

# Outcome Measures to Evaluate the Effectiveness of Pain Management in Older Adults With Cancer

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**E**ffective pain management in older adults requires a comprehensive approach. Of primary importance is a detailed pain assessment that identifies the cause of the pain, its specific characteristics, current approaches to treatment and their effectiveness, and the impact of pain on the older person's mood, ability to function, and quality of life. After the initiation or modification of a pain management plan, an essential component of effective pain management is to evaluate the effectiveness of the plan to determine the next course of action. Actions may include maintaining the current regimen or trying to optimize the treatment regimen by changing the dose, switching analgesic medications, adding treatments for side effects, and adding adjunctive pharmacologic or nonpharmacologic therapies.

Recent evidence suggests that to evaluate the effectiveness of a pain management plan, clinicians must move beyond evaluation of self-reported ratings of pain intensity (Dworkin et al., 2005, 2008; Turk & Dworkin, 2004; Turk et al., 2003, 2008). Indeed, clinicians should consider three specific areas when they evaluate the effectiveness of a pain management plan: (a) the effectiveness of the analgesic regimen; (b) the safety and tolerability of the analgesic regimen; and (c) the impact of the plan on an older person's mood and ability to function.

Unrelieved chronic pain can have a significant impact on older adults' activity levels and their ability to function. However, most clinicians focus their assessments on changes in pain intensity scores. Although pain intensity scores are assessed routinely, changes may not be that significant, as patients with chronic pain often have no more than a 30%–50% reduction in pain intensity (Weiner, 2007). However, evidence suggests that although patients may report similar levels of pain intensity before and after the initiation of a pain management program, activity levels improve with treatment (Dworkin et al., 2005). Indeed, outcomes such

**Purpose/Objectives:** To identify the most appropriate outcome measures to determine the effectiveness of pain management plans in older adults with cancer.

**Data Sources:** PubMed literature searches, medical and nursing textbooks, and clinical experience.

**Data Synthesis:** Unrelieved chronic pain can have a significant impact on older adults' activity levels and their ability to function. Hence, effective pain management in older adults requires a comprehensive approach, including assessment of functional outcomes. Because the goals of pain management are broad, healthcare professionals should use an array of functional outcome measures along with pain intensity ratings to better assess the effectiveness of analgesic medications.

**Conclusions:** Particularly in older adults, evaluation of functional outcomes provides a better indication of the effectiveness of pain management strategies than pain intensity ratings. Appropriate outcome measures for older adults in the outpatient setting include pain relief, physical functioning, emotional functioning, patients' ratings of global improvement and satisfaction with treatment, and symptoms and adverse effects associated with analgesic medications.

**Implications for Nursing:** Healthcare providers should manage pain in older adults with cancer in an interdisciplinary environment with pharmacologic and nonpharmacologic interventions. The primary goals are decreasing pain and improving function and quality of life.

as physical function, mood, endurance, sleep, appetite, and interpersonal interactions may improve with pain treatment and may better reflect the impact of analgesic therapy.

Consequently, an appraisal of the effect of an analgesic regimen on various aspects of a person's mood and functional status is essential to determine whether the pain management plan is effective. In fact, in older adults with cognitive impairment, evaluation of changes in functional status may provide more accurate understanding of the efficacy of treatment. In addition, the safety and tolerability of the analgesic regimen must be

assessed on an ongoing basis. Evaluation of side effects is extremely important in older adults who are taking a significant number of medications (American Geriatrics Society Panel on Pharmacological Management of Persistent Pain in Older Persons, 2009).

## Approaches to Evaluate the Effectiveness of Pain Management

An expert group called the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) enumerated the appropriate methods to evaluate the effectiveness of pain interventions. The international consortium of invited participants included representatives from academia, regulatory agencies (the U.S. Food and Drug Administration and the European Agency for the Evaluation of Medicinal Products), the U.S. National Institutes of Health, the U.S. Veterans Administration, consumer support and advocacy groups, and industry. Cumulatively, the group had a range of expertise in anesthesiology, clinical pharmacology, internal medicine, law, neurology, nursing, oncology, outcomes research, psychology, rheumatology, and surgery.

The IMMPACT consensus recommendations and evidence to support each of the recommendations can be found at [www.immpact.org](http://www.immpact.org). In addition, the group published a series of articles in the peer-reviewed literature on appropriate outcome measures to evaluate the effectiveness of analgesic medications. The outcome measures are meant to be used in clinical practice. In addition, they are meant to provide guidance to the U.S. Food and Drug Administration about appropriate outcome measures that should be considered as part of the approval of new analgesics. Importantly, standardization of the outcome measures across clinical trials of analgesic medications would enable meaningful comparisons among studies and pain treatments (Dworkin et al., 2008).

An IMMPACT survey of 959 patients who experienced chronic pain found that patients wanted clinicians and researchers to evaluate the effectiveness of analgesic medications through assessments of how the medications affected their ability to function, as well as their quality of life. In addition to pain reduction, patients wanted clinicians to consider the following outcomes as important indicators of the effectiveness of analgesic regimens: enjoyment of life, emotional well-being, and changes in fatigue, weakness, and sleep-related problems (Turk et al., 2008).

Based on a series of meetings, as well as data from the patient survey, the IMMPACT group recommended that healthcare professionals consider the following core outcome measures for chronic pain when assessing an analgesic's effectiveness: pain, physical functioning, emotional functioning, patients' ratings of global im-

provement and satisfaction with treatment, and symptoms and adverse events (Turk et al., 2003). In addition, the IMMPACT group recommended that clinical trials of analgesic medications for chronic pain should assess and report treatment adherence and reasons why patients withdrew from the studies.

## Assessment of Changes in Physical Functioning as an Outcome of Analgesic Treatment

**Generic self-report measures of physical functioning:** As listed in Table 1, the IMMPACT group specifically recommended two measures to evaluate physical functioning in patients with chronic pain (Dworkin et al., 2005): the Brief Pain Inventory (BPI) (Daut, Cleeland, & Flanery, 1983; Dworkin et al., 2005) and the Multidimensional Pain Inventory (MPI) Interference Scale (Kerns, Turk, & Rudy, 1985). The tools can be used to assess and compare physical functioning and the effects of treatments across diverse types of chronic pain. Both tools are valid and reliable measures that have been tested in several populations in multiple countries, including people with cancer pain (Cleeland et al., 1994; Cleeland, Gonin, Baez, Loehrer, & Pandya, 1997; Turk & Okifuji, 1999).

One of the tools used most commonly to assess the impact of pain on patients' ability to function is the interference subscale of the BPI (Daut et al., 1983). It asks patients to rate the level of interference from pain on seven functional outcomes (i.e., general activity, mood, walking ability, work, relations with other people, sleep, and enjoyment of life). Each item is rated on a numeric rating scale from 0 ("does not interfere") to 10 ("completely interferes"). The BPI was developed to assess pain in patients with cancer (Cleeland et al., 1994, 1997) but has been used in studies of patients with several types of chronic noncancer pain (Holen, Lydersen, Klepstad, Loge, & Kaasa, 2008; Tan, Jensen, Thornby, & Shanti, 2004).

The second tool recommended by IMMPACT to evaluate physical functioning was the MPI Interference Scale (Kerns et al., 1985). In contrast to the BPI, it does not evaluate the impact of pain on sleep. Therefore, it should be administered with a sleep measurement tool to evaluate the impact of chronic pain on sleep.

In clinical settings, healthcare providers can use the interference scale of the BPI to easily assess the impact of pain on patients' ability to function. If a pain management plan is effective, the patient will report either improvements in various aspects of function or maintenance of current levels of activity and function. In addition, clinicians can evaluate patients' ability to exercise and work.

Another option to evaluate overall function is the Medical Outcomes Study–Short Form (SF-36®). Normative data are available for this commonly used generic

**Table 1. Outcome Measures to Evaluate the Effectiveness of Pain Management in Older Adults With Cancer**

Measure	Type of Measure
<b>Emotional functioning</b>	
Center for Epidemiologic Studies–Depression Scale (Radloff, 1977; Sheehan et al., 1995)	Generic self-report of depressive symptoms
Geriatric Depression Scale (Yesavage et al., 1982)	Self-report of depressive symptoms designed for older adults
<b>Physical functioning</b>	
Activities of Daily Living Index (Katz et al., 1963, 1970)	Self-report of physical functioning designed specifically for older adults
Brief Pain Inventory Interference Scale (Daut et al., 1983)	Generic self-report
Karnofsky Performance Status Score (Karnofsky, 1977; Karnofsky et al., 1948)	Disease-specific self-report
Medical Outcomes Study–Short Form (SF-36®) (Ware & Sherbourne, 1992)	Generic self-report of physical and emotional functioning and quality of life
Multidimensional Pain Inventory Interference Scale (Kerns et al., 1985)	Generic self-report
Roland Morris Back Pain Disability Scale (Roland & Morris, 1983a, 1983b)	Disease-specific self-report
Short Physical Performance Battery (Guralnik et al., 1994)	Behavioral measurement of physical functioning
Timed Get Up and Go Test (Pondal & del Ser, 2008; Wall et al., 2000)	Behavioral measurement of physical functioning
Walking or gait speed (Woo et al., 1995)	Behavioral measurement of physical functioning
Western Ontario and McMaster Universities Osteoarthritis Index (Bellamy, 1989; Bellamy et al., 1988)	Disease-specific self-report

measure of health-related quality of life, and it has been found to be reliable and valid in studies of the general population (Ware, Kosinski, & Keller, 1996; Ware & Sherbourne, 1992) and patients with cancer (Mannion, Wilby, Godward, Lyratzopoulos, & Laing, 2007; Salati, Brunelli, Xiume, Refai, & Sabbatini, 2009).

**Disease-specific, self-report measures of physical functioning:** In some cases, for research purposes and for clinical practice evaluations, the IMMPACT group recommended that healthcare professionals use disease-specific measures to assess patients' levels of function-

ing (Dworkin et al., 2005). For example, the Roland Morris Back Pain Disability Scale (Roland & Morris, 1983a, 1983b) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (Bellamy, 1989; Bellamy, Buchanan, Goldsmith, Campbell, & Stitt, 1988) can be used for assessment of patients with low-back pain and osteoarthritis. The Roland Morris Back Pain Disability Scale has been used to evaluate the effectiveness of vertebroplasty to treat compression fractures in patients with multiple myeloma (McDonald et al., 2008). The WOMAC has been used to evaluate the effects of acupuncture on joint symptoms in patients on aromatase inhibitors (Crew et al., 2007, 2010).

In oncology, the Karnofsky Performance Status Scale (Karnofsky, 1977; Karnofsky, Abelmann, Craver, & Burchenal, 1948) often is used as an overall measure of physical function. Although it has demonstrated excellent validity and reliability (Schag, Heinrich, & Ganz, 1984), it may not be able to detect subtle changes in older adults' ability to function as a result of effective pain management.

**Self-report measures of physical functioning designed for older adults:** A variety of self-report measures of physical functioning, designed specifically for older adults, can be used to assess patients' responses to pain management interventions. Two of the most commonly used measures are the Independent Activities of Daily Living (IADLs) score and the Katz Index of Independence in Activities of Daily Living (Katz, Downs, Cash, & Grotz, 1970; Katz, Ford, Moskowitz, Jackson, & Jaffe, 1963). IADLs include ratings of the ability to use the telephone, shop, prepare meals, do housework, take medications, and handle finances. ADLs include ambulation, bathing, dressing, toileting, transferring from a bed to a chair, maintaining continence, and feeding.

The two measures have been used in studies of patients with cancer (Esbensen, Osterlind, & Hallberg, 2007; Schipper, Clinch, McMurray, & Levitt, 1984). In fact, Wedding, Rohrig, Klippstein, Pientka, and Hoffken (2007) showed that patients with increased functional impairment (represented by reduced IADLs) had shorter than predicted survival times. Potential changes in the relationship between dependence on others for ADLs and the effects of an analgesic regimen have not been established in older adults with cancer. However, clinicians can assess for changes in such activities as part of their routine evaluations of older patients.

**Behavioral measures of physical functioning:** Particularly in older adults, an equally effective way to evaluate a pain management plan is a performance-based measure of physical function. Indeed, the presence of pain or physical impairment was negatively correlated with walking speed (Woo, Ho, Lau, Chan, & Yuen, 1995). Therefore, healthcare providers can use

gait speed (Liu & Latham, 2009; Morrison, Flanagan, Fischberg, Cintron, & Siu, 2009; Zeni & Higginson, 2009) or the Short Physical Performance Battery (Guralnik et al., 1994) to evaluate the presence of functional impairment caused by pain.

A relatively easy to use, performance-based measure is the Timed Get Up and Go Test. During this examination, patients begin by sitting in a chair with arms folded across the chest. Then they are asked to stand, walk three meters, turn, and walk back to the chair and sit—all without using their arms for support. In healthy older adults, the test should take approximately 7–14 seconds to complete (Pondal & del Ser, 2008; Wall, Bell, Campbell, & Davis, 2000). Older adults who need more than 30 seconds tend to be dependent on transfers and need assistance with stair climbing. In the context of pain management, healthcare professionals can evaluate the effect of an analgesic regimen on a patient's ability to perform this test over time.

## Assessment of Changes in Emotional Functioning as an Outcome of Analgesic Treatment

**Self-report measures of depressive symptoms:** Chronic pain in older adults has been associated with a diagnosis of anxiety (odds ratio [OR] 2.33, 95% confidence interval [CI] 1.22–4.64) and depression (OR 2.48, 95% CI 1.40–4.55) (McCarthy, Bigal, Katz, Derby, & Lipton, 2009). Therefore, the IMMPACT group recommended evaluation of whether analgesic treatments have beneficial effects on the emotional functioning of patients with chronic pain (Dworkin et al., 2008).

Specific scales that can be used to measure depression in older adults include the Geriatric Depression Scale (GDS) (Lyness et al., 1997; Yesavage et al., 1982) and the Center for Epidemiologic Studies–Depression Scale (CES-D) (Radloff, 1977; Sheehan, Fifield, Reisine, & Tennen, 1995). The GDS is one of the most commonly used tools to study depression in older adults. Because it is easy to administer, primary care clinicians often use the GDS to evaluate for depression (Lyness et al., 1997). In addition, the authors of a 2009 meta-analysis suggested that the GDS has utility as a screening tool for depression in older adults in the primary care setting (Mitchell, Bird, Rizzo, & Meader, 2009). The GDS (Agarwal, Hamilton, Moore, & Crandell, 2010; Girones, Torregrosa, & Diaz-Beveridge, 2010; Weber, Roberts, Mills, Chumbler, & Algood, 2008) and CES-D (Carpenter et al., 1998; Given et al., 1993, 2004) have been used to assess depression in patients with cancer.

**Clinical evaluation of emotional functioning:** Many geriatricians recommend that clinicians who care for older adults should screen patients for depression routinely by asking a series of simple questions. The questions can include whether patients feel sad, whether they have had crying spells, and whether they have

experienced changes in their sleeping patterns. Indeed, a systematic evaluation of depressive symptoms can provide important information about an older person's level of emotional functioning and its relationship to chronic pain.

In older adults, researchers have documented relationships between depression and chronic pain. For example, in a study of 27,628 nursing home residents aged 65 years and older ( $\bar{X}$  age = 82.8 years), severe levels of daily pain were significantly correlated with depressive symptoms (OR 1.5, 95% CI 1.4–1.6) (Sawyer, Lillis, Bodner, & Allman, 2007). Given the strong association between depressive symptoms and chronic pain, clinicians should evaluate the impact of pain management plans on patients' levels of emotional functioning.

## Patients' Ratings of Global Improvement and Satisfaction With Treatment

One of the key recommendations from the IMMPACT group that clinicians can do very easily to evaluate the effectiveness of pain management plans is to assess patients' impressions of their overall improvement. Several studies found the Patient Global Impression of Change scale to be more sensitive to the effects of analgesic medications than 0–10 numeric rating scales of pain intensity (Dworkin et al., 2008; Farrar, 2000; Turk et al., 2003). This approach provides patients with an opportunity to aggregate all of the components of their experience—pain relief, improvement in physical and emotional functioning, and side effects—into one rating. Patients can be asked to rate their global impression of change in their level of pain as a result of the pain management plan using either a seven-item scale (with the ratings “much worse,” “worse,” “a little worse,” “no change,” “a little better,” “better,” and “much better”) or a nine-item scale (which also includes the ratings “very much worse” and “very much better”). Specifically, patients can be asked the following question: “Since you started taking the pain medication that was prescribed last week, how would you rate your level of pain?” Clinicians should specify that patients use either the seven-item or the nine-item rating scale to respond to this question.

## Conclusion and Implications for Nursing Practice

Oncology nurses play a critical role in the assessment and effective management of chronic cancer and noncancer pain. Older adults with cancer and noncancer pain present unique challenges in terms of pain assessment and management. To provide optimal pain management plans for older adults, pain assessments must go beyond evaluation of pain characteristics (i.e., description, location, intensity, aggravating and relieving factors, and

previous and current treatments and their effectiveness) and include evaluation of the impact of pain on older adults' ability to function.

Because the goals of pain management are broad, healthcare professionals can use an array of outcome measures to assess the effectiveness of analgesic medications. Numeric rating scales of pain intensity do not capture the full impact of pain on older adults, so oncology nurses should use more sensitive measures to evaluate the impact of pain on older adults' levels of function and quality of life. Oncology nurses should assess physical and emotional outcomes. If a pain management regimen is not improving a patient's ability to function or his or her mood, then the regimen requires modification. Nurses must establish pain management goals with patients, using broader outcomes rather than a simple focus on pain intensity. This approach is especially important in older adults to improve their functional

status and quality of life. Outcomes of interventions for chronic pain in clinical settings as well as in analgesic trials should include pain relief, physical functioning, emotional functioning, patients' ratings of global improvement and satisfaction with treatment, and side effects and adverse events.

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