	❑ Spiritual issues	❑ Memory / concentration	❑ Nausea
❑ Others		❑ Self-esteem / confidence	❑ Headaches
_____	_____		❑ Pain
	(1st) Most Pressing	(2nd) Most Pressing	(3rd) Most Pressing
	_____	_____	_____

4. ACTION TAKEN FOR EACH CONCERN

❑ No action taken	❑ No action taken	❑ No action taken
❑ No action needed	❑ No action needed	❑ No action needed
❑ Declined Help	❑ Declined Help	❑ Declined Help
❑ Help Given	❑ Help Given	❑ Help Given
❑ Referral	❑ Referral	❑ Referral
❑ Other (state)	❑ Other (state)	❑ Other (state)

Clinician _____ Designation _____ Date_____

Please file with additional information in notes & return the feedback form overleaf

Figure 1. Leicester screening tool for the radiotherapy setting. UHL indicates University Hospitals of Leicester.

Screening Program

All clinicians used the distress thermometer and/or the emotion thermometers screeners, which were integrated into a screening program that included assessment of unmet needs and clinician therapeutic response (see Fig. 1). Screening was implemented as part of routine clinical care starting in April 2009 for 9 months in the chemotherapy suite and in September 2010 for 6 months at the radiotherapy assessment center. The original screener took approximately 4 minutes to complete but this was streamlined after clinician feedback to a version that took about 3 minutes. All staff members were offered 1-hour induction training with the recommendation to attend up to 4 additional hourly sessions of support during the implementation phase. Training covered common emotional complications, how to screen, and the management of distress and related emotional issues. Communication training was available separately. Uptake of the training package was incomplete, with less than 25% of clinicians taking up training opportunities. During this pilot phase, clinicians had access to usual care, which included expert psycho-oncology referral. Even in the context of systematic screening, clinicians were permitted to use their own clinical judgment about the appropriateness of screening on a case-by-case basis, for example, by not screening when patients were too unwell or uncooperative. The project was ethically approved by the University Hospitals of Leicester Department of Cancer Studies as an audit of clinical practice.

All clinicians were invited to use the screener as part of routine care. Clinicians themselves used the screen on each clinical contact without automated help and without assistance from administrative staff. Clinicians were asked to screen all consecutive patients unless there was a clinical reason to avoid screening. Reasons for noncompletion included the patient being unable or unwilling to complete the screen. Clinicians themselves administered the screener during their own clinical assessments, typically during initial assessment (treatment planning) or during the early stages of treatment. Clinicians were encouraged to screen at least once per patient, with the maximum frequency dictated by clinical judgment. Screening was conducted regardless of patient sex, ethnicity, or disease stage using informal verbal translation if required (because many of our Gujarti speakers cannot read printed Gujarti). Clinicians decided on the benefits of screening while they were with the patient (Fig. 2) at the time of the index assessment.

Outcome Measurement

We rated clinician satisfaction with several short quantitative and qualitative questions regarding the success of screening and the burden of screening that were applied prospectively after each consultation (for the screening procedure, see below). Therefore, clinicians could evaluate their opinion regarding appropriateness of the tool across all types of clinical encounters. We measured several variables that could influence the success (or otherwise) of screening. These included the following clinician baseline measures: clinical rating of practicality of the screening program, clinician self-rated confidence, and clinician receipt of psychosocial training. We also asked about the following clinician-reported outcome measures: perception of improved clinician-patient communication, improved detection of psychosocial problems, propensity of the clinician to act therapeutically (help offered), and change in clinical opinion after screening (Fig. 2). We also measured several patient-reported measures: distress as well as anger, depression, anxiety, and desire for help. We examined rates of global satisfaction and predictions of satisfaction with screening using logistic regression. Finally, we collected feedback using free text boxes on the screening form and asked a random split-half subset of 25 clinicians about their experiences with screening in more detail, namely, the effect on communication, recognition of emotional problems, and practicality of the screen.

Analysis

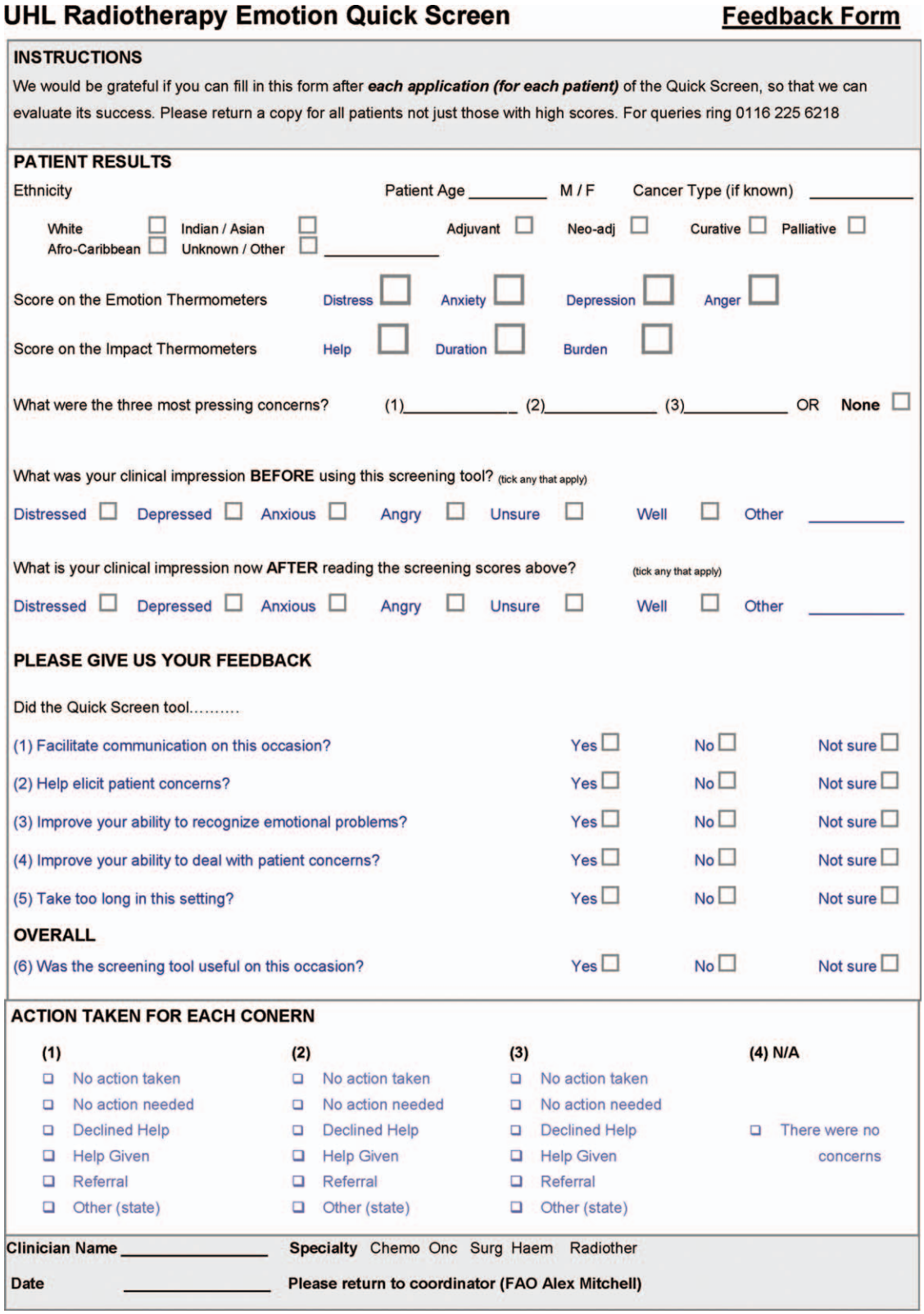
We used univariate logistic regression, multivariate regression and chi-squared test in StatsDirect 2.7.7 (StatsDirect Ltd., Cheshire, United Kingdom). StatsDirect calculates the probability associated with a chi-square random variable with n degrees of freedom.

RESULTS

Cancer clinicians screened 379 unique patients with at least 1 screening application and provided detailed feedback after 267 screening applications. Demographics of the screened sample are provided in Table 1.

Clinician Rating of Global Satisfaction

Across all 379 screening applications, clinicians believed that screening was useful in 43% of assessments but not useful in 35.9% of assessments, and they were unsure or neutral in 21.1% of assessments. The application of the screening program assisted staff in changing their clinical opinion in 41.9% of assessments. Most commonly, this was clarification of baseline uncertainty (50.9%), but it also included revaluation of an initially null assessment (ie, the patient appears nondistressed; 26%) or revaluation of a positive assessment (23.1%; ie, the patient appears distressed).



UHL Radiotherapy Emotion Quick Screen **Feedback Form**

INSTRUCTIONS

We would be grateful if you can fill in this form after ***each application (for each patient)*** of the Quick Screen, so that we can evaluate its success. Please return a copy for all patients not just those with high scores. For queries ring 0116 225 6218

PATIENT RESULTS

Ethnicity Patient Age _____ M / F Cancer Type (if known) _____

White ☐ Indian / Asian ☐ Adjuvant ☐ Neo-adj ☐ Curative ☐ Palliative ☐
Afro-Caribbean ☐ Unknown / Other ☐ _____

Score on the Emotion Thermometers Distress ☐ Anxiety ☐ Depression ☐ Anger ☐

Score on the Impact Thermometers Help ☐ Duration ☐ Burden ☐

What were the three most pressing concerns? (1)_____ (2)_____ (3)_____ OR **None** ☐

What was your clinical impression **BEFORE** using this screening tool? (tick any that apply)

Distressed ☐ Depressed ☐ Anxious ☐ Angry ☐ Unsure ☐ Well ☐ Other _____

What is your clinical impression now **AFTER** reading the screening scores above? (tick any that apply)

Distressed ☐ Depressed ☐ Anxious ☐ Angry ☐ Unsure ☐ Well ☐ Other _____

PLEASE GIVE US YOUR FEEDBACK

Did the Quick Screen tool.....

(1) Facilitate communication on this occasion?	Yes ☐	No ☐	Not sure ☐
(2) Help elicit patient concerns?	Yes ☐	No ☐	Not sure ☐
(3) Improve your ability to recognize emotional problems?	Yes ☐	No ☐	Not sure ☐
(4) Improve your ability to deal with patient concerns?	Yes ☐	No ☐	Not sure ☐
(5) Take too long in this setting?	Yes ☐	No ☐	Not sure ☐

OVERALL

(6) Was the screening tool useful on this occasion?	Yes ☐	No ☐	Not sure ☐

ACTION TAKEN FOR EACH CONERN

(1)	(2)	(3)	(4) N/A
☐ No action taken	☐ No action taken	☐ No action taken	
☐ No action needed	☐ No action needed	☐ No action needed	
☐ Declined Help	☐ Declined Help	☐ Declined Help	☐ There were no concerns
☐ Help Given	☐ Help Given	☐ Help Given	
☐ Referral	☐ Referral	☐ Referral	
☐ Other (state)	☐ Other (state)	☐ Other (state)	

Clinician Name _____ **Specialty** Chemo Onc Surg Haem Radiother

Date _____ **Please return to coordinator (FAO Alex Mitchell)**

Figure 2. Leicester screening tool feedback and evaluation section. UHL indicates University Hospitals of Leicester; N/A, not applicable; FAO, for attention of.

Table 1. Patient Demographics

Characteristic	Percentage of Patients (n = 379)
Palliative stage, %	15.5
Women, %	74.7
Age, y	
Mean	63.3
Range	33.0-83.9
Chemotherapy setting	65.7
Breast cancer	46.9
Lung cancer	6.7
Prostate cancer	7.2
Colorectal cancer	12.4
Bladder cancer	1.4
High distress, DT ≥3	31.4

Abbreviation: DT, distress thermometer.

Clinician Rating of Clinical Benefits

From the sample of 267 assessments with more complete data, in 51% of assessments, clinicians believed that the screening program helped improve clinical communication. In 40.6% of assessments, clinicians believed that the screening program helped with recognition of distress, anxiety, or depression (in 18.9%, they expressed no opinion). Clinicians believed that the simple paper-and-pencil screening program was practical for routine use in 45.3% of applications but impractical in 37.5% (in 17.2% of assessments, staff expressed no opinion).

Chemotherapy Versus Radiographers Feedback

Chemotherapy nurses rated the value of the tool after 249 nurse-patient interactions. They rated the screener useful in 42.9% of assessments and not useful in 43.4% of assessments, and they were uncertain or had no opinion in the remaining 13.7% of assessments. Radiographers rated the value of the tool after 130 clinician-patient interactions. They believed that the screening program was useful in 56 of 130 assessments (43%) and not useful in 21.5% of assessments, and they were unsure about 35.4% of assessments. Although ratings of chemotherapy nurses and radiographers were similar, the difference in those who rated assessments "not useful" was significant (chi-square statistic, 7.35; $P < .0001$). Chemotherapy nurses appeared to have more difficulty accommodating screening into busy initial assessments, although both groups reported that screening was a challenge when patient turnover was high.

Predictors of Favorable Staff Perceptions of Screening

On univariate logistic regression, the following variables were associated significantly with a favorable staff perception: clinicians rating the instrument as practical ($P < .0001$), low clinician confidence ($P < .001$), and high patient-rated anxiety ($P = .02$). Two outcome variables were linked with staff satisfaction with screening: talking with the patient about psychosocial issues ($P < .0001$) and a change in clinical opinion ($P < .0001$). On multivariate analysis, 3 variables were associated with high staff satisfaction with screening, namely, receipt of training ($P < .0001$); talking with the patient about psychosocial issues ($P < .0001$); and improved detection of psychological problems, such as depression/anxiety ($P < .0001$). On univariate chi-square analysis, clinicians who rated the program useful were twice as likely to change their clinical opinion after screening (chi-square statistic, 15.9; $P < .0001$; odds ratio, 2.5) (Table 2).

Table 2. Clinician Predictors of High Satisfaction with Screening

Variable	*T* Statistic	*P* (Significance of *T* Statistic)
Receipt of training	2.56	.0110
Improved communication	31.0	.00001
Improved detection	7.02	.00001

Narrative Feedback

We received narrative feedback comments, which we divided post hoc into concerns about completion bias, completion difficulties, outcome feedback, tool design comments, and tool application comments. These are listed in Table 3.

DISCUSSION

We collected data after 379 screening applications conducted by front-line chemotherapy nurses and treatment radiographers (radiation technologists). The opinion of clinicians regarding the value and feasibility of screening was mixed. A substantial minority believed that screening was not helpful, and this was greater among nurses than among radiographers (43.4% vs 21.5%; $P < .001$). In 37.5% of assessments, clinicians believed that our streamlined screening program was impractical for routine use. Nevertheless, it should be noted that clinicians generally were willing to persist with screening, provided they were supported in this. Yet the narrative comment, "*Need more time for new cases to complete this*," was the most common type of comment received. At the same time, clinicians also believed that screening was useful during 43% of assessments, and they were unsure or neutral in 21.1% of assessments. Indeed, the screening program assisted staff

Table 3. Staff Narrative Feedback Results

Concerns about completion bias
Wife interfered and biased results
Patient known to suffer from paranoid schizophrenia; this caused difficulty in assessing the patient
Patient was not confident in filling form, therefore needed guidance; this may have biased the results
This patient's anger relates to the length of time it has taken from diagnosis to treatment
Patient's concerns are more related to having a disabled daughter to care for rather than diagnosis itself
Although patient scored high last week, this is because of recent admission to hospital, and patient stated that this was not an accurate measurement of her "normal"
Completion difficulties
Need more time for new cases to complete this
Patient found it difficult to rate her feelings, as she is able to cope with family support
Patient unable to read, as did not have reading glasses
Outcome feedback
Referral to Macmillan nurses in view of palliative chemotherapy
Macmilllan nurse involvement was decided by the patient at this stage
Discussed coping with cancer and Macmillan nurses
Patient currently okay with family support; wants to get better and start treatment
Wig referral and appointment made for today to decrease patient's anxiety
Patient declined help, as she felt her emotions were "normal" given current events
Discussed thermometer with patient; he is very anxious to commence treatment
Patient already has Macmillan nurse, feels well supported at home
Full discussion with consultant has meant that the patient is not as confused
Tool design comments
The form could use a small space for written comments
There should be a section for those with a known history of mental illness
A section to explain why no action needed
Tool application comments
Need to be given to patient before having case talk

in changing their clinical opinion after 41.9% of assessments, most commonly by helping them clarify an uncertain initial judgment. This is the first study that we know of to systematically collect front-line cancer clinicians' opinions on the value of routine screening for distress. The study was unfunded and, thus, may provide better insight into the real-world feasibility of screening without the availability of dedicated screening researchers or administrators. Another strength of this study is that we collected data prospectively based on the actual implementation of a rapid paper-and-pencil–based screening program. Paper-and-pencil–based testing was favored over computerized methods mainly because of a lack of resources. Data were gathered at each clinician-patients interaction rather than by hypothetical survey. Thus, an individual clinician could report satisfaction with screening in some cases but dissatisfaction in others. We believe this is stronger methodologically than grouping clinicians' feedback into 1 category. One limitation, however, is that we did not collect patient opinions on the acceptability of screening. A second limitation is that we did not study the uptake of screening, although we previously reported that uptake was 78.3% in the chemotherapy setting studied alone.[51] A third limitation is that we did not validate the screener using a semistructured interview.

These data demonstrate that a screening program can be both useful and burdensome, depending on the clinical context. For settings in which patients obviously are unwell, clinical opinion may not be significantly worse than screening performance, because the sensitivity of unassisted detection is approximately 75% when searching for severe distress.[51] These results should be extrapolated only to screening that is applied by cancer clinicians themselves. The extent to which screening by cancer clinicians brings tangible benefits it is not certain, but this is an active area of research, as mentioned above. Screening using automated methods (touch screen) or using front-desk clinic staff may overcome some barriers cited here, but at additional initial cost. Nevertheless, screening may be most useful in cases of clinical uncertainty; and, in such situations, clinicians may be more likely to revise their clinical opinion on the basis of the screening result. We observed that, in approximately 25% of assessments in which the clinician reconsidered their clinical opinion, the clinician revised their judgment that the patient was well; and, in approximately 25% of assessments in which the opinion was reconsidered, the clinician revised their judgment that the patient was unwell. Clinicians rated the screening program as most useful in helping with communication in 50% of assessments, but they also believed that screening helped with recognition in approximately 2 of 5 assessments. The focus on communication rather than detection has been recognized previously, because nurses often want a therapeutic structure within which they can help patients to explore feelings, whereas physicians may want a formal method for diagnosis and rating symptoms.[47]

We also examined predictors of clinician satisfaction with screening. Clinicians who rated the instrument as practical, clinicians with low confidence, and clinicians assessing patients with more anxiety were more likely to believe that screening had value. This suggests that clinicians with high confidence may perceive that screening

has little to offer; but, paradoxically, clinicians with low confidence may fail to take up screening or training opportunities.[52] The relation between screening satisfaction and patient severity may produce a U-shaped curve. Screening patients with very high and very low distress may be perceived as bringing little added value to normal, unassisted judgment, as mentioned above. A favorable perception of screening also was linked with positive outcomes, namely, an increase in talking with the patient about psychosocial issues ($P < .0001$) and a change in clinical opinion ($P < .0001$). Thus, clinicians who favor screening are more likely to use it to their advantage, informing their clinical opinion and improving communication. It is worth noting that, even in instances in which clinicians did not rate the screening as useful, they nevertheless still changed their clinical opinion after screening in 19.4% of assessments. Assuming that a change in clinical opinion is a proxy for a worthwhile screening application, this suggests that screening still can be effective when clinicians use it reluctantly. On multivariate analysis, 2 additional variables—receipt of training ($P < .0001$) and improved detection of psychological problems—also were significant. This is concordant with the opinion that offering training in support of a screening program is likely to influence its success[53] by improving motivation to screen (for which satisfaction with screening is a proxy) and by improving quality of application and interpretation: that is, assessment skills.

Few previous studies have measured satisfaction with distress screening in a cancer setting. In a survey of attitudes, Mitchell et al[14] observed that 37% of United Kingdom clinicians did not regularly assess for emotional complications, only 5.9% did so using a formal questionnaire, and the majority (62.2%) relied on their own clinical judgment. The main barrier to successful screening was lack of time (cited by almost 60%), but insufficient training and low confidence also were influential. Lee et al[41] reported that 56% of nursing and allied health staff indicated that routine distress thermometer-based screening was "very" helpful for them in thinking about how to work with patients. Although that study was based on group clinician responses, it was not dissimilar to our finding that screening was helpful in 43% of assessments. In a pilot study of quality-of-life and distress screening using the Hospital Anxiety and Depression Scale (HADS), oncologists in the United Kingdom rated screening as useful in 87% of 28 consultations but believed that it contributed to patient management in only 54% of consultations using a touch screen.[54] In a larger follow-up randomized trial of that automated screening, only 68% of oncologists were willing to use screen-generated data routinely after cessation of a funded trial.[55] That said, 1 qualitative United Kingdom study suggested that, despite initial reservations, clinicians generally believe that screening can help talk to patients about their concerns before their consultation with the physician.[42] In our study, clinicians also stated that screening helped most with communication (in 51% of applications), but they also said it helped with recognition (40.6%). Indeed, by examining their clinical judgment before and after screening, we observed that screening assisted staff in revising their clinical opinion after 41.9% of assessments. Most commonly, this was clarification of baseline uncertainty, but it also included revaluation of an initial clinical opinion. We identified only 1 study to date that examined screening for distress in a radiotherapy setting. In 2010, Dinkel et al reported that 18.5% of radiographers believed that paper-based distress screening was too long. We also observed a higher than expected rate of clinician-reported barriers.[43] On 37.5% of occasions, clinicians believed that our screening program was impractical for routine use, and more chemotherapy nurses than radiographers rated the screening program as "not useful" (43.4% vs 21.5% of occasions; $P < .001$). It should be noted that we attempted to implement a rapid screening program that would have least burden to staff and patients (Fig. 1) and simplified it in response to clinician feedback. Nevertheless, our screener was completed by clinicians themselves (not by waiting room or reception staff), and it is clear that even rapid, clinician-led screening, at least in a paper-and-pencil format, although acceptable to the majority, is not universally favored by front-line clinicians.

In conclusion, screening for distress in routine cancer care is relatively difficult to implement. Screening can be perceived as an unnecessary burden by many front-line clinicians, yet screening also is perceived as beneficial when applied to more vulnerable, high-risk patients and when the screening program is supported by ongoing training or supervision. Once screening is implemented, many clinicians do perceive real benefits. Clinicians who are willing to apply screening often perceive an improvement in communication as well as an improvement in the detection and diagnosis of psychological problems, particularly in cases of initial clinical uncertainty. When setting up screening programs, organizations should be attentive to the needs of both motivated and unmotivated clinicians. Several worthwhile strategies have been proposed.[22,53] The burden of screening should be minimized, results should be fed back to clinicians in a

meaningful way, and clinicians should be encouraged to make local improvements and should be offered support and training in screening as well as in the subsequent management of distress and related concerns. Attendance at training sessions should be monitored. Those designing screening programs to be delivered by front-line clinicians should take into account burden of delivery, scoring, and interpretation. Clinicians should be involved in the implementation process and generally should be allowed to use their clinical judgment in situations in which they suspect screening errors (false-positive and false-negative results).

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Research report

Meta-analysis of screening and case finding tools for depression in cancer: Evidence based recommendations for clinical practice on behalf of the Depression in Cancer Care consensus group

Alex J. Mitchell [a,b,*], Nick Meader [c,d], Evan Davies [e], Kerrie Clover [f,g,h], Gregory L. Carter [h], Matthew J. Loscalzo [i,j], Wolfgang Linden [k], Luigi Grassi [l], Christoffer Johansen [m,n], Linda E. Carlson [o,p,q], James Zabora [r]

[a] Leicester Partnership Trust, Leicester LE5 4PW, UK
[b] Department of Cancer & Molecular Medicine, Leicester Royal Infirmary LE1 5WW, UK
[c] Centre for Reviews and Dissemination, University of York, UK
[d] National Collaborating Centre for Mental Health, Royal College of Psychiatrists' Research and Training Unit, 21 Mansell Street, London E1 8AA, UK
[e] United BioSource Corporation, 26-28 Hammersmith Grove, London W6 7HA, UK
[f] Psycho-Oncology Service, Calvary Mater Newcastle Hospital, Australia
[g] Department of Psychology, University of Newcastle, Australia
[h] Priority Research Centre for Translational Neuroscience and Mental Health, University of Newcastle, Australia
[i] Sheri & Les Biller Patient and Family Resource Center, United States
[j] Department of Population Sciences, City of Hope, Duarte, CA 91010-3000, United States
[k] University of British Columbia, Department of Psychology, 2515-2136 West Mall, Vancouver, B.C., Canada, V6T 1Z4
[l] Section of Psychiatry, Department of Biomedical and Specialist Surgical Sciences, University of Ferrara, Corso Giovecca 203 -44121, Ferrara, Italy
[m] National Centre for Cancer Rehabilitation Research, Institute of Public Health, Southern Danish University, Odense, Denmark
[n] Department of Psychosocial Cancer Research, Institute of Cancer Epidemiology, the Danish Cancer Society, Copenhagen, Denmark
[o] Department of Oncology, University of Calgary, Canada
[p] Department of Psychology, University of Calgary, Canada
[q] Department of Psychosocial Resources, Tom Baker Cancer Centre, Canada
[r] National Catholic School of Social Service, Shahan Hall, Washington, DC 20064, United States

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ABSTRACT

Background: To examine the validity of screening and case-finding tools used in the identification of depression as defined by an ICD10/DSM-IV criterion standard.
Methods: We identified 63 studies involving 19 tools (in 33 publications) designed to help clinicians identify depression in cancer settings. We used a standardized rating system. We excluded 11 tools without at least two independent studies, leaving 8 tools for comparison.
Results: Across all cancer stages there were 56 diagnostic validity studies (n = 10,009). For case-finding, one stem question, two stem questions and the BDI-II all had level 2 evidence (2a, 2b and 2c respectively) and given their better acceptability we gave the stem questions a grade B recommendation. For screening, two stem questions had level 1b evidence (with high acceptability) and the BDI-II had level 2c evidence. For every 100 people screened in advanced cancer, the two questions would accurately detect 18 cases, while missing only 1 and correctly reassure 74 with 7 falsely identified. For every 100 people screened in non-palliative settings the BDI-II would accurately detect 17 cases, missing 2 and correctly re-assure 70, with 11 falsely

* Corresponding author at: Department of Cancer & Molecular Medicine, Leicester Royal Infirmary LE1 5WW, UK. Tel.: +44 116 2463470; fax: +44 116 2256673.
E-mail addresses: ajm80@le.ac.uk (A.J. Mitchell), nmeader@cru.rcpsych.ac.uk (N. Meader), evan.davies@unitedbiosource.com (E. Davies), kerrie.clover@newcastle.edu.au (K. Clover), Gregory.Carter@newcastle.edu.au (G.L. Carter), Mloscalzo@COH.org (M.J. Loscalzo), wlinden@psych.ubc.ca (W. Linden), luigi.grassi@unife.it (L. Grassi), christof@cancer.dk (C. Johansen), lcarlso@ucalgary.ca (L.E. Carlson), zabora@cua.edu (J. Zabora).

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identified as cases. The main cautions are the reliance on DSM-IV definitions of major depression, the large number of small studies and the paucity of data for many tools in specific settings.
Conclusions: Although no single tool could be offered unqualified support, several tools are likely to improve upon unassisted clinical recognition. In clinical practice, all tools should form part of an integrated approach involving further follow-up, clinical assessment and evidence based therapy.

1. Introduction

Depression is one of the strongest determinants of health related quality of life and it also influences receipt of medical care and participation in treatment (Bui et al., 2005; Kennard et al., 2004; Skarstein et al., 2000; Stark et al., 2002; Steginga et al., 2008). A recent meta-analysis of 25 observational studies showed a 39% higher all-cause mortality rate in cancer patients diagnosed with major or minor depression (RR 1.39 95% CI, 1.10–1.89) (Satin et al., 2009). The point prevalence of major depression in the first two years following a cancer diagnosis is approximately 15% (Mitchell et al., 2011a). Yet there is undisputed evidence that depression is often overlooked by busy cancer professionals in palliative and non-palliative settings (Ford et al., 1994; Hedstrom et al., 2006; Jones and Doebbeling, 2007; Sollner et al., 2001). For example, one study involving 143 doctors and 2297 patients found that the clinical detection sensitivity of oncologists was 29% and their specificity was 85% (Fallowfield et al., 2001). In recorded discussions between oncologists and patients less than a third of consultations contain discussions of emotional concerns such as distress or depression (Rodriguez et al., 2010; Taylor et al., 2011).

In order to try and improve recognition, numerous tools have been developed varying from 1 item to 90 items (Vodermaier et al., 2009). Most are pencil and paper self-report tools but some use structured verbal questions and computerized delivery methods have also been developed (Zealley and Aitken, 1969). A large number of rating scales have been used to supplement unassisted clinical skills, although only a handful have been specifically designed for this population (Herschbach et al., 2008). The best known conventional self-report mood scale is the Hospital Anxiety and Depression Scale (HADS). Two recent reviews found that the HADS could not be recommended as a diagnostic instrument but it may be suitable as a screening tool (Luckett et al., 2010; Mitchell et al., 2010a). Another well-known self-report tool in cancer settings is the one-item, visual-analogue scale (VAS) Distress Thermometer (DT) (NCCN, 2007; Roth et al., 1998). The DT has usually been used to detect broadly defined emotional difficulties and this reflects an important recent trend to identify distress and anxiety as well as depression. While we support the importance of screening for distress, it is undoubtedly useful to also know how tools perform against robustly defined depression. It is also useful to examine which tools have proven validity and acceptability regardless of their original intent and even their original design. For example are tool which omit somatic symptoms more or less effective diagnostically?

Several organizations have recommended screening for emotional complications of cancer (Institute of Medicine, 2007; National Comprehensive Cancer Network, 2008; National Institute for Clinical Excellence, 2004; Neuss et al., 2005). Yet there is no consensus about which instrument is recommended in this population (Vodermaier et al., 2009; Ziegler et al., 2011). We suggest two main reasons for this. First, there has been no adequate data synthesis using quantitative (meta-analytic) methods. Recently developed meta-analytic techniques now allow a comparison of diagnostic tests even in the presence of variations in underlying prevalence. Second, there has been confusion about the terms case-identification, case-finding and screening. For the purposes of this analysis we used a pragmatic definition of screening and case-finding previously suggested as applicable to a clinical population (Mitchell and Malladi, 2010; Mitchell et al., 2011b). That is, screening is the application of a diagnostic test or clinical assessment in order to optimally rule-out those without the disorder with minimal false negatives (missed cases). Screening is often performed in a large population as the first of several diagnostic steps. We defined case-finding as the application of a diagnostic test or clinical assessment in order to optimally identify those with the disorder with minimal false positives (Mitchell et al., 2011b). Case finding is often performed in a selected population at high risk for the condition. With this in mind, our aim was to quantitatively compare every robustly validated tool for detecting depression in cancer settings using the principles of evidence based medicine.

2. Methods

2.1. Data sources and searches

A search for studies assessing the validity of screening and case finding instruments was made using seven electronic bibliographic databases (CENTRAL, CINAHL, Embase, HMIC, Medline, PsycINFO, Web of Knowledge). Each database was searched from inception to March 2011. The search was kept as broad as possible with search terms for screening, identification, depression, and cancer (for search strategy see Appendix 1). Additional papers were found by searching the references of retrieved articles, tables of contents of relevant journals, previous systematic reviews and meta-analyses and written requests to experts. We stratified a subgroup of studies that recruited patients either with explicitly defined advanced cancer or those treated in palliative settings.

2.2. Study selection

We included validation studies of mood questionnaires in cancer populations assessing case finding or screening. Following the search, the questionnaires examined in cancer settings included the Beck Depression Inventory (BDI), (Beck et al., 1996) BDI fast screen, (Beck et al., 1997) DT, (Roth et al., 1998) Edinburgh Postnatal Depression Scale (EPDS), (Cox et al., 1987) Patient Health questionnaire (PHQ-9), (Spitzer et

al., 1999) PHQ-2, (Kroenke et al., 2003) the two stem questions (Whooley et al., 1997) ('low mood' and 'loss of interest' by self-report or verbal enquiry) found in both the Diagnostic and Statistical Manual-Fourth Edition [DSM-IV] and the International Classification of Disease Tenth Edition [ICD-10], General health Questionnaire (GHQ-12 and GHQ-28), (Goldberg and Williams, 1988) Centers for Epidemiological Studies Depression Scale (CES-D), (Radloff, 1977) Zung Depression Scale (Zung), (Zung, 1965) HADS (includes subscales), (Zigmond and Snaith, 1983) Hamilton Depression Scale (HAMD) (Hamilton, 1960) (17 and 21 item versions were analyzed together due to lack of separate data), and several other methods (listed in Appendix 3). However 11 had not been independently validated therefore only 8 which had been robustly investigated were included (see tables). The reference standard was a robust psychiatric diagnosis of depression according to DSM of the American Psychiatric Association (for example DSM-IV (American Psychiatric Association, 1994)) or ICD (for example ICD-10 (World Health Organization, 1993)) of the World Health Organization criteria elicited by clinical interview or semi-structured interview. Studies that did not clearly state the comparator to be DSM or ICD diagnosis of depression were excluded (Hegel et al., 2008). We did not include studies that did not provide sufficient data to be extracted in the meta-analysis.

2.3. Data extraction and quality assessment

All published studies that met our eligibility criteria were assessed for methodological quality using quality ratings listed in the Quadas checklist (Whiting et al., 2003). We applied the minimum dataset rule (suggested by STATA meta-analysis developers) for a minimum of three studies to warrant inclusion in the meta-analysis. Data were extracted independently by three researchers (AJM, NM, ED) using a standardized data extraction form piloted on several previous systematic reviews conducted by the authors. There was disagreement about the quality of three studies which was resolved by consensus. Summary study information characteristics extracted were country of study, setting, patient characteristics (e.g. age and gender), scales used to identify depression, reference standard and blinding of the interviewers to the index test result. For the purposes of the meta-analyses sensitivity, specificity and prevalence of depression (as measured by the reference standard) were extracted for major depressive disorder, minor depressive disorder and any depressive disorder where available. In addition, if not provided in the papers, 2×2 tables (true positives, false positives, true negatives and false negatives) were calculated for inclusion in the meta-analysis. Secondary outcomes were an area under the curve analysis (see below) for screening and case-finding performance. Data were extracted independently by two researchers and differences were resolved by discussion.

2.4. Data synthesis and analysis

We undertook a meta-analysis of sensitivity and specificity data and since heterogeneity was moderate to high, employed a random effects meta-analysis. Analysis was conducted separately according to whether participants were classified as having major depressive disorder or any depressive disorder by the reference standard. Between-study heterogeneity was assessed using the I^2 statistic (Higgins et al., 2003). We also undertook a Bayesian plot of conditional probabilities that shows all conditional post-test probabilities from all pre-test probabilities regardless of prevalence (Diamond et al., 1980; Maceneaney and Malone, 2000). The area under the Bayesian positive curve (AUC+) allows statistical comparison of rule-in success and 1−AUC (or AUC−) allows statistical comparison of rule-out success without interference from prevalence variations and can be calculated simply using Microsoft Excel (McClish, 1992).

2.5. Standards of accuracy and level of recommendation

We rated both accuracy and acceptability. For accuracy we used the levels of evidence 1–5 suggested by the Oxford Centre for Evidence-based Medicine (see Appendix A) (http://www.cebm.net/index.aspx?o=1025) as applied to diagnostic test results from the area under the conditional probability curve and likelihood ratios (LR+ and LR−): (Mitchell and Malladi, 2010). Level 1 = AUC ≥ 0.9 or LR+ ≥ 9.0 or LR+ ≤ 0.11; Level 2 = AUC ≥ 0.8 or LR+ ≥ 4.0 or LR+ ≤ 0.25; Level 3 = AUC > 0.7 or LR+ ≥ 2.3 or LR+ ≤ 0.43. A subcategory code was applied according to pooled sample size; "a" where the sample was greater than 1000, "b" when the sample was greater than 500 and less than 1000 and grade c for less than 500. In order to grade acceptability we used the following qualitative rating of duration of testing (application and scoring combined). Less than 2 minutes = high; ≥2<5 minutes = moderate; ≥5<10 minutes = low-moderate; and ≥10 minutes = low.

3. Results

3.1. Search results

From 4451 possible hits involving the scales or tools, 768 involved patients with cancer and 209 examined aspects of scale accuracy. 158 publications were excluded, largely due to inadequate criterion standards or incompletely reported data, or the minimum dataset rule (see Appendix 3) leaving 33 included publications (Fig. 1) (Castelli et al., 2009; Miklavcic et al., 2008). 19 tools were identified but only 8 had at least two independent validity studies leaving 56 valid analyses pertaining to 8 tools. The methods that showed promise but lacked adequate independent validation were the Memorial Pain Assessment Card Mood VAS subscale, General Health Questionnaire, CES-D, Zung scale, HAMD, SIPP, PHQ9, PCM Acute Distress Scale and the PSYCH-6 subscale of the SPHERE. The data extraction is illustrated in Fig. 1 in accordance with Quality of Reporting of Meta-analyses guidelines and the list of included studies in Table 1 (Moher et al., 1999). There were 56 analyses overall with 38 analyses which were restricted to patients in non-palliative settings (mean sample 196.3 SD 107.2) and 16 analyses restricted to patients in palliative settings (mean sample 145.8 SD 16.7).[2] Methodological aspects are shown in Table S1.

[2] Two analyses were excluded once subgroups were divided due to the minimum dataset rule requiring three independent replications.

Fig. 1. Quorom figure of publication trail.

3.2. Diagnostic validity in non-palliative populations

From 38 analyses (total n = 7098), the weighted prevalence of depression was 17.6% (95% CI = 14.1% to 21.6%). There were three studies that tested a single question for depression and these had a weighted sensitivity of 64.3% (95% CI = 38.3% to 86.4%) and weighted specificity of 92.8% (95% CI = 85.7% to 97.6%). There were three studies on the BDI-II. From these the weighted sensitivity was 91.2% (95% CI = 82.8% to 97.0%) and the weighted specificity was 86.1% (95% CI = 79.9% to 91.4%). From five studies using the DT the weighted sensitivity was 81.9% (95% CI = 76.8% to 86.5%) and weighted specificity was 70.9% (95% CI = 63.7% to 77.6%). The remainder of studies involved the HADS. Weighted sensitivity and specificity for each version of the HADS were as follows: HADS-T (8 studies) 76.4% (95% CI = 70.0% to 82.2%) and 79.4% (95% CI = 59.9% to 93.5%); HADS-D (13 studies) 65.3% (95% CI = 50.3% to 78.9%) and 85.8% (95% CI = 76.9% to 92.7%) and HADS-A (4 studies) 77.1%8 (95% CI = 68.9% to 84.4%) and 84.3% (95% CI = 72.1% to 93.4%). A summary of results is shown in Fig. 2 and Table S2.

3.3. Evidence based recommendations in non-palliative settings

Two tools reached level 2 evidence for case-finding in non-palliative cancer patients, the BDI-II and the single stem question. The latter was graded at 2a due to its better sample size (n = 1308). However, only the BDI-II had level 2 evidence for screening (rule-out). The BDI-II performed adequately in both screening and case-finding but unfortunately despite higher accuracy it had only low-moderate acceptability. Therefore we could only give the one stem question a grade B recommendation for case-finding and all other methods a grade C recommendation for screening.

Table 1
Summary of included studies.

Author year	Country	Sample size	Females	Age	Instrument	Cancer population	Reference standard
Non-palliative cancer populations							
Akizuki et al. (2003)	Japan	205	68	61	DT One-item	Mixed	Clinician interview DSM-IV ADD
Alexander et al. (2010)	UK	200	200	Not reported	EPDS HADS-D	Breast	SCID DSM-IV MDD
Berard et al. (1998)	South Africa	100	87	50	HADS-D BDI	Mixed	Clinician interview DSM-IV ADD
Costantini et al. (1999)	Italy	132	132	53	HADS-D	Breast	DSM-III-R Clinician interview ADD
Grassi et al. (2006) (abstract)	Italy	109	NR	NR	HADS-D Distress thermometer	Mixed outpatients	CIDI ICD-10 interview ADD
Grassi et al. (2009)	Italy	109	83	55	HADS-D Distress thermometer	Mixed outpatients	CIDI ICD-10 interview ADD
Hall et al. (1999)	UK	266	266	Not reported	HADS-D	Breast	Clinician interview DSM-IV ADD
Hopko et al. (2007)	US	33	25	54	HAM-D BDI CES-D	Mixed	DSM-IV MDD
Jefford et al. (2004)	US	100	Not reported	Not reported	Two stem questions One-item	Mixed	DSM-IV clinician interview MDD
Katz et al. (2004)	Canada	60	13	61	BDI HADS-D CES-D	Mixed	DSM-IV clinician interview ADD
Kawase et al. (2006)	Japan	305	Not reported	62	One-item	Mixed	DSM-IV Clinician interview ADD
Krespi Boothby et al. (2010)	Turkey	255	255	58	HADS-D GHQ12	Breast_early	SADS DSM-IV MDD
Kugaya et al. (1998)	Japan	128	48	61	HADS-D	Mixed	DSM-III-R SCID MDD
Love et al. (2002)	Australia	303	303	Not reported	HADS	Stage I–II Breast	Clinician interview DSM-IV ADD
Meyer et al. (2003)	US	45	Not reported	Not reported	One-item	Mixed	DSM-IV Clinician interview ADD
Mitchell et al. (2008b)	UK	129	84	58	Two stem questions One-item	Mixed	DSM-IV MDD
Mitchell et al. (2009)	UK	129	84	58	DT Emotion thermometers	Mixed	DSM-IV MDD
Ozalp et al. (2008)	Turkey	208	208	51	HADS-D	Breast	SCID DSM-IV ADD
Patel et al. (2010)	Australia	100	100	53.1	HADS-D PSYCH-6	Breast	CIDI DSMIV/ICD10 ADD
Payne et al. (2007)	US	167	Not reported	Not reported	Two stem questions One-item	Mixed	Clinician interview DSM-IV ADD
Reuter and Harter (2000)	Germany	188	51	54	HADS-D	Mixed	Clinician interview DSM-IV ADD
Singer et al. (2008)	Germany	250	23	Not reported	HADS-D	Laryngeal	SCID DSM-IV Psychiatric ADD
Walker et al. (2007)	UK	361	276	62	HADS-D	Mixed	SCID DSM-IV ADD
Advanced or palliative populations							
Akechi et al. (2006)	Japan	205	68	61	Two stem questions One-item HADS-D	Advanced cancer in Palliative setting	Clinician interview DSM-IV ADD

(continued on next page)

Table 1 (*continued*)

Author year	Country	Sample size	Females	Age	Instrument	Cancer population	Reference standard
Chochinov et al. (1997)	US	197	103	Not reported	Two stem questions	Terminal cancer receiving palliative care	RDC ADD
Le Fevre et al. (1999)	UK	79	35	70	HADS-D	Hospice inpatients	ICD-10 (Revised Clinical Interview Schedule) MDD
Lloyd-Williams et al. (2000)	UK	100	56	57	EPDS One-item	Palliative setting	PSE ICD-10 ADD
Lloyd-Williams et al. (2001)	UK	100	56	57	HADS-D	Palliative setting	PSE ICD-10 ADD
Lloyd-Williams et al. (2004)	UK	74	36	67.89	EPDS One-item	Palliative setting	PSE ICD-10 MDD
Lloyd-Williams et al. (2007)	UK	249	139	61.9	EPDS Brief EPDS	Palliative setting	PSE ICD10 Depression
Love et al. (2004)	Australia	227	227	52	BDI fast screen HADS	Advanced (Stage IV) Breast	Clinician interview DSM-IV ADD
Mitchell et al. (2010b)	UK	472	321	59	Distress thermometer Emotion thermometers HADS PHQ9	Sub-sample of patients treated palliatively	DSM-IV MDD
Razavi et al. (1990)	Belgium	210	140	55	HADS-D	Inpatients of whom 62% had metastatic disease	CIS DSM-III MDD

Footer: two stem questions are 'low mood' and 'loss of interest' by either self-report or verbal enquiry; PSE — Present state examination; CIS — Clinical interview schedule; SCID — structured clinical interview for DSM; RDC — Research Diagnostic Criteria; CIDI — Composite International Diagnostic Interview; ADD — Any depressive disorder; MDD — major depressive disorder; Beck Depression Inventory (BDI), Edinburgh Postnatal Depression Scale (EPDS), Patient Health questionnaire (PHQ); General health Questionnaire; Centers for Epidemiological Studies Depression Scale (CES-D), Zung Depression Scale (Zung), Hospital Anxiety and Depression scale (HADS); Hamilton Depression Scale (HAM-D).

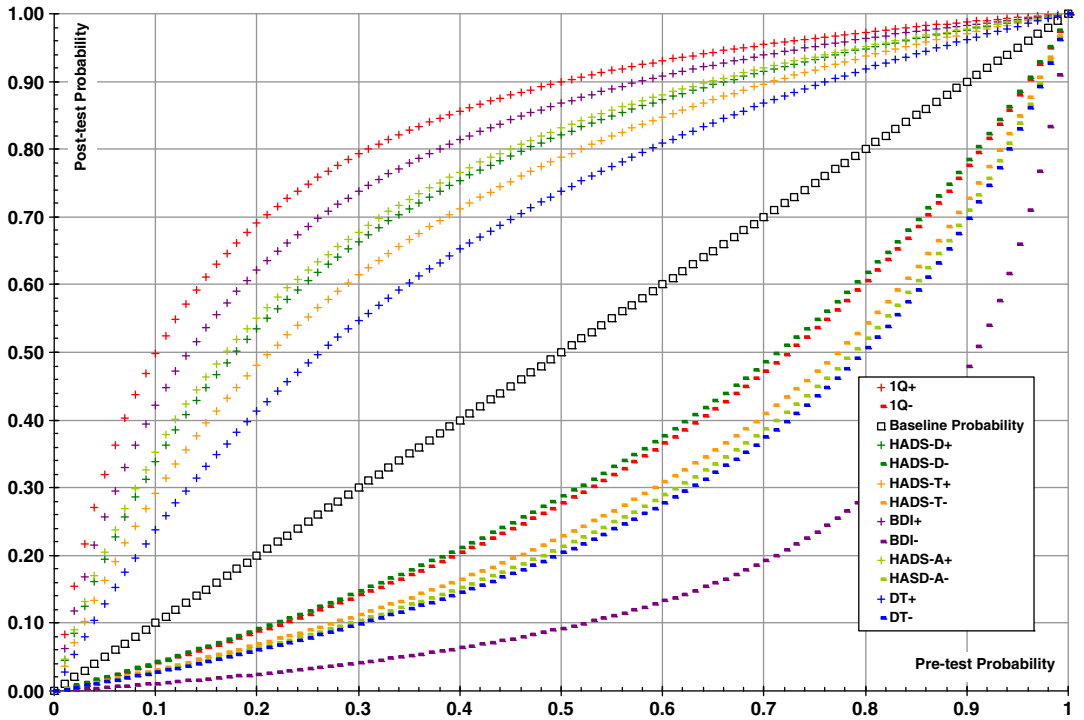

Fig. 2. Conditional probability comparison of accuracy of depression scales in nion- palliative (mixed cancer) settings by prevalence (black squares).

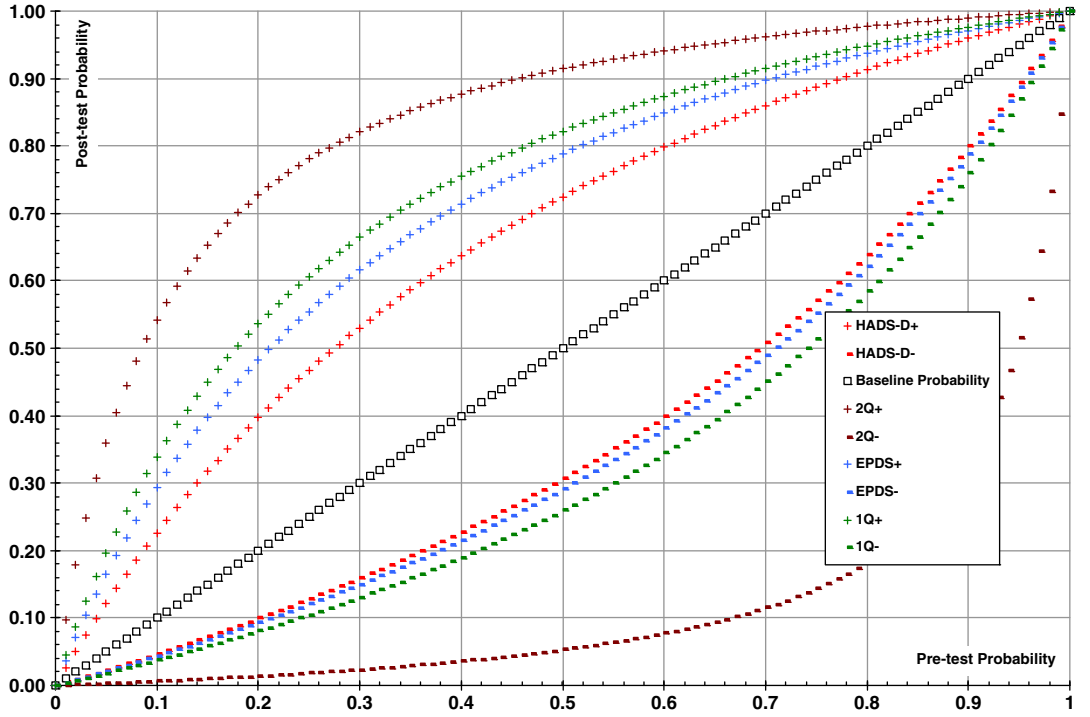

Fig. 3. Conditional probability comparison of accuracy of depression scales in palliative settings by prevalence (black squares).

3.4. Diagnostic validity in advanced cancer

Across 16 analyses (n = 4138) the weighted prevalence of depression in palliative settings was 19.0% (95% CI = 17.5% to 20.5%). There were 6 studies of a single question to detect depression, the weighted sensitivity was 70.2% (95% CI = 48.3% to 88.1%) and the weighted specificity was 84.8% (95% CI = 69.8% to 95.3%). There were three studies involving two

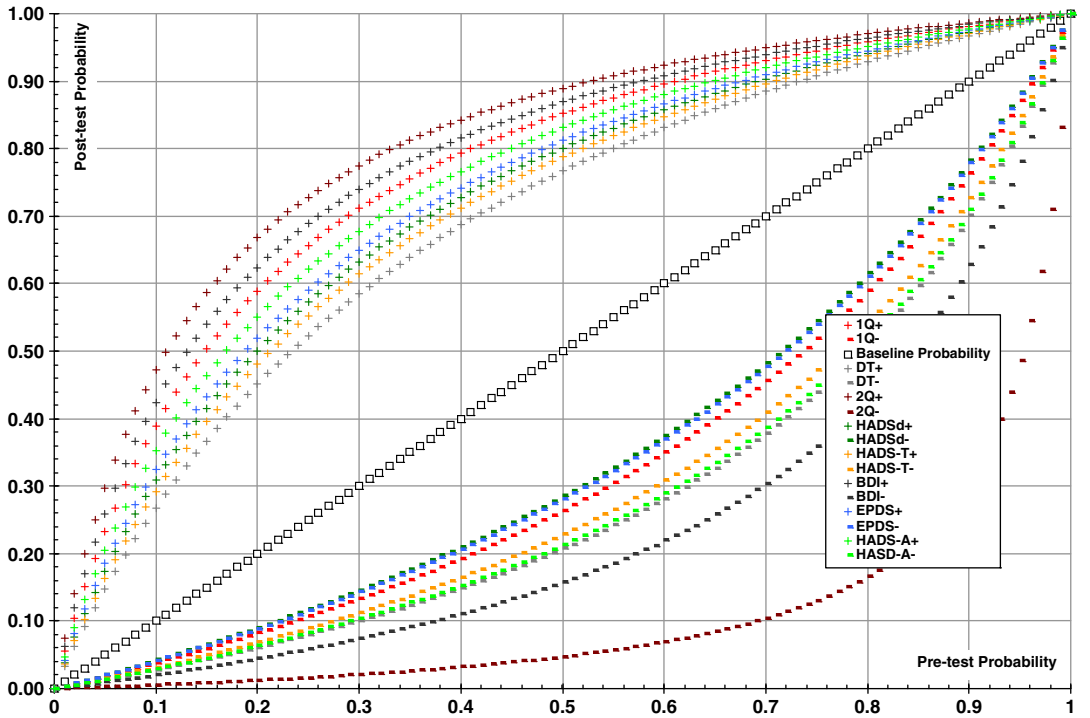

Fig. 4. Conditional probability comparison of accuracy of depression scales in any cancer settings by prevalence (black squares).

Table 2
Summary of diagnostic validity results—all cancers.

Instrument (items)	Pooled sample size	Pooled specificity	I^2	Clinical acceptability	Case-finding (rule-in ability)	
					Case-finding AUC	Pooled likelihood ratio +
1Q (1 item)	1780	0.881 (95% CI = 0.803889 to 0.940581)	94%	High	0.815 (95% CI = 0.764 to 0.866	5.27
2Q (2 items)	717	0.881 (95% CI = 0.803889 to 0.940581)	0.74	High	0.804 (95% CI = 0.771 to 0.894)	8.64
BDI-II (21 items)	293	0.874 (95% CI = 0.828164 to 0.914004)	72%	Low-moderate	0.780 (95% CI = 0.703 to 0.858)	6.65
DT (1 item)	653	0.709 (95% CI = 0.637 to 0.776)	86%	High	0.666 (95% CI = 0.576 to 0.757)	2.81
EPDS (10 items)	618	0.845 (95% CI = 0.782865 to 0.898957)	0.95	Moderate	0.728 (95% CI = 0.648 to 0.766)	4.32
HADS-A (7 items)	901	0.842 (95% CI = 0.721 to 0.934)	98%	Moderate	0.745 (95% CI = 0.689 to 0.800)	4.90
HADS-D (7 items)	3248	0.834 (95% CI = 0.756387 to 0.898674)	96%	Moderate	0.718 (95% CI = 0.695 to 0.748)	4.00
HADS-T (14 items)	1349	0.794 (95% CI = 0.599 to 0.935)	98%	Low-moderate	0.707 (95% CI = 0.661 to 0.752)	3.70

Legend:Level of evidence 1 = AUC ≥ 0.9 or LR + ≥ 9.0 or LR + ≤ 0.11; Level of Evidence 2 = AUC ≥ 0.8 or LR + ≥ 4.0 or LR + ≤ 0.25; Level of Evidence 3 = AUC > 0.7 or LR + ≥ 2.3 or LR + ≤ 0.43; a = sample greater than 1000; b = sample greater than 500.Grade of recommendation A = consistent level 1 studies; B = consistent level 2 or 3 studies or extrapolations from level 1 studies; C = level 4 studies or extrapolations from level 2 or 3 studies; D = level 5 evidence or troublingly inconsistent or inconclusive studies of any level.

questions, the weighted sensitivity was 94.9% (95% CI = 85.8% to 99.5%) and the weighted specificity was 91.1% (95% CI = 79.9% to 98.0%). There were 3 studies of the EPDS, the weighted sensitivity was 66.1% (95% CI = 46.5% to 83.2%) and the weighted specificity was 82.3% (95% CI = 77.9% to 86.4%). There were 4 studies of the HADS-D, the weighted sensitivity was 69.9% (95% CI = 50.7% to 86.1%) and the weighted specificity was 74.6% (95% CI = 59.4% to 87.2%). A summary of results is shown in Fig. 3 and Table S3.

3.5. Evidence based recommendations in advanced cancer

In terms of case-finding, the two stem questions had level 1b evidence and one stem question had level 2b evidence. We gave both methods a grade B recommendation. Two stem questions also had level 1b evidence in screening and also had high acceptability. We gave the two question approach a grade B recommendation.

3.6. Diagnostic validity in all cancer populations

Across all settings there were 63 diagnostic validity studies (n = 10,009). There were 9 studies involving a single question approach, weighted sensitivity was 68.3% (95% CI = 52.9% to 81.8%) and weighted specificity was 88.1% (95% CI = 80.4% to 94.1%) There were 5 studies of the DT, weighted sensitivity was 80.2% (95% CI = 75.5% to 84.5%) and weighted specificity 75.6% (95% CI = 57.5% to 90.0%) From 4 studies of two stem questions, weighted sensitivity was 95.6% (95% CI = 89.0% to 99.3%) and weighted specificity 88.9% (95% CI = 79.0% to 96.0%). From 4 BDI-II studies, weighted sensitivity was 83.6% (95% CI = 64.7% to 96.2%) and weighted specificity 87.4% (95% CI = 82.8 to 91.4%). There were 4 studies of the EPDS, weighted sensitivity was 66.8% (95% CI = 51.7% to 80.4%) and weighted specificity was 84.5% (95% CI = 78.3% to 89.9%). The remainder of studies involved the HADS in various forms. Sensitivity and specificity for each version of the HADS was as follows: HADS-T (8 studies) 76.4% (95% CI = 70.0% to 82.2%) and 79.4% (95% CI = 59.9% to 93.5%); HADS-D (18 studies) 66.6% (N = 18; 95% CI = 54.5 to 77.7%) and 80.9% (95% CI = 71.6% to 88.8%); and HADS-A (4 studies) 77.1% (95% CI = 68.9% to 84.4%) and 84.3% (95% CI = 72.1% to 93.4%). A summary of results is shown in Fig. 4 and Table 2.

3.7. Evidence based recommendations in all cancer populations

For case-finding, one stem question, two stem questions and the BDI-II all had level 2 evidence (2a, 2b and 2c respectively) and given their better acceptability we gave the verbal questions a grade B recommendation and the BDI-II grade C. For screening, two stem questions had level 1b evidence (with high acceptability) and the BDI-II had 2c evidence and therefore we gave two stem questions a grade B recommendation for screening and the BDI-II a grade C.

4. Discussion

4.1. Strengths and limitations

This study used an evidence based approach to examine the current literature concerning screening and case-finding tools for depression in clinical cancer populations. We conducted a systematic review, set a priori evidence based standards for study selection and applied a quality rating to each selected study based on current standards. We included all scales regardless of original intent or content, in essence examining diagnostic validity rather than face validity. We intentionally studied some applications not commonly employed (e.g. HADS-A for depression) in order to avoid prejudicing results prior to examining the available evidence. Interestingly, we found that the HADS-A had average performance in the diagnosis of major depression but nevertheless was superior to several conventional depression scales. We found no evidence that scale that omitted somatic symptoms were particularly advantageous although note that no head-to-head comparisons have been conducted. Other phenomenological studies question whether somatic symptoms do indeed contaminate the conventional concept of depression in cancer settings (Mitchell et al., 2012; Rayner et al., 2011). Quantitative analyses were undertaken using a range of appropriate agreement statistics for diagnostic accuracy correcting for variations in depression prevalence. Limitations of this study include the relatively low number of high quality studies with large samples, the small possibility of missed studies in the search strategy and constraints on the quantitative analyses by heterogeneity of study populations and instruments. A further limitation is the reliance on DSM or ICD criteria and clinical assessment or semi-

Case-finding (rule-in ability)		Screening (rule-out ability)			
Level of evidence	Grade of recommendation	Screening AUC	Pooled likelihood ratio −	Level of evidence	Grade of recommendation
Level 2a	B	0.654 (95% CI = 0.595 to 0.713900514)	0.360	Level 3a	C
Level 2b	B	0.887 (95% CI = 0.823 to 0.932)	0.049	Level 1b	B
Level 2c	C	0.824 (95% CI = 0.753 to 0.896)	0.187	Level 2c	C
Level 3b	C	0.714 (95% CI = 0.627 to 0.801)	0.255	Level 3b	C
Level 2b	C	0.652 (95% CI = 0.582 to 0.705)	0.392	Level 3b	C
Level 2b	C	0.705 (95% CI = 0.648 to 0.763)	0.272	Level 3b	C
Level 2a	C	0.648 (95% CI = 0.631 to 0.686)	0.400	Level 3a	C
Level 3a	C	0.693 (95% CI = 0.647 to 0.738)	0.298	Level 3a	C

structured interview procedures for the diagnosis of depression; these results are only valid if the gold standard is itself valid and not all criterion standards are necessarily equally valid.

4.2. Main findings

We found 8 tools which met the requirements for independent validation, and these were one and two stem questions, the Distress Thermometer (DT), the Hospital Anxiety and Depression Scale (in three formats), the Edinburgh Postnatal Depression Scale (EPDS) and the Beck Depression Inventory version two (BDI-II).

For case-finding, one stem question, two stem questions and the BDI-II all had level 2 evidence (2a, 2b and 2c respectively) and given their better acceptability and availability at no cost to clinicians, we gave the stem questions a grade B recommendation. For screening, the two stem questions had level 1b evidence (with high acceptability) and the BDI-II had level 2c evidence. Therefore the optimal single tool applied on an initial occasion, based on current data appears to be two stem questions, for the dual aims of case finding (Grade B recommendation) and screening (Grade B). This was also the finding of a recent narrative review (Vodermaier et al., 2009). However, this finding is based on a modest number of studies and applies only to the initial method of assessment.

We also subdivided studies into non-advanced cancer and advanced (includes palliative patients see methods) cancer. Study power was weaker when focusing on non-palliative populations. In non-palliative oncology settings the BDI-II was the most accurate tool but with only low-moderate acceptability. Surprisingly perhaps, the single stem question could cautiously consider for case-finding (Grade B recommendation) but no method was entirely satisfactory. In advanced cancer settings, the two stem questions had the best evidence after considering both accuracy and acceptability (Grade B for case-finding and Grade B for screening). We also note that some scales are subject to copyright conditions, which may be a further deterrent to their routine use.

Although the 'two stem questions' was the best-performing tool according to our criteria it still has some limitations in its screening and case finding properties. In particular, as Mitchell (2008) previously noted it has modest PPV at the typical prevalence rates found in cancer settings. These limitations are not so great as to completely preclude clinical usefulness and it nevertheless is likely to out-perform oncologists' unassisted clinical ratings. It may not be possible to develop a single all encompassing tool which will meet the needs of all clinicians in all settings, given variations in available resources, variations in the prevalence of depression; interest in other outcomes (distress, anxiety, fatigue, quality of life, pain) and personal preference for or historical use of particular instruments. However, there would be value in finding a common "language" or metric to compare and interpret findings across settings.

It is unlikely that better single tools will be developed without large-scale projects which offer comparative validation. Also, there are alternative approaches like using a two step assessment procedure using two tools, or using repeated assessments at different time points with a single tool, to improve accuracy while maintaining acceptability. Another important aspect of tool refinement is to include often overlooked properties such as feasibility, acceptability and responsiveness (Richardson et al., 2007). Sophisticated approaches utilizing techniques such as item-response theory, computer-aided testing and Rasch analyses may offer a way to improve upon existing tools. One final requirement is that costs must not be prohibitive and ideally the screener should be freely available for clinical implementation.

This review clearly identifies a major limitation in the literature surrounding the validation of tools for the detection of depression among cancer patients. Fewer than half of the 19 tools identified had been independently validated according to our stringent criteria. Similarly, 150 published studies had to be excluded since the criterion (gold) standard was inadequate for example comparisons against other questionnaires. This may be because studies which obtain clinical diagnosis or use structured clinical interviews are likely to be more difficult and costly than those using concurrent validation against another self-report scale. The establishment of concurrent validity has an acknowledged role in the development of tools. However, to develop the field, more studies employing clinical diagnosis or clinical interview as the gold standard would be worthwhile, providing they are adequately powered.

4.3. Clinical implementation

It has been well established that relying on clinicians' skills to detect depression is generally unsatisfactory in primary care and specialist settings (Fallowfield et al., 2001;

Singer et al., 2007). Yet most clinicians consider structured depression scales too long for routine use (Mitchell et al., 2008a; Pirl et al., 2007; Trask, 2004). One way to save assessment time is to employ a two-step process incorporating both screening (ruling out non-cases) and case-finding (ruling in probable cases). That is, only patients above threshold for the first step go on to be assessed using the second. The two stage approach has been employed by groups in Australia (Clover et al., 2009) the UK (Cull et al., 2001) and US (Fann et al., 2009). The additional potential advantage of using two different tools in a single two-step assessment procedure is that the full assessment can be conducted on a single occasion.

Regardless of the accuracy of any screening test, a screening program will have no effect unless identified cases receive treatment which alters outcomes. Moreover, the detection of cases without the availability of appropriate treatment might be considered unethical. Meta-analyses in non-cancer settings have questioned the effectiveness of screening when used alone (Gilbody et al., 2008). However, when coupled with system-level reorganization of care to include adequate follow-up, improvements in depression have been obtained. Indeed predictors of improvement include high initial distress and adequate follow-up or referral (Carlson et al., 2010). Randomized trials within cancer settings have obtained mixed results. A recent review found three of seven trials identified positive effects of screening on psychological outcomes, while one found positive effects only among patients depressed at baseline and three found no effect (Bidstrup et al., 2011). The review noted heterogeneity between trials and methodological limitations which inhibited the ability to make a conclusive decision regarding the value of screening. Depression is also only one of several common emotional disorders that deserve clinical attention (Mitchell et al., 2011a). The exclusive use of a depression scale may cause clinicians to overlook other important complications. Therefore scales that measure mixed emotional states, quality of life, unmet needs or general distress should also be considered (Vodermaier et al., 2009). Benefits of routine screening on outcomes other than depression have been posited with varying levels of evidence. Improved communication about quality of life issues has been reported by several investigators (Bidstrup et al., 2011; McLachlan et al., 2001; Taenzer et al., 2000; Velikova et al., 2004). Other possible benefits, which require further evaluation, include better use of physician and health care team time, tailored application of resources to the level of intervention required by patients and increased patient and physician satisfaction with the clinical encounter.

Assessment of depression in cancer populations may have some similarities to that in primary care (Gilbody et al., 2008). The U.S. Preventive Services Task Force (USPSTF) found no evidence of harm from screening for depression in adults and little evidence to recommend one screening method over another, suggesting the method chosen should be consistent with personal preference, patient population, and practice setting (O'Connor et al., 2009). The USPSTF also recommended screening adults for depression, only when staff-assisted supports are in place to assure accurate diagnosis, effective treatment and follow-up and cautioned against routinely screening adults for depression when staff-assisted supports are not in place.

5. Conclusion

Based on a relatively large number of small scale studies with high heterogeneity, several screening and case-finding tools may have reasonable diagnostic validity and acceptability, enough to be helpful beyond clinical recognition alone in the identification of depression in a variety of cancer populations. No single tool has sufficient evidence to gain unqualified support but considering accuracy alone the BDI-II and PHQ-2 are currently the optimal choice. A tool with at least level 2 evidence was identified in each setting for case finding and screening, with level 1b evidence established for screening in all cancer populations and for screening and case-finding in advanced cancer populations. After considering both accuracy and acceptability a two-step algorithm approach involving the two stem questions delivered by the clinician or in a self-report format, followed by clinical assessment or further scales may be the optimal current method of helping clinicians identify patients who may benefit from further assessment and management of depression.

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Conflicts of interest

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.jad.2011.12.043.

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JOURNAL OF CLINICAL ONCOLOGY

REVIEW ARTICLE

Screening for Distress and Unmet Needs in Patients With Cancer: Review and Recommendations

Linda E. Carlson, Amy Waller, and Alex J. Mitchell

Linda E. Carlson, Tom Baker Cancer Centre; Linda E. Carlson and Amy Waller, University of Calgary, Calgary, Alberta, Canada; and Alex J. Mitchell, Leicestershire Partnership Trust and University of Leicester, Leicester, United Kingdom.

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Corresponding author: Linda E. Carlson, PhD, Department of Psychosocial Resources, Holy Cross Site, 2202 2nd St SW, Calgary, Alberta, Canada T2S 3C1; e-mail: l.carlson@ucalgary.ca.

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A B S T R A C T

Purpose
This review summarizes the need for and process of screening for distress and assessing unmet needs of patients with cancer as well as the possible benefits of implementing screening.

Methods
Three areas of the relevant literature were reviewed and summarized using structured literature searches: psychometric properties of commonly used distress screening tools, psychometric properties of relevant unmet needs assessment tools, and implementation of distress screening programs that assessed patient-reported outcomes (PROs).

Results
Distress and unmet needs are common problems in cancer settings, and programs that routinely screen for and treat distress are feasible, particularly when staff are supported and links with specialist psychosocial services exist. Many distress screening and unmet need tools have been subject to preliminary validation, but few have been compared head to head in independent centers and in different stages of cancer. Research investigating the overall effectiveness of screening for distress in terms of improved recognition and treatment of distress and associated problems is not yet conclusive, but screening seems to improve communication between patients and clinicians and may enhance psychosocial referrals. Direct effects on quality of life are uncertain, but screening may help improve discussion of quality-of-life issues.

Conclusion
Involving all stakeholders and frontline clinicians when planning screening for distress programs is recommended. Training frontline staff to deliver screening programs is crucial, and continuing to rigorously evaluate outcomes, including PROs, process of care, referrals, and economic costs and benefits is essential.

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WHAT IS SCREENING FOR DISTRESS?

The National Comprehensive Cancer Network Distress Management Guidelines Panel defines distress as "a multifactoral unpleasant emotional experience of a psychological (cognitive, behavioral, emotional), social, and/or spiritual nature that may interfere with the ability to cope with cancer, its physical symptoms and its treatment. Distress extends along a continuum, ranging from common normal feelings of vulnerability, sadness, and fears, to problems that can become disabling such as depression, anxiety, panic, social isolation and spiritual crisis."[1(p6)] In this framework, distress related to cancer diagnosis and treatment is explicitly tied to a number of common practical, physical, and psychologic problems. Elevated levels of distress have been linked with reduced health-related quality of life (QoL),[2] poor satisfaction with medical care,[3] and possibly reduced survival,[4,5] although this mortality effect may be confined to later stages.[6]

Distress is not a precise clinical term that appears in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, which is used to assign formal psychiatric diagnoses, but it is part of the clinical significance criterion that is a qualifier for several mood disorders, including major depression and adjustment disorder. One reason for its adoption in cancer care is that the term distress is often more useful for cancer clinicians than psychiatric terms such as anxiety or depression. It is easily understood by the lay person and does not carry the stigma often associated with diagnostic labels and terms such as psychiatric, psychosocial, and emotional problems. It is usually well understood by non–mental-health clinicians, facilitating quick assessment with simple verbal enquiry or patient self-report.

Because the common distress scales do not allow case finding for psychiatric conditions such as major depression, distress screening is usually recommended as a first step, followed by further clinically appropriate assessment.[6,7] Typical evidence-based treatments for depression and anxiety, such as cognitive behavioral therapy, group therapy, or pharmacotherapy, are usually applicable to the treatment of distress, although more distress-focused intervention trials are needed. Other interventions such as resource counseling (for practical problems such as financial assistance or drug coverage) and symptom management (eg, for fatigue or pain) may also be indicated. The latter can be considered an attempt to address "meetable" unmet needs.

In the last decade, screening for distress has been positioned as the sixth vital sign in cancer care, in addition to the first five, which are measurements of pulse, respiration, blood pressure, temperature, and pain.[6,7] A number of international regulatory bodies and professional societies have recommended routine screening and management of distress as an integral part of whole-person cancer care, just as health care teams monitor and respond to the other vital signs.[6]

Prevalence and Predictors of Distress

Estimates regarding the prevalence of distress have been informed by studies using the Brief Symptom Inventory (BSI),[8] General Health Questionnaire (GHQ),[9] and Distress Thermometer (DT).[10] Pooled BSI data from two studies involving more than 7,000 patients illustrate that approximately four in 10 patients with cancer report significant distress.[11,12] Individuals with certain cancers such as lung, brain, and pancreatic cancers are more likely to be distressed, but differences by cancer type are generally modest. More powerful predictors of distress include poorer QoL, disability (eg, low Karnofsky performance score), and ongoing unmet needs.[12-15] Newer longitudinal studies have also shown that for some patients, distress, anxiety, and common problems such as fatigue and pain remain elevated months or years after their initial diagnosis.[16] One area of uncertainty is whether rates of distress are particularly high in palliative stages of cancer. One group recently found in a cross-sectional study that psychologic distress using the 12-item GHQ (GHQ-12) was approximately 25% in outpatients with cancer during or soon after treatment, 16% in community dwelling cancer survivors, and almost 60% in those receiving specialist palliative care.[13]

Brief Overview of Tools Versus Criterion Standards

Many tools have been developed and applied in screening for distress. The best known is the DT developed by the National Comprehensive Cancer Network, which was introduced as a simple, acceptable method to measure distress. Subsequent evidence showed it had good negative predictive value (the accuracy of a negative screen) comparable to longer tools.[17] We undertook a search of all distress screening tools for patients with cancer using Embase, Web of Knowledge, and Pubmed from inception to September 2011. Prior reviews were also searched.[17-20] The search produced 68 articles; the detailed search strategy is presented in Appendix Figure A1 (online only). Studies were excluded if they did not present accuracy data validated against distress-specific criterion measures (eg, ideally structured interviews using Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, or International Classification of Diseases, 10th Revision, criteria for any mental disorder but also Hospital Anxiety and Depression Scale total scale [HADS-T], GHQ, or BSI)[21-37] and if they were underpowered (defined as a sample size < 100).[38-42] Applying search criteria left 30 articles addressing the psychometric qualities of various distress screening tools, which are summarized in Table 1 (presented in full in Data Supplement).

Psychometric properties summarized for each include validity, reliability, and recommended cutoff scores. There were insufficient data to meaningfully compare tools tested in palliative versus nonpalliative settings. Further work is required to test whether specific tools are needed for different settings. Rarely did authors compare multiple approaches to distress, but in one small study, the DT was found to be equivalent to the GHQ-12 and BSI short form (BSI-18) in detecting distress in palliative care.[45] However, in a mixed cancer sample, Reuter et al[64] found the HADS-T to be nonsignificantly more accurate than the GHQ-12 against any mental disorder. However, also in a mixed cancer setting, Clover et al[95] found the DT to be outperformed by the Kessler-10 and PSYCH-6, a subscale of the Somatic and Psychological Health Report, largely because of the low positive predictive validity (accuracy of a positive screen) of the DT. Smaller differences were found by Singer et al[71] in a head-to-head comparison of the visual analog scale mood item, HADS-T, Hornheider Fragebogen, and European Organisation for Research and Treatment of Cancer—Emotional Function in patients with laryngeal cancer. A number of promising new tools such as the Psychological Distress Inventory, Mood Thermometer, and Emotion Thermometer have recently been tested, but all require independent validation to confirm their clinical utility. A common theme for distress tools is that screening questionnaires have high negative predictive value but somewhat disappointing positive predictive value, which reinforces the conclusion that there is currently no tool that can be relied on alone (without further follow-up).

WHAT ARE PSYCHOSOCIAL NEEDS ASSESSMENTS?

The application of a screening test is not usually sufficient to facilitate a change in patient outcomes; it is merely the first step in a process that requires further comprehensive assessment and timely provision of interventions that are evidence based.[72-74] Standardized distress screening tools such as the DT can assist clinicians in detecting patients currently in distress; however, they require additional help to pinpoint the presence of physical, practical, emotional, family, or spiritual problems contributing to distress.[1] Unfortunately, we also know that patients may experience significant problems but decline intervention from their health care team,[75] perhaps in favor of informal support from family and friends. Teams must try to facilitate delivery of psychosocial treatment in an acceptable and convenient form for those who may benefit. It may also be sensible to ask patients formally if they wish to receive input from clinical services (and to clarify why, if patients decline). Needs assessment is a strategy that focuses on identifying the unresolved concerns that patients are experiencing and determines if they require further assistance as well as the level of assistance they require.[76]

Tools for Conducting Needs Assessments

A range of tools have been developed to assess the unmet needs of patients with cancer. A search of all needs assessment tools for adult patients with cancer was conducted in Embase/MEDLINE from inception to September 2011 (Appendix Fig A2, online only, describes

Table 1. Description of Screening Tools for Distress

Measure	Purpose and Format	Population	Recommended Cutoff
BSI-18	Brief screening measure for psychologic distress and psychiatric disorders in patients with cancer	Mixed[43]	Men ≥ 10; women ≥ 13
	18 items: how distressed the individual has felt by each symptom during the past 7 days	Survivors[44]	Survivors ≥ 50 (T-score)
	Three subscales (depression, anxiety, and somatization) and one GSI score	Palliative[45]	Palliative ≥ 62 (T-score)
DT	Screening measure for global distress in patients with cancer	Mixed[46-56]	Mixed ≥ 4 (≥ 5,[55] ≥ 7[51])
	One item: individuals rate distress levels during the past week; scores range from 0 (none) to 10 (extreme distress)	Survivors[57]	Survivors, no optimal
		Palliative[45]	Palliative ≥ 5
One-item mood question with DT	Screening question for adjustment disorders and major depression in patients with cancer	Mixed[58]	DT ≥ 4
	DT plus one-item mood question: individuals grade mood during the past week; scores range from 0 (low mood) to 100 (usual relaxed mood)		Interview: ≤ 60 (Global Assessment of Functioning)
DT and IT	Brief screening tool for detection of adjustment disorders and/or major depression.	Mixed[59,60]	IT alone ≥ 4
	DT plus one-item IT: individuals rate the impact of distress (as scored on the DT) on daily life activity; score ranges from 0 (no impact) to 10 (high impact)		DT and IT combined: Distress, DT ≥ 2; IT ≥ 4 Adjustment, DT ≥ 4; IT ≥ 3 Depression, DT ≥ 5; IT ≥ 4 Depression and suicidal ideation, DT ≥ 5; IT ≥ 5
ET	Five thermometers (VASs) assessing four mood domains (distress, anxiety, depression, anger) and one "need for help" thermometer	Mixed[18,61]	DT ≥ 3 or 4; AnxT ≥ 3 or 5
	Four mood thermometers: individuals rate how much emotional upset they have experienced in the past week; scores range from 0 (none) to 10 (extreme)		DepT ≥ 3; AngT ≥ 2 or 3; DepT ≥ 2 or 3; HelpT ≥ 3
	Need for help thermometer: individuals rate how much help they need for these concerns; score ranges from 0 (can manage by myself) to 10 (desperately)		Optimal tool: *v* HADS-T AngT; *v* DSM-IV DepT
DT and CCS	Assist health professionals to interpret "at a single glance" the nature and intensity of distress	Mixed[62]	DT ≥ 4; CCS ≥ 4
	DT: ranges from 0 (no distress; green) to 5 (moderate distress; yellow), to 10 (extreme distress; red)		
	CCS: individuals rate the intensity of nine items (pain, nervousness, concentration, anxiety, worries about partner/family, sadness, anger, spiritual concerns, other physical problems) on scale ranging from 0 (no annoyance; pastel green) to 10 (very much annoyance; dark red)		
DT and MT	Two emotional thermometers evaluate the patient's level of distress (DT) and depression (MT)	Mixed[63]	General distress: DT ≥ 4; MT ≥ 3
	DT plus one-item MT: individuals rate how depressed they have been today and over the last week; score ranges from 0 (normal mood) to 10 (highly depressed)		Severe distress: DT ≥ 5; MT ≥ 4
GHQ-12	Screen for general psychologic morbidity and capture the construct of distress	Mixed[64]	GHQ-12 ≥ 5
	12 items: individuals rate somatic symptoms, anxiety/insomnia, depression, and social dysfunction over the last few weeks; scale ranges from 0 to 4 (higher score indicates poorer health)	Palliative[45]	
K-10	Provides global measure of psychosocial distress	Mixed[65]	K10 ≥ 22
	10 items: individuals rate nervousness, agitation, psychologic fatigue, and depression in the last 4 weeks; scales range from 1 (none of the time) to 5 (all of the time)		K-10 outperformed DT; combination K-10 and DT better
	Total score ranges from 10 to 50 (higher score indicates greater distress)		

(continued on following page)

Table 1. Description of Screening Tools for Distress (continued)

Measure	Purpose and Format	Population	Recommended Cutoff
PDI	Assesses general emotional condition and psychologic disorders related to illness adjustment	Mixed[66]	Mixed: PDI ≥ 28
	13 items: individuals rate depression, anxiety, tiredness, sexual desire, relationships with others, and self-image in the last week; scales range from 1 (not at all) to 5 (very much)	Breast[67]	Breast: PDI ≥ 29
	Global score ranges from 13 to 65 (higher score indicates greater distress)		
PDS	French adaptation of the NCCN Distress Thermometer	Mixed[68]	PDS ≥ 3
	One-item PDS: individual rates distress (ie, de'tresse) during the past week; score ranges from 0 (none) to 10 (extreme distress)		
QSC-R10	Screening instrument for self-assessment of psychosocial distress in patients with cancer	Mixed[69]	Cutoff > 14
	10 items: individuals indicate whether psychosomatic complaints, fears, information deficits, everyday life restrictions, and social strains apply to them and severity of the problem		
	Scales range from 0 (problem does not apply) to 5 (problem applies and is very serious; higher score indicates need for psychosocial support)		
SIPP	Self-report questionnaire to identify psychosocial problems in patients with cancer	Radiotherapy[70]	Subclinical: physical ≥ 4; psychologic ≥ 5
	24 items: individuals rate physical complaints, psychologic complaints, and social/financial and sexual problems; scales range from 0 (no) to 2 (yes; higher score indicates poorer functioning)		Clinical: physical ≥ 5; psychologic ≥ 9
VAS	Screening instrument for assessment of mood in patients with cancer	Laryngeal[71]	VAS ≥ 37
	One-item VAS: individuals rate mood over last 2 months; scale ranges from 0 (happy) to 100 (miserable)		

Abbreviations: AnxT, Anxiety Thermometer; AngT, Anger Thermometer; BSI-18, Brief Symptom Inventory short form; CCS, Colored Complaint Scale; DepT, Depression Thermometer; DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition; DT, Distress Thermometer; ET, Emotion Thermometer; GHQ, General Health Questionnaire; GSI, Global Severity Index; HADS-T, Hospital and Anxiety Depression Scale total scale; HelpT, Help Thermometer; IT, Impact Thermometer; K-10, Kessler-10; MT, Mood Thermometer; NCCN, National Comprehensive Cancer Network; PDI, Psychological Distress Inventory; PDS, Psychological Distress Scale; QSC-R10, Questionnaire on Distress in Cancer Patients short form; SIPP, Screening Inventory for Psychosocial Problems; VAS, visual analogue scale.

the search strategy). Prior reviews[79,80] were also searched. Of the 830 articles identified, 44 specifically addressed development or assessment of psychometric qualities of needs assessment tools. Tools were excluded if they assessed only one domain of need (eg, information needs),[82-85,124] were developed to audit the care provided to patients or assess satisfaction with care,[86] and made no attempt at validation against distress. Using these criteria, we found 38 studies including data on 29 tools. These are presented in brief in Table 2 (and in full in Data Supplement).

A majority of tools were developed for use with patients diagnosed with any type of cancer.[77,88-92,95-99,111-113,116,117,119,123] However, some were proposed as specific to advanced stage of disease,[78,87,100,104,107,114,115,120,125] clinical setting,[94,105,106,121] or survivors.[93,122] Others targeted particular diagnoses (eg, lung[100] and prostate cancers[108-110]). Two tools were developed specifically for screening patients with cancer in any setting (including primary care) to prompt further assessment and appropriate referrals to services.[101,102,125]

The most common strategy for establishing content validity of needs assessment measures was through literature reviews and adapting items derived from other scales, followed by clinical and/or expert opinion. The Needs Near the End-of-Life Scale, Problems and Needs in Palliative Care, Needs Assessment Tool: Progressive Disease—Cancer (NAT:PDC), and Sheffield Profile for Assessment and Referral to Care (SPARC) questionnaires were the most comprehensive in their approach to content validity, making use of multiple strategies to determine items. Items covered a wide range of need domains including physical, psychologic, social, spiritual, sexual, information, cognitive, and financial needs as well as care provision, to varying degrees. The number of items in reviewed tools ranged from 13 to 138. Although comprehensive in their coverage, tools such as the Problems and Needs in Palliative Care, Needs Assessment of Advanced Cancer Patients, Comprehensive Needs Assessment Tool in Cancer, Supportive Care Needs Survey (SCNS), and Cancer Rehabilitation Evaluation System included more than 50 items, which has implications for time limitations and patient burden if delivered manually.

Evidence of validity and reliability varied considerably between tools. In terms of construct validity, most tools relied primarily on factor analysis and correlations with existing measures; however, validation data were not provided for all tools and all subscales reviewed (Cancer Needs Distress Inventory (CaNDI), Cancer Needs Questionnaire short form, NAT: PD-C, and Survivors Unmet Needs Survey). Evidence of predictive validity was provided for two tools only (CaNDI and Cancer Care Monitor), and no construct validity information was available for some tools (Three Levels of Needs Questionnaire, Psychosocial Needs Assessment Survey, Supportive Needs Screening Tool, and SPARC). Evidence of

Table 2. Description of Needs Assessment Tools

Measure	Content and Format	Population
3LNQ	Assesses EORTC QLQ-C30 physical function, role function, depression, worry, concentration, nausea, pain, dyspnea, reduced appetite, social function, and fatigue items and three additional items: sexuality, feeling burden, and loneliness 14 items: patient rates problem intensity in the past week for 12 items; scale ranges from 1 (not at all) to 4 (very much); problem intensity on the three additional items; and felt need for 12 items ranging from no need to unmet need to met need	Advanced (stage III/IV)[87]
CaNDI	Needs-based measure of cancer-related distress including depression, anxiety, emotional, social, health care, practical needs 39 items: patient rates extent of problem in the last 2 weeks; scale ranges from 1 (not a problem) to 5 (very severe problem) and desire for help for each item (yes/no) Total distress score created using summed item scores; two subscale scores created for anxiety and depression	Mixed[88]
CARES	Self-report measure assessing the day-to-day problems and rehabilitation needs of patients with cancer 139 items (not all items completed by all patients: minimum, 93 items; maximum, 132 items): patients rate the extent to which item applies to them; scale ranges from 0 (does not apply) to 4 (very much) Global CARES score and five higher-order factors: physical, psychologic, medical interaction, marital, sexual, and other problems	Mixed[89-91]
CARES-SF	Short form of the CARES instrument 59 items (not all items completed by all patients: minimum, 38 items; maximum, 57 items): patients rate extent to which item applies to them; scale ranges from 0 (does not apply) to 4 (very much); global CARES-SF score and five higher-order factors: physical, psychologic, medical interaction, marital, sexual, and other problems	Mixed[89,92]
CaSun	Self-report measure of cancer survivors' supportive care needs 35 items: patient rates information/medical care, quality of life, emotional/relationships, life perspective needs since completing treatment; scale ranges from no need/not applicable to high need Six positive change items rated on 4-point scale ("yes, but I have always been like this"; "yes, this has been a positive outcome"; "no, and I would like help to achieve this"; "no, and this is not important to me")	Survivors (1 to 15 years)[93]
CaTS	Assess sensory/psychologic concerns and procedural concerns relating to cancer treatment 25 items: patients indicate what hospital staff could have done to help them cope better in the time before their treatment; scale ranges from 1 (strongly disagree) to 5 (strongly agree; higher score indicates greater need for assistance)	Lymphoma and colon[94]
CCM	Assesses physical symptoms, treatment side effects, acute distress, despair, impaired ambulation, impaired performance, and quality of life 38 items: patient rates how bad the physical symptoms/treatment side effects have been during the past week (scale ranges from 0 [not bad at all] to 10 [bad as possible]), or how true a statement regarding distress, despair, or impairment was in past week (scale ranges from 0 [not at all true] to 10 [completely true])	Mixed[95,96]
CNAT	Self-report tool assessing information, psychologic, health care staff, physical symptoms, hospital services, family/interpersonal, spiritual/religious, and social needs of patients with cancer of any type during any phase of illness 59 items: patient rates their level of need in the last month; scale ranges from 1 'No need' to 4 'high need'	Mixed[97]
CNQ-SF	Assesses psychologic, health information, physical and daily living, patient care and support, interpersonal communication needs 32 items: patients rate their level of need for help on a scale ranging from 1 (no need/not applicable) to 5 (high need)	Mixed[98]
CPILS	Assesses physical and emotional distress, employment/financial problems, and fear of recurrence in cancer survivors 29 items: patients rate the degree to which each problem applies to them; scale ranges from 0 (not a problem) to 2 (severe problem)	Mixed[99]
NA-ACP	Assesses daily living, symptom, psychologic, social, spiritual, financial, medical communication, and information needs in advanced cancer 132 items: patients rate their level of need for help in the past 4 months; scale ranges from 1 (no need/not applicable) to 5 (high need)	Advanced[78]
NA-ALCP	Assesses daily living, symptom, psychologic, social, spiritual, financial, medical communication, and information needs in patients with advanced lung cancer 38 items: patients rate their level of need for help in the past 4 months; scale ranges from 1 (no need/not applicable) to 5 (high need)	Advanced lung cancer[100]
NAT:PD-C	Health professional–completed screening measure for patients with advanced cancer and their caregivers assesses patient well-being, ability of caregiver/family to care for patient, and caregiver/family wellbeing 18 items: health professional rates patient/caregiver level of concern since last consultation; scale ranges from 1 (none) to 3 (severe); if rated as some or severe, health professional records action taken (directly managed, managed by someone in care team, referral required)	Patients with advanced disease and caregivers[101-104]
NEQ	Screening tool used to assess the physical, psychologic, social, spiritual, information, financial needs of hospitalized patients with cancer 23 items: patient indicates the presence or absence of needs	Hospitalized[105,106]

(continued on following page)

Table 2. Description of Needs Assessment Tools (continued)

Measure	Content and Format	Population
NEST	Assesses the financial needs, access to care, social connection, sense of purpose, physical needs, anxiety/depression, information needs, caregiving needs, relationship with others, distress, goals of care, and spirituality needs of patients with advanced cancer 13 items: patient rates level of concern; scale ranges from 0 (none) to 10 (a great deal)	Advanced[107]
PCNA	Assesses unmet information, support, and care delivery needs of men with prostate cancer 135 items: patient rates the importance of the need; scale ranges from 1 (not all important) to 10 (extremely important) Patient also indicates whether need was met; scale ranges from 1 (not met) to 10 (totally met)	Prostate[108]
PCNQ	Assesses the perceived needs relating to role limitations, general practitioner ongoing support, impotence and sexual issues, incontinence, personal integration and control, and specialist ongoing support of men diagnosed with prostate cancer 69 items: patient rates the level of need; scale ranges from strongly disagree to strongly agree Individual also indicates desire for help with identified needs; scale ranges from not at all to a lot	Prostate[109,110]
PNAS	Assesses the presence of information, practical, supportive, spiritual needs in patients with cancer 34 items: patients indicate whether they would like to know more about, help with, or someone to talk to; scale ranges from yes, yes but not now, no, does not apply	Mixed[111]
PNAT	Assesses the physical, psychologic, and social problems of patients with cancer 16 items: patient rates the degree of impairment; scale ranges from no impairment to severe impairment	Mixed[112]
PNI	Assesses practical, childcare, support networks, emotional and spiritual, information, health professional, and identity needs 48 items: patient rates the importance of the need over the past few weeks (scale ranges from 1 [not important] to 5 [very important]) as well as satisfaction of that need	Mixed[113]
PNPC	Assesses the physical/daily living, psychologic, social, spiritual, information, financial, sexuality, caregiver/family, quality of care, and general practitioner/specialist needs of patients with cancer in palliative setting 138 items: patient rates the degree of problem; scale ranges from 1 (yes) to 2 (somewhat) to 3 (no) Patient also rates desire for professional attention for each problem; scale ranges from 1 (yes, more) to 2 (as much as now) to 3 (no)	Palliative[114]
PNPC-sv	Tool assessing the physical/daily living, autonomy, psychologic, social, spiritual, information, and financial needs of patients with cancer in palliative setting 33 items: patient rates the degree of problem; scale ranges from 1 (yes) to 2 (somewhat) to 3 (no) Patient also rates desire for professional attention for each problem; scale ranges from 1 (yes, more) to 2 (as much as now) to 3 (no)	Palliative[115]
Problems Checklist	Tool assessing the daily living, relationship, emotion, and economic problems of patients with cancer 16 items: patients rate the extent to which they had difficulties or worries recently; scale ranges from 0 (no difficulty) to 3 (severe difficulty)	Mixed[116]
SCNS	Tool assessing the physical and daily living, psychologic, health system and information, sexuality, and patient care and support needs of patients with cancer 59 items: patients rate their level of need in the past month; scale ranges from 1 (no need/not applicable) to 5 (high need)	Mixed[77]
SCNS-SF34	Tool assessing the physical and daily living, psychologic, health system and information, sexuality, patient care and support needs of patients with cancer 34 items: patients rate their level of need in the past month; scale ranges from 1 (no need/not applicable) to 5 (high need)	Mixed[117] Prostate[118]
SNST	Tool assessing physical, social, psychologic, information, spiritual needs for use in an outpatient oncology setting 40 items: patient rates the presence of need experienced on a yes/no scale; time periods defined for specific needs based on evidence and clinician-defined usefulness (eg, pain experienced in last week, emotions experienced in last 2 weeks)	Mixed[119]
SPARC-45	Screening tool assessing communication and information, physical symptom, psychologic, religious and spiritual, independence and activity, family, social, and treatment needs of patients with advanced cancer 45 items: patient rates level of need on a scale ranging from 0 (not at all) to 3 (very much) and desire for help from health team on a yes/no scale	Advanced[120]
SPEED	Health professional–completed screening tool assessing the physical, spiritual, social, therapeutic, and psychologic needs of patients with cancer receiving palliative care admitted to the emergency department 13 items: patient rates the level of need; scale ranges from 0 (not at all) to 10 (a great deal)	Patients in emergency department[121]
SUNS	Tool assessing the emotional health, access and continuity of care, relationships, financial concerns, and information needs of cancer survivors 89 items: patients rate their level of need in the past month; scale ranges from 0 (no need) to 4 (very high need)	Survivors (1 to 5 years)[122]

Abbreviations: 3LNQ, Three Levels of Needs Questionnaire; CaNDI, Cancer Needs Distress Inventory; CARES, Cancer Rehabilitation Evaluation System; CARES-SF, CARES short form; CaSun, Cancer Survivors Unmet Needs; CaTS, Cancer Treatment Survey; CCM, Cancer Care Monitor; CNAT, Comprehensive Needs Assessment Tool in Cancer; CNQ-SF, Cancer Needs Questionnaire short form; CPILS, Cancer Problems in Living Scale; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30; NA-ACP, Needs Assessment of Advanced Cancer Patients; NA-ALCP, Needs Assessment for Advanced Lung Cancer Patients; NAT:PD-C, Needs Assessment Tool: Progressive Disease—Cancer; NEQ, Needs Evaluation Questionnaire; NEST, Needs Near the End of Life Scale; PCNA, Prostate Cancer Needs Assessment; PCNQ, Prostate Cancer Needs Questionnaire; PNAS, Psychosocial Needs Assessment Survey; PNAT, Patient Needs Assessment Tool; PNI, Psychosocial Needs Inventory; PNPC, Problems and Needs in Palliative Care; PNPC-sv, PNPC short version; SCNS, Supportive Care Needs Survey; SCNS-SF34, SCNS short form; SNST, Supportive Needs Screening Tool; SPARC, Sheffield Profile for Assessment and Referral to Care; SPEED, Screen for Palliative and End-of-Life Care Needs in the Emergency Department; SUNS, Survivors' Unmet Needs Survey.

reliability also varied, with some studies limiting reliability information to internal consistency using Cronbach's alpha (> 0.70 for acceptable reliability) and inter-item and item-total correlations. Others studies also included inter-rater reliability (Three Levels of Needs Questionnaire, NAT: PD-C, and Patient Needs Assessment Tool), alternate-forms reliability (Cancer Care Monitor [CCM]), and test-retest reliability (CaNDI, Cancer Rehabilitation Evaluation System (CARES), CARES short form, Cancer Survivors Unmet Needs, CCM, Needs Assessment of Advanced Cancer Patients, Needs Evaluation Questionnaire, Prostate Cancer Needs Questionnaire, and Patient Needs Assessment Tool). No reliability data were available for the Prostate Cancer Needs Assessment, Supportive Needs Screening Tool, SPARC, or SPEED.

Supplementing standardized distress screening tools with needs assessment tools may have the potential to enhance the ability of clinicians to identify and manage patients' concerns in a timely and appropriate manner.[18,126] Although distress screening tools can detect the presence of distress in patients, needs assessment tools provide a more comprehensive assessment of concerns and may be particularly useful for high-risk patients. Tools such as the CCM, CARES, CARES short form, CaNDI, SCNS, SCNS short form (for patients before or during treatment), and Cancer Survivors Unmet Needs (for survivors) have been subjected to more rigorous psychometric testing and hence would be our current recommendations. However, further evidence of psychometric quality is needed, particularly evidence of test-retest reliability, predictive validity, responsiveness, and clinical utility of these tools. Also untested is the ability of needs tools to improve patient-reported outcomes (PROs) in randomized trials.

HOW CAN SCREENING FOR DISTRESS BE IMPLEMENTED?

Process of Implementation

Despite strong recommendations of many professional societies and accreditation agencies, to date few cancer centers have adopted routine screening for distress or needs assessment,[127] although implementation trials are under way. Programs often show enhanced acceptability when assisted by dedicated funded trials staff; hence, real-world acceptability should be re-evaluated under routine care conditions. In clinical settings, it is not certain whether systematic screening can actually be accomplished in busy clinical environments such as on a surgical ward, in the chemotherapy suite, or in radiotherapy. The key question is whether screening programs remain acceptable to both patients and frontline cancer clinicians.

Several studies have now reported that it is possible to screen large numbers of patients with few refusals. For example, Carlson et al[128] accrued 89% of all eligible patients in lung and breast cancer clinics over an 18-month period; Shimizu et al[129] similarly accrued 92% of patients with cancer in a general oncology practice, and Ito et al[130] recruited 76% of eligible patients receiving chemotherapy. These studies each included more than 1,000 patients. Other researchers have also interviewed patients and staff to better understand their perceptions of the screening process. Fillion et al[131] assessed the implementation of screening for distress programs led by nurse navigators in two Canadian provinces. They interviewed nurse providers, psychosocial and spiritual staff, and hospital administrators about their experiences throughout the process of implementing screening programs. Staff members were enthusiastic about screening for distress and valued the training they received before implementation. They felt it fit well with their role as nurse navigators and saw through experience with patients that it could allow for a deeper conversation about issues that may not have been discussed otherwise.

Despite high accruals and positive perceptions, most screening implementation has occurred with the assistance of dedicated collaborative screening staff. Mitchell et al (manuscript submitted for publication) assessed implementation of a simple visual-analog screener without such assistance in routine cancer care. After 379 screening applications, clinicians felt screening was useful in 43% and not useful in 36% of assessments and were unsure or neutral in 21% of assessments. More than one third felt that the screening program was impractical for routine use (38%), and more chemotherapy nurses than radiographers rated the screening program as "not useful" (43% *v* 22%). Thus, despite much success of programs with dedicated staff, there is still a need for more research investigating the practicalities of adopting screening for distress programs in real-life clinical practice using existing staff.

One of the issues commonly cited as a barrier to implementing routine screening for distress is a concern that the yield from positive screening cases will overwhelm existing psychosocial services. Emerging data do not support this contention. For example, a study conducted among more than 1,100 patients with breast and lung cancers found that when invited to talk to a staff member about concerns identified in screening for distress, between 40% and 50% of patients accepted a telephone consultation, and in total, approximately 30% were eventually referred to services.[128] Similarly, 20% of patients with head and neck cancer screened for distress were referred to care,[132] and of those with high distress referred to services, 25% accepted the referral.[129] In a palliative setting, 33% were referred to services.[133] This is similar to base rates of psychosocial services use before the implementation of screening for distress programs (24%[134]). In fact, this raises the opposite concern: does screening really make a difference? The evidence for this is discussed in this article. It may be the case that after the implementation of screening, different people find their way to services or use a variety of resources previously unused. An important secondary objective of screening is to help meet the needs of underserved populations such as those with low income, ethnic minorities, and psychosocially distressed individuals. This urgently requires investigation in future studies.

Outcomes of Screening for Distress Programs

In contrast to work in primary care, there are few data available on the effects of screening for distress on PROs in cancer. A search for all studies that implemented screening for distress with assessment and management of symptoms, followed by further assessment and evaluation of the efficacy of the intervention, was conducted in Web of Knowledge and PUBMED from inception to September 2011 (Appendix Fig A3, online only, describes search strategy). Prior reviews were also searched.[73,135] Inclusion criteria were as follows: randomized controlled trials (RCTs) examining the effect of screening for distress on PROs, or nonrandomized studies with a usual care cohort (sequential, historical, or concurrent). We excluded single-arm studies without a comparative control group and studies that addressed impact of implementation on process of care/patient encounter only.[46,68,131,132,136-145] Applying search terms revealed only 14 articles (seven randomized and seven nonrandomized studies) addressing the impact of screening for distress on PROs (Table 3).

Table 3. Impact of Screening for Distress on Patient-Reported Outcomes

Author	Study Design and Methods	Sample	Measures	Results	Conclusions/Comments
Randomized					
Maunsell et al[146]	Two-arm RCT	251 patients with breast cancer	Primary outcome:distress, PSI	Primary outcome: distress decreased over time (both groups)	Systematic screening of distress, with extra psychosocial help offered to high-distress patients, did not improve QoL
	Both groups: basic psychosocial care (ie, contact with social worker at initial treatment); follow-up telephone interviews 3 and 12 months later	Intervention, n = 123; control, n = 127	Secondary outcome: overall health perception	Secondary outcomes: no between-group differences in distress, physical health, usual activities, return to work, marital satisfaction, use of other psychosocial services, or medical consultations	Limitations: basic psychosocial care provided to all patients may have been sufficient
	Intervention: telephone screening using GHQ-20 every 28 days (12 calls); patients scoring GHQ ≥ 5 referred to social worker	Exclusion criteria:previous treatment for cancer, distant disease at diagnosis, participant in other trial, no severe health problems	Usual activities: CHALS		
	Control: No telephone screening		Depression/anxiety: DIS Social support: SSQ Marital: LWMAT Stressful life events: LES		
McLachlan et al[147]	Two-arm RCT (allocation ratio: 2:1 intervention to control)	450 patients with cancer	Primary outcome: CNQ-SF (psychologic and information needs)	Primary outcome: no between-group difference in changes in psychologic/information needs	No meaningful difference between groups in changes in cancer needs or QoL over 6 months
	Both groups: Completed measures using touch-screen computer before consultation at baseline and 2 and 6 months	Intervention, n = 296; control, n = 154	Secondary outcomes: Other needs: CNQ-SF	Secondary outcomes: no difference in changes in other needs between two groups	Limitations: only 37% of services offered were accepted; attrition; high percentage with no/low needs, high function, and QoL; no staff training; possible contamination intervention effects
	Intervention: results summary available to physician and coordination nurse during consultation; individualized management plan based on scores and predefined guidelines developed for patients	Eligibility criteria: Attending medical oncology clinic, not first consultation, ECOG status ≤ 2, age ≥ 18 years, adequate follow-up scheduled, ≥ 90% prestudy items, fluent English	QoL: EORTC QLQ-C30 depression, BDI short form	Intervention: greater decrease in depression at 6 months (in patients depressed at baseline)	
	Control: usual clinical encounter; information not available to clinicians		6 months only: satisfaction with medical staff, information provision, overall satisfaction	No between-group differences in changes in satisfaction with care	
Detmar et al[148]	Randomized crossover trial (10 physicians randomly allocated; switched arms at midpoint)	214 patients receiving palliative chemo-therapy	Primary outcome: QoL topics discussed, checklist and audio tapes	Primary outcome: 10 of 12 QoL issues discussed more frequently in intervention group	Significant increase in QoL issues discussed and patient satisfaction with emotional support
	Both groups: complete screening measure (EORTC QLQ-C30) before consultation; follow-up for three outpatient visits	Intervention, n = 100; control, n = 114	Secondary outcomes: Awareness QoL: COOP	Secondary outcomes: no significant differences between groups on physician awareness QoL, patient QoL, satisfaction, or management	Modest effect on patient management and QoL
	Intervention: results given to patient and physician for review during consultation	Eligibility criteria: basic proficiency in Dutch language, age > 18 years, not enrolled onto concurrent HRQL study	QoL: SF-36	Intervention group reported greater improvements in mental health and role functioning	Limitations: limited staff education (half hour); many statistical tests
	Control: results not available to clinician/patient Management: medical record review Satisfaction/acceptability: interview		Satisfaction: PSQ		

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Table 3. Impact of Screening for Distress on Patient-Reported Outcomes (continued)

Author	Study Design and Methods	Sample	Measures	Results	Conclusions/Comments
Velikova et al[149] (secondary analysis[150])	Three-arm RCT (allocation ratio: 2:1:1 in favor of intervention group and stratified by cancer site)	286 patients	Primary outcomes: QoL: FACT-G	Primary outcome: intervention and attention control groups higher QoL than control group (no difference between intervention and attention control)	Increase in discussion of chronic symptoms and positive impact on well-being; clinically significant improvement in well-being (in intervention group)
	Intervention: completion of touch-screen screening measure (EORTC QLQ-C30, HADS), with feedback of results to physicians	Intervention, n = 144; attention control, n = 70; control n = 72		Proportion of patients with clinically meaningful improvement in FACT-G greater in intervention group	No impact on patient management
	Attention control: completion of touch-screen screening measure (EORTC QLQ-C30, HADS); no feedback provided to physicians		Secondary outcomes: audio-taped consultation content of any QoL issues included in EORTC QLQ-C30	Secondary outcomes:EORTC symptoms higher in intervention group; no difference in number of other symptoms discussed; several patient-reported outcomes improved	Some physician training
	Control: no touch-screen measurement of HRQL before clinic encounters	Eligibility criteria: commencing treatment, attend the clinic at least three times, fluent in English, not taking part in HRQL studies, and not exhibiting psychopathology			Limitations: QoL data discussed in 64% of encounters; significant dropouts; possible contamination
	All groups: Observed for 6 months				
Rosenbloom et al[151]	Three-arm RCT; stratified by diagnosis	213 patients	Screening measure: QoL: FACT-G (baseline and follow-up for structed interview and discussion or attention control; 6 months only for full control)	Primary outcomes: satisfaction and QoL did not change; no differences across groups in changes in QoL or satisfaction over time (FLIC or PSQ-III)	Providing QoL assessment and structured feedback of QoL results did not improve HRQL, clinical management strategies, or satisfaction
	All groups: completed questionnaires before regular consultation	Eligibility criteria: ddvanced breast, lung, or colorectal cancer, regional or distant spread, receiving chemo-therapy, age 18 to 75 years, > 6 months prognosis, no brain metastases or CNS issues, no psychosis or depression or psychotic symptoms	Primary outcomes: all time points (all groups); QoL: FLIC; mood: POMS-17; satisfaction: PSQ-III	Secondary outcomes: no statistically significant differences across groups in changes in clinical treatment	Limitations: high baseline scores, physician making more clinical decisions than nurses, discussion dependent on patient preference
	Structured interview and discussion: interviewed by nurse after questionnaire completed (baseline and 1 and 2 months)		Secondary outcomes: Treatment: five items completed by nurse		
	Assessment control: QoL results presented to nurse at baseline and 1 and 2 months; follow-up at 1, 2, 3, and 6 months				
	Full control: No feedback to nurses or interview; follow-up at 3 and 6 months				

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Table 3. Impact of Screening for Distress on Patient-Reported Outcomes (continued)

Author	Study Design and Methods	Sample	Measures	Results	Conclusions/Comments
Carlson et al[128]	Three-arm RCT (allocation ratio of 1:1:1)	585 patients with breast and 549 with lung cancers	Primary outcome: Distress: DT	Primary outcome: marginally significant differences between triage and minimal screen groups	Screening is feasible in large cancer center; screening with triage is most beneficial
	All groups: completed measures via computerized kiosk before consultation	Minimal screen, n = 365; full screen, n = 391; screening with triage, n = 378	Secondary outcomes: Anxiety and depression: PSSCAN Part C (completed by minimal screening group at 3 months follow-up only)	Lung only: 20% fewer in triage group reported continued high distress at follow-up compared with other groups	30% of patients in triage condition accepted referred to service; 10% in minimal screen; 14% in full screening condition
	3-month follow-up via email or telephone by a research assistant	Eligibility criteria: age ≥ 18 years, marked new in electronic medical record, attending breast or lung clinic		Breast only: full screening and triage groups had lower distress at follow-up than minimal screening	Limitations: no protection against contamination, no staff training, no absence of screening condition
	Minimal screening: DT only; no feedback			Secondary outcomes: no between-group differences in anxiety or depression; best predictor of decreased anxiety and depression was referral to psychosocial services	
	Full screen: DT and PSSCAN Part C; received personalized report and summary on electronic medical record				
	Full screening and triage: DT; PSSCAN Part C; received personalized telephone call within 3 days; etailed triage algorithm followed to discuss referral options with the patient				
Carlson et al (manuscript submitted for publication)	Two-arm RCT: (allocation ratio of 1:1)	3,133 patients	Primary outcome measures: Distress: DT; fatigue: full screen; pain: PT; anxiety and depression: PSSCAN Part C	Primary outcomes:significant decreases in all outcomes over time in both groups; no differences between groups	Screening for distress has the potential to decrease subsequent symptom burden up to 12 months after diagnosis
	Both groups: completed DT, full screen, PT, PSSCAN Part C, service use before consultation; follow-up at 3, 6, and 12 months	Computerized, n = 1,531; personalized, n = 1,602	Secondary outcomes measure: services accessed since last screening	Secondary outcome: patients with higher symptom burden and personalized triage group more likely to access services	Limitations: absence of control group, no staff training, triage occurred only after baseline visit
	Computerized: received a printout summary of concerns and instructions on how to access appropriate services	Eligibility criteria: age >18 years, attending tertiary cancer center, English proficiency		Access related to greater decrease in distress, anxiety, and depression	
	Personalized: received brief computer printout summary of concerns and contacted by screening team within 3 days; detailed triage algorithm followed to discuss referral options				

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Table 3. Impact of Screening for Distress on Patient-Reported Outcomes (continued)

Author	Study Design and Methods	Sample	Measures	Results	Conclusions/Comments
Nonrandomized					
Taenzer et al[152]	Sequential cohort study (allocation: sequentially recruited first into control group, then into experimental group)	57 patients with lung cancer	Primary outcome: QoL: EORTC QLQ-C30	Primary outcome: no difference in the number of QoL items endorsed	Increased detection of QoL problems in appointments; trend toward more concerns being charted and more actions being taken related to these concerns
	Intervention: completed screening measure (EORTC QLQ-C30 computerized version) before appointment; results given to clinician	Control, n = 26; intervention, n = 27	Secondary outcomes: Satisfaction: PDIS; exit interview with patients	Intervention group discussed more QoL items during consultation	Limitations: possible contamination, nonrandomized, no staff training
	Control: completed screening measure (EORTC QLQ-C30 print version) after clinic appointment	Eligibility criteria: primary, secondary, or metastatic lung diagnosis, lung clinic attendance, fluency in English, adequate eyesight	QoL categories charted: medical record audit	Secondary outcomes: No difference between groups in satisfaction with visits; high satisfaction in both groups	
				Intervention: records had greater number of QoL actions recorded	
Boyes et al[153]	Two-group study (allocation: alternate consenting patients assigned to groups via computer)	95 patients with cancer	Primary outcomes: physical symptoms	Primary outcomes: no significant differences between groups in changes in anxiety, depression	Has potential to improve patients' symptom control, but has little impact on emotional well-being
	Both groups: Patients completed computerized screening measure (SCNS, HADS, physical symptoms) before consultation; assessed at first visit and three following consecutive visits	Intervention, n = 42; control, n = 38	Anxiety/depression: HADS	Intervention patients reporting physical symptoms at first visit less likely to report at third visit	Limitation: small sample with high attrition, possible contamination, half of the oncologists discussed with patients; patients would have preferred seeing before consultation and getting a copy of their own
	Intervention: feedback report of summary scores and strategies for managing issues was printed and placed in patient file for discussion in consultation with oncologist	Eligibility criteria: age ≥ 18 years, first consultation, receive active treatment after first visit, considered by oncologist to be emotionally and physically able	Secondary outcomes: Needs: SCNS	Secondary outcome: No significant differences between the groups in the proportion of patients reporting any moderate/high unmet needs.	
	Control: no results made available to oncologist		Acceptability: survey administered to patients and oncologists	Patients: easy, acceptable, and willing to complete at each visit	
				Oncologists: two of four reported discussing feedback sheet with patients; three of four reviewed at beginning of consultation, easy to understand, adequate content	
Thewes et al[154]	Sequential cohort study (sequentially recruited first into control group, then into screened group)	83 patients	Primary outcomes: Referrals: medical record; distress: SPHERE short form	Primary outcome: 44% scored DT ≥ 5; of these, 10 (53%) were referred to social worker or psychologist	No impact on detection of rates of referral of distressed patients
	Both groups: Follow-up 6 months later	Screened, n = 43; control, n = 40	Secondary outcomes: Needs: SCNS-SF	No significant difference in PSYCH-6 between cohorts	Among patients screened and successfully referred, time to referral was shorter
	Screened: completed DT, SPHERE short form before consultation/chemotherapy education session; nurses encouraged to assess problems and explore interest in receiving referral to psychosocial staff	Eligibility criteria: newly diagnosed patients with malignant disease; age ≥ 18 years; able to provide informed consent; English proficiency		Secondary outcomes:time to referral shorter in screened cohort (5 *v* 14 days)	Limitations: small sample size/power, lack of follow-up with patients after screening, limited access clinicians
	Control: questionnaire (SPHERE short form) completed before consultation or chemotherapy education session			Screened cohort reported higher unmet information, psychologic, and daily living needs at 6 months	

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Table 3. Impact of Screening for Distress on Patient-Reported Outcomes (continued)

Author	Study Design and Methods	Sample	Measures	Results	Conclusions/Comments
Hilarius et al[155]	Sequential cohort design (initial cohort of patients recruited into usual care control arm; 2-month "washout" period; second cohort recruited into intervention arm)	219 patients; intervention, n = 119; control, n = 100	Primary outcome: QoL topics discussed	Primary outcome: discussion of HRQL-related topics increased	Facilitated the discussion of HRQL issues; increased nurses' awareness of patients' problems, HRQL-related record notations, and nurse counselling behavior
	Both groups: followed four consecutive outpatient visits; outcome measures completed at first and last visit	Eligibility criteria: one cycle of chemotherapy, proficiency in Dutch, age > 18 years, no overt psychopathology or serious cognitive problems, not participating in a concurrent HRQL study	Secondary outcomes: Satisfaction: PSQ form II; QoL: SF-36, FACT-BCS, FACT-C, FACT-L	Secondary outcomes: no statistically significant group differences for patient satisfaction, SF-36 scales, or FACT subscales	
	Intervention: completed screening measure (EORTC QLQ-C30 with breast, colorectal, or lung modules) using touch-screen computers before consultation (each visit); results summary provided to patient and nurse, copy in medical record		Awareness QoL: COOP-WONCA	Nurses' awareness of HRQL-related problems improved for daily activities and QoL	Limitations: quasi-experimental design; however, no history effect (ie, change in personnel or patient characteristics)
			QoL topics and patient management: medical records	QoL-related notations in medical records increased	No explicit practice guidelines linking QoL with patient management strategies; 25% attrition
			Questionnaire: experience intervention (intervention group only and nurses)	Only a modest effect on patient management activities	
Shimizu et al[100]	Retrospective cohort analysis (patients treated during program period *v* historical control data gathered during usual care period)	Control, n = 574; intervention, n = 491	Primary outcome: Referrals: medical record audit of patients referred to psychooncology and treated for major depressive or AD	Primary outcome:significantly more patients referred during intervention (5.3%) than usual care (0.3%)	Clinical psychologic screening program useful for identifying major depression and ADs in patients with cancer and of initiating appropriate treatment
	Control: 2-week recruitment period; received standard care and referrals based on clinical acumen	Exclusion criteria: patients with noncancer diagnosis and age < 18 years	Proportion patients who accepted referrals	Of high distressed, 93% referred to service; 25% accepted	Limitations: low acceptance of referrals and burden on nurses (time); control cohort not concurrent and not randomized
	Intervention group: 2-week recruitment period; received three-stage DISPAC program		Secondary outcomes: Distress AD impact: DIT	Secondary outcome: DIT higher in patients who accepted referrals; 92% completed DIT in intervention cohort; 37% reported high distress	
	Stage 1: complete DIT and submit to physician; stage 2: physician review DIT and recommend referral to POS if > cutoff; if accept referral, stage 3: seen by psychiatrist, psychologist, or nurse specialist and diagnostic interview conducted		Screening rates: medical record audit of percent screened, time taken for nurse to instruct patient on DIT		

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Table 3. Impact of Screening for Distress on Patient-Reported Outcomes (continued)

Author	Study Design and Methods	Sample	Measures	Results	Conclusions/Comments
Ito et al[130]	Retrospective cohort analysis (patients treated during NASPRP program period *v* historical control data)	Usual care, n = 478; intervention, n = 520	Primary outcomes: medical record audit of proportion of patients referred to psychiatric service and treated for major depressive or AD	Primary outcomes: no difference in proportion referred (1% usual care *v* 2.7% intervention) or proportion patients referred who did not fit DSM-IV criteria	Feasible and useful for introducing psychiatric treatment earlier
	Usual care: received standard care	Eligibility criteria: consecutive patients beginning chemotherapy during 6-month period	Days from the first chemotherapy session to first visit to psychiatric service	Fewer days between treatment and psychiatric service visit for intervention (12.9 *v* 55.6 days)	No benefit for increasing referrals to psychiatric service
	Intervention group: provided with information on psychiatric service and screened using DIT by pharmacists while providing routine instructions on chemotherapy regimens; administered during second visit for each patient beginning new chemotherapy regimen		Secondary outcome: screening rates, medical record audit of proportion patients screened	Secondary outcomes:76% screened at first visit; positive screening rate of 29%; 72% screened at second visit; positive screening rate 22%	Limitations: control not concurrent and not randomized, limited training to pharmacists (2 hours only)
Grassi et al[74]	Retrospective cohort analysis (patients treated during intervention period *v* historical control)	Usual care, n = 153; screened, n = 583	Primary outcome: referrals	Primary outcome: Control group: 153 of 2,268 referred to POS; 31.37% of referred DT < 4 (noncase) when assessed at POS	Implementation of the routine use of DT/PL seemed to determine a higher and more accurate referral of patients
	Screened: 1-year recruitment period and screened with DT and PL immediately	Eligibility criteria: newly diagnosed patients only	Secondary outcomes: Distress: DT; problems: PL	Screened group: 544 of 1,107 screened; 52.2% DT ≥ 4 and referred to POS; 46.8% seen by POS	Limitations:observational study, only 52% of patients attending clinic were screened in second cohort, no outcome data on patients referred to and observed by POS
	Control: usual care and referrals to POS based on clinical acumen; once referred, patients screened with DT and PL			Secondary outcomes: Screened: referred patients higher DT, pain, sleep, and sexual problems; DT patients reported more family, practical, emotional, and physical problems than noncases Control: DT patients reported more emotional and physical problems than noncases	

Abbreviations: AD, adjustment disorder; BDI, Beck Depression Inventory; CAPHS, Consumer Assessment of Healthcare Providers and Systems Clinician and Group Survey; CHALS, Canada Health and Activity Limitation Survey; CNQ-SF, Cancer Needs Questionnaire, short form; COOP, Dartmouth Primary Care Cooperative Information Health Assessment; DIS, Diagnostic Interview Schedule; DISPAC, Distress Screening Program in Palliative Care; DIT, Distress and Impact Thermometer; DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition; DT, Distress Thermometer; ECOG, Eastern Cooperative Oncology Group; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30; FACT-BCS, Functional Assessment of Cancer Therapy–Breast Cancer Subscale; FACT-G, FACT-General; FACT-L, FACT-Lung; FACT-C, FACT-Colorectal; FLIC, Functional Living Index–Cancer; FT, Fatigue Thermometer; GHQ, General Health Questionnaire; HADS, Hospital Anxiety and Depression Scale; HRQL, health-related quality of life; IT, Impact Thermometer; LES, Life Experiences Scale; LWMAT, Locke-Wallace Marital Adjustment Test; NASPRP, Nurse-Assisted Screening and Psychiatric Referral Program; PDIS, Patient-Doctor Interaction Scale; PL, Problem List; POMS, Profile of Mood States; POS, psychooncology service; PSQ III, Medical Outcomes Study Patient Satisfaction Questionnaire III; PSSCAN, Psychosocial Screen for Cancer Patients; PSI, Psychiatric Symptom Index; PSYCH-6, subscale of Somatic and Pyschological Health Report; PT, Pain Thermometer; QoL, quality of life; RCT, randomized controlled trial; SCNS, Supportive Cancer Needs Survey; SF-36, Medical Outcomes Study 36-Item Short-Form Health Survey; SPHERE, Somatic and Psychological Health Report; SSQ, Social Support Questionnaire; WONCA, World Organization Project of National Colleges and Academics.

Only seven of the studies were RCTs, conducted in Canada, the United Kingdom, the United States, Europe, and Australia. Patient groups included all types of cancers (four studies) and some mix of breast, lung, and/or colorectal cancers (three studies). Samples sizes ranged from 212[151] to 3,133 (Carlson et al, manuscript submitted for publication). Methodologies employed for screening included telephone follow-up of screening results with referrals (Carlson et al)[128,146] or in-person discussions with nurses or oncologists trained in screening.[147-149,151] Overall, results were mixed (primarily positive or null findings) but were likely subject to type II error resulting from low sample sizes. Only four of the RCTs resulted in positive outcomes on PROs such as QoL and distress. McLachlan et al[147] found improvements in the intervention group with respect to psychologic and health information needs at 2-month follow-up compared with the control condition, but this advantage was not evident at the 6-month follow-up. More recent studies have found positive results of intensive screening with follow-up compared with minimal screening with no triage with regard to the proportion of distress cases[128] and also shown benefit of both personalized and computerized triage strategies (Carlson et al). Of the seven nonrandomized studies, three trials[74,129,155] showed positive main outcome effects, although those studies that used historical cohort comparisons reported more uniform secondary outcomes; typically these were investigating process measures such as the number of referrals to psycho-oncology services and patient and staff satisfaction. Overall, four studies reported screening helped with patient-clinician communication.[148,149,152,155]

Earlier studies generally used QoL measures for screening tools,[146-149,151,152,155] whereas more recent studies have typically used the DT alone[129] or more often in combination (Carlson et al).[74,128,130,154] In terms of distinguishing studies that showed benefits of screening versus those that did not, staff training stands out as an important factor. Several studies that provided no training or training of a short duration (ie, one 2-hour session) either showed no benefits of screening[151,153] or improvements in the referral process but no improvements in subsequent measures of QoL or other PROs such as anxiety or depression symptoms.[74,129,130,155] Studies that showed the most benefit in terms of both PROs and improvements in communication and the referral process generally included either more intensive physician training[148,149] or used trained screening staff to provide triage.[128]

CONCLUSIONS AND RECOMMENDATIONS

Recommendations for Research

Several key recommendations for future research in the area of screening for distress and needs assessment follow from the analysis in our article. Given the paucity of outcomes and efficacy research on screening programs, there is a clear need for more studies evaluating the efficacy of screening compared with usual care regarding PROs. There is also a need for studies comparing various types of screening or methods of administering screening programs (ie, by psychosocial staff, clinical nurses, nurse navigators, social workers, and so on). To more fully understand the impact of screening programs over time, there is a need for longer-term follow-up across the cancer trajectory, including examination of extinction effects after the cessation of screening.

Because most studies only provided screening once at the time of admission to cancer care programs, there is a need for examination of the effects of repeated screening (ie, routine screening as recommended in guidelines). The most successful screening programs seem to include intensive staff training; therefore, studies are needed to evaluate the effect of staff training on screening for distress PROs as well as process of care outcomes. For screening for distress programs to be sustainable, it must be integrated into regular clinical practice; hence, there is a need for examination of implementation programs designed to integrate screening into existing programs run by frontline clinical staff. Finally, in the current health care environment, in which programs not only have to be clinically effective but also must show evidence of cost effectiveness, research including economic analyses of costs of programs versus potential and real savings to the health care system (ie, potential cost offsets) need to be conducted.

Recommendations for Successful Program Implementation

Through the work done to date, both from our own experience and the collected evidence reviewed in this article, much has been learned regarding the characteristics of successful screening for distress programs. When introducing screening programs into routine care, an essential component is spending enough time laying the groundwork; particularly imperative is the enlistment of the support of hospital administrators and clinic coordinators before trying to introduce programs. Before introducing screening, appropriate training of staff who will be administering the screening, receiving the reports, and providing services has emerged from the research as a crucial component. Providing ongoing support is also critical. Most researchers recommend applying the chosen screening tool at key points in the care trajectory and at times of crisis, for health providers to act in a timely manner.

At an organizational level, it is important to ensure that a variety of supportive care services are available for patients with unmet needs, ideally including psychosocial as well as practical support and treatment of physical issues such as pain, fatigue, and sleep disturbance. To ensure continuity of care, it is important that screening is linked with follow-up care and appropriate treatment. It is also important to follow screening triage guidelines and algorithms, but not at the expense of clinical flexibility. Some allowance for clinical judgment to override possible screening-related false negatives and false positives will help maintain enthusiasm of clinical staff. Similarly, organizations must allow staff to have the time to apply screening (if clinician led) and/or interpret results and follow-up when needed; hence, buy-in and support from administrative staff are key. On a policy level, one strategy to enhance implementation is to consider using well-informed patients to advocate screening programs. Patient input is also crucial to help evaluate pilot screening programs and protocols from the perspective of the recipient of care. To maximize reach, we also recommend reviewing to what extent the screening program is acceptable to older patients, those who are medically frail, and minority/underserved groups such as people new to a community for whom English may be a second language.

Screening for distress is a relatively new innovation in cancer settings, aiming to help clinicians detect meaningful emotional complications in a simple and acceptable format. Screening for distress is usefully augmented by assessment of meetable unmet needs and followed by further assessment and empirically supported treatments as needed. If barriers to implementation are addressed, screening for distress has the potential to improve recognition of

emotional disorders, facilitate communication, and significantly improve QoL for thousands of patients with cancer.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

The author(s) indicated no potential conflicts of interest.

AUTHOR CONTRIBUTIONS

Conception and design: Linda E. Carlson, Alex J. Mitchell
Collection and assembly of data: All authors
Data analysis and interpretation: All authors
Manuscript writing: All authors
Final approval of manuscript: All authors

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Appendix

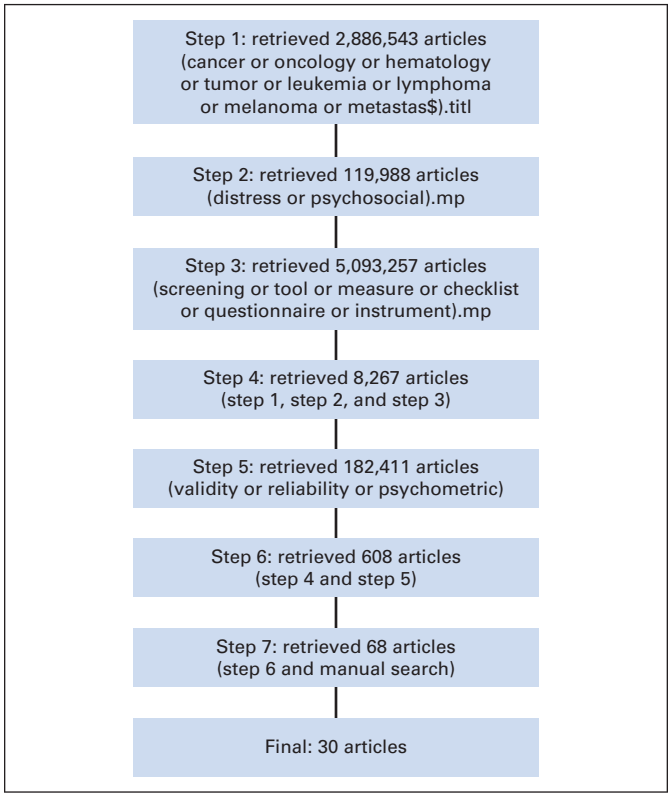

Fig A1. Search strategy for distress screening tools.

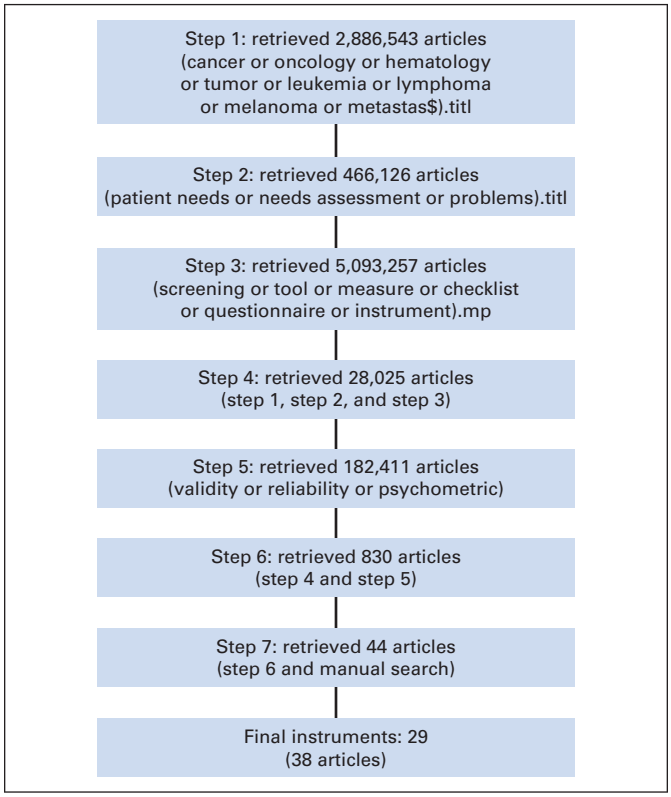

Fig A2. Search strategy for needs assessment screening tools.

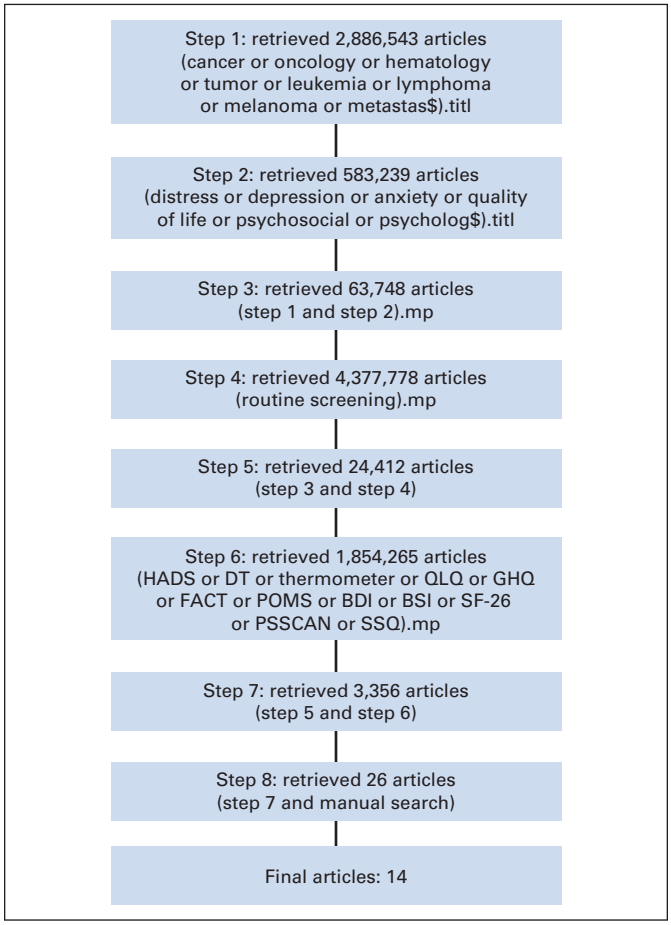

Fig A3. Search strategy for impact of screening for distress on patient-reported outcomes. BDI, Beck Depression Inventory; BSI, Brief Symptom Inventory; DT, Distress Thermometer; FACT, Functional Assessment of Cancer Therapy; GHQ, General Health Questionnaire; HADS, Hospital Anxiety and Depression Scale; POMS, Profile of Mood States; PSSCAN, Psychosocial Screen for Cancer Patients; QLQ, Quality of Life Questionnaire; SF-26, Medical Outcomes Study 36-Item Short-Form Health Survey; SSQ, Social Support Questionnaire.

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REVIEW ARTICLE

Screening for cancer-related distress: When is implementation successful and when is it unsuccessful?

ALEX J. MITCHELL

Department of Psycho-oncology, Leicestershire Partnership Trust, Leicester, UK and Department of Cancer Studies and Molecular Medicine, University of Leicester, UK

Abstract

Objective. Screening for distress is controversial with many advocates and detractors. Previously it was reasonable to assert that there was a lack of evidence but this position is no longer tenable. The question is now: what does the evidence show and, in particular, when is screening successful and when is screening unsuccessful? The aim of this paper is to review the most up-to-date recent findings from randomized and non-randomized trials regarding the merits of screening for distress in cancer settings. *Methods.* A search was made of the Embase/Medline and Web of knowledge abstract databases from inception to December 2012. Online theses and experts were contacted. Inclusion criteria were interventional (randomized and non-randomized) trials concerning screening for psychological distress and related disorders. Studies screening for quality of life were included. *Results.* Twenty-four valid interventional studies of distress/QoL screening were identified, 14 being randomized controlled trials (RCTs). Six of 14 screening RCTs reported benefits on patient well-being and an additional three showed benefits on secondary outcomes such as communication between clinicians and patients. Five randomized screening trials failed to show any benefits. Only two of 10 non-randomized sequential cohort screening studies reported benefits on patient well-being but an additional six showed secondary benefits on quality of care (such as receipt of psychosocial referral). Two non-randomized screening trials failed to show benefits. Of 24 studies, there were 17 that reported some significant benefits of screening on primary or secondary outcomes, six that reported no effect and one that reported a non-significantly deleterious effect upon communication. Across all studies, barriers to screening success were significant. The most significant barrier was receipt of appropriate aftercare. The proportion of cancer patients who received psychosocial care after a positive distress screen was only one in three. Screening was more effective when it was linked with mandatory intervention or referral. *Conclusions*. Screening for distress/QoL is likely to benefit communication and referral for psychosocial help. Screening for distress has the potential to influence patient well-being but only if barriers are addressed. Quality of care barriers often act as a rate limiting step. Key barriers are lack of training and support, low acceptability and failure to link treatment to the screening results.

Distress is the experience of significant emotional upset arising from various physical and psychiatric conditions [1]. Screening for distress is relatively new compared with screening for depression which has been more extensively investigated in a variety of settings. However, screening for distress is controversial. The evaluation of evidence regarding screening for distress should be no different to the evaluation of any other screening target such as screening for prostate cancer or cervical cancer. Several authors have put forward a coherent case against routine screening. These views are importance because screening is not so overwhelmingly effective and not without cost, such that no scrutiny of the evidence is needed. A considered negative view actually helps us decide how can we be sure if screening works? Also if screening is only partially successful, can improvements be made such that adoption into routine care makes clinical and financial sense? Screening has been suggested to improve patient outcomes in depression presenting in primary care, but positive benefits have equally been disputed [2,4,5]. The same argument for and against screening has played out in cardiovascular settings [3,5]. Fortunately, we have the opportunity to learn lessons from an extensive literature concerning screening for depression in primary care and other medical areas [4]. One lesson is that when the results of individual studies are mixed then it is difficult for reviewers to avoid confirmatory bias when evaluating the evidence. This

Correspondence: Alex J. Mitchell, Department of Psycho-oncology, Leicestershire Partnership Trust, Leicester, UK. E-mail: ajm80@le.ac.uk

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particularly applies to non-meta-analyses, although no method is entirely exempt from the possibility of bias. This has been very well-described from the perspective of screening for depression in primary care when two thorough reviews came to entirely opposite conclusions [5].

When evaluating screening for distress, the ideal comparison is with treatment as usual. Yet treatment as usual is by no means uniform. Treatment as usual may be high or low quality, high or low resource. It is very likely that routine screening would fail to show benefits when compared to an unscreened cohort seen by expert/interested clinicians who reliably offered a wide choice of patient friendly resources. However, this scenario is not common and almost all major centers show considerable variability in psychosocial care [6]. The introduction of screening reduces that variability at the point of diagnosis, but if treatment is not offered then screening is fruitless. For this reason, the challenge to centers screening for distress is to ensure effective treatment follows accurate diagnosis. When we evaluate screening studies, we are most interested in added value, that is, the additional merit of screening that would not otherwise be achieved by routine clinical judgement. Although routine clinical judgement is notoriously inaccurate compared with our current gold standards (e.g. DSMIV diagnoses) some cases are picked up and many people without distress are identified. Most physicians working with cancer patients are not confident in dealing with distress, most do not use any screening instruments and most have little education and training in psychosocial issues [7]. Figures from our Leicester cancer center suggest frontline clinicians have about 50% sensitivity and 80% specificity when looking for distress [8]. About half of identified cases are offered timely, appropriate treatment. Results are broadly consistent with other centers which also find approximately 20–30% of people with unmet psychosocial needs will have already been recognized and treated at any one point in time [9]. The purpose of screening is to improve on this figure, to address unrecognized problems in the remaining 70–80%. In short, screening aims to reduce inequalities in diagnosis that result from differing clinician abilities. In a well-designed randomized controlled trial (RCT) of screening versus clinical judgement (diagnosis), it would be reasonable to test the yield of screening versus judgement for cases not previously identified, providing this standard is applied equally to both arms. Yet, it is also reasonable to test the yield of screening versus judgement for all cases (whether or not previously identified) providing the screening study clarifies how many identified patients desire psychosocial help or referral because the fundamental aim of psychosocial care is to provide timely, appropriate and acceptable care for patients with current self-reported unmet needs regardless of their cancer stage, cancer diagnosis or past treatment history.

Should the target of screening be distress?

Screening must have a worthwhile treatable target and there has been a dispute whether distress is really a disabling condition. In recent years several organizations have promoted distress, rather than depression, as the key emotional patient-reported outcome measure in cancer care [10]. The distress concept has the advantage of lower perceived stigma than depression, and broad acceptability to patients. Its main disadvantage is that distress is poorly operationalized, and it corresponds only approximately to known psychiatric disorders. Distress can be mild but when moderate or severe can be considered a generic category of emotional suffering that encompasses psychiatric conditions such as depression, anxiety, and adjustment disorder in addition to non-psychiatric psychological and practical concerns [11]. Distress is not a specific category in Diagnostic and statistical manual of mental disorders, 4th ed. (DSMIV) or International classification of diseases, 10th ed. (ICD10) and therefore should not be considered a medical condition per se but a symptom. Yet there is accumulating evidence suggesting that the presence of distress is associated with reduced health-related quality of life [12], poor satisfaction with medical care [13] and possibly reduced survival after cancer [14]. A medical analogy is that screening for distress is like screening for high glucose, whereas identifying depression is analogous to detecting diabetes. Diabetes mellitus is only one cause of hyperglycemia, but hyperglycemia is a significant problem on its own. Distress, unmet needs and related psychiatric disorders are certainly treatable conditions [15]. Distress is closely linked with unmet needs and it is well-documented that many cancer patients report that their psychosocial and physical needs are not met [16].

National Screening Guidelines

Details of how to screen and how often to screen are subject to much local variation and few countries have any unified national policy [17,18]. Guidelines have not been sufficiently evidence-based to make a case that convinces both advocators and detractors of screening. Those against routine screening raise several worthwhile cautions. First, that screening should apply only to those not already currently recognized as depressed in receipt of treatment. Second, that those who screen positive often do not accept the treatment that is offered [19]. Third, the same treatment and care resources should be available to both groups (screened and not-screened) to effectively

isolate the effect of screening per se. Fourth, screening routinely may be inefficient given that many people have very mild complications. Fifth, screening can be resource intensive and can be a burden to staff and patients. These arguments should be considered whilst reviewing the forthcoming evidence below.

Evaluation of distress screening studies

Implementation can be defined as the 'systematic introduction of innovations and/or changes of proven value, the aim being that these are given a structural place in professional practice, in the functioning of organizations or in the health care structure' [20]. Screening implementation is the process whereby a screening method is applied to clinical practice, ideally under scrutiny in order to clarify hazards and benefits. Phases in the development and testing of a screening tool have been reported [21]. Several groups have reviewed diagnostic validity studies in depth but most have concentrated on depression per se [22–24] and meta-analyses have been carried out on both depression tools [25] and on distress tools [26]. Before discussing implementation studies it is essential to briefly review the methodology underlying screening studies (Table I) [27]. Once a screening tool has been developed and tested for potential accuracy against an accepted gold standard, it can be evaluated in a clinical setting. This is the implementation phase. The implementation can be non-comparative, or observational. Such studies are not without value. For example, the effect of screening on quality of care (process measures) or patient reported outcomes can be monitored using current or historical data. Observational studies will reveal how well screening is working, but will not reveal how much better screening is over usual care. For this, an interventional screening study is required. These can be randomized or non-randomized. In the typical randomized study, two equal groups of clinicians, or in the case of 'cluster randomization', two centers, are randomized to have either access to screening versus no access to screening. A variant on this design is to randomize two groups to have either access to results of screening or screening, but no feedback of the results of screening. In effect it is feedback of results that are randomized not screening. Theoretically this may help distinguish which effects are related to application of the screener and which to the receipt of screening results.

Table I. Methodology of screening studies.

Type screening study	Purpose of study	Description of study
Diagnostic validity study	Establish diagnostic accuracy of a tool against a gold standard instrument	A screening tool is tested against a criterion (gold standard) in a real world sample generating the sensitivity and specificity of the tool, as well as positive and negative predictive value which depend on the cut-off chosen and the prevalence of distress.
Non-randomized sequential cohort Implementation study	Establish the added value of screening on patient outcomes and quality of care	The screening tool is evaluated clinically in one group of clinicians with access to screening (or results of screening) compared to a second group (typically a historical group or second centre) who do not access to screening (or results of screening)
Randomized controlled Implementation study (screen vs no-screen)	Establish the added value of screening on patient outcomes and quality of care, controlling for baseline variability	Two equal groups of clinicians (or in the case of 'cluster randomization' centres) are randomized to have either access to a screening method vs no access to screening.
Randomized controlled Implementation study (screen + feedback vs screen no feedback)	Establish the added value of screening feedback on patient outcomes and quality of care, controlling for baseline variability	Two equal groups of clinicians (or in the case of 'cluster randomization' centres) are randomized to have either access to results of screening vs screening but no access to the results of screening (screen no feedback).
Observational Implementation screening study	Establish effect of screening on clinical practice (uncontrolled)	A screening tool is introduced in clinical practice and the effect on quality of care (process measures) or patient reported outcomes monitored. This can be conducted using current or historical screening data

The next methodological question is what outcome is relevant to screening studies? Historically the main outcome of interest has been patient well-being (also known as patient reported outcomes measures or PROMS). This review will focus on this key outcome but readers should be aware of secondary outcomes that are of interest but beyond the scope of this review. Secondary outcomes of interest are clinician behavior/quality of care. Clinician behavior includes the number of accurate diagnoses recorded, doctor-patient communication, referrals made to specialist services and psychosocial help given by clinicians. These 'quality of care' markers are sometimes called process measures but can influence PROMs. For example, Carlson et al. (2010) found that the best predictor of decreased anxiety and depression was receipt of referral to psychosocial services [28]. If screening studies show benefits in quality of care or clinician behavior but not patient well-being, then this suggests there are significant barriers to care downstream of the screening process. An important measure in all studies is acceptability of the screening program to patients and clinicians. This can be measured by satisfaction scores or by proxy measures such as uptake and participation.

The aim of this paper is therefore to review the latest evidence concerning the evidence for and against screening for distress/QoL and summarize the lessons from randomized studies and non-randomized studies which have been successful and unsuccessful in terms of primary (and to a lesser extent secondary outcomes and acceptability).

Methods

A search was made of the Embase/Medline and Web of knowledge abstract databases. Detailed methods are as described in a previous study, but updated to December 2012 [30]. The inclusion criteria were randomized and non-randomized interventional implementation studies regarding the effects of distress screening on key outcomes. All potentially valuable studies were included regardless of their outcome. The key outcomes were change in patient well-being, reported acceptability, receipt of psychosocial treatment (or referral for treatment) and clinician communication. Previous reviews were searched as well as theses and experts contacted [24,29,30]. We examined the following methodological aspects of each study: design and methods, setting and sample, uptake, predictors and confounders. Results were stratified into successful and unsuccessful screening studies based on the findings of at least one statistically significant (p-value of 0.05 or lower) positive primary or secondary outcome (hereby defined as a positive trial) a non-significant effect or a deleterious effect (hereby defined as a negative trial).

Results

From a total of 520 studies retrieved from the literature searches, 14 randomized trials were identified regarding the effect of screening for psychological distress and a synopsis is shown in Table II. A further 10 non-randomized studies were identified that measured changes in distress or related outcomes before and after screening without randomization. Several other studies with psychological PROMs were not included as they did not randomize or evaluate the effect of screening itself.

Brief summary of successful and unsuccessful distress screening implementation studies

Summary of evidence. Twenty-four valid interventional studies of distress/QoL screening were identified, incorporating 14 RCTs and 10 sequential cohort studies. Although patient well-being often improved, it did not necessarily show differential improvement compared with the control arm. Only six of 14 screening RCTs reported added benefits on patient well-being. An additional three showed benefits on secondary outcomes such as communication between clinicians and patients. Five randomized screening trials failed to show any benefits. Similarly, although two of 10 non-randomized sequential cohort screening studies reported benefits on patient well-being, an additional six showed secondary benefits on quality of care (such as receipt of psychosocial referral). Only two non-randomized screening trials failed to show any significant benefits.

Thus an appraisal of 24 screening implementation studies shows that there were 17 studies that reported some significant benefits of screening on primary or secondary outcomes and six that reported no significant effects and one that reported a non-significantly deleterious effect upon communication. The principal secondary benefits appear to be on referral to specialist services and communication. Distress and QoL screening appear to open the door to a dialogue with clinicians who can then determine which unmet needs have contributed to distress. As such distress screening can probably be supplemented by an unmet needs checklist (such as the NCCN's problem list). Acceptability was only studied in depth in 12 out of 24 studies. Of these, acceptability was good to very good in nine studies but mixed in three studies, but never poor. Overall then, the acceptability of distress/QoL screening appears to be satisfactory. At the study level additional lessons are apparent (below).

Lessons from successful randomized screening studies. Sarna (1998) conducted a small randomized trial in 48 patients whereby the results of screening with the

Table II. Brief summary of successful and unsuccessful distress screening implementation studies.

Author/Country	Screening target	Screening beneficial?	PROs improved?	Referrals improved?	Communication improved?	Acceptability of screening?
Randomized Unsuccessful						
Maunsell et al. (1996) [35] Canada	Distress Depression	No	No	NR	No	NR
Rosenbloom et al. (2007) [36] USA	Mood Quality of life	No	No	NR	NR	NR
Mills et al. (2009) [42] UK	Quality of life	No (deleterious)	No	NR	Yes but not significantly	High
Braeken et al. (2011) [37] Germany	Distress	No	No	Yes (but not significantly)	NR	Mixed
Hollingworth et al. (2012) [38] UK	Distress Quality of life	No	No	NR	NR	High
Randomized successful						
Sarna (1998) [31] USA	Distress	Yes	Yes	NR	Yes	NR
McLachlan et al. (2001) [32] Australia	Distress Depression Unmet needs	Partial (in depressed patients)	Yes (in depressed only)	NR	Yes (in depressed only)	NR
Detmar et al. (2002) [39] Netherlands	Quality of life	Partial	No	NR	Yes (but only for social functioning, fatigue and dyspnea)	NR
Velikova et al. (2004) [33] UK	Distress Quality of life	Yes	Yes	NR	Yes but not significantly	Mixed
Macvean et al. (2007) [43] Australia	Quality of life Unmet needs Depression	Yes	Yes (depression)	NR	NR	Good
Girgis et al. (2009) [44] Australia	Unmet needs Depression Quality of life	Partial (in communication and action)	No	Yes and significant (but full data not presented)	Yes and significant (but full data not presented)	High
Carlson et al. (2010) [28] Canada	Distress	Yes (in breast and lung cancer)	No	Yes significantly	NR	High
Carlson et al. (2012) [45] Canada	Distress	No	Yes	Yes (access to services) significantly	NR	High
Klinkhammer-Schalke et al. (2012) [34] Germany	Quality of life	Yes	Yes	NR	NR	Not reported
Non-randomized unsuccessful						
Boyes et al. (2006) [46] Australia	Depression/ anxiety Unmet needs	No	No	NR	NR	Yes
Mitchell et al. (2012) [47] UK	Distress Depression/ anxiety/anger	Not significantly	No	NR	NR	Partial

(*Continued*)

Table II. (*Continued*).

Author/Country	Screening target	Screening beneficial?	PROs improved?	Referrals improved?	Communication improved?	Acceptability of screening?
Non-randomized successful						
Taenzer et al. (2000) [48] Canada	Quality of life	Partial (in communication and action)	Yes	NR	Yes but not significantly	NR
Pruyn et al. (2004) [49] Netherlands	Distress	Yes	NR	Yes significantly	Yes but not significantly	Duration of consultations decreased & screening acceptable to 77% of patients
Bramsen et al. (2008) [50] Netherlands	Distress Quality of life	Yes	Partial	Yes significantly	NR	NR
Hilarius et al. (2008) [51] Netherlands	Quality of life	Partial (in recognition and action)	No	Yes (but not significantly)	Yes significantly overall	NR
Thewes et al. (2009) [52] Australia	Distress Unmet needs	Partial (in referral delay)	No	Yes but not significantly	NR	Yes
Shimizu et al. (2010) [53] Japan	Distress	Partial (in referral)	No/Unknown	Yes significantly	NR	NR
Ito et al. (2011) [54] Japan	Distress	Partial (in referral delay)	No	Yes, significantly	NR	NR
Grassi et al. (2011) [55] Italy	Distress	Partial (in referral)	No	Yes, significantly	No	NR

NR, not recorded.

Symptom Distress Scale (SDS), Hospital Anxiety and Depression Scale (HADS) and Karnofsky Performance Status (KPS) were fed back or not fed back to clinical nurses according to randomization [31]. Over six months of follow-up, symptom distress in the feedback group declined, but in the no feedback group it increased and the difference was statistically significant by six months. McLachlan et al. (2001)'s RCT involving quality of life, depression and unmet needs was the first well-powered study (450 patients) [32]. Patients completed self-reported questionnaires via a touch-screen computer with results feedback to the doctor and formulation of an individualized management plan in those with positive screens. In those depressed at baseline, there was a significantly greater reduction in depression for the intervention arm, indicating that screening/interventions most benefit those with most distress at baseline and that screening with resources is likely to be more effective than screening alone. Velikova and colleagues (2004) recruited 28 oncologists treating 286 cancer patients and randomly assigned them to screening along with feedback or screening alone (called attention-control) or a no screening condition using EORTC QLQ-C30 and touch-screen HADS [33]. A positive effect on emotional well-being was seen in the intervention with feedback versus control group suggesting screening with feedback is the most effective option. Acceptability, however was modest. Carlson et al. (2010) [28] took the Velikova et al. model and included minimal screening (no feedback), full screening (with feedback) [33] but added screening with feedback and optional triage and referral (enhanced screening). In breast cancer patients the full screening and triage groups both had lower distress at follow-up compared with minimal screening. Recently, Klinkhammer-Schalke for the Regensburg QoL Study Group (2012) randomized 200 breast cancer patients to receive either feedback of low QoL (with a report sent to clinician), or standard care [34]. Outcome QoL favored screening suggesting perhaps feedback of only the significant results are needed during screening.

Lessons from unsuccessful randomized screening studies. Maunsell et al. (1996) conducted an RCT of telephone GHQ-20 screening every 28 days (n = 123) against basic psychosocial care only (n = 127) and screening incorporated an automatic referral process [35]. However, distress decreased over time in both groups with little to differentiate between groups and no additional benefit of screening hinting at high quality care in the control arm. Rosenbloom et al. (2007) randomly assigned 213 metastatic patients to feedback or no feedback of Functional Assessment of Cancer Therapy- General (FACT-G) results [36]. No effect

of PROMs was found. Mills et al. (2009) also found null results using a focussed QoL diary completed at home. Braeken et al. (2011) conducted an innovative study using radiotherapists who were asked to apply a 24-item Screening Inventory of Psychosocial Problems (SIPP) but found no significant benefit attributable to screening, perhaps because the burden fell to busy frontline clinicians who had difficulty with implementation [37]. Similarly, Hollingworth et al. (2012) did not find significant differences in Profile of Mood States (POMS) or quality of life when screening was completed by frontline radiographer/nurses using the (DT) and problem list [38]. From these results it appears that frontline clinicians struggle to adapt screening into routine care.

Discussion

Screening for distress in cancer is a rapidly evolving field with an appreciable body of evidence. Previous work has largely focussed on the development and diagnostic validity testing of tools for measuring cancer-related distress. Despite strong recommendations of many professional societies and accreditation agencies, valid cautions against premature adoption of screening exist. Previously, it was reasonable to assert that there was a lack of evidence regarding distress screening but with 24 implementation studies this position is no longer tenable with one exception: screening in advanced cancer and palliative settings. Only three implementation studies have examined screening patients with advanced cancer with mixed results [31,39,40]. Overall, results of 24 screening implementation studies show that there are 17 studies reporting some statistically significant benefits of screening on primary or secondary outcomes. For those (apriori) advocates of screening this may be disappointing as six of 14 screening RCTs reported added benefits on patient well-being. For those (apriori) detractors of screening these findings may also be surprising, 17 of 24 implementation studies did reveal some benefit (over and above usual care) albeit often involving secondary outcomes, such as referral to specialists or communication.

How does this evidence inform the cautions against screening mentioned in the introduction? The first caution is that screening should apply only to those not already currently recognized as depressed/distressed and in receipt of treatment [19]. Although this has rarely been addressed Braeken et al. (2011) found that of those who received a referral in the screening RCT, 22% of referred screened patients were previously identified, and 29% of non-screened referred patients were previously identified [37]. In other words the yield was reduced in both screened and non-screened arms by taking into account previous care. The second caution is that those who screen positive often do not accept the treatment that is offered [19]. This is a genuine barrier to receipt of care. Carlson et al. (2012) found that over 12-months follow-up after screening, 20% received services in the screen and triage arm compared with 15% in the screen alone arm [28]. The third caution is the same treatment and care resources should be available to both groups (screened and not-screened) to effectively isolate the effect of screening. In fact, this has been extensively studied in the feedback implementation studies which compare screening with versus without feedback of results. In both arms care is typically treatment-as-usual. From eight feedback versus no-feedback implementation studies, six have found superiority of screening in relation to primary or secondary outcomes, and two have found no effect. The fourth caution is that screening routinely may be inefficient given that many people have very mild complications. Both screening and clinical judgement are more accurate when focussing on more severe cases, however the majority of burden resides in those with mild and moderate disease. The fifth caution is that screening can be resource intensive and can be a burden to staff and patients. This caution is partially upheld, whilst acceptability of screening is generally good, when conducted by frontline clinicians it is often perceived as burdensome. This is somewhat alleviated when screening is brief, has tangible benefits, associated with resources and staff support or when it is conducted in the waiting room screening or using computerized touch screens.

Across all studies, barriers to screening success were significant. At the clinician level the main barriers to screening are lack of time, lack of training and low personal skills or confidence. At the organizational level, barriers include lack of resources and the absence of a screening strategy [7]. However, from this research, the main barrier to successful implementation appears to be receipt of appropriate aftercare. The proportion of cancer patients who received psychosocial care after a positive distress screen was only 20–30%. This shows that aftercare is probably the key rate-limiting step. Screening was more effective when screening was linked with mandatory intervention or referral. This should take the form of a distress management plan to ensure that clinicians systematically act on screening results, and to ensure the healthcare system has resources for helping clinicians manage distress. A positive screening should be followed by thorough clinical assessment and competent management [41]. Depending on the needs identified for specific populations, the actions that follow screening could involve, e.g. a stepped approach, ranging from group-based psycho-education for people with mild–moderate distress to structured individual therapy for those with high distress.

This analysis of the randomized trials and non-randomized implementation studies suggests that some caution regarding systematic routine screening is rational but that evidence does show that screening for distress/QoL has modest but significant benefits largely on quality of care. Additional unmeasured benefits may include feedback on the prevalence of distress to healthcare providers that can be used to directly help patients but also to improve the service delivery system. Audit of systematic assessment is mandatory for service improvement, and a very short step to screening itself. Factors that can influence the success of screening are becoming clearer. It does no longer seems tenable to screen only for one or two psychiatric disorders (such as depression, anxiety), worthy though these target are. Multi-domain screening incorporating unmet needs is much more likely to benefit patient well-being as a whole. Without addressing aftercare, systematic adoption of distress screening in clinical practice is probably not worthwhile. By addressing aftercare, systematic adoption of distress screening in clinical practice is probably worthwhile but issues of acceptability, resources and clinician support must not be overlooked. Key barriers that prevent screening being effective appear to be the same barriers that prevent high quality of psychosocial care in general. Namely, availability and acceptability of a range of suitable treatments, availability and acceptability of experts (e.g. psychologists, psychiatrists) in psychosocial care. In short, screening success may be determined by two key factors: acceptability and resources.

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M.D. Thesis

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Dr Alex J Mitchell **ajm80@le.ac.uk**

Honorary Senior Lecturer in Psycho-oncology, Department of Cancer & Molecular Medicine,

University of Leicester LE51WW