



# **Complete Summary**

#### **GUIDELINE TITLE**

Special treatment situations: behavioral interventions for management of primary head pain. Standards of care for headache diagnosis and treatment.

## **BIBLIOGRAPHIC SOURCE(S)**

Farmer K, Freitag F. Special treatment situations: behavioral interventions for management of primary head pain. In: Standards of care for headache diagnosis and treatment. Chicago (IL): National Headache Foundation; 2004. p. 83-92. [18 references]

#### **GUIDELINE STATUS**

This is the current release of the guideline.

## **\*\* REGULATORY ALERT \*\***

#### FDA WARNING/REGULATORY ALERT

**Note from the National Guideline Clearinghouse**: This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the U.S. Food and Drug Administration (FDA) requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the <u>FDA Web</u> site for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all nonsteroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and overthe-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. See the <u>FDA Web</u> <u>site</u> for more information.

#### **COMPLETE SUMMARY CONTENT**

\*\* REGULATORY ALERT \*\* SCOPE METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

#### SCOPE

#### DISEASE/CONDITION(S)

Primary headache disorders

#### **GUIDELINE CATEGORY**

Management

## **CLINICAL SPECIALTY**

Family Practice Internal Medicine Neurology

#### INTENDED USERS

Health Care Providers Physicians

## **GUIDELINE OBJECTIVE(S)**

- To improve the medical treatment of headache
- To discuss the theory and application of behavioral approaches in the management of primary headache disorders

#### TARGET POPULATION

Patients with primary headache disorders

## INTERVENTIONS AND PRACTICES CONSIDERED

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- 1. Cognitive behavioral therapy (CBT)
  - Assertiveness training
  - Cognitive restructuring
  - Coping skills
- 2. Relaxation training
  - Progressive muscle relaxation
  - Autogenic training
  - Meditation
- 3. Biofeedback
  - Thermal biofeedback (hand-warming)
  - Electromyographic (EMG) biofeedback

# MAJOR OUTCOMES CONSIDERED

- Headache frequency, intensity, and/or duration
- Headache activity

# METHODOLOGY

# METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

# DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

# NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

## **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

Not applicable

## METHODS USED TO ANALYZE THE EVIDENCE

Review

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

#### Expert Consensus

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guidelines presented in this monograph represent the consensus of an advisory panel of practitioners chosen by the National Headache Foundation (NHF) for their expertise. In addition to incorporating the US Headache Consortium's recommendations, their conclusions reflect clinical experience and the most recent medical literature.

# **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Not applicable

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Not stated

# **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

Not applicable

## RECOMMENDATIONS

## MAJOR RECOMMENDATIONS

## **Behavioral Interventions for Management of Primary Head Pain**

When patients seek medical consultation for headaches, they often feel like failures because, despite efforts at self-treatment, nothing seems to provide relief. And they are usually concerned that their lives are being ruined by disabling headaches. They cannot make plans for fear of being unable to follow through or they may recognize that their productivity at home, work, or school is diminishing. A few may wonder if they have a brain tumor. Of course, they expect to receive a thorough physical and neurological examination, appropriate lab tests, and prescription medication for their pain. In addition, however, they need to learn how to regain control over their condition and their lives. Because disabling headaches affect the person's entire system and the ability to function, the treatment plan needs to include behavioral as well as pharmacological measures.

Behavioral intervention may be as simple as education about primary headache disorders. If anxiety or depression is complicating the headache pattern, cognitive behavioral therapy may be indicated. For those patients who complain of cold

hands and cold feet and are having an increasingly difficult time in meeting the demands of home, work, or school, relaxation training and biofeedback are useful. Behavioral options help patients become involved in their own treatment, which greatly assists compliance with the management plan and increases satisfaction with treatment. In addition, behavioral interventions increase the efficacy of the medications used to treat disabling headaches. When patients meet certain criteria for therapy (see Table below), behavioral treatments can be used to reduce headache frequency, severity, associated disability, and the need for medication at the same time that they instill a sense of control over headache attacks. This review, directed to the primary care provider, covers the theory and application of behavioral approaches in the management of primary headache disorders.

#### **Identifying Patients for Behavioral Interventions**

- Preference for nonpharmacologic interventions
- Poor tolerance of pharmacologic treatment
- Medical contraindications to pharmacologic treatments
- Inadequate response to pharmacologic treatment
- Pregnancy, planned pregnancy, or nursing
- History of excessive use of analgesics or other acute medications
- Life stress, defiant coping skills, or comorbid psychological disorder

## Cognitive Behavioral Therapy (CBT)

CBT combines cognitive therapy with behavior therapy. Individuals identify, through the help of a therapist, certain thinking patterns that are exacerbating the physical condition, in this case disabling headaches. By these habitual, often automatic thoughts, distortions occur in perception, making individuals feel anxious, depressed, or angry, which leads to self-defeating behaviors. The behavioral part of therapy teaches patients to stop these habitual reactions to troublesome events. It also focuses on methods to calm the body and mind for enhanced productivity, creativity, and a sense of relaxation and control. Stress management training is a type of cognitive behavioral therapy that teaches headache patients how to cope with everyday stressors in order to avoid precipitating, exacerbating, or prolonging headache attacks. Ideally, patients treated with CBT learn and adopt strategies for dealing with their headache-causing stressors and stressful situations. The duration of CBT depends on the individual, but a course of treatment typically lasts from 3 to 12 sessions.

A wealth of evidence supports the use of CBT in the management of primary headache. For example, in a recent review of 7 studies assessing the clinical benefits of CBT in migraine patients, Campbell et al estimated an average of 49% improvement in headache activity (a composite score of headache frequency, intensity, and/or duration). Similarly, among tension-type headache patients, CBT can reduce headache activity by almost 50%. Judicious patient selection is crucial, however, as one study found that patients with chronic head pain are minimally responsive to cognitive behavioral interventions. Combining behavioral modalities may also be helpful, particularly if a patient does not respond to CBT alone. One group of investigators combined cognitive behavioral training with biofeedback and achieved an average of 38% improvement in headache activity. Examples of cognitive behavioral approaches include assertiveness training, cognitive restructuring, and coping skills. These approaches may increase treatment compliance among headache patients.

## Assertiveness Training

Some headache patients, especially migraineurs, have low self-esteem and have a difficult time saying no, especially to family members, because of fear of rejection, abandonment, or an aggressive confrontation. Many patients in this situation might benefit from assertiveness training.

Assertiveness training involves 4 steps:

- 1. Identify when a behavior is being asked that the person does not want to do usually signaled by feelings of guilt, anxiety, ignorance, or dread
- 2. Practice saying no in unimportant situations, such as to a cashier in a supermarket
- 3. Say no to those who will understand, such as a friend
- 4. Finally, say no to the person who demands behaviors that produce negative feelings

The process of identifying and mastering these issues can significantly improve a headache patient's condition.

#### Case Study

Christina is relaxing at home, tired after a busy day at the office. The phone rings, and she thinks, "Mom's nightly phone call is early." After reporting to her mother the events of the day, she has to cut the call short because of a headache that is developing behind her right eye. These headaches are starting to happen more frequently, at least 4 times a week, and they usually occur after speaking to her mother.

#### **Recommendations**

The guideline authors advised Christina to purchase an answering machine and to screen her phone calls. They also suggested that she return the phone calls at her convenience. Since her mother usually slept late, the authors recommended that she call her mother at 7 a.m. (when Christina first woke up), rather than wait for her mother to contact her. Within a week, her mother stopped the practice of nightly phone calls. Soon afterwards, Christina's headache frequency decreased to 1 or 2 per month.

## Cognitive Restructuring

Cognitive restructuring is identifying and changing negative self-talk that occurs automatically. With a recurrent, episodic pain syndrome such as headache, the individual may begin to feel like a victim, helpless, at the mercy of the attack. In cognitive restructuring, a physician or a psychologist and the patient create affirmations to replace negative self-talk. Getting patients to make statements such as "I deserve health" to replace "I have to suffer like my mother" is an important first step in cognitive restructuring. Some migraineurs feel like failures because they cannot control their attacks. They judge themselves as unreliable because they cannot meet their responsibilities and sometimes let others down. Disabling headaches prevent them from doing what they want to do but may also be punishment for being such a "bad" person. A powerful affirmation for migraineurs is "I forgive myself for being imperfect."

## Case Study

With the approach of her menstrual period, Phyllis feels anxious and dreads this time of the month. She knows she will have to spend a day or two in bed in a dark room, making excuses for not being able to work, to care for her family, or to be with friends. Her mother used to suffer the same way until she went through menopause. Phyllis wonders whether a hysterectomy would get rid of these sick headaches.

## **Recommendations**

Instead of accepting that disabling headaches are inevitable and that she is a failure who is destined to be miserable, Phyllis was asked to recite affirmations ("I deserve health and harmony") to counteract the negativity of her defeatist thinking. In addition, the guideline authors worked to develop ways to reduce the frequency, severity, and duration of her attacks. The authors instructed her that taking a nonsteroidal anti-inflammatory drug (NSAID) beginning 2 or 3 days before the anticipated menstrual migraine might reduce the intensity of the attack or prevent it altogether. Emboldened by the success of treatment, Phyllis developed a more positive outlook. Finally, the authors initiated a program of exercise and biofeedback training, which further shortened the duration of her menstrually-related attacks.

# Coping Skills

Change is a common risk factor for disabling headaches. Once headache patients recognize this trigger, they need to bolster their vulnerable nervous systems with positive behaviors, such as exercise, recreation, and self-nurturing activities. With these skills, individuals find that control over headaches generalize to other aspects of life. No longer do their headaches occur "out of the blue."

## Case Study

It's allergy season and Fred seems to get a headache every day. He also just started a new job and is learning the business. He used to exercise regularly, but recently he has been skipping his morning walk, sometimes for a week at a time. Lately, he seems to function at only one speed, full steam ahead. At work, he takes an over-the-counter remedy and closes his office door to get away from the pressure cooker at the office.

## **Recommendation**

The guideline authors recommended that Fred find time to relax in his office, using mental imagery to push his worries about his demanding boss from his

mind. The authors instructed him to visualize himself in successful professional situations, such as winning a big contract for a project he developed and presented to a client. The authors also pointed out that he needed to reestablish the routine of a brisk workout before he leaves for work. With these coping measures in place, the authors were able to work with Fred to reduce his attack frequency and severity.

# **Relaxation Training**

Relaxation training has been recognized as an effective therapy for more than a century. In headache management, as with other nonpharmacologic approaches, clinicians most often use relaxation training as a prophylactic treatment. Three types of relaxation training are still widely used today: progressive muscle relaxation, autogenic training, and meditation (see table below); it is important to be familiar with each of the types and to understand when and how to apply them in clinical practice. Patients can usually be taught to incorporate 20 to 30 minutes of relaxation exercises into their daily routine within 10 treatment sessions, although sometimes fewer sessions are required.

Research supports the use of relaxation training in the treatment of migraine and tension-type headache. Several studies have shown that migraine patients who are taught to use relaxation techniques have been able to reduce their headache activity by about 40%. Significantly, thermal biofeedback combined with relaxation training can be less effective in migraine prevention than relaxation alone. Tension-type headache patients have been able to use relaxation training to cut headache activity by about 40%, similar to rates seen in migraine. However, when investigators combined relaxation techniques with electromyographic biofeedback, they improved the rates of reduction of tension-type headache activity to about 50%.

# Types of Relaxation Training

- Progressive muscle relaxation: Alternately tensing and relaxing muscle groups throughout the body
- Autogenic training: Using self-instructions of warmth and heaviness
- Meditation: Using a silently repeated word or sound

# Biofeedback

In biofeedback, which uses principles derived from Ayurvedic medicine, headache patients learn to monitor and regulate physiologic functions in order to gain control of their condition. There are 2 major types of biofeedback instruction: thermal (also called hand-warming) and electromyographic (EMG). Thermal biofeedback records skin temperature from a finger thermometer. EMG biofeedback measures electrical activity in the muscles through an electrode. The downside to EMG biofeedback is that the patient must return to the office to practice with the EMG machine.

Biofeedback essentially instructs patients to regulate their nervous system to respond to stressors through the parasympathetic rather than the sympathetic system. To train headache patients well enough in biofeedback techniques to

realize benefits requires repetitive treatment sessions. Patients need to practice at least 10 minutes daily; otherwise, more sessions are required with a therapist.

When practiced regularly, biofeedback techniques can achieve significant reductions in headache activity. In subjects with migraine, EMG biofeedback has reduced headache activity by approximately 55%; thermal biofeedback, when combined with relaxation training, reduced headache activity by about 35%. Among tension-type headache patients, EMG biofeedback cut headache activity by around 50%. Among tension-type headache patients, EMG biofeedback, when combined with relaxation training, reduced headache activity slightly less than EMG alone.

Both types of biofeedback training can be effective in headache management but only when used in appropriate patients. For example, both migraine and tensiontype headache patients can use EMG and thermal techniques, but cluster patients find that relaxation triggers a headache during their cluster period. Although biofeedback techniques are employed mainly as a preventive treatment, some patients may be able to use them to modify the course of an existing headache, such as during prodrome or mild headache, thereby reducing or eliminating the need for acute medication.

In a 3-year study that compared the effectiveness of ergotamine tartrate and relaxation-biofeedback training, both methods reduced headache activity by 50% or more. However, over time, the subjects treated with ergotamine were more likely to have obtained additional medical treatment for headaches and to use either prophylactic or narcotic medications.

Behavioral interventions for primary headaches have their origins in the pioneering work of Wolff, whose careful observations led him to describe how thoughts, behaviors, and bodily reactions evolve in response to stress to induce migraine attacks. Green et al made the seminal observation that headache sufferers tended to have finger temperatures around 70 degrees Fahrenheit (F). By contrast, individuals without severe headaches recorded finger temperatures of about 85 degrees F.

With recent work suggesting that migraine and tension-type headache are manifestations of a continuum of head pain (as opposed to distinct disease states), Wolff's ideas are equally persuasive for tension-type patients. Thus, the available research on nonpharmacologic headache therapies suggests a commonsense approach to headache management, in which risk factors are avoided and health-promoting, protective factors are encouraged (refer to Figure 8.1 of the original guideline document). Teaching headache patients to regulate their reactions to stressors with CBT, relaxation training, biofeedback - or some combination of behavioral techniques - can improve overall therapeutic outcomes by reducing headache activity as well as the need for acute and preventive medications.

## CLINICAL ALGORITHM(S)

None provided

# **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

In addition to incorporating the US Headache Consortium's recommendations, the conclusions reflect clinical experience and the most recent medical literature.

# **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

#### **POTENTIAL BENEFITS**

When patients meet certain criteria for therapy, behavioral treatments can be used to reduce headache frequency, severity, associated disability, and the need for medication at the same time that they instill a sense of control over headache attacks.

#### **POTENTIAL HARMS**

Not stated

# QUALIFYING STATEMENTS

## QUALIFYING STATEMENTS

Drug therapy is constantly evolving as new research, clinical trials, case reports, and opinions are published. Many of the drugs recommended in these guidelines are not approved by the US Food and Drug Administration (FDA) for treatment of headache, nor are they necessarily the same as those therapies recommended by the manufacturer for labeled indications. Their use in headache, however, may be supported by the scientific literature and by the authors' clinical experiences. While efforts have been made to ensure accuracy, the authors and publisher do not assume responsibility for the consistent updating of available information for these guidelines, nor for any errors or omissions, nor for any consequences thereof. The onus is on the practitioner to evaluate recommendations in light of the clinical condition of the patient and recent medical literature. The authors advise the practitioner to consult other sources, especially the manufacturers' warnings and precautions, before prescribing any drug with which they are unfamiliar. Practitioners are also advised that while these guidelines will address the needs of many patients, there will be circumstances calling for exceptions to these recommendations.

# IMPLEMENTATION OF THE GUIDELINE

## **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

#### **IMPLEMENTATION TOOLS**

Chart Documentation/Checklists/Forms Foreign Language Translations Patient Resources Slide Presentation

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

#### IOM CARE NEED

Getting Better Living with Illness

#### IOM DOMAIN

Effectiveness Patient-centeredness

# **IDENTIFYING INFORMATION AND AVAILABILITY**

#### **BIBLIOGRAPHIC SOURCE(S)**

Farmer K, Freitag F. Special treatment situations: behavioral interventions for management of primary head pain. In: Standards of care for headache diagnosis and treatment. Chicago (IL): National Headache Foundation; 2004. p. 83-92. [18 references]

## ADAPTATION

Not applicable: The guideline was not adapted from another source.

#### DATE RELEASED

2004

## **GUIDELINE DEVELOPER(S)**

National Headache Foundation - Private Nonprofit Organization

## SOURCE(S) OF FUNDING

National Headache Foundation

## **GUIDELINE COMMITTEE**

Not stated

# COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Kathleen Farmer, PsyD, and Fred Freitag, DO

# FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: None available

Print copies: Available from the National Headache Foundation, 820 N. Orleans, Suite 218, Chicago, IL 60610; Phone: (888) NHF-5552; Web address: www.headaches.org

# AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- The complete headache chart. Chicago (IL): National Headache Foundation (NHF); 2 p. Electronic copies available in Portable Document Format (PDF) from the <u>National Headache Foundation Web site</u>
- National Headache Foundation fact sheet. Chicago (IL): National Headache Foundation (NHF); 2004 Oct. 2 p. Electronic copies available in Portable Document Format (PDF) from the <u>National Headache Foundation Web site</u>.

Print copies: Available from the National Headache Foundation, 820 N. Orleans, Suite 218, Chicago, IL 60610; Phone: (888) NHF-5552; Web address: www.headaches.org

## PATIENT RESOURCES

The National Headache Foundation (NHF) has created a variety of educational resources for patients, including informative brochures, a patient diary for migraines, Power Point presentations, and patient guides; many of these resources are available in both Spanish and English. Some of these items are available as print copies for purchase through the <u>NHF online store</u>. Electronic versions of other resources are available through the consumer education section of the <u>NHF Web site</u>.

Print copies: Available from the National Headache Foundation, 820 N. Orleans, Suite 218, Chicago, IL 60610; Phone: (888) NHF-5552; Web address: www.headaches.org.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

# NGC STATUS

This NGC summary was completed by ECRI on April 12, 2005. The information was verified by the guideline developer on April 26, 2005. This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs).

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# NGC DISCLAIMER

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