

NATIONAL VA PAIN OUTCOMES WORKING GROUP

NATIONAL VA PAIN MANAGEMENT
COORDINATING COMMITTEE

VHA PAIN OUTCOMES TOOLKIT

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DEPARTMENT OF VETERANS AFFAIRS
810 Vermont Avenue, N.W.
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VHA PAIN OUTCOMES TOOLKIT

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VHA PAIN OUTCOMES TOOLKIT

SECTION 1: INTRODUCTION

Veterans Health Administration (VHA) National Pain Management Strategy

VHA has initiated a comprehensive national strategy for pain management. The overall goal of the new VHA National Pain Management Strategy is to prevent pain and suffering in persons receiving care in the veterans healthcare system. The specific objectives of this strategy are to:

- Provide a system-wide VHA standard of care for pain management that will reduce suffering from preventable pain.
- Assure that pain assessment is performed in a consistent manner.
- Assure that pain treatment is prompt and appropriate.
- Include patients and families as active participants in pain management.
- Provide for continual monitoring and improvement in outcomes of pain treatment.
- Provide for an interdisciplinary, multi-modal approach to pain management.
- Assure that clinicians practicing in the VHA healthcare system are adequately prepared to assess and manage pain effectively.

Outcomes Toolkit Objectives

The VHA Pain Outcomes Toolkit was developed by the [VA National Pain Outcomes Workgroup](#), a subgroup of the [VA National Pain Management Coordinating Committee](#), as part of the VHA's National Pain Management Strategy. The toolkit was designed to assist healthcare providers and facilities devise methods and implement processes to measure pain treatment outcomes. Measuring the effectiveness of pain treatment and pain service delivery mechanisms is critical to the VHA's goal of improved pain treatment services.

Definition of Outcomes Measurement

Outcomes measurement refers to "...the systematic collection and analysis of information that is used to evaluate the efficacy of an intervention" (Clark & Girona, 2002). *Systematic collection* means that data are gathered at multiple time points using the same methods or instruments. *Analysis* refers to the process of condensing and examining the data to identify meaningful trends or changes. Analysis may indicate that changes in processes or practices should be undertaken to improve treatment outcomes or to remove system barriers to care.

Usually, in clinical settings outcomes measures are collected before and after an intervention with the assumption that any changes observed in the measure can be attributed to the effects of the intervention. However, it is important to remember that other known or unknown factors also could account for the observed changes, particularly in healthcare settings where multiple interventions or events may have transpired between the initial assessment and the post-intervention assessment. Therefore, multiple episodes of data collection are preferred as they facilitate the identification of trends in the data that may be more reliable indicators of intervention-related change.

Why Measure Pain Outcomes?

There are several reasons that pain treatment outcomes monitoring are an integral part of today's healthcare delivery systems. First and foremost, treatment outcomes data are critical to insuring that patients with pain receive effective and timely care. Outcomes data can be used to direct treatment decisions to maximize success, to generate pain treatment guidelines that in the past were based only on anecdotal observations of treatment effectiveness, and to identify service delivery system problems or barriers. Second, many government agencies, accreditation bodies, professional societies, and other organizations now require the collection and analysis of pain outcomes data. Within the VHA, the National Pain Management Strategy includes objectives for using outcomes to monitor the effectiveness of pain treatment. Outside the VHA, pain outcomes measurement now is required by some major healthcare accreditation agencies. For example, the Rehabilitation Accreditation Commission (CARF) was one of the first to develop elaborate outcomes standards for pain treatment programs. More recently, standards for pain management across the spectrum of health care service delivery settings have been adopted and applied by the Joint Commission for the Accreditation of Healthcare Organizations (Rehabilitation Accreditation Commission, 2002). Other national and local bodies also have begun to recognize the necessity of monitoring the effects of pain treatment. Pain treatment guidelines, such as those developed by the Agency for Health Care Policy and Research (Agency for Health Care Policy Reform, 1992, 1996) and the American Pain Society (American Pain Society, 1995). Similarly, healthcare insurers have expressed an interest in the cost effectiveness of pain treatment (Kulich & Lande, 1997), and may require that treatment effectiveness be established before claims will be paid.

SECTION 2: SELECTING OUTCOMES MEASURES

Selecting appropriate outcomes measures is the key to developing a meaningful outcomes monitoring system. Three factors should be considered as part of the outcomes selection process (Clark & Girona, 2002):

- Pain outcomes focus (patient focused or process focused)
- Type of pain (acute, chronic, or pain at end-of-life)
- Practice setting

Pain Outcomes Focus

Patient focused outcomes measures focus on changes in individuals' pain experience following interventions. To quantify change, measures must be administered at least twice (before and after treatment). For treatments spanning lengthy time intervals, repeated administrations (e.g., every month) may provide a more detailed picture of change.

Patient focused measures often are used to evaluate a single patient's response to treatment. When they are used collectively to evaluate a specific treatment intervention or program of interventions, they serve as aggregate outcomes measures. The most common patient focused outcome measure is pain intensity. Other measures might include pain-related interference, emotional distress, or physical capacities.

Process focused measures focus on the pain service delivery system, and usually are components of performance improvement activities. In some cases measures may be collected only once, but more often they will be collected repeatedly over time to evaluate trends in the measures or to assess the impact of a system intervention.

Results may be used to evaluate how well the pain service delivery system is meeting facility goals, regulatory statutes, or accreditation body (e.g., JCAHO) standards. Common measures include pain clinic waiting times, adequacy of pain assessment and treatment documentation, or compliance with patient pain education standards.

Type of Pain

The selection of outcomes measures should include a consideration of the type of pain most often treated in the setting of interest:

- *Acute pain* typically refers to pain etiologically related to an injury, disease, or medical procedure (e.g., post operative pain) that is expected to be transitory.
- *Cancer pain* is used to identify pain associated with active cancer.
- *Chronic pain* is used to identify longstanding pain (typically pain that persists beyond the expected timeframe for healing) that is not due to cancer and is not expected to resolve on its own. Chronic pain may be constant (i.e., present all or most of the time), or episodic (i.e., periods of constant pain with intervening pain-free intervals).

Pain types are not necessarily mutually exclusive. An individual with acute or cancer pain also may simultaneously experience chronic pain from an unrelated condition. Distinctions between pain types are important as appropriate treatments and associated outcomes measures may

vary for each. For example, if *acute* pain is the focus, primary measures might include pain intensity and pain medication side effects. When *chronic* pain is the focus, measures of psychosocial functioning, pain interference, or other outcomes domains likely are as important as pain intensity measures.

Practice Setting

Practice setting refers to attributes of the pain service delivery environment. Pain treatments may range from minimally complex (e.g., medication management) to highly technical (e.g., dorsal column stimulator implants).

In general, pain service settings that require minimal resources and utilize uncomplicated treatments may not warrant elaborate, expensive, and time-consuming outcomes measurement practices when less complex approaches would suffice. In contrast, more complex treatment settings requiring greater resource investment or patient risk may want to utilize broader, multi-domain outcomes measures in order to assess change in a variety of pain experience areas.

The rationale underlying this variation in outcomes approach is twofold. First, from a cost-benefit perspective, when resource investment is greater, such as in complex pain treatment settings, it is reasonable to expect that outcomes should be improved. Utilization of more comprehensive outcomes measures that assess function in a greater range of domains may provide evidence of a greater range of treatment-related improvements. Second, complex pain treatment settings are likely to treat individuals with more complicated and severe pain conditions and increased pain-related dysfunction that extends across multiple domains of function. Therefore, more elaborate measures of outcomes may be needed to accurately reflect both the extent of pain-related disability and the degree of improvement attained.

SECTION 3: MEASURING PATIENT-FOCUSED OUTCOMES

There are a multitude of patient focused pain measures available to practitioners. Only brief descriptions of the most popular measures are included in this document as many have been reviewed in detail elsewhere (cf, Turk & Melzack, 2001).

Numerous experts in the field of pain and pain management have encouraged a multidimensional perspective of pain that promotes measurement of several key domains of the experience of pain when conducting comprehensive pain assessments and/or when evaluating outcomes of pain management efforts (cf, Block, Kremer, & Fernandez, 1998; Gatchel & Turk, 1998; Turk & Melzack, 2001). Most commonly these include the domains of pain intensity or severity, pain interference (variously measured as perceived disability, deficits in physical capacity, decline in social or family relationships, and changes in employment status or performance), and emotional distress. Kerns (1996), in particular, has argued that these domains should be considered primary, as opposed to secondary, outcome domains. Additional outcome domains that are often viewed as important or critical include healthcare utilization and costs as well as patient satisfaction.

The selection of specific patient focused measures should include a consideration of demonstrated reliability and validity. Reliability refers to the consistency of test results when administered under identical circumstances (Johnston, Keith, & Hinderer, 1992). Two common indices of reliability include measures of internal consistency, that is, the degree to which items of a measure are intercorrelated, and test-retest reliability, or the degree of stability of the measure over a specific period of time. The typical statistical index of internal consistency is the alpha statistic. Alphas range from 0 to 1.0 with higher alphas indicating greater reliability. In general, indices above .70 are considered adequate for clinical purposes. Test-retest reliability commonly is expressed as a correlation, with indices above .70 generally indicating adequate stability of the measure. Reliability is necessary for a measure to be valid, but measures can be reliable but not valid (Green, 1992).

Validity refers to how well the measure assesses or “captures” what it was designed to measure (Johnston et al., 1992). There are a variety of methods used to evaluate the validity of a measure which most often is expressed using simple correlations. For example, one index of the validity of a new measure of pain severity for persons with chronic pain might be the overall correlation between scores on the new measure with those on an already accepted measure of pain intensity. Note, however, that these validity coefficients will be much smaller than the instrument’s reliability values. Typically, validity coefficients that fall in the .30 or higher range provide good support of a measure’s validity in the dimension assessed, although coefficients as small as .15 or lower also may support validity depending on the characteristics of the measures examined.

Several pain accreditation bodies (e.g., Rehabilitation Accreditation Commission) and professional associations (e.g., the American Congress of Rehabilitation Medicine) require that facility or program outcomes measures have demonstrated their reliability and validity (Johnston et al., 1992; Rehabilitation Accreditation Commission, 2002). Whenever possible, measures used to track VHA pain outcomes should conform to these standards for reliability and validity. However, note that some patient focused pain outcomes measures do not have such supporting data available. In these cases additional caution should be exercised so as to avoid conclusions that may be erroneous. In addition, it is preferable that, when available, pain outcomes measures used in the VHA have been validated with samples of veterans.

Measuring Pain Intensity

Pain intensity is the indicator used most often to evaluate the efficacy of pain treatments. Intensity measures fall into three general categories: Numeric Rating Scales, Visual Analog Scales, and Verbal Rating Scales. Visual Analog Scales and Numeric Rating Scales consist of a single item to quantify the intensity of “current”, “usual”, “least”, or “worst” pain. *Research indicates that “least” and “usual” pain ratings provide the best estimate of actual pain intensity* (Jensen, Turner, Turner, & Romano, 1996).

Numeric Rating Scales (NRS). Numeric rating scales utilize a numeric range (typically 0 to 10 or 0 to 100) to quantify pain intensity, can be administered in oral or written form, and are the most commonly used method of assessing pain levels. Anchors parallel those described above. Patients are instructed to choose a single number from the 11 or 101-point options that best represents their pain. The NRS has been found to be valid and reliable, and to be sensitive to changes in acute, cancer, and chronic pain. *The numeric pain score utilized in the VHA’s Pain as the Fifth Vital Sign initiative relies on an 11-point NRS measure.* In the VHA version of the measure, standardized anchors (0 = “no pain” and 10 = “worst pain imaginable”) have been selected to encourage consistency across institutions and settings. The VHA’s “Pain as the 5th Vital Sign Toolkit” (VHA, 2000: document available at www.vachronicpain.org) may serve as a helpful resource for adoption and utilization of this measure.

Visual Analog Scales (VAS). Visual analog scales rely on a visual cue (usually a ten-centimeter line anchored with the phrases “no pain” and “worst possible pain” or “excruciating pain”) to evaluate pain intensity. Usually the line is horizontal, although vertical presentations (e.g., the “pain thermometer”) also are available. Instructions require that patients bisect the line at the point matching their “current”, “usual”, “best”, or “worst” level of pain. The pain score is the length of the segment starting at “no pain” and terminating at the point indicated by the respondent. Research has indicated that the VAS is a valid and sensitive measure of pain intensity in patients with acute, cancer, and chronic pain (Ogon, Krismmer, Soellner, Kantner Rumpfmair, & et al, 1996; ; Breivik, Bjornsson, & Skovlund, 2000). Comparisons between horizontal and vertical line presentations have yielded mixed results, but there is some evidence that a horizontal orientation may improve sensitivity of the measure (Ogon et al., 1996; Jensen, Turner, Romano, & Fisher, 1999; Breivik & Skoglund, 1998).

Verbal Rating Scales (VRS). Verbal rating scales consist of words or word-pairs used to describe pain that are rank ordered along a continuum of severity. A score is assigned to the chosen descriptor based on the empirically derived ranks of the chosen words (Jensen & Karoly, 1992). Perhaps the most widely known VRS is the *McGill Pain Questionnaire* (MPQ; Melzack, 1975a) which consists of 20 lists of descriptors of the sensory, affective, and evaluative dimensions of pain (Melzack, 1975b). The standard scoring procedure yields a Pain Rating Index (PRI) which is computed for each of the three pain dimensions and may be summed to provide an overall PRI. The PRI is sensitive to change and has been validated for use with acute, cancer, and chronic pain populations (Davis, 1989; Lowe, Walker, & MacCallum, 1991; Sist, Florio, Miner, Lema, & Zevon, 1998).

From a practical point of view, the NRS or the VAS may be preferred to the MPQ or other verbal scales as pain intensity measures as their results can be treated as ratio-level data which allows for greater latitude in analysis. When choosing between the VAS and the NRS, the former may be preferred when the greatest measurement precision is desirable, while the benefits of the latter are easier administration and scoring.

Other validated pain intensity measures that might be considered include the *Faces Pain Scale* (Bieri, Reeve, Champion, Addicoat, & Ziegler, 1990), which was originally developed to assess

pain in children but has been validated for use with the elderly (Herr, Mobily, Kohout, & Wagenaar, 1998), and the *Pain Thermometer* (Choiniere & Amsel, 1996).

Measuring Pain Interference

Measures of pain interference assess the nature and degree that pain negatively impacts one or more domains of functioning. Reductions in pain interference are important goals for treatment, and outcome measures sensitive to these changes should be incorporated into any outcomes package used in settings where prolonged pain is an issue.

Sickness Impact Profile (SIP). The SIP is a frequently used 136-item measure of perceived impairment (Brown, 1995; Williams, 1988) with excellent test-retest reliability (.92) and internal consistency (.94; Bergner, 1981). The instructions for the version most often used with individuals with pain were altered by Turner and Clancy (1988) to reflect pain-related impairment rather than general physical impairment. The SIP contains two Domains (Physical and Psychosocial) and a total of 14 subscales used to assess pain interference across a wide range of functioning. The SIP scales have been found to be sensitive to changes in functioning resulting from multidisciplinary pain treatment (Jensen, Strom, Turner, & Romano, 1992), and they possess good concurrent validity in chronic pain and cancer pain patients (Beckham, Burker, Lytle, Feldman, & Costakis, 1997; Watt Watson & Graydon, 1989). Based on the frequency that this instrument has been used in the pain research literature, the SIP is the “gold standard” for detailed assessment of self-reported pain interference.

Roland and Morris Disability Index (RMD). The RMD is a 24-item scale comprised of 23 SIP items and one additional item (Deyo, 1986). The RMD correlates most closely with the SIP Physical scale, while the association with the SIP Psychosocial items is much lower (Jensen et al., 1992). The scale has demonstrated good internal consistency (Hsieh, Phillips, Adams, & Pope, 1992), sensitivity to change (Jensen et al., 1992), discriminative validity (Leclaire, Blier, Fortin, & Proulx, 1997), and, when used with chronic low back pain patients, stability (Jensen et al., 1992). The RMD has been utilized in a number of pain outcomes studies, and is useful as a brief measure of self-perceived disability. However, data suggests that it may be less sensitive to some psychosocial aspects of the pain experience than the SIP.

Oswestry Low Back Pain Disability Questionnaire (ODQ). The ODQ is a 10-item questionnaire assessing pain and pain-related limitations in daily activities (Fairbank, Couper, Davies, & O'Brien, 1980). Testee's choose 1 of 6 response options for each item, and scores are summed across items. The ODQ has evidenced adequate stability (Davidson & Keating, 2002) and internal consistency (Hsieh et al., 1992), as well as discriminative validity (Leclaire et al., 1997) and sensitivity to change (Davidson & Keating, 2002). ODQ item content suggests that it may be most useful for patients with more severe limitations or disability (Baker, Pynsent, & Fairbank, 1989).

Pain Disability Index (PDI). The PDI (Pollard, 1984) is a brief (7-item), easy to use measure of pain interference in physical and psychosocial role performance that has good internal consistency ($\alpha = .87$; Tait, 1987) and one-week test-retest reliability (ICC $r = .91$; Gronblad et al., 1993). Research indicates that it is sensitive to change (Strong, Ashton, & Large, 1994), and it has been validated for use with chronic and post-operative pain patients (Pollard, 1984). Although less comprehensive than the SIP, the PDI may be useful when a short but psychometrically sound measure of general pain interference is desired.

Measuring Emotional Distress

Significant pain often is accompanied or preceded by emotional distress and emotional status and traits can have a significant impact on treatment outcome. Thus, comprehensive pain outcomes approaches should include methods to assess the varieties of emotional distress. There are numerous emotional distress instruments available for use. The measures that follow were selected based upon on brevity, ease of use, and general acceptance among pain researchers for outcomes assessment.

Depression Measures. The *Beck Depression Inventory* (BDI) is a brief (21-item) measure of depressive symptoms and complaints (Beck, 1987). The BDI possesses adequate psychometric properties (Beck, 1988), and is sensitive to multidisciplinary pain clinic treatment changes (Kleinke, 1991). A newer version of the BDI (BDI-II) now is available that may be more sensitive to core symptoms of depression (Beck, Steer, Ball Roberta, & Ranieri, 1996).

A frequently used alternative to the BDI is the 20-item *Center for Epidemiologic Studies-Depression Scale* (CES-D; Radloff, 1977). The CES-D has both high internal reliability ($\alpha = .85$) in normal populations and good concurrent validity when used with individuals with chronic pain (Beckham et al., 1997; Radloff, 1977).

Anxiety Measures. The most frequently used measure of anxiety today is the *State-Trait Anxiety Inventory* (STAI). The STAI is a 40-item self-report inventory of state anxiety (current anxiety) and trait anxiety (propensity to experience anxiety). There is a high concordance between pain and anxiety (Polatin, Kinney, Gatchel, Lillo, & Mayer, 1993), and the STAI is widely used as a pain outcomes measure. It has acceptable psychometric properties (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983), and it is sensitive to change (Mongini, Defilippi, & Negro, 1997).

Pain-related Fear. Recent data suggest that pain-related fear may be a key component in the development and maintenance of pain-related physical disability (McCracken, Faber, & Janeck, 1998). Pain-related fear (also referred to as *kinesiophobia*) may be defined as the constellation of fearful feelings and avoidance behaviors in anticipation of a re-experiencing of painful sensations or of a re-injury (Kori, Miller, & Todd, 1990). Research has demonstrated that for some individuals with chronic pain pain-related fear may mediate treatment-related improvement (Vlaeyen, de Jong, Geilen, Heuts, & van Breukelen, 2001).

The *Pain Anxiety Symptoms Scale* (PASS; McCracken, Zayfert, & Gross, 1992) is one of the two most frequently used measures of pain-related fear. The PASS includes 40 items distributed across four subscales measuring pain-related anxiety symptoms (cognitive and physiological), escape and avoidance behaviors, and pain-related fears (McCracken, Zayfert, & Gross, 1992). The PASS has adequate internal consistency (McCracken et al., 1992), good predictive validity (McCracken et al., 1998), and acceptable validity (McCracken, Gross, Aikens, & Carnrike, 1996).

The *Tampa Scale of Kinesiophobia* (TSK; Kori et al., 1990) is perhaps a better measure of pain-related fear. The TSK is a 17-item instrument with items assessing pain-related fear of movement or of pain sensations due to concerns about injury or reinjury (Kori et al., 1990). Recent data suggest that the TSK may be a better predictor of a range of pain symptoms and behaviors (Crombez, Vlaeyen, Heuts, & Lysens, 1999), and it has been found to be a better predictor of disability than pain intensity, biomedical signs and symptoms, or negative emotionality measures (Crombez et al., 1999; Vlaeyen et al., 1999). A revised version of the TSK (TSK-R; 12 items) now is available that has been validated with veterans treated for chronic pain in outpatient and inpatient settings (Cohen, Clark, & Girona, 2003; Girona, Clark,

& Young, 2003). The TSK-R demonstrates good reliability, and exploratory (Cohen et al., 2003) and confirmatory (Girona et al., 2003) factor analyses have identified two factors that account for the majority of TSK-R score variance: fear of (re)injury and morbid somatic focus. The TSK-R can be downloaded from the www.vachronicpain.org website.

Measuring Physical Capacities

Physical capacities denotes an individual's theoretical physical capabilities that are limited by physical status variables such as strength, endurance, and range of motion. In contrast, *functional capacities* refer to an individual's "maximum work abilities" (Dabatos, Rondinelli, & Cook, 2000), or their peak performance in specified tasks. As self-reports of physical capacities among individuals with chronic pain often do not correspond with their actual physical capabilities (Clark, 1996), objective physical capacity measures may serve as better indicators of treatment-related changes in this domain.

At present there are no "gold standard" objective outcomes measures of pain-related physical or functional capacity in use within the VHA or private sector health care systems. Instead, a variety of methods have been employed in attempts to quantify treatment related changes in the physical abilities of individuals with pain.

Practitioner Ratings. The most common physical capacity measures employed as outcomes indicators in pain clinic settings are practitioner ratings (usually on a 0 to 5 scale) of strength, flexibility, and sensory or motor function. Indeed, practitioner ratings have long been used in neurological evaluations and in assessments conducted by physical therapists or other rehabilitative disciplines. Ratings are based on physical examination findings and on task performance. Advantages of this approach are that physical capacity ratings are easy to generate, require little additional time, and necessitate minimal external equipment.

Unfortunately, practitioner ratings are subject to the standard range of observer biases (Hoyt, 2000) and often lack consistent scale anchors, which reduce their reliability and validity. Additionally, despite their apparent objectivity, practitioner ratings are in fact highly subjective since they rely on each individual's clinical experience and internalized schema, which may account for their poor inter-rater reliabilities (Deyo, 1988; Elam et al., 1991; Lieberman et al., 1996).

Observational Measures. A number of observational measures have been employed to quantify changes in the physical capacities of individuals with chronic pain. Several intricate behavioral ratings scales of physical impairment or functional capacities have been developed primarily for pain research (e.g., Follick, Ahern, & Aberger, 1985; Keefe & Block, 1982). Typically, these methods utilize trained observers either to record the frequency of key behaviors or to rate observed physical function during a series of standardized tasks. Interrater or interobserver agreement coefficients establish the reliability of measurement, and resulting scores demonstrate the necessary correspondence with alternative measures of the same functions.

Observational measures are of limited value in most clinical settings as they require extensive rater training, detailed recording and scoring, lengthy administrations, elaborate data analysis, and, frequently, videotaped records. Nevertheless, if sufficient resources are available, observational measures may be of great value.

An alternative type of observational measure that has been used to track general rehabilitation outcomes is the *Functional Independence Measure* (FIM; Keith, Granger, Hamilton, & Sherwin, 1987). The FIM is a collection of 18-items assessing patients' independence in selected areas of function. Testers must attain a criterion level of competence with the instrument before they begin administrations. Testers then rate the testee's level of independence on each item, based

on the tester's observations of their abilities. Good to excellent FIM interrater reliabilities have been reported (Hamilton, Laughlin, Fiedler, & Granger, 1994), and validity with several patient groups has been established (Dodds, Martin, Stolov, & Deyo, 1993; Oczkowski & Barreca, 1993; Wilson, Houle, & Keith, 1991). Although most VHA and private sector inpatient rehabilitation services use the FIM as an index of function and to benchmark rehabilitation outcomes, the FIM is less useful for measuring pain-related physical capacities or treatment outcomes. FIM items were designed to assess functional capacities in patients with relatively severe disabilities, such as those associated with strokes or traumatic brain injuries. Individuals with less pervasive conditions, such as those with chronic pain, tend to score very high on the instrument even prior to treatment interventions due to their high baseline functional status. As a result, initial FIM scores approach the ceiling of the instrument allowing little room to discriminate function between individuals or to assess treatment-related change.

"Biometric" Approaches. Biometric approaches rely on various hardware devices to quantify physical function, capacities, or movement. They may include physiological recordings of autonomic or somatic nervous system activity, measures of motor output (e.g., force, speed, weight), or three-dimensional computerized representations of motion or movement collected during standardized tasks. There are numerous biometric "systems" approaches marketed by private vendors that purport to be reliable and valid measures of functional capacities. Each of these approaches is based on unique combinations of measures and hardware that are presumed to either simulate actual functional behaviors or predict functional capacities. Biometric approaches often are utilized in injury litigation cases or in federal or state disability decisions (e.g., Social Security disability or Worker's Compensation) where questions concerning functional capacities exist.

Although the comprehensive nature and precision of biometric approaches to physical capacity measurement is appealing, they are not suitable for general use as pain outcomes measures for numerous reasons. First, they require lengthy administration times (typically 3 to 4 hours or more) that far exceed available time intervals. Second, their hardware cost is substantial (approximately \$12,000 to \$100,000), and many charge additional fees for each completed assessment. Third, for the most part they were designed to assess work-related performance (i.e., functional capacities) rather than physical capacities per se. Thus, many of the simulated work tasks that form the basis of these biometric approaches may not be relevant to a VHA patient population characterized by multiple disabilities, low rates of employment, and sedentary lifestyles.

Performance Measures. Performance measures are those where objective indices of function (e.g., time to complete, number of repetitions completed, degree of incline obtained, grip strength) during an assigned task are recorded and compared either to normative or clinical data or to pretreatment indices of function. Several of these measures have generated substantial research interest and have been found to be reliable and valid indicators of function. For example, the dual inclinometer method of assessing trunk range of motion has been found to be reliable (Keeley et al., 1986), has demonstrated good correspondence with flexion and extension X-ray results (Mayer, Kishino, Keeley, Mayer, & Mooney, 1985), and has been adopted as the "standard" method for assessing spinal mobility by the American Medical Association (Engelberg, 1993). Similarly, hand dynameters have been found to be the most accurate available measure of hand strength (Mathiowetz, Weber, Volland, & Kashman, 1984), as long as standardized grip positions are employed (Mathiowetz, Rennells, & Donahoe, 1985). However, most performance measures of range of motion or strength lack evidence of validity or reliability. For example, physical therapists traditionally rely on goniometers when assessing range of motion despite concerns regarding their reliability when used in cervical (Nilsson, 1995), lumbar (Rondinelli, Murphy, Esler, Marciano, & Cholmakjian, 1992), or extremity (Rome & Cowieson, 1996) assessments.

Alternatives include more integrated performance measures such as the *Physical Capacities Evaluation* (PCE; Clark, 1996), which is loosely based on an instrument developed by Woods (1989). The PCE is comprised of a collection of performance tasks that assess extremity and back function. Unfortunately, it is not practical for general clinical use as it requires the availability of a therapeutic pool to administer. Additionally, like other integrated measures which employ subtests or subtasks, the PCE yields a single overall score based on performance on a series of tasks utilizing different muscle groups. As a result, when pain-related limitations are confined to a single body area (e.g., lower extremities), the resulting summed scores tend to minimize the severity of the individual's dysfunction and may mask the extent of actual treatment-related changes that are obtained.

Current Status Summary. At present there are no “gold standard” physical capacities outcomes measures available to pain practitioners. Standardization of assessment methods is lacking, and practitioner ratings of function remain very popular despite numerous studies demonstrating their poor reliability. Although there are a few commercial systems that may eventually provide adequate validation data, they are very expensive and time intensive, limiting their utility for clinical settings. The best-supported performance measures, which tend to be less resource intensive, are the dual inclinometer method of assessing changes in trunk range of motion, and the use of hand dynameters to evaluate upper extremity strength. In settings where rapid assessment is necessary, current alternatives appear limited to goniometer measures or practitioner ratings until alternative approaches are developed and validated.

Measuring Employment Status

Among the most common criteria used to evaluate chronic non-cancer pain treatment program success are return to work and improvements in disability compensation status. In fact, support for the effectiveness of multidisciplinary pain centers (MPCs) is largely based on data that document the success of these programs in returning participants to work and in closing disability claims (Flor, Fydrich, & Turk, 1992). Furthermore, CARF requires that accredited pain rehabilitation programs consider return to work as a key outcome domain (Rehabilitation Accreditation Commission, 2002). Work status also may be an important variable in evaluating the success of acute or cancer pain interventions in the context of a broad focus on psychosocial functioning.

Employment Status Measures. Unlike other outcomes variables, assessment of changes in employment status does not necessarily involve the administration of validated instruments to gather work-related data. Instead, current employment status usually is elicited as a routine component of an initial screening or more comprehensive pain assessment interview. In this context, recent employment history also is elicited and may include assessment of a range of indicators of work functioning. It is important to note that, depending on the goals of the program or intervention and the population being served, return to work may or may not be viewed as a viable outcome. However, a broad array of alternative work-related variables may be reasonable to consider as measures of the effectiveness of the program or intervention.

Most commonly, work status is measured as a categorical variable in which the participant is characterized as being employed full-time, part-time, or not at all. Usually student status is coded in a similar manner for these purposes. Persons who report that he or she works to maintain a household and/or provides childcare or other care giving usually is coded as such, as is retired status. Successful outcome usually is measured by an improvement (moving “up” in categories) in employment status.

An alternative to this practice is to consider employment as a continuous variable in which paid work is coded in terms of number of days, weeks, or months over a specific period of time that

the individual was employed or unemployed. Outcome is measured as a change in this variable as a function of the pain intervention.

Another alternative method is based on an evaluation of progress toward individually established goals for employment. For example, a veteran participating in a chronic pain management program may set a goal of reducing absenteeism from work. Or another veteran receiving treatment for chronic upper extremity pain may have a goal of vocational retraining for an alternative career. Progress toward these specific goals may be used as important measures of successful pain management.

Resolution of claims for disability or withdrawal from disability roles that impact availability for employment may be important outcomes for some programs or individuals. However, most experts and available data are consistent in supporting a view that this is often an unlikely outcome. For example, the extensive evaluation that usually accompanies a disability determination, and the strong social and financial incentives associated with receipt of disability compensation support this claim.

For some veterans, including retirees or persons already established as being disabled, an increase in avocational activities may be appropriate measure of pain treatment success. Volunteering in a work setting, increases in household chores or activities around the home, initiation of hobbies, or other changes consistent with general productiveness may serve as appropriate outcomes indicators.

Measuring Healthcare Utilization/Costs

Over the past decade there has been a dramatic change in patterns of reimbursement or payment for healthcare delivery. Historically, healthcare has been delivered almost entirely with an emphasis on health-related outcomes, whereas “cost-effectiveness” was only a minor concern. This perspective has now been replaced by the need to attend to major societal and economic forces that demand that the costs of care serve as a primary factor in determining healthcare service delivery. In this environment, the only viable pain management system is one that emphasizes efficiency and cost-effectiveness.

It has been estimated that over \$125 billion is now spent on direct and indirect costs related to chronic non-cancer pain alone (Okifuji, Turk, & Kalauokalani, 1999). The need to balance the delivery of humane pain management and restrictions on the availability of funds for these services is a critical issue. A successful pain management system is one that is able to demonstrate cost-effectiveness, rather than effectiveness alone.

Despite several published reports that support the cost-effectiveness of multidisciplinary approaches to pain management (e.g., Ferrell & Griffith, 1994; Turk, 1996), challenges to the strength of these data are common, particularly from the perspective of healthcare system administrators. Federico (1996) for example, emphasizes the need for increased standardization and guidelines for pain care as well as published research data from scientifically rigorous controlled studies that report on the relative cost-effectiveness of pain treatment programs.

Cost-Effectiveness. Demonstrations of both effectiveness and efficiency in the management of pain are at the core of any discussion of “cost-effectiveness”. The availability of multifactorial data using methods proposed in this Toolkit that document improved patient outcomes is an important, if not essential, component of this process. However, as noted above, demonstrations of efficacy of an intervention or program may not be sufficient in the current managed care environment where resources are limited. In addition, it is increasingly important that costs associated with the delivery of pain management services also are assessed using

methods judged to be reliable and valid. Ultimately, cost-effectiveness can be judged only through a close inspection of benefits (or harm) for persons receiving pain management services in direct comparison to costs associated with these services.

Direct comparison of two or more pain management interventions for the same pain condition and/or sample of patients is probably the most common strategy for examining and reporting on the relative cost-effectiveness of the interventions. For example, Flor, Turk, and their colleagues in their examination of the cost effectiveness of MPCs derived their indices by a comparison of effects of MPCs versus surgical costs for the same conditions (Flor et al., 1992; Turk, 1996).

An important concept in discussions of the cost-effectiveness of pain management systems of care is that of cost-offset. Cost-offset refers to the delayed benefits of an intervention that can be operationalized as reductions in healthcare costs subsequent to the intervention that are reasonably believed to be attributable to the pain intervention. For example, pain management intervention cost-offset effects can be attributed if there is a demonstration of a reduction in healthcare system utilization and associated costs during the 12 months immediately following a pain management intervention relative to the 12 months immediately preceding the delivery of the service.

Measuring Healthcare Utilization And Associated Costs. There is a wide range of variables that may be targeted for developing estimates of costs associated with pain management services. The most common strategy for examining healthcare system utilization is some method for counting activities best characterized as direct patient care services. Depending on the specific facility, type of program, and population served, and the specific purpose of the analyses, it may prove useful to distinguish between medical and surgical, rehabilitation medicine, and mental health services, and/or pain-relevant utilization versus utilization unrelated to the pain condition. There also may be a specific reason to set a threshold for some categories of service utilization, such as an analysis of extensive utilization of a specific outpatient clinic.

Examples of some relevant utilization indices are presented below:

Type of Service	Site of Service	Measure
Medical	Emergency Department	Number of visits Procedures performed
	Inpatient	Number of admissions/ Episodes of care Bed days of care Procedures performed
	Outpatient	Number of primary care visits Number of specialty care visits Number of specialty clinics with >3 visits in 6 month period Number of pain clinic or other pain-related specialty clinic visits Procedures performed
Rehabilitation Medicine	Inpatient	Number of admissions/ Episodes of care Bed days of care Procedures performed
	Outpatient	Number of visits Procedures performed
Mental Health	Emergency Department	Number of visits Procedures performed
	Inpatient	Number of admissions/ Episodes of care Bed days of care Procedures performed
	Day Treatment	Number of days of care Procedures performed
	Outpatient	Number of visits Procedures performed

Costs associated with the use of both prescribed and non-prescribed (over-the-counter) analgesic medications (e.g., opioids) and other medications commonly used for pain management (e.g., benzodiazepines, non-steroidal anti-inflammatories, anticonvulsants, tricyclic antidepressants) are another important measure of healthcare utilization (see Section 5 for more information). Substantial cost savings may be realized by substituting generic or other less expensive medications for those that are more costly, *provided that equivalent outcomes are attained*.

For individual veterans, these utilization indicators can be derived from CPRS GUI (see Section 5 for more information). Utilization of non-VHA services and medications most often require patient self-report and/or reports from significant others. Use of standardized methods for eliciting data related to non-VHA utilization is recommended. Efforts to corroborate these self-

report via acquisition of outside medical and pharmacy records, with the consent of the veteran, can enhance confidence in their accuracy.

When it is desirable to obtain utilization data for groups of veterans, for example, a cohort of participants in a pain management program, it may be helpful to consult with experts from the local Information Resource Management (IRM) office who may be able to extract summaries or aggregated data for your specific purposes (see Section 5 for more information).

Attributing costs to healthcare system utilization is another potentially useful step in the process of examining cost-effectiveness. Costs for most direct patient care services (e.g., outpatient visits, bed days of care in an inpatient medical unit) provided in VHA facilities can be calculated by multiplying units of service by mean unit costs obtained by consulting with Decision Support System (DSS) personnel. Costs for services received in non-VHA settings may be estimated from private sector values for the region in which the service was provided. Pharmacy costs can usually be obtained from local authorities. Additional costs associated with pain-related diagnostic procedures and non-pharmacological pain interventions can be calculated in a similar manner. Once monetary values for services are obtained, changes in actual medical costs occurring from pretreatment to posttreatment can be computed. However, when focusing specifically on medical utilization effects of pain interventions it may be important to distinguish between *pain-related* visits or costs and those that are attributable to other factors (e.g., preventive health care or unrelated medical conditions) where we would not expect to see any impact of pain treatment.

When evaluating the cost effectiveness of pain treatment, costs associated with the provision of the pain management intervention also should be examined. For some multidisciplinary pain centers the intensity of services provided and costs associated with them may be unexpectedly high when administrative and other indirect costs are considered. Equipment and supply costs are also important to include in these analyses. Only then can the potential cost savings of pain interventions be computed accurately.

Measuring Patient Satisfaction

Patient satisfaction is an important aspect of care that influences patient behavior and treatment outcomes. The American Pain Society Commission on Quality Assurance Standards has stated that patient satisfaction with clinical services received is part of the quality assurance of care delivery. Patient satisfaction is included as an outcome variable in the revised APS Patient Outcomes Questionnaire (APS, 1995). Satisfied patients are more likely to comply with treatment and establish better relationships with their providers, whereas dissatisfied patients tend to comply poorly with their prescribed therapeutic regimens (Aharony & Strasser, 1993; Carr-Hill, 1992). The difficulty in measuring patient satisfaction stems from the heterogeneity of patient satisfaction measures, the lack of clarity concerning the meaning of satisfaction and its relationship to other measures, and whether respondents can separate satisfaction with pain management from satisfaction with other aspects of care such as the caring dispositions of health care providers (Hester, Miller, Foster, & Vojir, 1997; Hudak & Wright, 2000). Factors such as the organizational context and the provider type (chiropractic care vs. primary care physicians) also can influence patient satisfaction reports (Hester et al., 1997; Solomon, Bates, Panush, & Katz, 1997).

This discussion is not intended to make specific recommendations or present detailed reviews of patient satisfaction questionnaires. Comprehensive reviews of patient satisfaction measures are provided elsewhere in the literature (e.g., Ferris, 1992; Pascoe, 1983). Rather, general principles are reviewed to assist in choosing a measure based on the user's intent, and information concerning the pain-related content of the national VHA customer satisfaction survey of healthcare experiences of patients also is presented.

Characteristics of Satisfaction Measures. Patient satisfaction measures differ in their content (focus or substance of the measure) and their method (how the measure is administered and presented). Hudak and Wright (2000) suggest that the content of patient satisfaction questionnaires be classified along four axes: global vs. multidimensional, care vs. treatment outcome, generic vs. disease specific, and direct vs. indirect. Some questionnaires may assess only single dimensions of the pain experience (e.g., pain intensity ratings). In contrast, multidimensional measures are query multiple dimensions of service and care. Examples of multidimensional measures include the Patient Satisfaction Questionnaire (PSQ) and the Client Satisfaction Questionnaire (CSQ; Larson, Attkisson, Hargreaves , et al., 1983; Ware, Snyder, Wright, et al, 1979). The PSQ is a 43-item questionnaire reflecting six dimensions of quality related to hospital care: access to care, availability of services, technical quality of care, interpersonal care, communication, and financial aspects of care. The dimensions of care examined in the CSQ include the physical surroundings, general satisfaction, and the interpersonal and technical aspects. Global measures are considered less informative than multidimensional measures and tend to produce scores that are skewed towards high levels of satisfaction (Ferris, 1992). Multidimensional measures typically are more reliable and have higher levels of validity than the global measures (Sitzia & Wood, 1997).

The PSQ and CSQ are examples of generic measures that can be used to assess patient satisfaction in any clinical setting. The content of these measures is broad enough to allow comparisons across conditions and settings, but unlike disease-specific measures, they cannot reflect sources of satisfaction/dissatisfaction unique to a particular disease or health care setting. The Patient Satisfaction Scale (PSS) is a multidimensional *disease-specific* measure of patient satisfaction designed specifically to assess satisfaction among patients with low back pain (Cherkin, Deyo, & Berg, 1991). If the focus of satisfaction assessment is with care (the patient's rating of the quality of the medical care process), a generic measure is appropriate. However, if the focus is treatment outcome (the patient's rating of a particular treatment intervention), a disease-specific measure will more precisely gauge patient satisfaction (Hudak & Wright, 2000).

Another way to evaluate measures is whether they use direct or indirect scales to assess satisfaction. The PSQ is an example of an indirect method as it assesses patients' attitudes about the health system or care in general. The CSQ and the PSS are examples of direct measures that require patients to think about the services they received when answering questions. Direct measures are considered more precise than the indirect measures when probing satisfaction with specific medical encounters or treatment interventions.

Patient satisfaction measures also differ in the methods used to administer the instrument. Measures may be factual (what actually occurred) or affective (the patient's perception of what occurred), questions may be open-ended or closed, they may be self- or interviewer administered, and they may utilize varied response formats (e.g. 4, 5, or 6-point scales). Each of these methods has their advantages and disadvantages depending on the setting and the user's purpose. More detailed explanations of the methods used in patient satisfaction measures are available elsewhere (e.g., see Cleary, 1997; Ferris, 1992; Hudak & Wright, 2000; Ware & Hays, 1988).

Choosing Patient Satisfaction Measures. In summary, the following general principles should be considered when choosing a patient satisfaction measure:

1. Multidimensional measures are preferred over single dimension measures due to their wider breadth of information. Multidimensional measures may be supplemented by a global measure.
2. The actual items in the measure should be carefully examined in relation to the clinical setting and patient population. It may be desirable to add questions to address dimensions not covered in the standardized measure.
3. Assess satisfaction with care separately from satisfaction with treatment outcome.
4. Direct measures are preferred over indirect measures when probing satisfaction with specific medical encounters or treatment interventions.
5. Use of both closed and open-ended questions is recommended for a better understanding of patient satisfaction.
6. Interview non-responders and patients who have left the program to probe for sources of dissatisfaction.

National VHA Customer Satisfaction Survey. Since 1995, the Office of Quality and Performance has administered a mailed customer satisfaction survey in an effort to systematically assess those ambulatory care experiences identified by veterans as priority components of high quality medical care. Beginning in the spring of 2002, the Survey of Healthcare Experiences of Patients (SHEP) is surveying random samples of all patients seen by a provider. Information about this project and customer satisfaction data is available at the Office of Quality and Performance website, <http://vaww.oqp.med.va.gov/DEFAULT.asp>

The survey results report scores for Veteran Health Service Standards, Overall Quality, and Provider Wait Times. Scores are provided for each VISN and scores are reported at the national, VISN, VAMC, and clinic organization levels. Veterans Health Service Standards (VHSS) are summary scores that reflect patient satisfaction in the following domains:

- **Outpatient** – Access, Continuity of Care, Courtesy, Education and Information, Emotional Support, Overall Care Coordination, Visit Coordination, Pharmacy (mailed), Pharmacy (pickup), Specialist Care, Patient Preferences.
- **Inpatient** - Access, Courtesy, Education and Information, Emotional Support, Physical Comfort, Family Involvement, Transition, Overall Care Coordination, and Patient Preferences.

The inpatient survey data domain Physical Comfort includes specific questions about pain experience and treatment.

Future analyses of functional status and healthy behavior data from the SF-12V Health Survey is planned. The SF-12V is included in the mailed satisfaction survey to both inpatients and outpatients. The SF-12V includes questions that assess the functional impact of pain. A web-based application is being developed that will support online dynamic access to SHEP data as it is collected with tools to analyze the information more extensively.

Questions incorporated in the 2002 National Survey and SF-12V that relate to pain treatment or outcomes are presented in [Appendix I](#).

Multidimensional Pain Outcomes Measures

Multidimensional pain outcomes measures are used to assess treatment-related change in several outcomes domains simultaneously. Major advantages of this approach are that they can be used for benchmarking outcomes across facilities (when facilities utilize the same instrument), they tend to be better integrated, and they may be shorter than collections of unidimensional measures that cover the same outcomes domains. Major disadvantages are that they are more complex and may require increased administration, scoring, and interpretation time. Therefore, multidimensional measures are best utilized in intensive chronic pain treatment settings where the measurement of pain-related changes across all outcomes domains is desirable.

West Haven – Yale Multidimensional Pain Inventory (WHYMPI). The WHYMPI (Kerns, Turk, & Rudy, 1985) is a comprehensive measure of pain-related functioning that has been identified as one of the most frequently used measures of the chronic pain experience (Mikail, DuBreuil, & D'Eon, 1993). The MPI is comprised of 52 items comprising three sections and 12 subscales. Section one consists of five scales measuring a range of pain-related experiences, including pain intensity, pain interference, negative mood, life control, and perceived support. Section two contains three scales measuring the responses of significant others to the patients' expressions of pain. The third section includes four activity scales. The WHYMPI has good internal consistency ($\alpha = .70 - .90$) and adequate two-week test-retest reliabilities ($r = .62 - .91$; Kerns et al., 1985). Criterion-related, concurrent, and factorial validity has been demonstrated in numerous studies for heterogeneous samples of persons with chronic, non-cancer pain, and for several specific non-cancer and cancer pain samples. It has been used extensively in outcome research and has been demonstrated to be sensitive to treatment-related change (e.g., Altmaier, Lehmann, Russell, Weinstein, & Kao, 1992; Kerns, Turk, Rudy, & Holzman, 1986). WHYMPI cluster analyses have revealed a three-group typology (dysfunctional, interpersonally distressed, and adaptive copers) of patients with chronic pain (Turk & Rudy, 1990). This typology may assist clinicians in attempting to match pain interventions to patient characteristics identified by the WHYMPI. Advantages of the WHYMPI are that it has been validated specifically with veterans, it assesses most of the relevant pain outcomes domains, and it provides an excellent assessment of the interpersonal aspects of individual's pain experiences.

Pain Outcomes Questionnaire- VA (POQ-VA). The POQ-VA is an outcomes package developed for use with veterans and consisting of intake (45 items), post-treatment (28 items), and follow-up (36 items) questionnaires. The POQ-VA represents the culmination of a five-year cooperative effort with the American Academy of Pain Management to revise, improve, and adapt a preexisting pain outcomes instrument (the *National Pain Data Bank*) for use with VA patients experiencing pain. The POQ-VA is the only pain instrument developed specifically to assess treatment outcomes across all of the pain-related domains of functioning identified by the Rehabilitation Accreditation Commission (2002) as essential for comprehensive outcomes measurement. Outcomes domains include pain intensity, pain interference (ADLs, Mobility), Negative Affect, Vitality (activity level), pain-related fear (Fear), vocational functioning, patient satisfaction, and medical resource utilization from intake through follow-up. Core POQ-VA (formerly known as the National Pain Data Bank VA-Version 2.0) scales have been found to have adequate to high internal reliability and good stability (Gironda, Azzarello, & Clark, 2002), and generalizability coefficients, which are indices of the fidelity of true score measurement (Heaton, Chelune, Talley, Kay, & Curtiss, 1993), indicated excellent scale reliability. Validation studies using veterans treated in outpatient and inpatient pain treatment settings revealed that the POQ-VA demonstrated good concurrent validity in relation to a number of widely accepted "gold standard" measures of pain-related impairment (Clark & Gironda, 2000; Clark, Gironda, & Young, 2003), as well as good sensitivity to treatment-related change (Clark et al., 2003). Confirmatory factor analysis has revealed that the POQ-VA scales reflect a stable latent factor

structure representing two higher-order factors (emotional distress and pain interference; Young, Clark, & Girona, 2003). The *POQ-VA* is available for downloading from the www.vachronicpain.org website, and also is available in a short form version (*POQ-SF*).

Brief Pain Inventory (BPI). The BPI (Cleeland & Ryan, 1994) is a 32-item inventory that assesses pain history, pain intensity, response to medication/treatment, and pain interference. The BPI has been translated into many languages, and it has been validated for use with cancer and chronic disease pain patients. Factor analyses have identified two-factors of pain severity and pain interference across samples and language versions (Caraceni et al., 1996; Radbruch et al., 1999; Saxena, Mendoza, & Cleeland, 1999; Wang, Mendoza, Gao, & Cleeland, 1996).

Note, however, that psychometric data thus far primarily apply to cancer and chronic disease samples rather than to individuals with chronic non-cancer pain. In addition, although the brevity of the BPI is a potential advantage, its scope is less comprehensive than the other available multidimensional instruments. Thus, although it may be the outcomes measure of choice with respect to individuals with cancer pain other instruments may be preferred when changes across many outcomes domains are important.

SECTION 4: PROCESS OUTCOMES MEASURES

Process outcomes dimensions or “service delivery outcomes” (Clark & Gironda, 2002) focus on monitoring and improving pain service delivery systems. Often they are part of facility Performance Improvement (PI) efforts. Accreditation organizations such as JCAHO often focus more on process outcomes, although some JCAHO standards may relate to patient focused outcomes as well. For example, while the patient’s self-report of pain could be used as a patient focused outcome to determine the effectiveness of pain treatment, when it is used as evidence of compliance with pain screening and documentation policies it is acting more as a process outcome. As a process outcome, the *intent* of the patient’s self-report of pain changes from evaluating the effectiveness of the pain intervention provided to evaluating the service delivery system.

Generally, the way in which process outcome measures are gathered differs from the manner that patient outcome measures are collected. Process measures usually involve tracking or monitoring aspects of service delivery or patient documentation. Rarely do process measures involve the use of validated instruments. Instead, process outcomes most often are measured by reviewing medical record documentation or facility records.

Process outcome measures may be developed to evaluate pain policy compliance or to assess compliance with pain standards promulgated by external organizations such as JCAHO. Often they are used to evaluate the impact of a system intervention designed to improve service delivery. Examples of some pain process outcomes are changes in pain clinic waiting times, compliance with the mandate to routinely collect pain scores as the Fifth Vital Sign, proportion of pain patients undergoing repetitive medical diagnostic procedures, percentage of individuals with significant pain who receive pain education, and others.

When developing or selecting pain process measures, one must first define the process that is of interest. Often this may be accomplished by referring to relevant facility or national policies or external pain standards. In this regard, it may be helpful to review the list of attributes of successful pain management systems developed for the VHA/Institute for Healthcare Improvement Pain Management Collaborative Project which is presented in [Appendix II](#). This document defines numerous process standards for pain management excellence that also may be useful as measures of pain process outcomes.

Measuring Process Outcomes

Process outcome measures data may be extracted from a variety of sources, including medical records (including CPRS), patient interviews or surveys, PI monitors, and local or national patient care data files.

Chart Reviews. Chart reviews or audits can be either electronic or paper. Data collection forms and compliance checklists often are used to compare the quality of service delivery provided to an individual patient with system standards of care. In most settings it is not necessary to evaluate every case receiving the targeted service. Instead, a predesignated number of randomly selected charts can be reviewed at established intervals.

Samples of some chart review forms are included in [Appendix III](#). Often it will be necessary to revise existing audit tools or to develop new tools to evaluate process outcomes. When developing pain compliance templates or audit tools, developers may find it useful to consult

several articles that address this issue (Clark & Girona, 2002; Ferrell, Wisdom, Rhiner, & Alletto, 1991; Ferrell, McCaffery, & Ropchan, 1992).

Patient Interviews and Satisfaction Surveys. When process outcomes measures require that data from service consumers be gathered, patient interviews or surveys can be utilized to assess the pain process outcome dimensions. Patient interviews should be structured and standardized so that each consumer responds to identical questions. Opportunities for additional comments can be incorporated at the end of the interview.

When designing patient surveys or questionnaires for use, item wording, clarity, and reading level should be considered and adjusted to meet the target population's verbal abilities (Clark & Girona, 2002). A pain process evaluation tool that includes both a chart audit and a patient interview that was tested for content validity, interrater reliability, practicality of administration and test/retest reliability, is included available from Ferrell, Whedon, & Rollins (1995).

Performance Improvement Monitors. Most healthcare institutions have in place numerous PI indicators that are used to track different aspects of care. Often these indicators will overlap with pain service delivery outcomes. For example, medication error monitors will include cases where pain-related medications were dispensed incorrectly. Or, facility clinic waiting times monitors will gather data on pain clinic waiting times as well as on other clinics. Many additional areas of overlap are possible.

If existing PI monitors do not cover critical pain service delivery components, consideration should be given for developing new PI monitors that address the relevant pain service delivery issues. For example, a monitor might be established for determining the percentage of patients with pain greater or equal to a trigger value of four who undergo detailed pain assessments.

Patient Care Data Files. Aggregated pain service delivery outcomes data also can be extracted from patient care files maintained either locally or nationally. Local files may contain pain scores collected at locally determined intervals that may be aggregated across patients to evaluate changes in the effectiveness of overall pain care provided by the institution. Alternately, facilities utilizing clinical reminders for pain may be able to evaluate various aspects of pain care delivery (see Section 5 for a more detailed discussion).

Key Process Outcomes Monitors

There are five key pain service delivery processes that are central to excellence in pain care:

- Comprehensive pain assessment has occurred
- Treatment/Clinic waiting times are reasonable
- Patients and their families receive education about pain treatment options and their rights and responsibilities
- A pain plan of care is present
- Providers are educated regarding appropriate pain care

Pain Assessment. The VHA National Pain Management Strategy mandates that pain assessment is performed in a consistent manner. As stated in the *Pain as the 5th Vital Sign Toolkit*, "reliable and comprehensive assessment of pain is the cornerstone of effective pain management", and that "effective pain management hinges on the availability of a thorough and reliable assessment of pain". The importance of pain assessment is highlighted by research showing that the failure to routinely assess pain and pain relief is the most common reason for the undertreatment of pain in U.S. hospitals (American Pain Society, 1999).

JCAHO standards (<http://WWW.jcaho.org>) that address the importance of pain assessment are:

- PE.1.4: Pain is assessed in all patients.
- RI.1.2.8: Patients have the right to appropriate assessment and management of pain

Evidence that comprehensive pain assessment is occurring requires that documentation of completed assessments be present in the medical record. Assessments may be in the form of provider consultation reports, provider progress notes, or completed pain assessment templates. Note that the presence of numeric pain *scores* in the medical record is not sufficient evidence that pain *assessment* has occurred. Routine pain screening for the presence and intensity of pain, as outlined in the “Pain as the 5th Vital Sign” directive, should lead to completion of a comprehensive pain assessment when some specific pain intensity threshold is reached (e.g., a pain score of >3 on a 0-10 numeric rating scale).

Waiting Times. One of the goals of the VHA National Pain Management Strategy is to “assure that pain treatment is prompt and appropriate”. Waiting times are an important aspect of this goal. JCAHO also emphasizes the importance of waiting times as illustrated in the following standard:

- RI.1.2.8: Patients have the right to appropriate assessment and management of pain.

Examples of waiting times relevant to pain service delivery adequacy include:

- Waiting time between clinic referral and first available appointment
- Waiting time between stated clinic appointment time and the time the patient actually is seen
- Waiting time between the initiation of a pain medication order and the administration of the pain medication (inpatient setting)
- Waiting time between the patient’s pain medication request and the time the medication is dispensed (inpatient setting)

Some waiting times may be calculated based on evidence present in CPRS (e.g., number of days between clinic referral and scheduled appointment). Others will require that specific monitors be established to quantify the time intervals. Waiting times and other process measures also can be assessed using patient questionnaires. The American Pain Society Patient Outcome Questionnaire (American Pain Society, 1995) is an example of a questionnaire that examines several process domains including medication waiting times.

Patient Education. Patient education is another important component of pain service delivery systems. The importance of education efforts is addressed in the VHA National Pain Management Strategy objective to “include patients and families as active participants in pain management”. Similarly, the 1992 AHCPA Acute Pain Management guidelines (Acute Pain Management Guideline Panel, 1992) include patient education as one of four major pain management goals. JCAHO standards also address the importance of pain education:

- PF.1.7: Patients are taught that pain management is a part of treatment. A positive outcome requires an understanding of pain, the risk for pain, and the importance of effective pain management.
- RI.1.2: Patients are involved in all aspects of their care
- RI.1.2.8: Patients have the right to appropriate assessment and management of pain.

Appropriate components of education for individuals with pain include information regarding diagnosis and prognosis, possible effects on emotional, social, and familial functioning or roles,

treatment rights and responsibilities, and available treatment options including their risks, side effects, and known complications.

Evidence of patient and family education may be found in general progress notes, specific patient education forms, or patient education templates. Alternatively, pain patients or their family members could be interviewed or surveyed regarding the type and nature of pain education they received. Navas & Sommer (1999) provide information on potential sources for patient surveys. Examples of possible patient education survey items are presented in [Appendix IV](#).

Pain Plan of Care. In order to systematically treat pain, a pain plan of care (i.e., treatment plan) should be present in the medical record. Ideally, plans of care should include a description of the pain treatment methods that will be utilized, their frequency, treatment goals, methods that will be used to measure progress towards the stated goals, and evidence that the person with pain was involved in the development of the pain treatment plan. Pain plans of care should be active as long as pain continues to be defined by the patient as a significant problem, and they need to be reviewed and revised whenever significant changes in the person's condition are observed, or when the treatment methods selected have not been effective.

JCAHO standards that address the importance of pain treatment plans include:

- PF.1.7: Patients are taught that pain management is a part of treatment
- RI.1.2: Patients are involved in all aspects of their care
- RI.1.2.8: Patients have the right to appropriate assessment and management of pain.
- CC.6.1: The discharge process provides for continuing care based on the patient's assessed needs at the time of discharge.

The adequacy of pain plans of care usually is assessed by reviews of inpatient or outpatient records. Chart review checklists can be developed to facilitate these reviews. Exemplary plans will include the components noted above, along with evidence of ongoing reassessment of the individual's pain problems and response to treatment and documentation of any multidisciplinary involvement in treatment.

Provider Education. Assuring that providers are educated in appropriate pain management treatment methods is another stated objective of VHA National Pain Management Strategy. The JCAHO standard that directly applies to this issue is:

- RI.1.2.8: Patients have the right to appropriate assessment and management of pain.

Provider education has been recognized as a critical component in the provision of appropriate pain treatment services. The AHCPH Cancer Pain Guidelines (Jacox, Carr, & Payne, 1994) identifies inadequate provider education as a major barrier to effective pain management. In fact, eight of the ten goals of the Cancer Pain Guidelines are related to staff education and competency. Traditional voluntary educational approaches such as continuing medical education (CME) activities have not led physicians to improve how they manage pain or other medical problems (Davis et al., 1999; Weissman, 1996). Alternatives to voluntary pain CME approaches may include attendance at mandatory training activities, completion of formal web-based training courses, self-study, or experiential-based training.

The selection of process monitors for staff education in pain will depend on the pain training approach adopted in each locale of interest. *Attendance monitors* simply document that staff have participated in the designated pain training. The training activities may take place at the local facility or at regional or national conferences or meetings. Education tracking systems,

which are operating at all VHA sites, can be utilized to document staff participation in pain education activities. In contrast, *competency monitors* require a demonstration of knowledge or

skill. Competency approaches to training may utilize knowledge tests to document that participants have demonstrated some criterion level of pain knowledge before credit for the training is awarded.

More elaborate approaches may rely on tests of pain knowledge and attitudes administered prior to and following a program of pain education to quantify changes induced by the training activities. Margo McCaffery has developed and validated a reliable test of nurses' pain knowledge and health provider attitudes (<http://mayuday.coh.org/Instruments/k&a.htm>) that could be utilized as a measure of the effectiveness of provider education. An example of a pain knowledge test is included in [Appendix V](#).

There are several resources available to all VHA sites to educate clinical staff on pain issues and to assess pain management knowledge. Each VHA VISN Library has received a copy of the following pain management educational resources: 1) *Assessing Compliance with the New JCAHO Pain Management Standards for Complex Organizations* (includes 2 videos); 2) *Pain Management* (CD-Rom); 3) *Pain Management Patient Education Manual*; and 4) *Pain Management: An Interactive CD-ROM for Clinical Staff Development*. Contact your VISN Librarian for assistance in locating these items. The CD-ROM's include knowledge tests which are scored for per cent of correct responses. Minimum scores can be selected as a local competency criterion.

SECTION 5: SPECIAL ISSUES

Evaluating Medication Use Outcomes

The multifactorial nature of pain, particularly chronic pain, makes it necessary to evaluate the outcomes of pharmacologic treatment using multiple criteria (Kozma, 1995; Kozma, Reeder, & Schulz, 1993; Ortmeier, 1997; Turk & Okijuji, 1998). For instance, it is not enough that a drug may produce a significant improvement in a specific clinical endpoint, e.g. an improved adverse drug event (ADE) profile. The improved ADE profile also must lead to improved outcomes (Kozma, 1995).

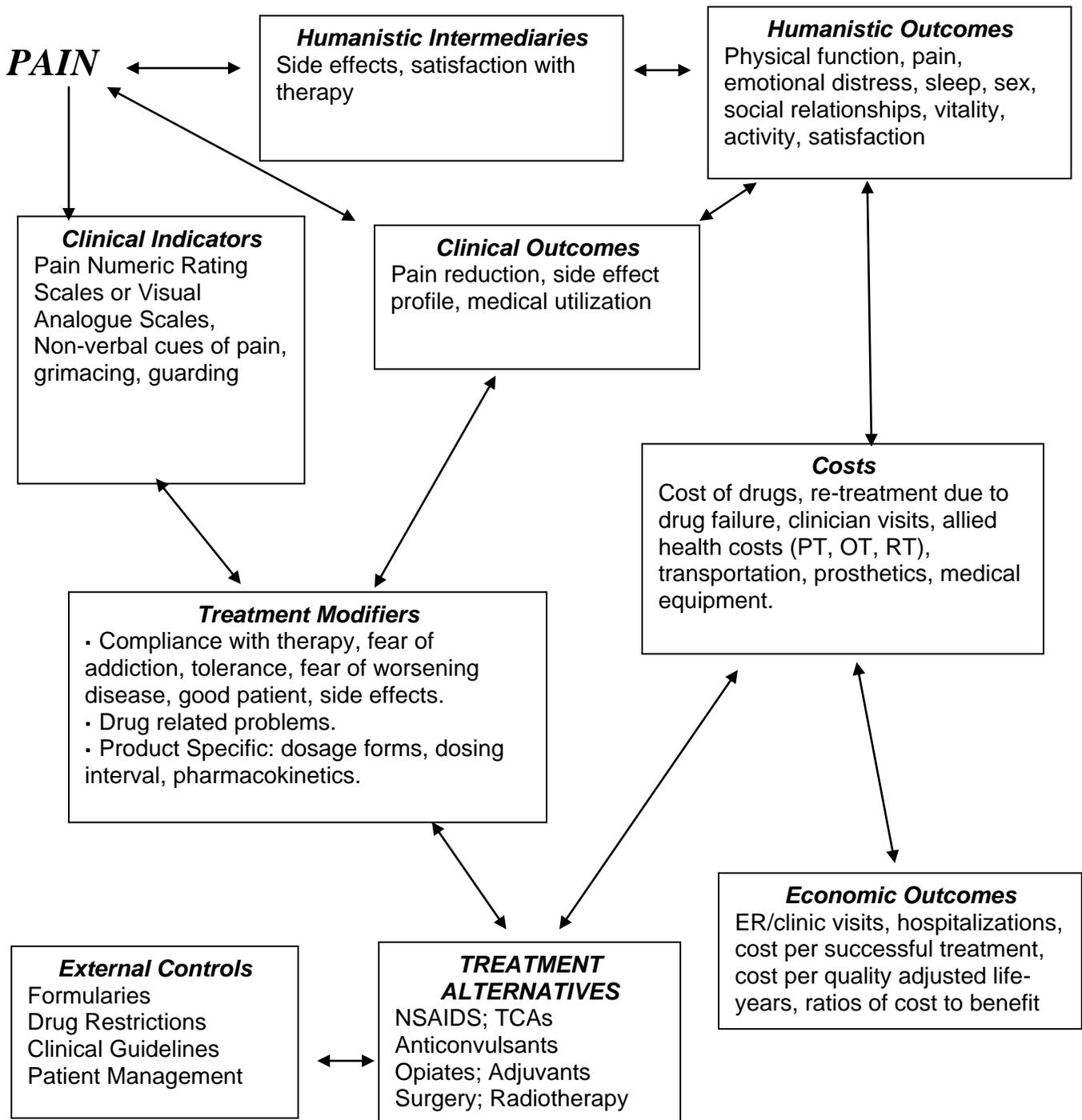
The ECHO (Economic, Clinical and Humanistic Outcomes) model provides a theoretical framework for the identification, collection and use of outcomes data to assess pharmaceutical treatment alternatives (Kozma, 1995; Kozma et al., 1993; Ortmeier, 1997). The model proposes causal relationships among diseases, health outcomes and decisions about medical care interventions.

The ECHO model assumes that the outcomes of medical care can be classified along three general dimensions: clinical, economic, and humanistic outcomes. These dimensions are defined as follows:

- *Clinical outcomes*: medical events that occur as a result of disease or treatment (pain reduction, side effect profile).
- *Economic outcomes*: direct, indirect, and intangible costs compared with the consequences of medical treatment alternatives (ER/clinic visits, cost of hospital care, cost of lost productivity, drugs and supplies).
- *Humanistic outcomes*: consequence of disease or treatment on patient functional status or quality of life measured along several dimensions (e.g., physical function, social function, general health and well being, sleep, increased activity level, patient satisfaction).

The use of the ECHO model should assist in identifying and selecting outcomes for inclusion in pharmaco-economic analyses, identifying important patient populations for the treatment alternatives of interest, and assessing the relative value of competing alternatives (Kozma et al., 1993). The application of this model to pain pharmaceutical therapy outcomes is presented in Figure 1.

Figure 1. Evaluating Pain Treatment Outcomes: the ECHO Model.



Clinical Outcomes. Figure 1 illustrates the process whereby health care providers evaluate clinical indicators of disease or symptoms (pain intensity, non verbal cues of pain) and make decisions regarding treatment alternatives. Clinical indicators, used as the basis for selection of treatment alternatives, are surrogates for clinical outcomes. Treatment modifiers (e.g., compliance with therapy, side effects, dosing interval) may affect both clinical indicators and clinical outcomes.

- Pain ratings. Pain rating scales such as the Numeric Rating Scale have been used to monitor pharmacotherapy outcomes. It is important to recognize that pain scales alone are not sufficient to evaluate the overall response to treatment or patient satisfaction with drug therapy. Patients may express satisfaction with treatment despite having severe pain (Ward & Gordon, 1996; McNeill, Sherwood, Starck, & Thompson, 1998). Even though patients may not experience an improvement in pain intensity, other quality of life measures (general activity and sleep) may improve significantly, resulting in improved patient satisfaction. Additionally, patients may indicate that they still have pain but do not wish to receive a stronger dose of pain medication (McNeill et al., 1998).
- Drug related problems. Pharmaceutical care is an outcome oriented, cooperative, systematic approach to providing drug therapy directed at the improvement of all dimensions of health related quality of life (Hepler, 1996). The identification of drug related problems (DRPs) are central to the pharmaceutical care process. Drug related problems have been defined as “*an undesirable event, a patient experience that involves, or is suspected to involve drug therapy, and that actually, or potentially, interferes with a desired patient outcome*” (Hepler & Strand, 1990). DRP’s have been grouped into the following major types:
 - Needing pharmacotherapy but not receiving it (a drug indication)
 - Taking or receiving the wrong drug
 - Taking or receiving too little of the correct drug
 - Taking or receiving too much of the correct drug
 - Experiencing an adverse drug reaction
 - Experiencing a drug-drug or drug-food interaction
 - Not taking or receiving the drug prescribed
 - Taking or receiving a drug for which there is no valid medical indication

Since the pharmaceutical care model is applicable to specialty practice, DRPs may be used to monitor and evaluate medication outcomes in pain management.

- Medical Utilization. Hospital admissions, readmissions, and length of stay have been used to evaluate medication outcomes. Medication use may be responsible for hospitalizations or prolonged hospital stays in cases of therapeutic failure or significant adverse drug events or toxicity. Like hospitalizations, unscheduled clinic visits and emergency room visits also may reflect the effects of pharmacotherapy, and can be used to evaluate medication outcomes.

Economic Outcomes. Economic outcomes are described in terms of cost and consequences of treatment and are derived from the direct cost of providing medical care, the direct non-medical costs associated with obtaining care, and the indirect costs linked to lost productivity related to illness. As depicted in Figure 1, economic outcomes have intermediaries introduced from the clinical and humanistic sides of the model. The clinical side includes the direct costs of medical care associated with each treatment, including medication, laboratory, emergency room visit, inpatient hospitalization, and return visit costs. The humanistic side includes productivity costs associated with time lost from work. Direct non-medical costs include expenses for transportation to the hospital or physician’s office for treatment, lodging for family members during treatment, and home health care expenses. Economic outcomes may be expressed as ratios of costs to benefits (in dollars), cost effectiveness (e.g., number of painful exacerbations versus treatment expenses), or utility (e.g., changes in quality-adjusted life-years; Kozma et al., 1993).

Humanistic Outcomes. Humanistic outcomes refer to patient evaluations of the impact of treatment on their lives e.g., health-related quality of life, satisfaction with care, and functional status. Pharmacotherapy may influence humanistic outcomes to the degree that it affects the

patient's ability to engage in or enjoy his/her activities of daily living. For example, the anxiolytic, antidepressant and hypnotic effects of certain drugs may enhance quality of life while adverse drug reactions such as insomnia, memory loss, or impotence may negatively affect it.

Patients may express satisfaction with pain management despite having high levels of pain intensity. In fact, patient *dissatisfaction* with pain management and their desire for stronger pain medications have been related to the degree at which pain interferes with general activities and sleep (McNeill et al., 1998), rather than to pain intensity per se.

Recommendations for Medication Use Outcome Measures. Specific recommendations for pharmacotherapy outcome measures are presented in the following table. In many clinical settings it often is difficult to isolate the effects of an individual pain intervention on observed changes in patient functioning or reported distress. Patients may be involved in multiple treatments simultaneously (e.g., pharmacotherapy, physical therapy, psychotherapy), each of which may contribute to observed outcomes in unique ways. Similarly, patients with pain often may be treated with multiple classes of medications which complicate judgments regarding the efficacy of any specific agent. Therefore, when evaluating pharmacotherapy effectiveness it is important to be aware of concurrent treatments or medications that may be contributing to the obtained outcomes. Sometimes it will not be possible to determine the differential effectiveness of each treatment component.

Medication Use Outcome Measures

Outcome Surrogate	Outcome Measures	What to Measure?
<i>Clinical Outcomes</i>		
Pain Rating	Patient's perceived pain rating	Pain intensity by means of validated scales e.g., the pain NRS or the VAS.
Drug Related Problems	Needing pharmacotherapy but not receiving it (a drug indication)	# of patients that are not taking or receiving required pain medication
	Receiving the wrong drug	Medication administration errors
	Not taking or receiving the drug prescribed	Compliance behavior
	Taking or receiving too little or too much of the correct drug	# of patients being under or over treated
	Experiencing an adverse drug reaction	# of patients experiencing an ADE # and types of ADEs
	Experiencing a drug-drug, drug-food interaction	# of patients experiencing a drug-drug, drug-food interaction drug-drug, drug-food interaction sequelae
	Taking or receiving a drug for which there is no valid medical indication	# of patients receiving duplicate pharmacological agents # of patients on polypharmacy
Hospitalizations	Admissions, re-admissions and/or length of stay due to ADEs associated to pain-related drug therapy or failure of drug therapy to control pain.	# of hospital admissions or readmissions Time to readmission (days) Length of hospital stay (days)
Unscheduled clinic visits, emergency room visits	Unscheduled clinic visits, emergency room visits due to ADEs associated to pain-related drug therapy or failure of drug therapy to control pain.	# of unscheduled clinic visits # of emergency room visits

Outcome Surrogate	Outcome Measures	What to Measure?
<i>Economic Outcomes</i>		
Direct cost of providing medical care	Cost of drugs, re-treatment due to drug failure, hospitalizations, office visits, allied health treatment (PT, OT, RT), laboratory work, X-Rays, prosthetics/medical equipment	<p>Drug costs</p> <p>Cost per day of hospitalization</p> <p>Office visit and allied health costs including nursing and pharmacy time</p> <p>Laboratory test costs</p> <p>Radiographic test costs</p> <p>Dollar value of prosthetics and medical equipment</p>
Direct non-medical costs associated to obtaining care	Transportation to the hospital or physician's office, lodging, toll & parking fees	<p>Transportation and lodging related costs accrued by the patient and caregiver</p> <p>Hired caregiver costs</p>
Indirect costs associated with lost productivity related to illness	Time lost from work, reduced productivity	<p>Lost income from time lost from work or reduced productivity.</p> <p>Include time lost from work of caregiver.</p>
<i>Humanistic Outcomes</i>		
Patient satisfaction with therapy	Patient 's satisfaction with pharmacotherapy for pain management	Patient satisfaction by means of patient satisfaction questionnaires e.g., the APS-POQ
Daily functioning	Pharmacotherapy effects on physical and psychosocial functioning	<p># of adverse drug events</p> <p>Changes in measures of daily activity, physical capacity, social and sexual functioning, mood, pain intensity, sleep, and vitality</p>

Measuring Family and Social Outcomes

Contemporary models of the experience of pain emphasize the social, and particularly the family, context (Jacob & Kerns, 2001; Otis, Cardella, & Kerns, in press). This perspective encourages attention to the role of the social environment in the development and maintenance of the experience of pain and in understanding processes of adaptation and adjustment. Conversely, the model draws attention to the impact of pain on important interpersonal relationships.

Involvement of the family in pain management efforts is explicitly stated as an objective of the VHA National Pain Management Strategy. This objective is most commonly manifested as documented efforts to provide education to family members (and significant others) in the context of patient-oriented pain management. Active inclusion of significant others in the comprehensive assessment of pain, collaborative treatment planning, in the delivery of pain interventions, and in reassessment is indicated by the perspective described above. In certain situations, active participation of significant others in these processes is likely to be critical to effective pain management. For example, the spouse of a demented and uncommunicative veteran may be critical in evaluating pain severity and its impacts on functioning, in the reliable delivery of pain medications, and in assessing the efficacy of the intervention. Education of and active collaboration with the spouse in the development of an intervention plan may be essential. Another example comes from multidisciplinary pain management centers that commonly expect significant others to become active participants in the program. These factors should be considered in the development of a comprehensive set of outcome measures for evaluating individual or program success.

Attention to the broader social and cultural context of pain also has been emphasized. Increasingly research has documented reliable racial and ethnic differences in the experience of pain including variables such as pain perception, treatment seeking, and analgesic responsiveness. Attention to cultural diversity factors in the development and implementation of a comprehensive system for effective pain management is critical, and in the delivery of individually-tailored plans for pain management.

Measuring Family Outcomes. Consistent with the VHA National Pain Management Strategy objectives and the JCAHO pain management standards is the need for reliable documentation of pain-relevant family education. Development of a system for performance improvement in this domain that focuses on ongoing monitoring, feedback, and performance improvement efforts is indicated.

Depending on the scope and goals of a specific pain intervention or program, inclusion of any of a number of family-relevant outcomes measures also may be indicated. The process for selecting these measures should be informed by the principles outlined earlier in this Toolkit. Measures in this area range from those that are broad in scope and not specifically related to pain management (e.g., the Locke-Wallace Marital Adjustment Scale; (Locke & Wallace, 1959) to those that are behaviorally-specific and pain-relevant (e.g., the significant other response scales from the West Haven-Yale Multidimensional Pain Inventory; Kerns et al., 1985). Standardized measures of potentially important outcome domains (e.g., significant other adherence to recommendations for pain medication delivery, significant other satisfaction with pain treatment efforts) are not yet available and may need to be developed for a specific purpose. A comprehensive review of the available measures in this area has recently been published (Jacob & Kerns, 2001).

Measuring Pain Outcomes in the Cognitively Impaired

The assessment of pain to plan interventions and assess outcome relies on strategies for the communication of the patient's subjective experience to the clinician. Cognitive impairment can interfere with this communication and poses a difficult challenge to the accurate assessment of pain and pain treatment outcomes.

Elderly Veterans. Elderly veterans are a group with a high prevalence of pain and substantial risk for cognitive impairment. Estimates of the prevalence of pain in nursing home settings range from 45% to 80% (Ferrell, 1991; Fox, Raina, & Jadad, 1999). The prevalence among community-dwelling elderly has been estimated at between 25% and 50% (Ferrell, 2000); Parmalee, 1996).

Cognitive impairment is likely to be encountered routinely in assessing pain in the elderly. The overall prevalence of non-dementia cognitive impairment among community-dwelling elderly has been estimated between 10.7% and 23.4% with prevalence increasing by age (Unverzagt et al., 2001); Di Carlo, Baldereschi, Amaducci, Maggi, Grigoletto, Scarlato, & Inzitari, 2000). The overall prevalence of elderly with dementia has been estimated to be 5% to 10%. Age-specific studies indicate that the prevalence of dementia doubles with every five years of age at least up to age 90 to 95 (Kukull & Ganguli 2000). The likelihood of cognitive impairment and dementia increases with residential placement status. The fastest growing segment of the U.S. population consists of persons older than the age of 85 years with 15% meeting the criteria for dementia (Henderson 1990). Approximately one-half of the U.S. population lives to the age of 75 years and nearly one quarter live to the age of 85 (Berg 1994).

The percentage of elders complaining of one or more pain problems is similar between cognitively intact and mildly to moderately impaired persons. However, persons with severe cognitive impairment tend to report fewer complaints (Parmalee, 1996). Nevertheless, fewer verbal complaints does not necessarily mean less pain. It may reflect changes in communication ability associated with cognitive impairment such as reduced initiation of verbal behavior. *Failure to report pain should not be assumed to mean the absence of pain.*

Other groups with cognitive impairment. Pain assessment has not been studied in other adult groups with risk for cognitive impairment such as the developmentally disabled and persons with traumatic brain injury (Schwartz, 1999; Bryant et al, 1999). In the absence of data with other groups, strategies that have proven to have utility with cognitively impaired elders provide a starting point for use with these populations. Instruments developed for use with children also could be of value, but have not been systematically studied for use with cognitively impaired adults (Gagliese, 2001).

Clinicians assessing pain in cognitively impaired persons need to consider the multidimensional qualities of pain. Pain has emotional, cognitive, and sensory qualities that are manifested in personal and interpersonal behaviors. These qualities may be assessed through structured inquiry and structured observation.

Assessment of the Presence and Intensity of Pain. Assessment of the presence and intensity of pain is accomplished through the use of patient self-report, observational measures and proxy report. Unidimensional pain intensity scales can be used to quantify pain intensity and track that dimension. Most of these scales have not been adequately cross-validated in groups of cognitively impaired adults, so the score on one scale cannot be assumed to reflect the same score on another scale. To assess outcomes across patients, the same scale should be used in the same fashion with all of the persons being assessed. To assess outcomes within a single patient over time, the same scale should be used in same fashion in each assessment.

Self-report of pain presence and intensity. Self-report of pain presence and intensity requires that the patient communicate the existence of pain through verbal or nonverbal behaviors and rate the intensity of the pain along a dimension encompassing no pain to the worst possible pain. This requires some degree of abstract reasoning. Several studies have demonstrated that elderly patients with mild to moderate cognitive impairment can respond reliably to measures of pain intensity (Chibnall & Tait, 2001; Ferrell, Ferrell, & Rivera, 1995; Manz, Mosier, Nusser-Gerlach, Bergstrom, & Agrawal, 2000; Weiner, Peterson, & Keefe, 1998).

Reliability can be increased by referencing the question in the here and now and using the same instrument repeatedly over time as a cognitively impaired individual's ability to use self-report scales can improve with practice. The interviewer needs to focus the assessment question in order to obtain the most accurate results for interpretation. It is helpful to ask the patient "How much pain are you having right now?" instead of "How much pain have you had over the last week or month". The latter questions require additional integration of information and demand more cognitive ability (Ferrell, 2000).

Techniques drawn from the assessment of children's pain might improve reliability and validity of self-report (McGrath & Gillespie, 2001). Clinicians should inquire about the patient's definition of pain to determine to what extent the patient perceives pain as a sensory, emotional, and behavioral event. This will help the clinician in educating the patient about the use of the self-report tool and aid in the interpretation of the individual's response. It also can be helpful to *calibrate* the tool for use with a single patient by asking him or her to describe painful events that have been experienced that correspond to different pain intensities. Patients can be prompted with common events that occur in a clinical setting such as needle sticks.

There are four main forms of pain intensity scales that have been studied for use with the cognitively impaired elderly: *Verbal Descriptor Scales*, *Numeric Rating Scales*, *Visual Analog Scales* and *Facial Picture Scales*. Different patients show different abilities to complete each of these forms, so if a patient is not able to complete one type of scale, it is worthwhile to try an alternative form. Up to 83% of mild to moderately impaired elderly and 30% of severely impaired elderly are able to complete at least one type of scale (Ferrell et al., 1995; Manz et al., 2000).

Verbal Descriptor Scales ask the patient to choose a phrase to describe pain intensity. The *Present Pain Intensity Scale* of the McGill Pain Inventory is one standard example. Completion rates between 65% and 79% have been demonstrated in samples of cognitively impaired adults (Herr & Garand, 2001; Krulewitch et al., 2000).

The *Numeric Rating Scale* asks patients to rate their pain on an eleven-point range from no pain to worst possible pain. Many cognitively impaired patients can respond to a verbal presentation of the scale, while others may require a graphic presentation of the pain numerals. Both vertical and horizontal presentations have been found to be effective. Some patients prefer a vertical presentation in the form of a pain thermometer. Between 47% and 58% of cognitively impaired adults were able to complete this scale (Herr & Garand, 2001).

Facial Picture Scales consist of a series of progressively distressed facial expressions. The patient is asked to pick the face that corresponds to their current level of pain intensity. These tools were designed for use with pediatric populations. Limited data is available regarding their use in cognitively impaired adult populations. The *Faces Pain Scale* and the *Wong-Baker Faces Scale* are examples of this class of instrument. Unfortunately, these scales are likely to tap affective components of pain as well as pain intensity which can complicate interpretation. Completion rates for the *Faces Pain Scale* in cases of mild to moderately impaired elders range from 50% to 76%. Only 20% to 41% of severely impaired patients may be able to complete the scale (Manz et al., 2000; Scherder, 2000; Krulewitch et al., 2000).

The *Visual Analog Scale* is a 10 cm horizontal or vertical line with anchors at each end of “no pain” and “worst possible pain” (or some analogous phrase). This tool is easy to complete, but is thought to require more abstract thinking ability than other tools (Gagliese, 2001). Completion rates in cases of mild to moderately impaired elders ranged from 52% to 76%. Only 41% of elders with severe impairment were able to complete the scale (Krulwich et al., 2000).

In cases of mild to moderate impairment, clinicians may choose to utilize a verbal descriptor scale or numeric rating scale depending on patient ability to complete the scale. In cases of severe impairment, patients are likely to prefer a verbal descriptor scale. Observations of pain behaviors along with self-report can help to strengthen confidence in self-report ratings.

Observation of pain behaviors. In cases where patients are not able to provide a reliable self-report, pain behaviors can be assessed to help determine the presence and intensity of pain (Turk, et al., 1985; Fordyce 1976). These include cues such as changes in posture and gait, nonverbal vocalizations, facial expressions and changes in usual behaviors. However, many of these behaviors are not specific to pain and can be easily misinterpreted in cases of cognitive impairment. Behavioral observations also are subject to inadequate sensitivity. Severe cognitive impairment can limit the patient’s behavioral repertoire even in the presence of pain (Oberlander, Grunau, Pitfield, Whitfield, & Saul, 1999).

Family members can aid clinicians in identifying pain behaviors. However, surrogate reporting of pain tends to be inaccurate. Family members tend to overestimate pain intensity, while health care providers tend to underestimate pain severity (Desbiens & Mueller-Rizner, 2000; Weiner, Peterson, & Keefe, 1999; Bowman, 1994).

Observation of pain behaviors must occur in a structured manner to have validity. Target behaviors need to be identified for each patient. The assessment should take place when these behaviors are most likely to occur. Staff members need to be trained to reliably identify the behaviors (Keefe, Lumley, Anderson, Lynch, Studts, & Carson, 2001). Observations of facial reactions have been shown to be good indicators of pain in adults with cognitive impairment, but require extensive training and equipment (Hadjistavropoulos, LaChapelle, MacLeod, Snider, & Craig, 2000; Hadjistavropoulos & Clark, 2001).

Pain behavior checklists can be helpful in guiding assessment. Assessment of pain behavior should include observation during rest and during movement or usual daily activities (Hadjistavropoulos et al., 2000; Weiner, Pieper, McConnell, Martinez, & Keefe, 1996). However, there is a lack of checklists that have demonstrated adequate validity and reliability in adults with cognitive impairment.

The *Checklist of Nonverbal Pain Indicators* is a six-item checklist that has been developed to assess pain behaviors at rest and during movement in cognitively impaired elderly. It also incorporates a verbal descriptor scale. It has demonstrated reliability and validity in an initial study with patients with hip fractures (Feldt, 2000; Feldt, Ryden, & Miles, 1998). However, the instrument has not been validated in other types of pain. In addition, the checklist’s reliability has not been tested in groups of differing degree of cognitive impairment.

Assessment of Other Dimensions of Pain. Pain is a complex, multidimensional experience that includes cognitive, emotional and behavioral factors as well as pain presence and intensity. Assessment of pain in persons with cognitive impairment should include attention to mood and beliefs that affect the patient’s pain experience and contexts that affect the patient’s pain behavior. Specific instruments for use of assessment of these components of pain have not been studied in patients with cognitive impairment. However, clinicians should consider

including standard instruments for use with patients who have mild to moderate cognitive impairment.

Summary and Recommendations. Research on assessment of pain in cognitively impaired adults has focused on elderly adults with dementias. The results of many studies suggest that most persons with mild to moderate cognitive impairment can provide reliable report of pain intensity using standard numeric-rating scales.

Verbal descriptors scales are easier to complete for some patients, especially those with more severe impairment. Persons with cognitive impairment seem to have the most difficulty with the Visual Analogue Scale. One way to help facilitate better understanding of the pain intensity scale rating with a patient is to establish the intensity rating of a past, common pain event, such as stubbing a toe or having a mild burn. The patient is then instructed to compare that pain intensity from that event to the pain condition being assessed. This technique can be used with numeric rating scales or verbal descriptors.

Observations of pain behaviors strengthen confidence in self-report ratings. It is important to assess pain behaviors using a standardized format and to assess pain both at rest and with movement. Surrogates such as medical staff and family members can provide important adjunct information about pain behaviors, but surrogates tend to underestimate or overestimate pain intensity.

Using CPRS GUI and Vista Software to Track Pain Outcomes

Document the Pain Score Vital Sign. In 1999, the Vitals/Measurements package, Version 4.0, was enhanced to include a pain score as the 5th Vital Sign. All facilities that are using the VHA Information Systems and Technology Architecture (VistA) and Computerized Patient Record System Graphical User Interface (CPRS GUI) can enter pain scores electronically when other vital signs are entered. This can be done in the Vitals package, and from the CPRS GUI Cover Sheet, or Encounter Form under the Notes tab. The pain score is supposed to be recorded in every patient record at regular intervals to document changes in pain intensity. Instructions for recording a pain score in the computerized patient record can be found in the Pain as the 5th Vital Sign Toolkit (http://vaww.va.gov/pain_management/508FrameTest2.htm). Instructions for Viewing and Entering Vitals in the Computerized Patient Record System (CPRS) User Guide, GUI version. If you have questions about the software or the instructions, please contact your local Information Resources Management (IRM) service office or your local Clinical Application Coordinator (CAC).

Document Information Relating to Pain Management. Sites can use Clinical Reminders and Reminder Dialogs to record data related to pain management as progress note text, or encounter data, such as vital signs and health factors.

As a decision support tool, Clinical Reminders:

- Provide timely information about patients' health maintenance schedules
- Assist in compliance with VHA performance measures
- Assist in compliance with Health Promotion and Disease Prevention Guidelines
- Assist in targeting patients with particular diagnoses and procedures or site-defined criteria
- Provide pertinent information for clinical decision making

Reminder Dialogs can be created and linked to Clinical Reminders and accessed from the CPRS GUI Notes during Progress Note editing. Reminder Dialogs can be set up to:

- Prompt for data entry of information to resolve/satisfy Clinical Reminders
- Provide reminder resolution by recording Health Factors and Education Topics
- Add text to progress notes
- Update patient encounter data and Vital Signs
- Place orders

The Health Factors and Education Topics that are recorded to resolve the reminders can later be used to report on pain management outcomes.

Clinical Reminders for Pain Management Sponsored by the VA National Pain Management Coordinating Committee. As a continuation of VHA's commitment to pain management, the National Pain Management Strategy Coordinating Committee has sponsored the development of pain reminders and reminder dialogs that sites can use to document pain management in the patient's electronic record. These reminders may be used independently of one another, or as a group, depending on local preferences and installation methods and they were designed to be used with either inpatients or outpatients.

- Pain History
- Pain Management Education
- Clinician Pain Plan of Care
- Clinician Pain Reassessment
- Nurse Pain Plan of Care
- Nurse Pain Reassessment

Criteria for the development of these reminders were:

- 1) The reminders should meet or exceed existing JCAHO and CARF requirements regarding pain assessment and treatment
- 2) The reminders should be consistent with existing (e.g., Post Operative Pain) and forthcoming (e.g., Chronic Opioid Therapy) treatment guidelines
- 3) The reminders should be of some use for local pain treatment outcomes monitoring

These reminders and reminder dialogs are posted to the Clinical Reminders website under Examples and How-to's (<http://vista.med.va.gov/reminders/Pain.htm>).

The packed reminders and dialogs can be downloaded by sites as local reminders and adapted to the needs of the individual site. There are also background and instructional documents for each reminder, as well as tips for using the reminders and a pain history self-report form that can be printed and given to patients to fill out prior to data entry.

Example: Pain History reminder dialog

Reminder Resolution: Pain History

Patient has reported a pain score of 8 (11/13/2002 19:33). This is a significant level of pain. A comprehensive Pain History is required for effective pain management. (Check the box to include in PN text)

Allergies/ADRs Recorded (Check the box to include in PN text): Allergies Unknown

Information Only: When is a detailed pain history required?

PAIN HISTORY

Pain history completed using an alternative format

Is this a new pain to this facility?

Yes, this is a new pain. (Record the pain history in this dialog, then refer to Provider/ Nurse Plan of Care or Provider/Nurse Reassessment, which ever is appropriate)

Yes, this is a chronic pain that has not been treated before at this facility. (Record the pain history in this dialog, then refer to Provider/Nurse Plan of Care or Provider/Nurse Reassessment, which ever is appropriate)

No, this pain is not new and there is a pain history in the medical record (refer to Provider/Nurse Plan of Care or Provider/Nurse Reassessment, which ever is appropriate)

No, this pain is not new, but pain history has not been recorded in the medical record. (Record the pain history in this dialog, then refer to Provider/Nurse Plan of Care or Provider/Nurse Reassessment, which ever is appropriate)

Patient did not report or update pain history.

Patient unable to report pain history at this time.

Patient declined to report pain history at this time.

Clear Clinical Maint Visit Info < Back Next > Finish Cancel

CLINICAL REMINDER ACTIVITY

<No encounter information entered>

* Indicates a Required Field

Example: Pain History reminder dialog expanded

Reminder Resolution: Pain History

PAIN HISTORY

Pain history completed using an alternative format

Is this a new pain to this facility?

Yes, this is a new pain. (Record the pain history in this dialog, then refer to Provider/ Nurse Plan of Care or Provider/Nurse Reassessment, which ever is appropriate)

Check if patient is currently being treated for this pain at another facility...

GLOBAL LEVELS OF PAIN: The next questions refer to overall levels of pain.

PRIMARY PAIN

*PRIMARY PAIN LOCATION: Where does it hurt the most?

INTENSITY OF PRIMARY PAIN: If 0 is no pain and 10 is the worst pain imaginable, how would you rate your primary pain?

QUALITY OF PRIMARY PAIN - How does your primary pain feel?

ONSET OF PRIMARY PAIN : When did your primary pain begin?

NATURE OF PRIMARY PAIN:

ALLEVIATING FACTORS: What makes the pain better?

AGGRAVATING FACTORS: What makes the pain worse?

EFFECTS OF PRIMARY PAIN: What aspects of your life have changed as a result of your pain? (select all that apply)

SYMPTOMS RELATED TO PAIN MEDICATIONS: Are you having any symptoms related to medication you are taking for pain?

PRESCRIPTION MEDICATIONS: Are you taking any prescription medications for your pain?

OVER-THE-COUNTER MEDICATIONS: Are you taking any over-the-counter medications? Any herbal, natural, or home remedies?

SECONDARY PAIN LOCATION: Do you have pain in other locations?

Yes, this is a chronic pain that has not been treated before at this facility. (Record the pain history in this dialog, then refer to Provider/Nurse Plan of Care or Provider/Nurse Reassessment, which ever is appropriate)

No, this pain is not new and there is a pain history in the medical record (refer to Provider/Nurse Plan of Care or Provider/Nurse Reassessment, which ever is appropriate)

Clear Clinical Maint Visit Info < Back Next > Finish Cancel

CLINICAL REMINDER ACTIVITY

Pain History:

PAIN HISTORY

Patient indicates this is a new recent onset pain that has not been treated before at this facility.

Health Factors: V-PAIN NEW PAIN

* Indicates a Required Field

A number of Health Factors are recorded as the reminders are processed that resolve the reminders, and provide data for outcomes reports. This is an example of some health factors created by processing these reminders dialogs:

Category Health Factor	Date
V-PAIN ACCEPTABLE	
V-PAIN ACCEPTABLE 0	11/13/2002
V-PAIN EDUCATION BARRIERS	
V-PAIN Patient/Family Outcome	11/15/2002
V-PAIN HISTORY	
V-PAIN HISTORY RECORDED	11/13/2002
V-PAIN LEAST	
V-PAIN LEAST 4	11/13/2002
V-PAIN NEW PAIN CATEGORY	
V-PAIN NEW PAIN	11/13/2002
V-PAIN PLAN OF CARE	
V-PAIN CLINICIAN PLAN OF CARE	11/13/2002
V-PAIN CLINICIAN REASSESSMENT	11/15/2002
V-PAIN NURSE PLAN OF CARE	11/13/2002
V-PAIN NURSE REASSESSMENT	11/15/2002
V-PAIN PRIMARY PAIN LOCATION	
V-PAIN LOC ABDOMEN	11/13/2002
V-PAIN USUAL	
V-PAIN USUAL 8	11/13/2002

Creating Local Clinical Reminders and Reminder Dialogs to Record Data on Pain Management.

Sites can create their own local Reminders to prompt users to enter the pain score or to document information on pain management. Many sites have already created a pain screening reminder to remind staff to record pain scores for every patient. If the reminder was due, it would display on the CPRS GUI Coversheet. Sites could set the reminder logic to make the reminder due:

- If the patient did not have any pain score
- Once a year if the current pain score was ≤ 3
- Once a month if the pain score was > 3

Sites do not have to create pain reminders and dialogs from scratch. Since the *Pain, the 5th Vital Sign Toolkit* was released in the winter of 1999, many sites have developed reminders and reminder dialogs related to pain screening, pain assessment, and pain management. If you find another site that has pain reminders and dialogs that work well for them, they might be willing to share them directly via the Reminder Exchange Utility. Or they may have posted them to the Clinical Reminders Examples and How-to's web page. In any case, users should work closely with their local Clinical Application Coordinator (CAC) to develop Clinical Reminders and Reminder Dialogs that are appropriate for their needs.

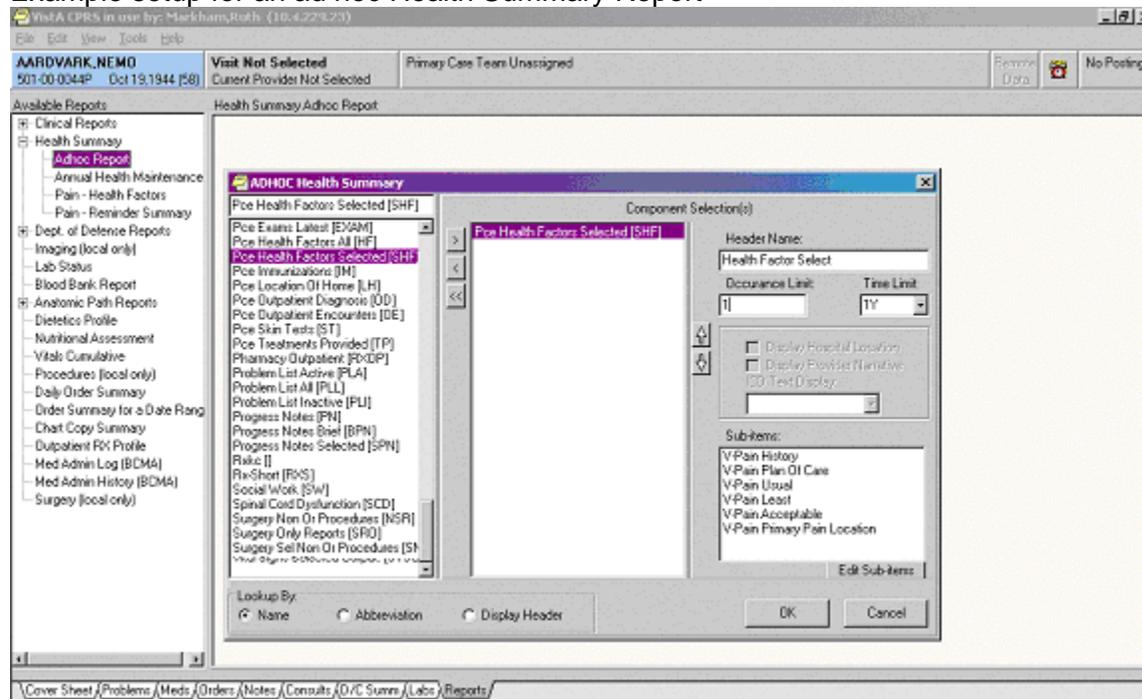
Reporting Pain Management Outcomes. Users can retrieve information about pain management outcomes from the electronic patient record using the reporting functionality of Health Summary and Clinical Reminder packages.

Ad Hoc Health Summary Reports

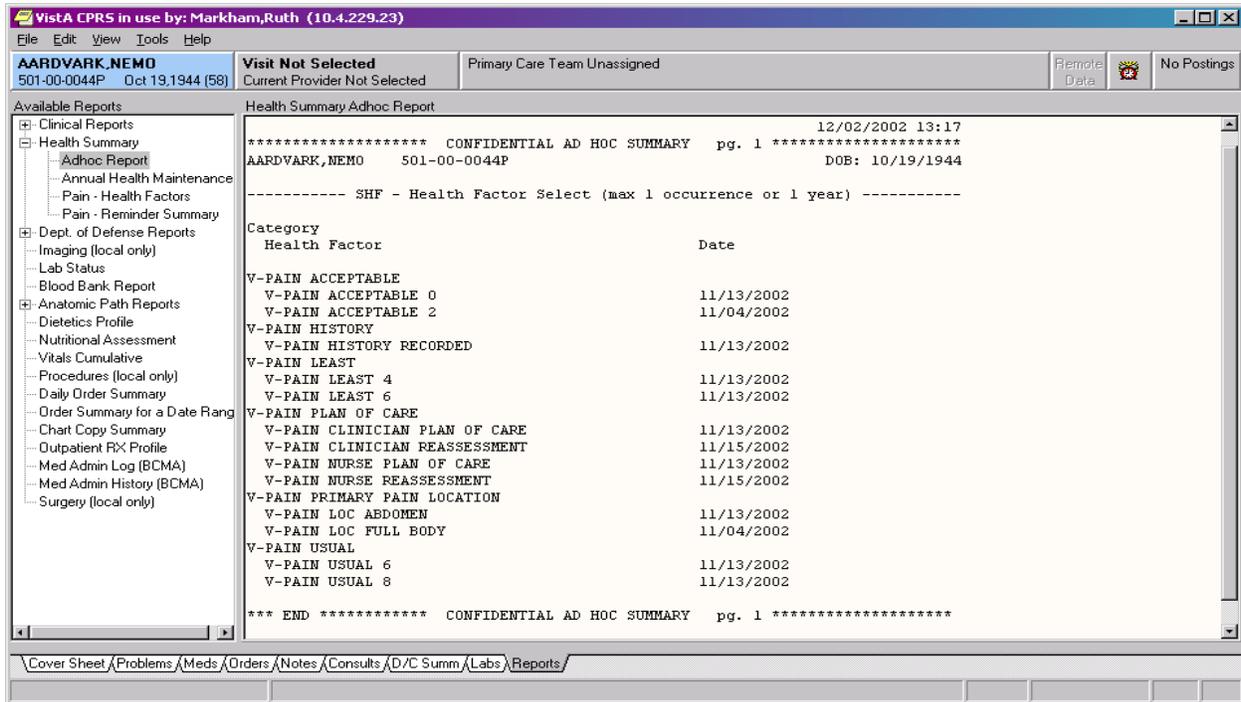
The Health Summary application provides ad hoc reporting functionality that can be used to create a quick, one-time reminder report. Users can select items from a list of Health Summary components to create an ad hoc report that contains information about pain reminders, health factors and education topics. These are some of the components that provide pain management information:

- CLINICAL REMINDERS BRIEF (CMB)
- CLINICAL REMINDERS DUE (CR)
- CLINICAL REMINDERS MAINTENANCE (CM)
- CLINICAL REMINDERS SUMMARY (CRS)
- PCE EDUCATION (ED)
- PCE EDUCATION LATEST (EDL)
- PCE HEALTH FACTORS ALL (HF)
- PCE HEALTH FACTORS SELECTED (SHF)

Example setup for an ad hoc Health Summary Report

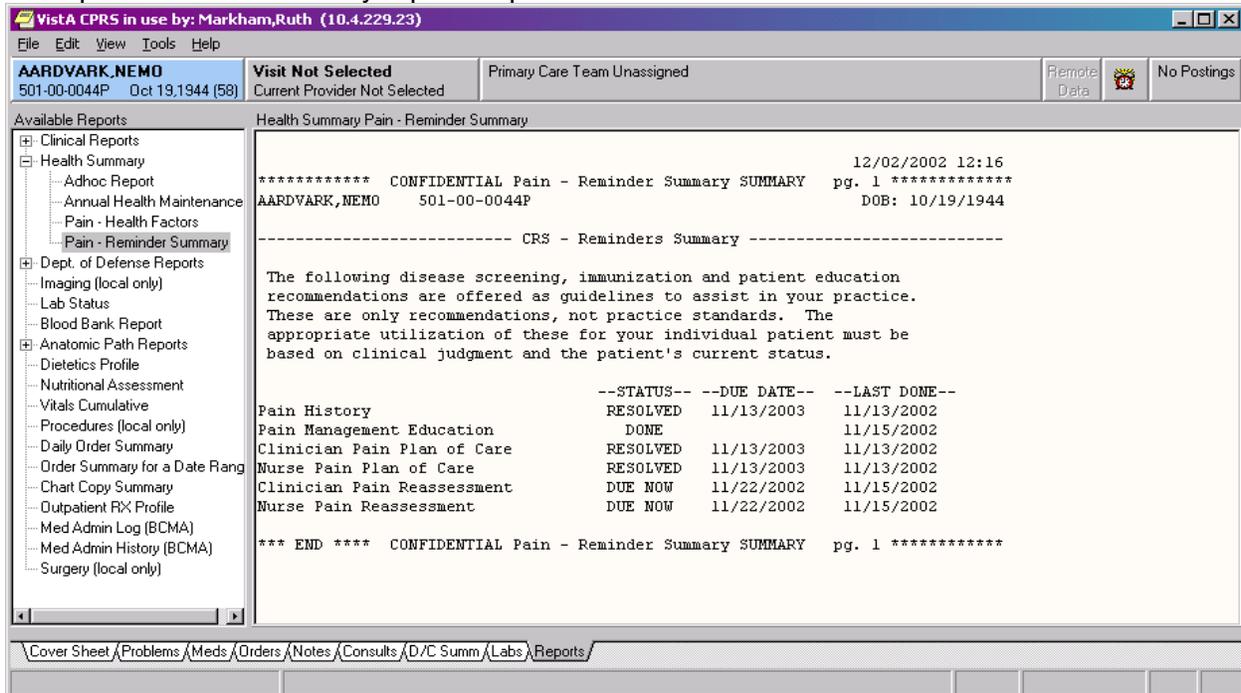


Example display of an ad hoc Health Summary Report



Once the user has designed a report that provides useful information, users should contact their local CAC. The CAC can create a Health Summary report with the same parameters and add it to the list of Health Summary reports that displays on the CPRS GUI reports tab and allows access by multiple users at the site.

Example of Health Summary report output



The CPRS GUI Reports tab will only produce Health Summary reports for the current patient. The Health Summary options in the roll and scroll version of Health Summary provides the means to produce reports for several patients at one time:

- Patient Health Summary Option - displays or prints a health summary for one or more patients, or a group of patients by location, such as the operating room, ward, or clinic.
- Ad Hoc Health Summary Option - lets users select any or all health summary components and assign component characteristics for one or more patients.
- Range of Dates Patient Health Summary Option - lets users print health summaries of a specified, pre-defined health summary type for multiple patients. After patients are selected, the user can pick a date range. Data for summaries is based on the date range.
- Visit Patient Health Summary - lets users print health summaries of a specified, pre-defined health summary type for multiple patients.
- Hospital Location Health Summary - lets users print or display on your screen health summaries for all patients at specific or multiple hospital locations (ward, clinic, or operating room).

Developing Health Summary Reports. For more information on creating Health Summary Reports, users should consult the Health Summary User Manual and Health Summary Technical Manual located in the VistA Documentation Library (VDL) (<http://vista.med.va.gov/vdl/>).

Contact your local Clinical Application Coordinator for assistance in creating Health Summary reports. You could also talk to other sites to see what Health Summary reports they have found to be useful.

Additional assistance may be obtained by participating in the Clinical Reminders conference call that is held the third Friday of each month. This is a forum where sites can share information and ask questions related to reminders and reminder dialogs. Refer to the Clinical Reminders website for information about past and future presentations (<http://vista.med.va.gov/reminders/confcalls.htm>).

Clinical Reminder Reports. Clinical Reminder Reports can be a powerful data extraction tool for measuring pain outcomes. They can be created to report summary or detailed level information about pain reminders that are due or reminders that have been satisfied. Reminder Reports also can provide clinical coordinators with data extracted based on reminder definitions.

Reminder Reports:

- Provide a tool for tracking compliance with reminders
- Can look at overall performance for a stop code or provider panel, or can drill down to a team of patients or to a single clinic
- Can measure change over time

Reminder Reports can be set up for:

- Individual patients, location, OE/RR team, PCMM provider or PCMM team
- Inpatient, outpatient, selected hospital locations
- All clinic stops, selected clinic stops, or selected clinic groups
- Previous encounters or future appointments
- Encounter beginning and ending date range
- Effective due date
- Detailed or summary report output
- Reminder category or individual reminder

Reminder reports can be used to:

- Identify outpatients in a panel who have reminders due
- Aggregate reporting for a service line
- Create patient specific reports for intervention
- Identify inpatients with a reminder due
- Identify patients who are scheduled for a clinic visit in the next month who need an intervention
- Identify patients who have left the clinic in the past week who have missed an intervention
- Track patient education
- Track patients with certain characteristics or needs

Selection criteria can be saved in a report template so the report can be run on a recurring basis.

Example of a Detailed Reminder Report - lists due patients for a single reminder

```
Jan 20, 2000 5:17:32 pm Page 2
Clinical Reminders Due Report - Detailed Report for 1/20/2000
Blood Pressure Check: 7 patients have reminder due
      Date Due      Last Done Next Appt
      - - - - -      - - - - -      - - - - -
1  DINARO, MUCHO (3779)      8/28/1998      8/27/1998      None
2  ESSTEPON, GLORD (3234)    1/20/2000      N/A            None
3  HOLMES, SHERLOCK (5377)   1/20/2000      N/A            None
4  HOOD, ROBIN (2591P)      8/19/1999      8/18/1999      None
5  MARLEY, JACOB (5678)     9/4/1998       9/3/1998       None
6  TEST, KEVIN (5734)       2/3/1999       2/3/1997       None
7  TRAT, JACK (2342)        1/20/2000      N/A            None
Report run on 8 patients.
Applicable to 8 patients.
End of the report.
```

Example of a Summary Reminder Report - totals applicable/due counts for multiple reminders

```
Jan 20, 2000 5:09:11 pm Page 2
Clinical Reminders Due Report - Summary Report for 1/20/2000
# Patients with Reminders

                Applicable   Due
                -----   ----
1 Mammogram                0     0
2 Weight                    8     6
3 Blood Pressure Check     8     7
Report run on 8 patients.
```

Reminder reports can be printed as a formatted report or as delimited output so the data can be exported to a spreadsheet program, such as Microsoft EXCEL. These data then can be presented in a variety of formats.

Example of a reminder report with delimiters (^) that can be imported into a spreadsheet:

```
TITLE:TEST SUMMARY^TEMPLATE:TEST REPORT
START:9/13/1974^END:1/29/2002^RUN:1/29/2002 5:05:19 pm
^^INDIVIDUAL LOCATIONS ONLY
0^ELY 660GC_GENERAL MEDICINE^^
1^Advanced Directives Education^24^22^GENERAL MEDICINE
2^IHD Elevated LDL^0^0^GENERAL MEDICINE
0^PATIENTS^25^^GENERAL MEDICINE
0^ELY 660GC_ONCOLOGY^^
1^Advanced Directives Education^13^12^ONCOLOGY
2^IHD Elevated LDL^1^0^ONCOLOGY
```

Clinical Reminders used to trigger reminder reports do not have to be the same as the reminders that are displayed. Separate reminders often are needed for reporting versus cover sheet assignment.

Refer to the following sites for further information about reminder reports:

- VistA Documentation Library (VDL) <http://vista.med.va.gov/vdl/>
- Clinical Reminders web page: <http://vista.med.va.gov/reminders/>
- VistA University web page: <http://vaww.vistau.med.va.gov/vistau/default.htm>
- Reminder Reports Presentation: Reminder Reports for Provider Feedback and Performance Tracking: <http://vista.med.va.gov/reminders/confcalls.htm>

Contact your local CAC for assistance in creating reminder reports. You could also talk to users at other sites to see what reminder reports they have developed for pain management.

VHA External Peer Review Program (EPRP)

The VHA Office of Quality and Performance's Performance Measurement Program (PMP) establishes a set of performance monitors that are consistent with the strategic goals of the VHA and designed to assure quality, access, and satisfaction with care provided in VHA facilities. As a step toward the establishment of the performance monitors, the PMP calls for the development of performance indicators. Once the precise definitions of the indicators and scientifically sound methods for data collection and validation have been developed, these indicators have the potential to be established as performance monitors with established thresholds for benchmarking performance.

The External Peer Review Program (EPRP) supports the VHA Performance Measurement Plan by conducting a systematic review of a representative sample of medical records each quarter to monitor compliance with standards, and reports progress toward established goals to VHA leadership. At the current time, records are sampled from primary care clinics and eight additional ambulatory settings (e.g., cardiology clinic).

Consistent with the VHA National Pain Management Strategy, the PMP included a pain-relevant monitor in their FY00 and FY01 reports. EPRP reported quarterly on the proportion of records sampled that had a documented pain score (i.e., 0-10 numeric rating of pain intensity) in the immediately preceding 12 months. By the fourth quarter of FY01, 98% of records sampled nationally had a documented pain score in the preceding 12 months. Subsequently these performance monitors were discontinued and a new set of pain-relevant monitors that are more consistent with the current state of activities in the VHA system have been developed.

Beginning in FY02, the PMP and EPRP instituted three new pain-relevant performance indicators. Once the scientific validity of these indicators are established via a period of monitoring, these indicators have the potential to be designated as performance monitors upon which facility and VISN performance will be evaluated. These pain indicators are:

- Percent of patients with pain assessed on a scale of 0-10 on the most recent visit
- Percent of patients with pain reported > 3 with an intervention recorded
- Percent of patients with a pain intervention recorded who had a follow-up assessment (pain management effectiveness evaluated).

It may be reasonable to consider using these EPRP indicators as targets for performance improvement, as process measures, and/or as outcome measures for evaluating the performance of organized system for improving pain management.

SECTION 6: WEB LINKS FOR OUTCOMES RESOURCES

Chart reviews:

http://www.cityofhope.org/prc/web/pdf/pain_audit_tools.pdf

International Association for the Study of Pain-Desirable Characteristics For Pain Treatment Facilities

<http://www.iasp-pain.org/desirabl.html>

JCAHO standards:

<http://www.jcaho.org>

<http://www.partnersagainstpain.com/html/inst/inst.htm>

Pain Outcomes Instruments

National Pain Data Bank-VA Revised version: www.vachronicpain.org

Tampa Scale of Kinesiophobia-Revised: www.vachronicpain.org

Provider Education:

http://www.cityofhope.org/prc/web/html/rn_needs.htm

http://www.cityofhope.org/prc/web/html/brief_pain.htm

http://www.cityofhope.org/prc/web/html/rehab_professionals.htm

<http://www.cityofhope.org/prc/web/pdf/Knowledge%20and%20Attitudes%20Survey.pdf>

http://www.cityofhope.org/prc/web/pdf/controlling_pain.pdf

<http://mayuday.coh.org/Instruments/k&a.htm>

Rehabilitation Accreditation Commission- Pain Program Standards/Outcomes Assessment

www.carf.org

VHA CPRS Clinical Reminders and Reminder Reports

- VistA Documentation Library (VDL) <http://vista.med.va.gov/vdl/>
- Clinical Reminders web page: <http://vista.med.va.gov/reminders/>
- VistA University web page: <http://vaww.vistau.med.va.gov/vistau/default.htm>
- Reminder Reports Presentation: Reminder Reports for Provider Feedback and Performance Tracking: <http://vista.med.va.gov/reminders/confcalls.htm>

VHA Learning Catalog)

<http://vaww.sites.lrn.va.gov/VACatalog/>

(Type in "Pain" in the left search box to locate pain resources)

VHA National Customer Survey Information

<http://vaww.oqp.med.va.gov/DEFAULT.asp>

VHA Pain as the 5th Vital Sign Toolkit

http://vaww.va.gov/pain_management/508FrameTest2.htm

VHA Pain Management Website

http://vaww.va.gov/pain_management/

VHA/DOD Post Operative Pain Guidelines

http://www.oqp.med.va.gov/cpg/pain/pain_base.htm

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APPENDIX I

VHA Customer Satisfaction Survey Questions Pertaining To Pain

VHA 2002 Inpatient Customer Satisfaction Survey

31. When you had pain, was it usually severe, moderate, or mild?

Severe Moderate Mild Didn't have pain

32. How many minutes after you asked for pain medicine did it usually take before you got it?

0 to 5 minutes

6 to 10 minutes

11 to 15 minutes

16 to 30 minutes

More than 30 minutes

Never got pain medicine

Never asked for pain medicine

Didn't have pain

33. Do you think that the hospital staff did everything they could to help control your pain?

Yes, definitely Yes, somewhat No Didn't have pain

34. Overall, how much pain medicine did you get?

Not enough Right amount Too much Didn't have pain

35. Sometimes people who are in pain don't ask for pain medication. Was this true for you?

Yes No Didn't have pain

36. If you answered yes to the question above, was it because...

You were concerned it might be habit forming

A patient should expect to put up with some pain

You felt it would be a bother if you asked for it

No one told you pain medication was available

You were concerned about possible side effects

You were concerned about what might happen if you mixed pain medications with your other medication

Other

Questions from SF-12V on 2002 Inpatient and Outpatient Surveys

60. During the past 4 weeks, how much did *pain* interfere with your normal work (including both work outside the home and housework)? (*Outpatient question 68*)

Not at all A little bit Moderately Quite a bit Extremely

68. Have you been treated by a VA provider for chronic pain in the past 12 months? (77)

Yes No

69. If you have been treated by a VA provider for chronic pain, please rate the effectiveness of your pain treatment? (*Outpatient question 78*)

Poor Fair Good Very Good Excellent

The above questions address patient satisfaction with different domains of their pain management experience. These domains include *staff disposition to treat pain* (questions 32-34), *pain interference with activities of daily living* (question 60), and *treatment effectiveness* (questions 34, 69). The National VHA Customer Satisfaction Survey - Survey of Healthcare Experiences of Patients is an instrument that can be used for benchmarking purposes and comparisons across VA Medical Centers.

APPENDIX II

Attributes of a Successful Pain Management System

(Cleeland, Schall, Nolan, Reyes-Gibby, Paice, Resenburg, Tollett, & Kerns, 2000).

Selection of important measures for assessing process outcomes of a pain management system may be informed by consideration of several key attributes of a successful system of care. The following list of attributes of a successful pain management system were developed by the planning committee and core faculty for the VHA/Institute for Healthcare Improvement Pain Management Collaborative Project chaired by Charles Cleeland, Ph.D. Operationalization of these attributes and translation or selection of specific measures or indicators of process and/or outcome may be a reasonable approach to establishing the effectiveness of a pain management system of care.

Assessment is routine and timely

- Pain ratings are obtained and documented as “the 5th vital sign” during every clinical encounter, including telephone follow-ups and following drug administration
- Pain screening and assessment is completed on admission and documented
- Protocols for assessment consistent with good clinical practice are developed

Access to appropriate level of treatment

- Pain management is provided by a multidisciplinary team with the primary care provider as the central link
- An integrative treatment plan is informed by a comprehensive pain assessment
- Specialty consults are available to the primary care provider
- Referrals to specialized pain clinics are made when needed

Treatment protocols in place and understood

- Protocols are available for the most common conditions and are used to establish care plans
- Reminders for adherence to the care plan are built into the system
- Standards for time between assessment of pain and action and for response time for medication requests are established

Healthcare providers knowledgeable

- An educational plan is in place at the institutional level
- Different strategies including one-on-one consultations, unit based programs, and grand rounds are considered
- Providers have competencies to manage 80% of the conditions they see

Patients and families are knowledgeable

- A plan for education is in place
- Educational information about pain is supplied to all patients and caregivers
- Educational information is provided prior to admission or surgery, and is part of discharge planning
- The impact of the education is monitored and the need for additional interventions determined

Pain management standards in place

- A facility-wide policy for pain is established that meets JCAHO standards
- A standard nursing policy is established for pain management
- Limits are set for acceptable variation for key parameters within the system

Performance improvement plan in place

- System goals for key outcomes are agreed on
- A schedule for review of progress is established

Necessary improvements to the system are identified and implemented

APPENDIX III

Examples of a Medical Record Pain Audit Tool

Medical Record Review - Pain Management
James A. Haley Veterans Affairs Hospital, Tampa, Florida

Patient: _____ **Date:** _____ **Diagnosis:** _____ **Unit / Clinic:** _____

- | | | | | |
|-----|--|---------------------------------------|-----------------------------------|--|
| 1. | Pain assessed using 0 – 10 scale at initial contact: | <input type="checkbox"/> Yes | <input type="checkbox"/> No | Pain Score: _____ |
| 2. | Type of Pain: | <input type="checkbox"/> Acute | <input type="checkbox"/> Cancer | <input type="checkbox"/> Chronic <input type="checkbox"/> No Pain |
| 3. | Pain Assessment in Progress Notes: | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> NA |
| 4. | Assessment includes: | <input type="checkbox"/> Quantity | <input type="checkbox"/> Location | <input type="checkbox"/> Quality <input type="checkbox"/> Duration <input type="checkbox"/> Patient's Goal |
| 5. | Pain recorded on Vital Sign Flowsheet/ GUI | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> NA Why: _____ |
| 6. | Pain Scale Used | <input type="checkbox"/> Yes | <input type="checkbox"/> No | Highest Pain Score: _____
Lowest Pain Score: _____
Most frequent level: _____ |
| | (Pain level reported most often in last 48 hours or 3 mo) | | | |
| 7. | The plan of care addresses pain | Medical: <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> NA |
| | | Nursing: <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> NA |
| 8. | The plan of care was altered if pain > 3 or the patient's goal not met | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> NA |
| 9. | Pain education documented | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> NA |
| 10. | Effectiveness of medication evaluated using 0 –10 scale
(was plan evaluated at next clinic visit?) | | <input type="checkbox"/> Yes | <input type="checkbox"/> No <input type="checkbox"/> NA |
| 11. | Was pain management included in DC plan /instructions? | | <input type="checkbox"/> YES | <input type="checkbox"/> NO <input type="checkbox"/> NA |
| 12. | Was pain education included in DC plan / instructions? | | <input type="checkbox"/> YES | <input type="checkbox"/> NO <input type="checkbox"/> NA |

APPENDIX IV

Examples of Possible Patient Education Survey Items

I received an explanation of how my pain would be relieved.

Disagree Not Sure Agree

I would have liked a better explanation.

Disagree Not Sure Agree

Please rate the adequacy of explanation of what was done for you.

Excellent Very Good Good Fair Poor

Please rate the adequacy of answers to your questions.

Excellent Very Good Good Fair Poor

When you had questions to ask did you always get answers you could understand?

Yes No Not Sure

How much information was given to you during your hospital stay/visit?

Not enough Right amount Too much I didn't need or want information

Were you informed of the next step in your health care?

Yes Yes, sometimes No

Were you told of the medication side effects before going home?

Yes No Not necessary, I knew the information Not necessary, no medications

Were you provided with enough information to know how to care for yourself after discharge from the hospital?

Yes No

APPENDIX V

Duke University Medical Center Competency Questionnaire

(Reproduced with the permission of Shashidhar Kori, M.D.)

[Q1] What is your specialty?

- (A) Pediatrics
- (B) OB/GYN
- (C) Medicine
- (D) Surgery
- (E) Psych
- (F) Family Medicine
- (G) Other

Please enter your response here >>

[Q2] (Complete the blank). Studies indicate that more than _____% of the cancer pain experienced by terminally ill patients can be effectively controlled using currently available oral therapies.

- (A) Twenty
- (B) Ninety
- (C) Fifty
- (D) Fifteen

Please enter your response here >>

[Q3] The addition of psychological intervention (e.g., relaxation training, imagery, activity pacing) to medical management can result in a significant improvement in pain relief.

- (T) True
- (F) False

Please enter your response here >>

[Q4] Patients often describe bone pain as:

- (A) Shooting
- (B) Deep and aching
- (C) Spasms and cramping
- (D) Colicky

Please enter your response here >>

[Q5] Which of the following classes of drugs can be effective adjuvants to morphine when treating specific types of pain?

- (A) NSAIDS
- (B) Antidepressants
- (C) Anticonvulsants
- (D) All of the above

Please enter your response here >>

[Q6] When titrating morphine, the dose should never be raised by more than 25% over a 24-hour period.

- (T) True
- (F) False

Please enter your response here >>

[Q7] Which of the following are true about NSAIDS?

- (A) NSAIDs are contraindicated in patients allergic to aspirin.
- (B) NSAIDs should be used with caution in patients with renal dysfunction.
- (C) NSAIDs can be useful analgesics in patients with cancer pain.
- (D) All of the above are true.

Please enter your response here >>

[Q8] To calculate the equivalent daily parenteral dose of 30 mg of oral morphine, divide the oral dose of morphine by 3.

- (T) True
- (F) False

Please enter your response here >>

[Q9] The most appropriate oral regimen for a patient requiring 80 mg of intravenous morphine in the preceding 24 hours is:

- (A) Propoxyphene and acetaminophen (Darvocet)
- (B) Tramadol (Ultram)
- (C) Continuous release oxycodone plus oxycodone immediate release for breakthrough pain
- (D) Oral meperidine (Demoral)

Please enter your response here >>

[Q10] When pain related to nerve damage or dysesthesia occurs, which of the following may be an effective adjuvant to morphine:

- (A) Amitriptyline (Elavil)
- (B) Scopolamine
- (C) Gabapentin (Neurontin)
- (D) Both A and C above

Please enter your response here >>

[Q11] Due to concerns about addiction and tolerance, morphine or other strong opioids should not be used in patients with nonmalignant chronic pain.

- (T) True
- (F) False

Please enter your response here >>

[Q12] Completing a history and physical are the first steps of an effective assessment of all types of pain.

- (T) True
- (F) False

Please enter your response here >>

[Q13] When beginning opioid therapy it is useful to do which of the following:

- (A) Initiate therapy for constipation
- (B) Tell the patient that drowsiness and pruritis may improve
- (C) Encourage the patient to take the medication only when in severe pain
- (D) Both A and B above

Please enter your response here >>

[Q14] Appropriate agents for PCA (patient controlled analgesia) include all of the following except:

- (A) Morphine
- (B) Meperidine
- (C) Fentanyl
- (D) Hydromorphone

Please enter your response here >>

[Q15] Most patients on opioid therapy require individually titrated doses of potent bowel stimulants such as:

- (A) Senna (Senokot)
- (B) Bisacodyl (Dulcolax)
- (C) Docusate (Colace)
- (D) Either A or B above

Please enter your response here >>

[Q16] If a patient's pain is relieved by distraction, the pain is most likely psychogenic in origin.

- (T) True
- (F) False

Please enter your response here >>

[Q17] When a patient can no longer swallow, all of the following are appropriate alternative routes of opioid administration except:

- (A) Transmucosal
- (B) Subcutaneous
- (C) Intramuscular
- (D) Rectal

Please enter your response here >>

[Q18] Health care providers accurately assess the pain of patients.

- (T) True
- (F) False

Please enter your response here >>

[Q19] Children feel less pain than adults.

- (T) True
- (F) False

Please enter your response here >>

[Q20] Clinically significant respiratory depression is a common problem when appropriately dosing opioids in the management of moderate to severe pain.

- (T) True
- (F) False

Please enter your response here >>

[Q21] Relaxation, visualization, and distraction are examples of techniques useful to treat which of the following types of pain:

- (A) Neuropathic
- (B) Visceral
- (C) Acute
- (D) Malignant
- (E) All of the above

Please enter your response here >>

[Q22] All of the following are true about meperidine (Demerol) except:

- (A) Meperidine is useful to treat rigors.
- (B) Meperidine increases the risk of seizures.
- (C) Meperidine is the drug of choice to treat sickle cell pain crises and post op pain.
- (D) Meperidine is more likely to cause chemical dependency than morphine.

Please enter your response here >>

[Q23] The dosing of Percocet is limited by the following:

- (A) The amount of opioid in the product
- (B) The amount of acetaminophen in the product
- (C) The amount of aspirin in the product
- (D) The amount of ibuprofen in the product

Please enter your response here >>

[Q24] Long-acting opioids have the following advantages over short-acting preparations:

- (A) More consistent blood levels
- (B) Less potential for abuse
- (C) Convenience of dosing
- (D) All of the above

Please enter your response here >>

[Q25] Patients with chronic pain syndromes can build up their activity level most effectively if they try to do as much as they can and let pain be their guide.

- (T) True
- (F) False

Please enter your response here >>

[Q26] All of the following are true about codeine except:

- (A) The active metabolite of codeine is morphine.
- (B) Codeine in combination with acetaminophen is a schedule III compound.
- (C) 60 mg of codeine is a stronger analgesic than 600 mg of ibuprofen.
- (D) Nausea and vomiting is common with codeine.

Please enter your response here >>

APPENDIX VI

Members of the VA National Pain Outcomes Workgroup

<p>Michael E. Clark, PhD, Chair Clinical Director, Pain Program (116B) James A. Haley Veterans Affairs Hospital 13000 B. B. Downs Blvd. Tampa, FL 33612-4798 813.972.2000 x7484; 7112; 7114 Fax: 813.978.5867 e-mail: michael.clark2@med.va.gov Website: www.vachronicpain.org</p>	<p>Robert Kerns, PhD Chief, Psychology Service (116B) VA Connecticut Healthcare System 950 Campbell Ave. West Haven, CT 06516 203.937.3841 Fax: 203.937.4951 e-mail: robert.kerns@med.va.gov</p>
<p>Michael H. Craine, PhD Section Chief, Psychology (116B) Denver VAMC 1055 Clermont St. Denver, CO 80220 303.399.8020, ext. 2577 Fax: 303.393.5076 michael.craine@med.va.gov</p>	<p>Ruth Markham, EDS 4179 Riverboat Rd. Suite 200 Salt Lake City, UT 84123 801.904.4545 Fax: 801.904.4782 e-mail: ruth.markham@med.va.gov</p>
<p>Julie A. Jones, RN, CNS Black Hills HCS VABHHS 500 North 5th Street Hot Springs, SD 57747 605.745.2000, ext. 2469 Fax: 601.745.2802 julie.jones2@med.va.gov</p>	<p>Mitchell Nazario, Pharm. D. Pharmacy Service (119) San Juan VAMC 10 Casia St. San Juan, PR 00921-3201 787.641.7582, ext. 11476 mitchell.nazario@med.va.gov</p>

APPENDIX VII

Members of the VA National Pain Coordinating Committee

<p>John Booss, MD Director, Neurology—field based VAMC (200) West Haven, CT 06516 Phone: 203.932.5711; ext. 3544 Fax: 203.937.4755 e: booss.john@westhaven.va.gov</p>	<p>Martha Bryan, EdD Assistant Director, Health Services Research and Development Service 1400 I Street, Suite 700 Washington, DC 20420 Phone: 202.408.3665 e: martha.bryan@hq.med.va.gov</p>	<p>Michael E. Clark, PhD Clinical Director, Chronic Pain Rehabilitation Program (116B) Bruce B. Downs Blvd. Tampa, Fl 813.972.2000 x 7484; 7112; 7114 fax: 813.903.4847 e: michael.clark2@med.va.gov</p>
<p>Audrey Drake, RN, MSN, CNAA Program Director, Nursing (118) VACO 810 Vermont Ave. NW Washington, DC 20420 Phone : 202.273.8424 fax: 202.273.9066 e: audrey.drake@hq.med.va.gov</p>	<p>Robert Kerns, PhD Chief, Psychology Service VA Connecticut HCS West Haven, CT 06516 Phone : 203.937.3841 fax: (203) 937-4951 e: robert.kerns@med.va.gov</p>	<p>Ruth Markham, SLC OI 295 Chipeta Way Salt Lake City, UT 84108 Phone : 801.588.5842 fax: 801.588.5004 e: ruth.markham@med.va.gov</p>
<p>Jack Rosenberg, MD VISN 11 Coordinator for Pain Mgmt. 2215 Fuller Road Ann Arbor, MI 48105 Phone : 734.936.5842 fax: 734.769.7056 e: jackrose@umich.edu</p>	<p>Richard W. Rosenquist, MD Dir., Pain Medicine Division Dept. of Anesthesia University of Iowa Hospitals Iowa City, Iowa 52242 Phone : 319.356.2320 fax : 319.356.2940 e: richard-rosenquist@uiowa.edu</p>	<p>Paul Rousseau, MD ACOS for GEC VAMC; 650 E. Indian School Road Phoenix, AZ 85012 Phone : 602.277.5551 fax: (602) 222-6514 e: ArizonaMD@aol.com</p>
<p>Charles D Sintek, MS, RPh, BCPS Clinical Pharmacy Mgr. (119B) VAMC; 1055 Clermont ST. Denver, CO 80220 Phone: 303.393.2806 Fax: 303.393.4624 e: charles.sintek@med.va.gov</p>	<p>Anne Turner Health Education Officer Employee Education System Suite 500 Medical Forum 950 22nd St., North Birmingham, Al 35203 Phone 205-731-1812 ex 310 Fax 205-731-1824 e : anne.turner@lrm.va.gov</p>	<p>Jane H. Tollett, RN, PhD National Pain Management Coordinator VHACO (114) 810 Vermont Ave., NW Washington, DC 20420 Phone: 202.273.8537 Fax: 202.273.9131 e: jane.tollett@hq.med.va.gov</p>