

## **Distress Screening and Intervention in Clinical Trials**

### **Overview of Distress Screening and Follow-up**

What is psychosocial distress? An unpleasant experience of an emotional, psychological, social, or spiritual nature that interferes with the ability to cope with cancer treatment. It extends along a continuum, from common normal feelings of vulnerability, sadness, and fears, to invasive concerns of depression, anxiety, panic, and feeling isolated or in a spiritual crisis (National Comprehensive Cancer Network, 1999).

How common is distress? Nearly 50% of all patients with cancer experience moderate levels of distress (IOM, 2008).

What is a distress screening? The early identification of the potential root causes of psychosocial distress, prior to a patient reaching the threshold for a clinical diagnosis of depression and/or anxiety. Distress screening should use a validated instrument that captures patient reported metrics.

How often is distress screening required? Data shows that screening for distress, intervening and rescreening in as little as 30 days reduces overall distress by 25% and also the number of items about which people are distressed by 25% (Gayer, et al., 2013).

### **Impact of Distress Screening and Follow-up**

What is the impact of intervention? According to Andersen et al. (2004, 2008, 2010), patients with breast cancer engaged in social and emotional intervention have significant benefits over those who do not:

- a. 45% reduced risk of breast cancer recurrence
- b. 56% reduced risk of breast cancer death
- c. 59% change of breast cancer death even WITH recurrence
- d. 41% reduced risk of death following recurrence for the intervention arm with immune indices significantly higher among those in the intervention arm
- e. Increase in T-cell development
- f. Decrease in anxiety
- g. Increase in family support
- h. Decrease in number of smokers
- i. Decrease in number of cigarettes smoked
- j. Fewer symptoms/toxicities from cancer treatment

Psychosocial care reduces the overall cost of medical care

- a. In cancer:
  - i. Patients with depression have higher health care utilization (33.66 visits vs. 18.8 visits for those without depression).
  - ii. Patients with depression have higher annual health care costs (\$8,400 per individual per year) (Jeffrey et al., 2011).

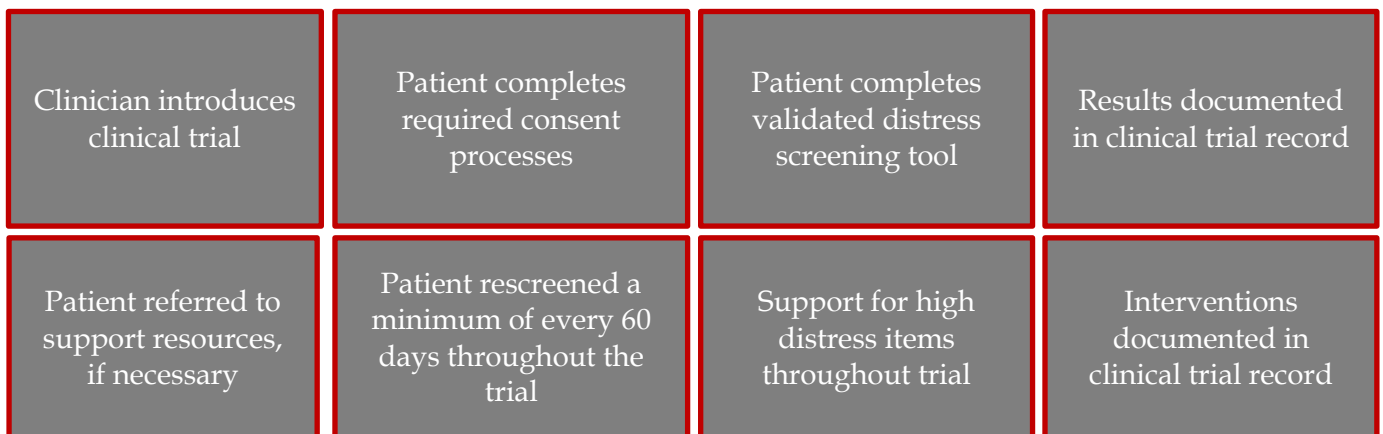
- iii. Patients with breast cancer participating in a six-week cognitive-behavioral session, billed the health care system 23.5 percent less than the control arm and a total of \$6,199 less over the course of the study (Simpson et al., 2001).
- iv. Men with prostate cancer participating in group intervention decreased health care contacts from 10 to 4.4 over a 6-month period while the control group remained stable at 8 contacts (Pennebaker, 2000).
- b. In 1993, Greenberg et al. documented the cost of depression in the U.S. to be \$44 billion per year.
- c. A 20 year Kaiser Permanente study demonstrated that 60% of all medical visits were by the 'worried well' with no diagnosable disorder (Cummings and Vandenbos, 1981).
- d. A second Kaiser study (Sobel, 2000) indicated that patients who participated in psychotherapeutic interventions:
  - i. Decreased average length of hospital stay by 77.9%
  - ii. Decreased frequency of hospitalization by 66.7%
  - iii. Decreased physician office visits by 47.1%
  - iv. Decreased emergency room visits by 45.3%
  - v. Decreased number of prescriptions received by 4%

Adherence to medication is impacted by risk of depression - a study presented at the 2014 American Society of Hematology Annual Meeting demonstrated that patients with financial burden who also had a risk for depression were nearly twice as likely to be non-adherent to their medication regimen (Buzaglo et. al, 2014).

- a. 57% of patients at risk for depression who also have financial burden report non-compliance with medication compared to 32% with financial burden alone.
- b. 18% of patients with no risk for depression or financial burden report non-compliance with medication.

Role of distress screening and follow-up in the clinical trial process

- c. Identify early potential causes for trial abandonment
- d. Improve patient outcomes
- e. Improve efficiency of clinical trial resources
  - i. Human
  - ii. Financial
- f. Enhance trial completion timeline



**Organizations supporting the importance of distress screening and intervention in oncology**

- I. Institute of Medicine (IOM)
  - a. *"Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs"*
  - b. *"Delivering High Quality Cancer Care: Charting a New Course for a System in Crisis"*
- II. American College of Surgeons Commission on Cancer 2012 *Patient-Centered Standards* – Standard 3.2 *"The Cancer Committee develops and implements a process to integrate and monitor on-site psychosocial distress screening and referral for the provision of psychosocial care."*
- III. American Society of Clinical Oncology, *Quality Oncology Practice Initiative (QOPI)*
- IV. Community Oncology Alliance, *Medical Home*
- V. Psychosocial Oncology Society, Oncology Nursing Society, Association of Oncology Social Work, *Implementing Screening for Distress: The Joint Position Statement*

## References

- Adler, N.E., Page, A.E.K. (2008). Cancer care for the whole patient: Meeting psychosocial health needs. Institute of Medicine (IOM). Washington, DC: The National Academies Press.
- American College of Surgeons. (2012). Cancer program standards 2012: Ensuring patient-centered care. Retrieved February 4, 2014 from <http://www.facs.org/cancer/coc/programstandards2012.pdf>
- American Society of Clinical Oncology. QOPI: The Quality Oncology Practice Initiative. Retrieved February 4, 2014 from <http://qopi.asco.org/>
- Andersen, B.L., Farrar, W.B., Golden-Kreutz, D.M., Glaser, R. et al. (2004). Psychological, behavioral, and immune changes following a psychological intervention: A clinical trial. *Journal of Clinical Oncology*, 22 (17), 3570-3580.
- Andersen, B.L., Yang, H.C., Farrar, W.B., Golden-Kreutz, D.M. et al. (2008). Psychological intervention improves survival for breast cancer patients: A randomized clinical trial. *Cancer*, 113, 3450-3458.
- Andersen, B.L., Thornton, L.M., Shapiro, C.L., Farrar, W.B., Mundy, B.L., Yang, H.C., and Carson, W.E. (2010). Biobehavioral, immune, and health benefits following recurrence for psychological intervention participants. *Clinical Cancer Research*; 16(12); 4490.
- Buzaglo, J.S., Karten, C., Weiss, E.S., Miller, M.F., Morris, A. (2014). The Financial Costs of Chronic Myeloid Leukemia and Implications for Quality of Life and Adherence: Findings from the Cancer Experience Registry. Annual Meeting of the American Society of Hematology.
- Cummings, N.A. & VandenBos, G.R. (1981). The twenty years Kaiser-Permanente experience with psychotherapy and medical utilization: Implication for national health policy and national health insurance. *Health Policy Quarterly* 1: 159-175.
- Gayer, C., Buzaglo, J.S., Miller, M.F., Morris, A., Kennedy, V. & Golant, M. (2013). Meeting Patient-Centered Standards: CancerSupportSource – A Community-based Distress Screening Program. *Journal of the National Comprehensive Cancer Network*, 11 (4), 373-374.
- Greenberg, P.E., Stiglin, L.E., & Finkelstein, S.N. (1993). The economic burden of depression in 1990. *Journal of Clinical Psychiatry* 54: 405-418.
- Jeffrey, D.D. (2011). Cancer as a chronic disease among military beneficiaries: The cost of depression as a cancer comorbidity. Annual Meeting of the American Psychological Association.
- Levit, L., Balogh, E., Nass, S., & Ganz, P.A. (2013). Delivering high-quality cancer care: Charting a new course for a system in crisis. Institute of Medicine (IOM). Washington, DC: The National Academies Press.
- National Comprehensive Cancer Network. 1999. NCCN practice guidelines for the management of psychosocial distress. *Oncology (Huntingt)* 13 (5A): 113-47.
- NCQA. (2011). Patient centered medical home. Retrieved February 4, 2014 from <http://www.communityoncology.org/UserFiles/pdfs/pcmh-2011-overview.pdf>
- Pennebaker, J.W. (2000). Telling stories: The health benefits of narrative. *Lit Med* 19: 3-18.
- Simpson, J.S.A., Carlson, L.E., & Trew, M. (2001). Impact of a group psychosocial intervention on Health utilization by breast cancer patients. *Cancer Practice* 9: 19-26.
- Sobel, D.S. (2000). The cost-effectiveness of mind-body medicine interventions. *Prog Brain Res* 122: 393-412.