

# Improving Cancer Pain Control With NCCN Guideline–Based Analgesic Administration: A Patient-Centered Outcome

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## Abstract

Improving the control of cancer-related pain (CRP) is a clinical and ethical imperative. Clinical research has documented improved treatment tolerance and survival rates among patients with cancer who have effective pain control. Barriers to CRP control include inadequate patient and physician education. Meta-analyses of patient education studies correlate improvements in CRP control with improved communications with health care providers and the implementation of strategies that assist with adherence to medication schedules. These strategies build patient confidence, allowing better self-management of pain and reduced psychological consequences. For physicians, ample educational resources exist in CRP management. However, in both the inpatient and outpatient settings, compliance with NCCN Clinical Practice Guidelines in Oncology for Adult Cancer Pain continues to be less than 70%, and more than one-third of patients continue to receive inadequate doses of analgesics. Patient-centered outcomes have become an integral end point in health policy, and the nation's medical training, research, and delivery systems are transforming to a value-based accreditation and reimbursement system. Pain control is a significant patient-centered outcome in cancer care, because pain adversely impacts function and affects all domains of quality of life. Agreement is clear on the value of health care interventions that relieve suffering from cancer pain and restore personal dignity. (*J Natl Compr Canc Netw* 2014;12:1243–1249)

Patient outcomes have become an integral end point as the nation's medical training, research, and delivery system transforms into a patient-centered, value-based accreditation and reimbursement system. The components of patient-centered outcomes are broad, ranging from individual values to socioeconomic considerations. The value criteria within patient-centered health care include outcomes that improve quality survival, relieve suffering, avoid morbidity, improve function, and restore personal dignity.

Many of these value criteria have already been the focus in the evolution of cancer care. Rather than the aggressive treatments to cure cancer at any personal and socioeconomic cost, quality-of-life considerations lead many of the multidisciplinary organ-sparing therapeutic approaches that achieved equivalent or better rates of local control and survival. The current focus of personalized medicine and patient-centered outcomes further individualizes the delivery and goals of medical care.

However, the goal of relieving pain is universal, because the consequences of suffering are profound. Pain causes patients to become debilitated by fatigue and loss of function and reduces performance status, which in turn reduces tolerance to cancer therapy and the potential for therapeutic response. Caregivers retain traumatic memories of feeling helpless and witnessing horrible suffering. Most of the suffering from cancer-related pain (CRP), though, is unnecessary because it can be controlled through the application of therapeutic principles defined in clinical practice guidelines. Failure to control CRP, through acts of omission, has both personal and socioeconomic consequences, including hospital readmissions.<sup>1</sup>

Control of CRP is now more than an ethical obligation, because uncontrolled pain has been documented to affect cancer-related survival. Clinical research has shown improved treatment tolerance and survival rates

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among patients with cancer who have effective pain control. In a landmark study, all patients with newly diagnosed stage IV lung cancer received usual oncologic care, but better control of CRP resulted in a statistically significant improvement in overall survival of 11.6 versus 8.9 months ( $P=.02$ ).<sup>2</sup> Another prospective, randomized, controlled study among 202 patients with advanced-stage cancer also observed, as an unexpected finding, an increase in overall survival with improved pain control.<sup>3</sup> With better CRP control, 53.9% of the group was alive at 6 months compared with only 37.2% of the group whose pain was not as well controlled ( $P=.06$ ). Therefore, given the influence of pain as an independent predictor for survival, pain management, like hematologic parameters, should be controlled for in the conduct and analysis of clinical trials.

The inadequate management of pain caused by cancer and its treatment has both health-related and financial consequences. Applying only standard management during head and neck chemoradiation, one study showed that 54% of patients experiencing oral mucositis had severe pain, 60% had a weight loss of more than 5% during radiation, and 11% had treatment interruptions.<sup>4</sup> Radiation treatment interruptions are particularly consequential because they can result in lower rates of local disease control. Depending on the grade and uncontrolled pain of mucositis during chemoradiation, costs increased between \$1700 and \$6000 per patient.

Reflecting changes in health policy, emphasis is increasingly being placed on patient-centered outcomes throughout the continuum of cancer care.<sup>5</sup> In the next 2 years, the Patient-Centered Outcomes Research Institute (PCORI) will commit up to \$1.5 billion to research projects that include CRP management studies.<sup>6</sup> With a \$100 million award, the National Patient-Centered Clinical Research Network (PCORnet) infrastructure was developed. Composed of 11 large health system–based networks and 18 patient group–based networks, PCORnet will generate interoperable data sets to evaluate clinical outcomes and service delivery questions. Results from these data sets will further refine health care delivery. Although it is a preventable cause of poor patient-centered outcomes, inadequate management of CRP may impact future health policy decisions.

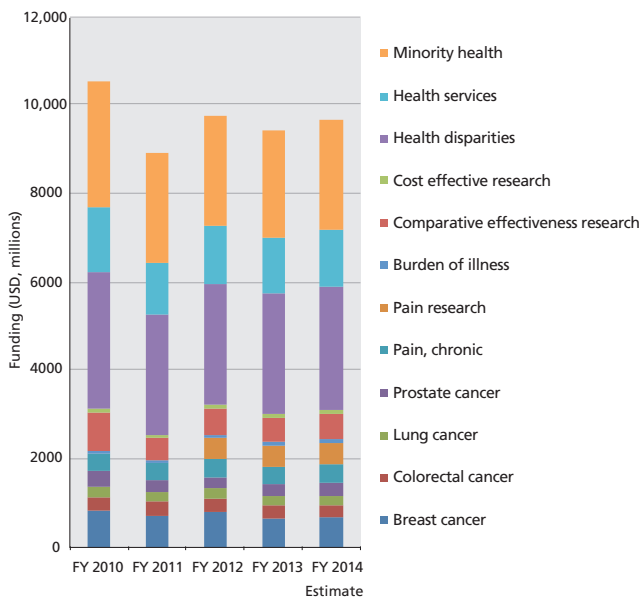
As a reflection of the influence that potential harms and the socioeconomic costs of cancer in-

terventions have had on health care policy, federal agencies now call for less frequent cancer screening, and watchful waiting is now among the therapeutic recommendations for diagnosed cancer. Pain, distress, and symptoms that impair activities of daily living are among the potential harms of cancer screening and treatment that are cited by the U.S. Preventive Services Task Force.<sup>7</sup> These adverse outcomes and symptoms, which are either temporary or permanent, were considered sufficiently harmful to change the widely accepted screening and therapeutic paradigm for prostate cancer that had long been advocated by the NCI, the American Cancer Society, and multiple medical specialty organizations.

Investment of money is a reflection of priorities. Although funding for therapeutic cancer research has remained relatively flat, funding of health economics and outcomes research (HEOR) and social sciences has increased significantly. The National Institutes of Health (NIH) funding of pain research totaled \$404 million (baseline funding plus additional funding from the American Recovery and Reinvestment Act) in fiscal year (FY) 2010, and increased to \$877 million in FY 2013.<sup>8</sup> NIH funding of the burden of illness research increased from \$56 million to \$74 million over the same period. Meanwhile, more than \$500 million was allocated to the funding of comparative effectiveness research (CER), which is twice that spent on colorectal cancer research (Figure 1). In the NCI budget, \$6,589,913 was awarded for cervical cancer education, and \$441,368,876 was spent on behavioral and social science in FY 2012.<sup>9</sup>

Additional funding for CER/HEOR has been made outside of the NIH. The FY 2010 budget for the Agency for Healthcare Research and Quality (AHRQ) is included in Table 1.<sup>10</sup> In FY 2013, AHRQ funded patient-centered health research (PCHR) at \$72.4 million, representing an increase of \$31.8 million over the FY 2012 enacted level, as shown in Table 2.<sup>11</sup> The PCHR initiative of AHRQ has 2 funding sources: \$10 million from the Public Health Service evaluation funds, and \$62.4 million from the Patient-Centered Outcomes Research Trust Fund, the latter of which represents an increase of \$38.4 million over the FY 2012 level. Apart from AHRQ, the FY 2014 budget approved by the PCORI Board of Governors included \$182 million in expenditures and up to \$528 million in CER funding.<sup>12</sup> The newly adopted strategic plan to advance the

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**Figure 1** National Institutes of Health (NIH) Research Portfolio Online Reporting Tools (RePORT) for fiscal year (FY) 2010 through FY 2013 with an estimate for FY 2014. The column FY 2010 represents the sum of funding for FY 2010 and the additional funding from the American Recovery & Reinvestment Act. Note the NIH investment in comparative effectiveness research, in addition to that by the Agency for Healthcare Research and Quality and Patient-Centered Outcomes Research Institute. Data from NIH Research Portfolio Online Reporting Tools (RePORT). Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC). Available at: [http://report.nih.gov/categorical\\_spending.aspx](http://report.nih.gov/categorical_spending.aspx). Accessed August 5, 2014.

goals of patient-centered outcomes research includes the following initiatives:

- Substantially increase the quantity, quality, and timeliness of useful, reliable evidence to improve health care decision-making
- Speed the implementation and use of findings from patient-centered outcomes research
- Influence clinical and health care research funded by others to be more patient-centered

To help achieve these goals, PCORI approved the formation of an Advisory Panel on Clinical Trials, in addition to facilitating a sustainable infrastructure for the conduct and dissemination of CER.

Despite a shift of priorities to patient-centered outcomes in federal research initiatives and greater acknowledgment of the clinical problem of CRP, limited progress has been made in reducing the morbidity of CRP. Recognizing the impacts of inadequate CRP management on clinical and socioeconomic outcomes, accreditation and federal agencies

are now participating in changing clinical oncologic practice through including the assessment and control of CRP as a quality and outcomes indicator in the transition to a value-based health care system. The issue then becomes, why is control of CRP still an issue?

The well-documented barriers to control of CRP include lack of physician education, poor clinical assessment of pain, patient reluctance to use analgesics, health system barriers including inadequate access to analgesics, and regulatory barriers. Inadequate control of CRP continues despite more than 2 decades of awareness, advocacy, and educational efforts to address these barriers. Among these efforts are CRP management guidelines developed by the WHO, federal agencies, multiple medical organizations, and NCCN.

The Joint Commission also requires pain assessment and management for accreditation. Recognizing the need to improve cancer pain control, the Accreditation Council for Graduate Medical Education (ACGME) program requirements for graduate medical education in medical oncology (effective July 1, 2012) must include expertise in pain management to provide multidisciplinary patient care and fellow education to develop essential competency in clinical practice.<sup>13</sup> In parallel with the evolution of health policy, the ACGME is transitioning to an outcomes-based accreditation process, the Next Accreditation System (NAS), in which physicians will be measured on their competency in performing essential tasks for clinical practice.<sup>14</sup> Among those essential tasks will be management of CRP.

Despite this, the barriers to control of CRP remain largely unchanged, and pain remains prevalent in cancer care.<sup>15</sup> Lack of patient compliance, assessed within meaningful use, is often used to explain inadequate control of CRP. However, this explanation represents a disconnect in logic when placed in the context that patients with cancer are compliant with other supportive care medications, such as antiemetics, and with oral chemotherapeutic agents. Apparently, patient fears related to potential life-threatening toxicities of oral chemotherapeutic agents are better allayed than fears relating to addiction and tolerance to analgesics.

Patient education regarding the administration of analgesics for CRP is effective. A meta-analysis of 21 educational intervention studies in 3501 patients

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**Table 1 Budget for the Agency for Healthcare Research and Quality for Fiscal Year 2010<sup>a</sup>**

Program	FY 2008 Appropriations <sup>b</sup>	FY 2009 Omnibus <sup>b</sup>	FY 2009 Recovery Act <sup>b,c</sup>	FY 2010 President's Budget <sup>b</sup>
<b>Research on Health Costs, Quality, and Outcomes</b>				
Budget authority	\$0	\$0	\$700,000	\$0
PHS evaluation	\$276,564	\$314,053	\$0	\$314,053
<i>Subtotal</i>	<i>\$276,564</i>	<i>\$314,053</i>	<i>\$700,000</i>	<i>\$314,053</i>
FTEs	278	278		316
<b>Medical Expenditure Panel Survey</b>				
Budget authority	\$0	\$0	\$0	\$0
PHS evaluation	\$55,300	\$55,300	\$0	\$55,300
<i>Subtotal</i>	<i>\$55,300</i>	<i>\$55,300</i>	<i>\$0</i>	<i>\$55,300</i>
<b>Program Support</b>				
Budget authority	\$0	\$0	\$0	\$0
PHS evaluation	\$2,700	\$2,700	\$0	\$2,700
<i>Subtotal</i>	<i>\$2,700</i>	<i>\$2,700</i>	<i>\$0</i>	<i>\$2,700</i>
FTEs	22	22	0	22
<b>Subtotal</b>				
Budget authority	\$0	\$0	\$700,000	\$0
PHS evaluation	\$334,564	\$372,053	\$0	\$372,053
<b>Total operational level</b>	<b>\$334,564</b>	<b>\$372,053</b>	<b>\$700,000</b>	<b>\$372,053</b>
FTEs	297	300		338

Abbreviations: FTE, full-time employees; FY, fiscal year; PHS, public health service.

<sup>a</sup>Includes appropriations from the American Reinvestment and Recovery Act.

<sup>b</sup>Monetary amounts in thousands.

<sup>c</sup>In FY 2009, the American Recovery and Reinvestment Act provided \$1.1 billion for comparative effectiveness research. Of this total, \$400 million was transferred to the National Institutes of Health. A total of \$400 million is available for comparative effectiveness research to be allocated at the discretion of the Secretary of the Department of Health and Human Services. A new Federal Coordinating Council for Comparative Effectiveness Research will help set the agenda for these funds. The remaining \$300 million is available for the Agency for Healthcare Research and Quality to conduct and support comparative effectiveness research. These funds are available for obligation in FY 2009 and FY 2010. The number of FTEs in FY 2010 includes an estimated 38 nonpermanent FTEs to be compensated using Recovery Act funds.

From Department of Health and Human Services, Fiscal Year 2010. Agency for Healthcare Research and Quality. Justification of Estimates for Appropriations Committees. Available at: <http://www.ahrq.gov/cpi/about/mission/budget/2010/2010.pdf>. Accessed August 5, 2014.

with cancer found significant improvements in patient knowledge and attitudes about pain management, reduced average pain-intensity scores, and reduced intensity of the worst pain level experienced.<sup>16</sup> Another meta-analysis of 26 studies found that the attributes of successful cancer pain educational programs involved the systematic and standardized implementation of a well-developed program, much like those used to educate patients about chemotherapy administration and central line placement.<sup>17</sup>

Beyond knowledge transfer, meta-analysis data found that significant improvements in CRP control involved strategies that enabled patients. Mostly aimed at improving communications with health care providers, examples of enabling interventions included improving patient compliance with completing pain rating scales and diaries, documentation of medications, a phone help line, and a written pain management plan.<sup>18</sup> Beyond improving medication

adherence and communication, these strategies also increased patient confidence, allowing better self-management of pain, and reduced the psychological consequences of pain, including the perceived lack of control and isolation. Increased patient involvement in disease management is consistent with current health care initiatives, including meaningful use.

Physician education and experience in pain assessment and management is another well-recognized barrier to CRP management. The discussions about the need for CRP management education of health care providers and patients, however, are contradictory to the usual experience in oncology. The results of seminal clinical trials are rapidly incorporated within oncology practices. In contrast, implementation of clinical practice guidelines, including those by NCCN, to improve cancer pain management continues to lag behind. A retrospective chart

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**Table 2 Budget for the Agency for Healthcare Research and Quality for Fiscal Year 2013**

	FY 2011 Enacted <sup>a</sup>	FY 2012 Enacted <sup>a</sup>	FY 2013 Request Level <sup>a</sup>	+/- over FY 2012 Enacted <sup>a</sup>
<b>Research on HCQO:</b>				
Patient-centered health research	\$29,000	\$40,600	\$72,400	\$31,800
PCORTF transfer (non-add)	\$8,000	\$24,000	\$62,400	\$38,400
Evaluation funds	\$21,000	\$16,600	\$10,000	-\$6,600
Prevention/care management	27,904	27,904	27,904	\$0
USPSTF - prevention and public health fund (non-add)	7,000	7,000	7,000	\$0
Prevention research - prevention and public health fund (non-add)	5,000	5,000	5,000	\$0
Value	3,730	3,730	3,614	-\$116
Health information technology	27,645	25,572	25,572	\$0
Patient safety	65,585	65,585	62,614	-\$2,971
Crosscutting activities related to quality, effectiveness, and efficiency	111,789	108,377	88,931	-\$19,446
<b>HCQO, Total Program Level</b>	<b>\$265,653</b>	<b>\$271,768</b>	<b>\$281,035</b>	<b>\$9,267</b>
<b>HCQO, PHS Evaluation Funds</b>	<b>\$245,653</b>	<b>\$235,768</b>	<b>\$206,635</b>	<b>-\$29,133</b>
<b>Medical Expenditure Panel Surveys</b>	58,800	59,300	59,300	0
<b>Program support</b>	67,600	73,985	68,422	-5,563
<b>Total Program Level</b>	<b>392,053</b>	<b>405,053</b>	<b>408,757</b>	<b>\$3,704</b>
PHS evaluation funds	372,053	369,053	334,357	-\$34,696
Prevention and public health fund	12,000	12,000	\$12,000	\$0
PCORTF transfer	8,000	24,000	\$62,400	\$38,400

Abbreviations: FY, fiscal year; HCQO, health costs, quality, and outcomes; PCORTF, Patient-Centered Outcomes Research Trust Fund; PHS, public health service, USPSTF: United States Preventive Services Task Force.

<sup>a</sup>Monetary amounts in thousands.

From Department of Health and Human Services, Fiscal Year 2013. Agency for Healthcare Research and Quality. Justification of Estimates for Appropriations Committees. Available at: <http://www.ahrq.gov/cpi/about/mission/budget/2013/2013.pdf>. Accessed August 5, 2014

review of 109 patients admitted to the oncology service of an academic medical center between April and September of 2011 found only a 64% adherence to the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Adult Cancer Pain (available at NCCN.org). Pain relief was defined as a pain score less than or equal to 4 or a 50% reduction in pain from baseline within 24 hours after initiation of opioid therapy. Compared with only 41% of the nonadherent patient group, pain relief was achieved in 63% of inpatients receiving analgesics based on NCCN Guidelines for Adult Cancer Pain.<sup>19</sup> Prescription of opioid analgesics as an outpatient, ironically placed patients at higher risk for guideline non-adherence and inadequate analgesia.

In the outpatient setting at a tertiary care cancer center, 3023 ambulatory patients at risk for pain with invasive breast, prostate, colon/rectum, or lung cancers were involved in a prospective study to as-

sess pain management. At initial assessment, 67% of patients had pain or required analgesics; in 33% of these cases, the analgesic prescribed was inadequate.<sup>20</sup> More concerning, no improvement in analgesic prescribing was found between the initial and follow-up visits 28 to 35 days later. Significant patient predictors of inadequate pain management in this study were a good performance status, having limited disease burden, and being treated at a minority treatment site; minority patients were twice as likely have inadequate CRP control. Unlike previous studies, however, patient reluctance and fears regarding analgesic addiction were not significant predictors of poor pain control in this patient group.

Physician- and patient-rated evaluations of incident/breakthrough pain, neuropathic pain, and psychological distress in 1017 patients were compared in a multicenter international study. Consistent with prior studies, patient-reported outcomes (PROs) provided a



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better classification and discrimination of CRP than physician assessments.<sup>21</sup> Agreement between patients and physicians was only 65.9% for incident/breakthrough pain, 74.1% for neuropathic pain, and 69.3% for psychological distress. The agreement between patient and physician reports, however, was found to be better for other physical symptoms, such as fever, and the absence of a symptom.<sup>22,23</sup>

Data capture of PROs enables health care providers to evaluate the adequacy of CRP control, especially that of breakthrough pain, for individual patients. Such data capture also assists with practice outcomes evaluations needed for value-based clinical reimbursement systems and federally mandated meaningful use reports. Uncontrolled CRP, accounting for a significant percentage of emergency room visits and hospital admissions, increases the cost of health care, reduces quality of care, and may result in significant reimbursement penalties.

## Summary

From every perspective, the control of CRP is an essential aspect of oncology care. CRP is a dominating symptom that affects quality of life and causes indelible distress for caregivers. Clinical trials have shown that the control of CRP influences overall survival.<sup>2,3</sup> Untreated CRP, occurring in more than one-third of outpatients and inpatients, results in significant morbidity and socioeconomic cost, accounting for approximately one-fourth of emergency room and hospital admissions.

Health care policy is now placing significant emphasis on patient-centered outcomes that improve quality of life. Federal agencies and task forces now recommend that there should be greater consideration of the potential harms of diagnostic and therapeutic interventions. These harms include not only the risks and toxicities but also the potential short- and long-term pain, distress, and impact on activities of daily living. As quality survival becomes the primary goal of cancer therapy, the morbidity associated with uncontrolled pain resulting from cancer or its diagnosis and treatment can impact health care policy decisions.

Many governments have dealt with spiraling health care costs through developing guidelines for care that incorporate HEOR. Value-based accreditation and reimbursement systems and patient-centered outcomes are driven by health care reform.

These changes in health policy are enveloping every aspect of medicine, from clinical trials to meaningful use evaluations of clinical practice. Supported by the infrastructure of an institute, patient-centered outcomes are now a priority end point that will influence every aspect of cancer therapy. Already identified as a factor that influenced health policy related to cancer screening and treatment, controlling pain along with other symptoms and toxicities associated with cancer and its treatment will remain a patient, socioeconomic, and ethical priority.

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