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COMMENTARY/POSITION PAPER

The role of implementation science in improving distress assessment and management in oncology: a commentary on "Screening for psychosocial distress among patients with cancer: implications for clinical practice, healthcare policy, and dissemination to enhance cancer survivorship"

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Abstract

Despite considerable evidence that psychosocial interventions can effectively relieve distress in patients with cancer, many individuals who could benefit from these interventions do not receive them. A proposed solution to this problem is the establishment of programs in oncology settings that routinely screen for distress and refer patients for appropriate psychosocial care. This commentary addresses a review by Ehlers et al. that describes policies and procedures related to distress screening, summarizes prior research on this topic, and identifies key areas for future research. Among their major conclusions is the need for research to fill the gap in knowledge about how best to implement new distress screening programs as well as optimize the use and efficiency of existing programs. This commentary focuses on how the types of study methods, designs, and outcomes that are commonplace in implementation science to facilitate the integration of research into practice can be applied to distress screening programs. Priorities identified include designing and conducting pragmatic clinical trials, evaluating multilevel interventions, and using hybrid designs to simultaneously evaluate clinical effectiveness and barriers and facilitators of implementation. Use of these approaches holds considerable potential for developing an evidence base that can promote more widespread adoption of effective distress screening programs and inform further development of standards and policies related to the psychosocial care of patients with cancer.

Keywords

Psychosocial oncology, Implementation science, Pragmatic clinical trials, Multilevel interventions

Recognition of the need for psychosocial care and its benefits for patients with cancer was greatly advanced in 2008 with the publication of the Institute of Medicine (now National Academy of Medicine) report *Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs* [1]. Among the report's major conclusions was that, despite evidence of the effectiveness of psychosocial services, many cancer patients who could benefit from these services do not receive them.

In addition to drawing attention to this problem, the report proposed several possible solutions. First, the report identified a model designed to allow for the appropriate provision of psychosocial services in oncology settings [1]. Key features of the model include a process for identifying patients' psychosocial needs that is designed to trigger development and enactment of plans to address those needs. Second, the report issued a set of recommendations designed to improve the delivery of psychosocial care [1]. Key recommendations include encouraging development of reliable and valid tools and strategies to identify and address psychosocial needs, ensuring that provision of appropriate psychosocial services is included in standards defining the quality of cancer care, and promoting and supporting efforts aimed at dissemination and uptake of efficient provision of psychosocial care.

The article by Ehlers et al. [2] can be viewed, in part, as an evaluation of progress achieved since the publication of the 2008 National Academy of Medicine report. As described by the authors, several distress screening tools have been developed and validated, evaluated for their utility as screening measures, and determined to be both feasible for routine use and acceptable to patients and staff. In addition, they note that in recent years a growing number of interventions have been shown to be efficacious in addressing the various forms of distress experienced by patients with cancer. Regarding efforts to ensure that standards of care address psychosocial care, Ehlers et al. point to the American College of Surgeons Commission on Cancer Standard 3.2 issued in 2015 [3]. This standard mandates the development and implementation of processes for distress screening and referral for provision of psychosocial care at participating institutions. The issuance of this standard is significant as over 1,500 centers in the USA that treat more than 70% of all patients with newly diagnosed cancer are

evaluated for accreditation by the Commission on Cancer [4]. Reflecting its importance, the issuance of this standard stimulated several publications that sought to disseminate relevant information on ways to meet the requirements [5] and promote greater uptake of distress screening and referral [6].

Despite these and other efforts, Ehlers et al. identify a lack of knowledge on how best to implement new distress screening and management programs as well as optimize the use and efficiency of existing programs. In particular, they point to the need for more research on distress measure selection, distress screening practices, referral practices subsequent to screening, and receipt of recommended care. Importantly, they indicate that research is needed to understand and address multilevel barriers at the patient, provider, health care system, and policy levels toward adoption and appropriate use of evidence-based distress screening and management programs.

These gaps point to the need to expand the scope of work in psychosocial oncology to include the later phases of translational research in an effort to more rapidly and efficiently integrate research into routine practice. For most of its relatively short history, psychosocial oncology research has focused on discovering opportunities to address problems, moving these discoveries into the first application of interventions, and using these and other sources of knowledge to develop evidence-based recommendations [7]. In contrast, there has been relatively little research to date on how to move evidence-based interventions and recommendations into routine clinical practice [7]. The remainder of this commentary will review and discuss specific ways in which future research informed by implementation science can improve the delivery of psychosocial care as part of routine cancer care and address many of the gaps identified by Ehlers et al. The National Institutes of Health defines implementation science as the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health [8].

Although numerous interventions have been shown in randomized controlled trials to be efficacious in addressing distress in patients with cancer [9], many of these interventions have low potential for implementation as part of routine care because of their complexity, the amount of resources required to deliver them, and the limited range of distress-related problems they address. An argument can be made that the type of intervention best suited for distress screening and management is a multicomponent care pathway that includes screening to identify the severity and source(s) of distress, distress management based on algorithms designed to provide patients with appropriate evidence-based interventions, ongoing monitoring, and treatment modifications and repeat screenings as applicable. Few studies have evaluated this type of approach. A recent systematic review [10] cited by Ehlers et al. [2] identified only five trials of interventions aimed at improving the rate of routine screening and referral for detected distress in patients with cancer. The methodological quality of most of these trials was judged to be weak and only one study reported a significant improvement in referral rates. Interestingly, this trial was judged to be the only study to adopt a comprehensive approach toward implementation [10].

The findings of this systematic review illustrate the need for additional research to identify effective distress screening and management interventions suitable for implementation. Findings also illustrate the need to identify those implementation strategies that promote successful intervention adoption and integration into cancer care delivery settings. Three recommendations, informed by implementation science, can be offered for the design of future trials to address these needs.

The first recommendation is to conduct clinical trials of interventions that feature pragmatic design elements. A useful distinction has been drawn between trials that are primarily explanatory versus those that are primarily pragmatic [11]. The former are typically designed to evaluate the benefits an intervention may produce under well-controlled conditions whereas the latter are typically designed to evaluate the benefits an intervention may produce in routine clinical practice relative to usual care. More recent elaborations have viewed clinical trials as arrayed along an explanatory–pragmatic continuum based on their design features. For example, the PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) considers nine design features (e.g., eligibility criteria, flexibility of intervention delivery) that collectively inform the extent to which the trial is more explanatory or more pragmatic [12]. These design features, in turn, have important implications for the applicability of trial results to routine care settings. For example, with respect to the eligibility criteria domain, a study with numerous exclusion criteria would be considered more explanatory whereas a study with few exclusion criteria would be considered more pragmatic. Similarly, for flexibility of intervention delivery, a study that featured a protocol requiring strict adherence would be considered more explanatory whereas a study that featured a flexible protocol with few restrictions on co-interventions would be considered more pragmatic. Pragmatic trials are critically important for generating evidence that is relevant, actionable, and reflective of patients, providers, and delivery settings to which the trial results would apply and the intervention would be used outside the context of a research study. A recently published article illustrates the use of PRECIS-2

criteria to evaluate an integrative oncology trial along the explanatory–pragmatic continuum [13].

The second recommendation is to conduct clinical trials of multilevel interventions [14]. Much of the intervention research in psychosocial oncology has tested interventions directed solely toward patients or, in some cases, toward patients and their family members or caregivers. At least two additional levels should be considered when seeking to evaluate a distress screening and management program. These levels are the clinical care providers (e.g., oncologists, oncology nurses, social workers) and the practice or organizational setting (e.g., specialty clinic, cancer center). Distress screening and management programs can be viewed as complex interventions [15] based on the number of interacting components, the numbers and types of individuals involved, and the extent to which the intervention will need to be adapted to local needs and resources. Engaging providers and the practices and organizations in which they work would seem to be essential for designing interventions that are feasible and acceptable if they require changes in clinical workflow, changes in professional roles and responsibilities, and additional institutional resources. Given these considerations, many trials of multilevel interventions randomize at the level of the practice or institution (i.e., use a cluster randomized trial design) rather than at the level of the patient to avoid the potential for confounding and in acknowledgment of the multiple levels at which the intervention functions [16]. A recently published study illustrates the design and conduct of a cluster randomized trial to test a multilevel intervention to improve symptom management. In this study, 19 cancer inpatient units were randomly assigned to implement a clinician-delivered bedside pain assessment and management tool or to continue with usual care [17]. The effects of the intervention were tested by comparing changes in the percentages of patients with a clinically significant improvement in their pain at the inpatient unit level.

The third recommendation is to conduct clinical trials using hybrid effectiveness-implementation study designs. Briefly, the purpose of hybrid designs is to accelerate the transition from effectiveness trials to implementation trials by incorporating elements of each into a single study, albeit with a different primary and secondary focus depending on hybrid design type (1, 2, or 3). For example, in the hybrid type 1 design, the primary aim is to determine the effectiveness of an intervention and the secondary aim is to better understand the context for implementation [18]. The primary aim seeks to answer the question of whether the intervention is beneficial for patients in the setting(s) in which it was tested whereas the secondary aim seeks to identify barriers and facilitators of the implementation tested in the trial. For a study of a distress screening and management program, outcomes for the primary aim may be patient-reported measures of psychological distress whereas outcomes for the secondary aim may be quantitative measures of feasibility and acceptability captured during the course of the study combined with qualitative measures of barriers and facilitators captured through interviews with patients and providers. A recently published protocol illustrates many of these methods to study the implementation of linked symptom monitoring and depression treatment programs designed for specialist cancer services. Guided by the RE-AIM evaluation framework [19], the authors specify the measures and the data sources to be used to assess the reach, effectiveness, adoption, implementation, and maintenance of the programs [20].

There is increasing recognition of the importance of implementation science in improving the management of distress and other common symptoms in patients with cancer. For example, the Blue Ribbon Panel report issued as part of the National Cancer Institute's Cancer Moonshot included a recommendation to accelerate, through implementation science, the clinical adoption of systems that monitor patient-reported symptoms and provide decision support using symptom management guidelines [21]. The National Cancer Institute subsequently issued funding opportunity announcements and recently awarded funds for a research consortium that will conduct a set of multicenter, multilevel studies using hybrid effectiveness–implementation designs [22]. These studies are being conducted with the goal of identifying evidence-based, scalable, and sustainable models for how symptom monitoring and management can be routinely incorporated into a variety of oncology practice settings and delivered to a range of patient populations.

In summary, addressing existing gaps in knowledge about distress screening and management for patients with cancer will require continued work to evaluate assessment and screening tools suitable for clinical use and to identify interventions ready for implementation. In addition, the scope of work needs to be expanded to include the types of study methods, designs, and outcomes that are commonplace in implementation science to facilitate the integration of research into practice. Priorities include designing and conducting pragmatic clinical trials, evaluating multilevel interventions, and using hybrid designs to simultaneously evaluate clinical effectiveness and barriers and facilitators of implementation. Use of these approaches holds considerable potential for developing an evidence base that can promote more widespread adoption of effective distress screening and management programs and can inform further development of standards and policies related to the psychosocial care of patients with cancer.

Compliance with Ethical Standards

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References

1. Institute of Medicine. *Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs*. Washington, DC: National Academies Press; 2008.
2. Ehlers SL, Davis K, Bluethmann SM, et al. Screening for psychosocial distress among patients with cancer: Implications for clinical practice, healthcare policy, and dissemination to enhance cancer survivorship. *Transl Behav Med*. 2019;X:xx–yy.
3. American College of Surgeons. Cancer Program Standards (2016 Edition). Available at https://www.facs.org/quality-programs/cancer/coc/standards. Accessibility verified December 17, 2018.
4. American College of Surgeons. Available at https://www.facs.org/media/press-releases/2016/oaa0216. Accessibility verified December 17, 2018.
5. Pirl WF, Fann JR, Greer JA, et al. Recommendations for the implementation of distress screening programs in cancer centers: Report from the American Psychosocial Oncology Society (APOS), Association of Oncology Social Work (AOSW), and Oncology Nursing Society (ONS) joint task force. *Cancer*. 2014;120(19):2946–2954.
6. Wagner LI, Spiegel D, Pearman T. Using the science of psychosocial care to implement the new American College of Surgeons Commission on Cancer distress screening standard. *J Natl Compr Canc Netw*. 2013;11(2):214–221.
7. Jacobsen PB. New Challenges in Psycho-Oncology Research II: A health care delivery, dissemination, and implementation research model to promote psychosocial care in routine cancer care. *Psychooncology*. 2017;26(4):419–423.
8. National Institutes of Health. Department of Health and Human Services: PAR-18-007. Available at https://grants.nih.gov/grants/guide/pa-files/PAR-18-007.html. Accessibility verified December 17, 2018.
9. Faller H, Schuler M, Richard M, Heckl U, Weis J, Küffner R. Effects of psycho-oncologic interventions on emotional distress and quality of life in adult patients with cancer: Systematic review and meta-analysis. *J Clin Oncol*. 2013;31(6):782–793.
10. McCarter K, Britton B, Baker AL, et al. Interventions to improve screening and appropriate referral of patients with cancer for psychosocial distress: Systematic review. *BMJ Open*. 2018;8(1):e017959.
11. Treweek S, Zwarenstein M. Making trials matter: Pragmatic and explanatory trials and the problem of applicability. *Trials*. 2009;10:37.
12. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: Designing trials that are fit for purpose. *BMJ*. 2015;350: h2147.
13. Carlson LE, Oberoi DV, Qureshi M, Subnis U. Integrative oncology trials in the real world: Assessing the pragmatism of an ongoing integrative oncology trial of mindfulness and t'ai chi/qigong. *J Altern Complement Med*. 2018;24(9-10):926–932.
14. Cleary PD, Gross CP, Zaslavsky AM, Taplin SH. Multilevel interventions: Study design and analysis issues. *J Natl Cancer Inst Monogr*. 2012;2012(44):49–55.
15. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M; Medical Research Council Guidance. Developing and evaluating complex interventions: The new Medical Research Council guidance. *BMJ*. 2008;337:a1655.
16. Hemming K, Eldridge S, Forbes G, Weijer C, Taljaard M. How to design efficient cluster randomised trials. *BMJ*. 2017;358:j3064.
17. Fallon M, Walker J, Colvin L, Rodriguez A, Murray G, Sharpe M; Edinburgh Pain Assessment and Management Tool Study Group. Pain management in cancer center inpatients: A cluster randomized trial to evaluate a systematic integrated approach—The Edinburgh Pain Assessment and Management tool. *J Clin Oncol*. 2018;36(13):1284–1290.
18. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness–implementation hybrid designs: Combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care*. 2012;50(3):217–226.
19. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: The RE-AIM framework. *Am J Public Health*. 1999;89(9):1322–1327.
20. Wanat M, Walker J, Burke K, et al. L inked symptom monitoring and depression treatment programmes for specialist cancer services: Protocol for a mixed-methods implementation study. *BMJ Open*. 2017;7(6):e016186.
21. National Cancer Institute. Implementation of Integrated and Evidenced-Based Symptom Management Throughout the Cancer Trajectory. Available at https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel/implementation-science-working-group-report.pdf. Accessibility verified December 17, 2018.
22. National Cancer Institute. IMPACT, Improving the Management of symPtoms during And following Cancer Treatment. Available at https://impactconsortium.org/. Accessibility verified January 3, 2019.