



***Lifting The Burden:***  
**The Global Campaign to Reduce the Burden of Headache Worldwide**

**in collaboration with**



**European Headache Federation**

**Aids for management of common headache  
disorders in primary care**

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## Aids for management of common headache disorders in primary care

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Medical management of headache disorders, for the vast majority of people affected by them, can and should be carried out in primary care. It does not require specialist skills. Nonetheless, it is recognised that non-specialists throughout Europe may have received limited training in the diagnosis and treatment of headache.

This special supplement of *Journal of Headache and Pain* is the output of a collaboration between the European Headache Federation (EHF) and *Lifting The Burden*: the Global Campaign to Reduce the Burden of Headache Worldwide, a programme for the benefit of people with headache conducted under the auspices of the World Health Organization. It contains a set of management aids designed by various specialist working groups expressly to assist primary-care physicians in managing a group of very common disorders effectively. We hope for benefits for both patients and physicians. In the first case, there should be better outcomes for the many people with headache who need medical treatment. In the second, physicians are helped to deliver appropriate care more efficiently and more cost-effectively.

Whilst the focus of this publication is Europe, these management aids have been developed to be useful cross-culturally and may suit a wider population.

The European principles of management of common headache disorders in primary care are the essential core of these aids. These are set out in 12 sections, each one more-or-less stand-alone. They are supplemented in Appendices 1 and 2 by a measure of headache burden (the HALT index), intended for pre-treatment assessment of illness severity, an outcome measure (the HART index), which is a guide to follow-up and need for treatment-review, and a series of patient information leaflets developed to improve patients' understanding of their headache disorders and their management.

EHF and *Lifting The Burden* offer these aids freely available for use without restriction. They will need translating into many languages. Therefore, also included, in Appendix 3, are a set of translation protocols. These have been prepared by a working group of *Lifting The Burden* to ensure that translations as far as possible are unchanged in meaning from the English-language originals.

*This work was performed under a collaborative arrangement between World Health Organization and World Headache Alliance, International Headache Society and European Headache Federation*

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## European principles of management of common headache disorders in primary care

### Introduction

Headache disorders are amongst the top ten causes of disability in Europe [1]. Three of these (migraine, tension-type headache and medication-overuse headache) are important in primary care because they are common and responsible for almost all headache-related burden. Their management belongs largely in primary care. A fourth headache disorder (cluster headache) is also important because it is severely painful, treatable but often misdiagnosed.

The purpose of these principles is to help primary-care physicians correctly diagnose these few disorders, manage them well when they can, recognise warnings of serious headache disorders and refer for

specialist care whenever necessary. These principles are likely to be most useful if read through at least once in their entirety, but are set out in 12 stand-alone management aids in three sections:

**Guides to diagnosis** (some parts of these will need to be assimilated into routine practice whereas other parts can serve as check lists and aide-mémoires)

1. Headache as a presenting complaint
2. Diagnosis of headache
3. Typical features of the common headache disorders
4. Differential diagnosis of the common headache disorders

**Guides to management** (these are information sources to be referred to

once the diagnosis has been made; management aid #6 includes guidance on information to patients)

5. General aspects of headache management
6. Advice to patients
7. Medical management of acute migraine
8. Prophylactic management of migraine
9. Medical management of tension-type headache
10. Medical management of cluster headache
11. Management of medication-overuse headache

#### **Guide to referral** (a reference and reminder)

12. Headache management in primary care: when to refer

These principles are supplemented by additional management aids developed by *Lifting The Burden*:

- the Headache-Attributed Lost Time (HALT) index, a measure of headache burden
- the Headache and Assessment of Response to Treatment (HART) index, a measure of treatment effect and guide to follow-up
- a series of patient information leaflets.

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#### **Development process**

##### Stakeholder involvement

The initial development group, a collaboration between the European Headache Federation (EHF) and *Lifting The Burden*: The Global Campaign to Reduce the Burden of Headache Worldwide, were headache specialists from Belgium, Denmark, France, Germany, Italy, Netherlands, Spain and UK. The pilot group were primary care physicians from the same countries. The consultation group were members of the National headache societies within the European Headache Federation representing Albania, Austria, Belgium, Belarus, Bulgaria, Croatia, Denmark, Finland, France, Germany, Greece, Hungary, Israel, Italy, Lithuania, Netherlands, Poland, Portugal, Romania, Russia, Serbia and Montenegro, Slovenia, Spain, Sweden, Switzerland and United Kingdom. Patient representatives and advocates were consulted through the Board of the European Headache Alliance.

##### Rigour of development

The development process was review of all treatment guidelines in use in Europe and published or otherwise available in English, and harmonization through selection of whatever recommendations within them carried greatest weight.

Evidence-based recommendations were always preferred to those without explicit supporting evidence. Discordance between recommendations was resolved through direct reference to original evidence or, where this was lacking, through consensus of expert opinion.

##### Clarity and presentation

The aim was to give straightforward and easily-followed guidance to primary-care physicians who were assumed to be non-expert. There was recognition that availability and regulatory approval of drugs and reimbursement policies varied from country to country. For that reason, different possible options were considered and are set out wherever appropriate, but otherwise the emphasis was on unambiguous advice.

##### Applicability

These principles assume that headache services are developed and adequately resourced in all countries in Europe, even though this is not the case at present. Separate initiatives by EHF and *Lifting The Burden* are being undertaken to support better organisation of headache services in all countries in Europe. These recommendations will be monitored by the pilot group and reviewed annually by the development group.

##### Editorial independence

EHF was the sole funding body supporting development of these principles. Members of the development group declared the following possible conflicts of interest:


consultancy agreements with and/or research funding from ACRAF SpA, Addex Pharma, Allergan, Almirall, Alpharma, Astra Zeneca, Bayer Healthcare, Berlin Chemie, Böhringer Ingelheim, Bristol-Myers Squibb, CoLucid, Eli Lilly, Glaxo-SmithKline, Grünenthal, Helsinn Healthcare, Hoffmann La Roche, Janssen-Cilag, Johnson & Johnson, Lusofarmaco, Menarini, Merck Sharpe and Dohme, 3M Medica, Novartis, Pfizer, Pierre Fabré, Solvay Pharma, SanofiAventis, Sanofi-Synthélabo, Schaper and Brümmer, Weber & Weber.

These principles make no recommendations that favour one proprietary medication over another with similar effects.

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#### **References**

1. Stovner LJ, Hagen K, Jensen R et al (2007) The global burden of headache: a documentation of headache prevalence and disability worldwide. *Cephalalgia* 27:193–210

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### 1. Headache as a presenting complaint

Most people have occasional headache, and regard it as normal. Headache becomes a problem at some time in the lives of about 40% of people in Europe. Four headache disorders are common in primary care (Table). All have a neurobiological basis. They are disabling and impair quality of life.

One patient may have more than one of these disorders concomitantly.

There are a large number of other *secondary headache disorders*. Some of these are serious, and they must be recognized (see Management aid #4. *Differential diagnosis of the common headache disorders*), but overall they account for <1% of patients presenting with headache.


**Table** The common headache disorders in primary care

**Migraine** usually episodic, occurring in 12-16% of the general population, in women more than men in a ratio of 3:1

**Tension-type headache** usually episodic, affecting >80% of people from time to time; in at least 10% it recurs frequently, and in 2-3% of adults and some children it is chronic, occurring on more days than not

**Cluster headache** intense and frequently recurring but short-lasting headache attacks, affecting up to 3 in 1,000 men and up to 1 in 2,000 women

**Medication-overuse headache** a chronic daily headache syndrome occurring in up to 3% of adults, 5 women to each man, and 1% of children and adolescents; this is a secondary headache, but it occurs only as a complication of a pre-existing headache disorder, usually migraine or tension-type headache

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## 2. Diagnosis of headache

### Taking a diagnostic history

The history is all-important in the diagnosis of the primary headache disorders and of medication-overuse headache (Table). There are no useful diagnostic tests. The history should elicit any warning features of a serious secondary headache disorder.

### Warning features in the history

Any new headache in an individual patient, or a significant change in headache characteristics, should be treated with caution.

Specific warning features are:

- thunderclap headache (intense headache with “explosive” or abrupt onset) (suggests subarachnoid haemorrhage)
- headache with atypical aura (duration >1 hour, or including motor weakness) (may be symptoms of TIA or stroke)
- aura without headache in the absence of a prior history of migraine with aura (may be a symptom of TIA or stroke)
- aura occurring for the first time in a patient during use of combined oral contraceptives (indicates risk of stroke)
- new headache in a patient older than 50 years (may be a symptom of temporal arteritis or intracranial tumour), or in a pre-pubertal child (requires specialist referral and diagnosis)
- progressive headache, worsening over weeks or longer (may indicate intracranial space-occupying lesion)
- headache aggravated by postures or manoeuvres that raise intracranial pressure (may indicate intracranial tumour)
- new headache in a patient with a history of cancer, HIV infection or immunodeficiency (likely to be secondary headache).

### Diagnostic diary

Once serious causes have been ruled out, a headache diary kept over a few weeks clarifies the pattern of headaches and associated symptoms as well as medication use or overuse.

### Physical examination of headache patients

Migraine, tension-type headache, cluster headache and medication-overuse headache are diagnosed solely on history. Signs are present in cluster headache patients when seen during attacks. Physical examination is mandatory when the history is suggestive of secondary headache.

### Warning features on examination

- pyrexia associated with headache
- focal neurological signs associated with headache

### Investigation of headache patients

Investigations, including neuroimaging, are indicated when the history or examination suggest headache may be secondary to another condition.

### Table Questions to ask in the history

**How many different headaches types does the patient have?** A separate history is needed for each.

#### Time questions

- Why consulting now?
- How recent in onset?
- How frequent, and what temporal pattern (episodic or daily and/or unremitting)?
- How long lasting?

#### Character questions

- Intensity of pain?
- Nature and quality of pain?
- Site and spread of pain?
- Associated symptoms?

#### Cause questions


- Predisposing and/or trigger factors?
- Aggravating and/or relieving factors?
- Family history of similar headache?

#### Response questions

- What does the patient do during the headache?
- How much is activity (function) limited or prevented?
- What medication has been and is used, in what manner and with what effect?

#### State of health between attacks

- Completely well, or residual or persisting symptoms?
- Concerns, anxieties, fears about recurrent attacks and/or their cause?

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### 3. Typical features of the common headache disorders

#### Migraine

Migraine occurs in two principal subtypes, migraine without aura and migraine with aura. One patient may have both.

#### *Migraine without aura*

**Adults** with this disorder typically describe:

- recurrent episodic moderate or severe headaches which:
  - are often unilateral and/or pulsating
  - last 4 hours to 3 days
  - are often associated with nausea and/or vomiting
  - are aggravated by routine physical activity
- during which they limit activity and prefer dark and quiet
- with freedom from symptoms between attacks.

#### **In children:**

- attacks may be shorter-lasting
- headache is more commonly bilateral and less usually pulsating
- gastrointestinal disturbance is more prominent.

#### *Migraine with aura*

Migraine with aura affects one third of people with migraine and accounts for 10% of migraine attacks overall. It is characterised by aura preceding headache, consisting of one or more neurological symptoms that develop gradually over >5 minutes and resolve within 60 minutes:

- hemianopic visual disturbances, or a spreading scintillating scotoma (patients may draw a jagged crescent if asked)
- and/or unilateral paraesthesiae of hand, arm and/or face
- and/or (rarely) dysphasia.

Otherwise similar to migraine without aura.

Typical aura without headache may occur in patients with a past history of migraine with aura.

#### Tension-type headache

This disorder occurs in three subtypes. Only two of these are

medically important: frequent episodic tension-type headache and chronic tension-type headache.

#### Frequent episodic tension-type headache:

- occurs in attack-like episodes, at least once a month, lasting hours to a few days
- can be unilateral but is more often generalised
- is typically described as pressure or tightness like a vice or tight band around the head, or is felt in the neck
- lacks the associated symptom complex of migraine.

#### Chronic tension-type headache

- occurs by definition on  $\geq 15$  days a month for >3 months and may be daily and unremitting
- otherwise is similar to frequent episodic tension-type headache.

#### Cluster headache

This highly recognisable condition occurs in two subtypes, episodic cluster headache and chronic cluster headache.

Episodic cluster headache occurs in bouts (clusters), typically of 6-12 weeks' duration, once a year or two years, and then remits until the next cluster.

Chronic cluster headache, which persists without remissions, is less common. It may develop from and/or revert to episodic cluster headache.

#### Cluster headache:

- mostly affects men
- manifests as strictly unilateral, excruciating pain around the eye
- recurs frequently, typically once or more daily, commonly at night
- is short-lasting, for 15-180 minutes (typically 30-60 minutes)
- has highly characteristic and strictly ipsilateral autonomic features including any of:
  - red and watering eye
  - running or blocked nostril
  - ptosis
- causes marked agitation (the patient, unable to stay in bed, paces the room, even going outdoors).

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**Summary of features distinguishing the common headache disorders** (NB: two or more may occur concomitantly)

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	Migraine	Tension type headache (TTH)	Cluster headache (CH)
<b>Temporal pattern</b>	recurrent attack-like episodes, lasting 4 hours to 3 days;  frequency often 1-2/month but variable from 1/year to 2/week;  freedom from symptoms between attacks	<b>Episodic TTH:</b> recurrent attack-like episodes lasting hours to a few days;  1-14 days affected per month;  freedom from symptoms between attacks  <b>Chronic TTH:</b> ≥15 days affected per month (often daily and unremitting)	<b>Episodic CH:</b> short-lasting attacks (15-180 minutes) recurring frequently (typically ≥1 daily) in bouts of 6-12 weeks' duration once a year or two years, and then remitting  <b>Chronic CH:</b> similar, but without remissions between bouts
<b>Typical headache characteristics</b>	often unilateral and/or pulsating	can be unilateral but more often generalised; may be felt in the neck;  typically described as pressure or tightness	strictly unilateral, around the eye
<b>Headache intensity</b>	typically moderate to severe	typically mild to moderate	very severe
<b>Associated symptoms</b>	often nausea and/or vomiting;  often photo- and/or phonophobia	none  (mild nausea, but not vomiting, may accompany chronic TTH)	strictly ipsilateral autonomic features: any of red and watering eye, running or blocked nostril, ptosis
<b>Reactive behaviour</b>	avoidance of physical activity (maybe bed rest); preference for dark and quiet	none specific	marked agitation

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### Medication-overuse headache

Medication-overuse headache, a chronic daily headache syndrome, is an aggravation of a prior headache (usually migraine or tension-type headache) by chronic overuse of medication taken to treat headache or other pain.

All acute headache medications may have this effect. Frequency, regularity and duration of intake are important determinants of risk.

A history can be elicited of increasingly frequent headache episodes, with increasing medication use, over months to many years.

### Medication-overuse headache

- is associated with:
  - regular use of simple analgesics on ≥15 days a month and/or
  - regular use of opioids, ergots or triptans, or any combination of these, on ≥10 days a month
- occurs daily or near-daily
- is present – and often at its worst – on awakening in the morning
- is initially aggravated by attempts to withdraw the medication.

Diagnosis of medication-overuse headache is confirmed if symptoms improve within 2 months after overused medication is withdrawn.



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#### **4. Differential diagnosis of the common headache disorders**

Each of the primary headaches is in the differential diagnosis of each of the others. Medication-overuse headache is in the differential diagnosis of migraine and tension-type headache.

Otherwise, the differential diagnosis includes a small number of serious secondary headaches that are important to recognise.

Warning features in the history or on examination

- headache that is new or unexpected in an individual patient, or develops new features
- thunderclap headache (intense headache with abrupt or “explosive” onset) (may be indicative of subarachnoid haemorrhage)
- headache with atypical aura (duration >1 hour, or including motor weakness) (may be symptoms of TIA or stroke)
- aura without headache in the absence of a prior history of migraine with aura (may be a symptom of TIA or stroke)
- aura occurring for the first time in a patient during use of combined oral contraceptives (indicates risk of stroke)
- new headache in a patient older than 50 years (may be a symptom of temporal arteritis or intracranial tumour) or in a pre-pubertal child (requires specialist referral for diagnosis)
- progressive headache, worsening over weeks or longer (may indicate intracranial space-occupying lesion)
- headache associated with or aggravated by postural change or other manoeuvres that raise intracranial pressure (may indicate intracranial tumour)
- new headache in a patient with a history of cancer, HIV infection or immunodeficiency (likely to be secondary headache)
- otherwise unexplained pyrexia associated with headache (may indicate meningitis)
- focal neurological signs associated with headache (suggests secondary headache)

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## 5. General aspects of headache management

The following principles are generally important for all headache disorders managed in primary care.

### Acknowledging impact

- Recurrent disabling headache is a burden on the person with it, and has an impact on other people. These include the family, work colleagues and employer.
- Recurrent disabling headache may lead to lifestyle compromise, either in response to attacks or in a bid to avoid them. In this way, episodic headache can have continuous impact.

The HALT index developed by *Lifting The Burden* (Appendix 1) is an instrument for assessing burden in terms of lost time.

### Realistic aims of management

- Headache disorders cannot be cured but can be effectively managed in most cases.
- They usually remit in old age.

### Reassurance and explanation

- Many people with recurrent headache wrongly fear underlying disease. Appropriate reassurance should never be omitted.
- Explanation is a crucial element of preventative management in patients with migraine or frequent episodic tension-type headache who are at risk of escalating medication consumption.

A series of patient information leaflets developed by *Lifting The Burden* (Appendix 2) are currently available in Danish, Dutch, English, French, German, Italian, Portuguese and Spanish. They provide basic explanations of migraine, tension-type headache, cluster headache and medication-overuse headache and their treatment.

### Causes and triggers

- Whilst patients want to know the cause of their headache,

this may not be possible. Both genetic and environmental factors contribute to processes that are not well understood.

- Many patients seek help in identifying triggers. The importance of trigger factors in migraine is over-emphasised. When they are relevant to individual patients, they are usually self-evident. Triggers may be less readily identified when they are cumulative in their effect, jointly contributing to a “threshold” above which attacks are initiated. Even when identified, triggers are not always avoidable.
- Contrary to popular belief, there is no “migraine diet”. The only dietary triggers with evidential support are alcohol and monosodium glutamate.

### Follow-up

Every patient to whom treatment is offered, or whose treatment is changed, requires follow-up in order to ensure that optimum treatment has been established.

The use of an outcome measure is recommended. The HART index (Appendix 1) is expressly to guide follow-up in primary care.

Persistent management failure is an indication for specialist referral.


### Diaries and calendars

*Diaries are recommended for:*

- recording symptoms and temporal patterns that contribute to correct diagnosis
- recording medication use and overuse
- revealing associations with the menstrual cycle and other triggers.

*Calendars are recommended for:*

- encouraging compliance with prophylactic medication
- recording treatment effect
- monitoring acute medication use or overuse during follow-up
- charting outcomes.

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## 6. Advice to patients

Patients with headache disorders commonly request information. Many find or have found misleading information on the internet.

Non-drug treatments

Patients enquiring about the following may be given this advice:

- **Biofeedback and relaxation therapies** can be helpful, and are potentially useful options when drug treatments must be avoided. Their basis requires that only skilled therapists should provide them, but very few skilled therapists are available in most countries.
- **Physiotherapy** has proven benefits in some patients with tension-type headache. It requires skilled and individualised therapy which is not widely available in many countries.
- **Acupuncture** benefits some people with migraine or tension-type headache although large clinical trials have failed to distinguish between acupuncture and sham procedures. It requires skilled and individualised therapy.
- **Transcutaneous electrical nerve stimulation (TENS)** may help in chronic pain but is of unproven value in treating headache disorders.
- **Herbals** are mostly not recommended. Butterbur has some efficacy according to clinical trials and is approved for use in some countries but preparations on sale elsewhere are variable in content and have uncertain toxicity. Feverfew preparations on sale everywhere are highly variable in content and their toxicity is not well understood.
- **Homoeopathy** is of unproven value. There is no arguable case for over-the-counter sales of homoeopathic remedies.
- **Reflexology** has no scientific basis.
- **Devices:** many are on the market, some costly and promoted with unsupportable claims of efficacy. “Testimonials” can be attributed to placebo effect and should be disregarded.

- **Cold packs** applied to the head and/or neck are found by some people to relieve pain or discomfort.
- **Dental treatment**, including splints and bite-raising appliances, is of unproven value in treating headache and should be discouraged for this purpose.
- **Spectacles** should be professionally prescribed and worn when needed, but refractive errors are rarely a cause of troublesome headache.
- **Closure of patent foramen ovale (PFO):** there is insufficient evidence to support the hypothesis that migraine frequency is improved by PFO closure, a procedure which carries a small but relevant risk of serious adverse events including stroke, pericardial tamponade, atrial fibrillation and death. Further prospective trials are underway, and PFO closure should not be undertaken for migraine prophylaxis outside these trials.
- **Other surgical procedures on the face or neck** produce no benefit and are potentially harmful.

Hormonal contraception and HRT

Headache is often a side-effect of combined oral contraceptives (COCs) and many women report onset or aggravation of migraine after starting them.

The following advice on hormonal contraception may be given to patients with migraine:

- both migraine with aura and the ethinyloestradiol component of COCs are independent risk factors for stroke in young women
- alternatives to COCs are recommended for women with migraine with aura and additional risk factors for stroke (including smoking)
- progestogen-only contraception is acceptable with any subtype of migraine.

Hormone replacement therapy (HRT) is not contraindicated in migraine; decisions about commencing or continuing HRT should be made according to generally applicable criteria.


### Resources for the patient

*Lifting The Burden* has produced a series of patient information leaflets on the common headache disorders and their treatment and one on female hormones and headache (Appendix 2). These are currently available in Danish, Dutch, English, French, German, Italian, Portuguese and Spanish.

### World Headache Alliance

WHA is a charitable umbrella organisation. Its website carries much information for people with headache, and links to many other helpful sites including those of its member organisations in 26 countries.

**For more information, visit [www.w-h-a.org](http://www.w-h-a.org)**

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## 7. Medical management of acute migraine

All adults with migraine should have access to acute medication.

Children with short-lasting attacks may respond well to bed-rest without medical treatment.

In adults and children, *regular* use of acute medication at high frequency (on >2 days/week) risks the development of medication-overuse headache.

### Drug intervention

All patients should climb a treatment ladder (*stepped management*), usually treating three attacks at each step before proceeding to the next. This strategy, if followed correctly, reliably achieves the most effective and cost-effective individualised care.

#### *Step one: symptomatic therapy*

- simple analgesic
- plus, if needed, an antiemetic.

Analgesics	Antiemetics
acetylsalicylic acid 900-1000 mg (adults only) <i>or</i> ibuprofen 400-800 mg <i>or</i> diclofenac 50-100 mg <i>or</i> ketoprofen 100 mg <i>or</i> naproxen 500-1000 mg <i>or</i> (where these are contraindicated) paracetamol 1000 mg	domperidone 20 mg <i>or</i> metoclopramide 10 mg

Local guidelines may recommend trying more than one analgesic in step one before proceeding to step two.

Paracetamol has limited evidence of efficacy and is not first-line treatment.

#### *Principles of step one*

- use soluble analgesics, or mouth-dispersible formulations
- take early in the attack, in adequate dosage
- a prokinetic antiemetic inhibits gastric stasis, an early feature of migraine that impairs bioavailability of oral medication
- rectal administration may be preferable in the presence of vomiting:
  - analgesic suppositories (any of diclofenac 100 mg, ibuprofen 400 mg, ketoprofen 100-200 mg or naproxen 500-1000 mg)
  - if needed, antiemetic suppositories (either domperidone 30 mg or metoclopramide 20 mg).

#### *Step one for children (when needed)*

- analgesic: ibuprofen 200-400 mg according to age and weight
- antiemetic: domperidone 10-20 mg according to age and weight.

#### *Step two: specific therapy*

##### Specific anti-migraine drugs, formulations and doses available for step two (availability varies from country to country)

almotriptan	tablets 12.5 mg
eletriptan	tablets 20 mg and 40 mg (80 mg may be effective when 40 mg is not)
frovatriptan	tablets 2.5 mg
naratriptan	tablets 2.5 mg
rizatriptan	tablets 10 mg (and 5 mg, to be used when propranolol is being taken concomitantly); mouth-dispersible wafers 10 mg
sumatriptan	tablets and rapidly dissolving tablets 50 mg and 100 mg; suppositories 25 mg; nasal spray 10 mg (licensed for adolescents) and 20 mg; subcutaneous injection 6 mg
zolmitriptan	tablets 2.5 mg and 5 mg; mouth-dispersible tablets 2.5 mg and 5 mg; nasal spray 5 mg
ergotamine tartrate	tablets 1 mg and 2 mg; suppositories 2 mg

### *Principles of step two*

- where available, and unless contra-indicated, triptans should be offered to all patients failing step one
- ergotamine has very low and unpredictable bioavailability, which impairs its efficacy, and complex pharmacology and long duration of action, which lead to poor tolerability
- triptans should not be used regularly on more than 10 days per month to avoid the risk of medication-overuse headache
- triptans differ slightly, but there are large and unpredictable individual variations in response to them; one may work where another has not; patients should try several, in different formulations, and choose between them
- the initial dose of all oral triptans (except, in some cases, eletriptan) is one tablet
- a second dose for non-response is not recommended by most triptan manufacturers but, taken not less than 2 hours after the first, may be effective in some cases
- triptans are more effective when taken whilst headache is still mild (this instruction should be given only to patients who can reliably distinguish migraine from tension-type headache)
- when nausea is present, domperidone 20 mg or metoclopramide 10 mg may be added
- when vomiting is present, sumatriptan suppositories, zolmitriptan nasal spray (absorbed through the nasal mucosa) or sumatriptan subcutaneous injection may be preferred
- when all other triptans are ineffective, sumatriptan by subcutaneous injection 6 mg should be considered
- triptans are associated with return of symptoms within 48 hours (relapse) in up to 40% of patients who have initially responded.

### *Treatment of relapse*

- a second dose of a triptan is usually effective
- this second dose may lead to further relapse (when this happens repeatedly, the triptan should be changed)
- NSAIDs may be an effective alternative.

### *Avoidance of relapse*

- limited evidence suggests that either of the following may prevent some relapses:
  - concomitant use of a triptan and an NSAID
  - use of a triptan followed by an NSAID 6-12 hours later.

### *Contraindications to step two*

Pregnancy is a general contraindication to ergotamine and to all triptans. There are specific precautions attached to some triptans (see pharmacopoeia).

All triptans and ergots should be avoided by people with:

- uncontrolled hypertension
- coronary heart disease, cerebrovascular disease and peripheral vascular disease
- multiple risk factors for coronary or cerebrovascular disease.

### *Step two for children*


No specific anti-migraine drug has been shown to have efficacy in children (under 12 years old). Failure of step one is an indication for specialist referral.

### *Follow-up*

Every patient to whom treatment is offered, or whose treatment is changed, requires follow-up in order to ensure that optimum treatment has been established. Use of a calendar is recommended to monitor acute medication use or overuse and record treatment effect. The use of an outcome measure is recommended. The HART index (Appendix 1) is expressly to guide follow-up in primary care. Failure of acute therapy may be an indication for prophylaxis (see Management aid #8. *Prophylactic management of migraine*).

### *Information for patients*

*Lifting The Burden* has produced an information leaflet on migraine and its treatment (Appendix 2). This is currently available in Danish, Dutch, English, French, German, Italian, Portuguese and Spanish.

	in conjunction with	<b><i>Lifting The Burden</i></b>
	<b>European principles of management of common headache disorders in primary care</b>	

## 8. Prophylactic management of migraine

Any patient whose quality of life is impaired by migraine, whether adult or child, may require prophylaxis in addition to acute medication.

Indications for prophylaxis

Prophylactic therapy may be *added* when:

- attacks cause disability on two or more days per month, *and*
- optimised acute therapy does not prevent this, *and*
- the patient is willing to take daily medication.

Other indications for prophylaxis are:

- risk of over-frequent use of acute therapy, even when it is effective (but prophylactic drugs are inappropriate for medication-overuse headache)
- for children with frequent absences from school.

Effective drugs

**Prophylactic drugs with good evidence of efficacy**  
(availability and regulatory approval vary from country to country; use of drugs off-licence rests on individual clinical responsibility)

beta-adrenergic blockers without partial agonism	atenolol 25-100 mg bd or bisoprolol 5-10 mg od or metoprolol 50-100 mg bd or propranolol LA 80 mg od-160 mg bd
topiramate	25 mg od-50 mg bd
flunarizine	5-10 mg od
sodium valproate	600-1500 mg daily
amitriptyline	10-100 mg nocte

All of these drugs have contra-indications and side-effects (refer to pharmacopoeia).

### *Principles of prophylaxis*

- A calendar should be kept by every patient on prophylaxis to assess efficacy and promote compliance.
- Poor compliance is a major factor impairing efficacy of migraine prophylactics; once-daily dosing is associated with better compliance.
- The dose of any drug should start low in the suggested range and be increased in the absence of troublesome side-effects.
- Drugs that appear ineffective should not be discontinued too soon; 2-3 months may be the minimum to achieve and observe efficacy.
- Failure of one drug does not predict failure of others in a different class.
- Tapered withdrawal may be considered after 6 months of good control, and should be considered no later than after 1 year.
- Amitriptyline may be preferred when migraine coexists with tension-type headache, depression or sleep disturbance.
- Propranolol has best evidence of safety during pregnancy.

### *Prophylaxis in children*

- Beta-blockers (dosage adjusted according to body weight) or flunarizine (dosage adjusted according to age) may be tried.

### Follow-up

Every patient to whom prophylactic treatment is offered, or whose treatment is changed, requires follow-up in order to ensure that optimum treatment has been established.

Use of a calendar is recommended to encourage compliance with prophylactic medication and record treatment effect.

The use of an outcome measure is recommended. The HART index (Appendix 1) is expressly to guide follow-up in primary care.

### *If prophylaxis fails*

- failure may be due to subtherapeutic dosage or insufficient duration of treatment
- review the diagnosis

- review compliance
- review other medication, especially for overuse
- when prophylaxis still fails to have clear benefit, discontinue it
- if all options fail, specialist referral is indicated.

Information for patients

*Lifting The Burden* has produced an information leaflet on migraine and its treatment (Appendix 2). This is currently available in Danish, Dutch, English, French, German, Italian, Portuguese and Spanish.

#### *Hormonal contraception and HRT*

Many women report onset or aggravation of migraine after starting combined oral contraceptives (COCs). Others report improvement of pre-existing migraine.

The following advice on hormonal contraception may be given:

- both migraine with aura and the ethinyloestradiol component of COCs are independent risk factors for stroke in young women
- alternatives to COCs are recommended for women with migraine with aura and additional risk factors for stroke (including smoking)

- progestogen-only contraception is acceptable with any subtype of migraine.

Hormone replacement therapy (HRT) is not contraindicated in migraine. Decisions about commencing or continuing HRT should be made according to generally applicable criteria.

*Lifting The Burden* has produced an information leaflet on female hormones and headache (Appendix 2).

#### *Botulinum toxin (Botox)*

Patients may ask about this treatment.

There is insufficient evidence to support the efficacy of Botox in migraine prevention. This treatment is not currently recommended.

#### *Patent foramen ovale (PFO) and migraine*

Patients may ask about this treatment.

There is insufficient evidence to support the hypothesis that migraine frequency is improved by PFO closure. This procedure carries a small but relevant risk of serious adverse events including stroke, pericardial tamponade, atrial fibrillation and death. Further prospective trials are underway. PFO closure should not be undertaken for migraine prophylaxis outside these trials.



	in conjunction with	<b><i>Lifting The Burden</i></b>
	<b>European principles of management of common headache disorders in primary care</b>	

## 9. Medical management of tension-type headache

Drug therapy has limited scope in tension-type headache but, within these limitations, is effective in many patients. *Either* acute medication or prophylaxis may be indicated. Acute medication should be used with care when headache is frequent because of the risk of medication overuse.

### Acute intervention

- Symptomatic treatment with over-the-counter analgesics is appropriate for episodic tension-type headache occurring on  $\leq 2$  days per week:
  - acetylsalicylic acid 600-1000 mg (adults only)
  - ibuprofen 400-800 mg
  - paracetamol 1000 mg is less effective.
- Episodic tension-type headache on  $>2$  days per week is an indication for prophylaxis in place of, rather than in addition to, acute intervention.
- These treatments are unlikely to be effective in chronic tension-type headache and put the patient at risk of medication-overuse headache.

### *Principles of acute intervention*

- Opioids should be avoided; in particular:
  - codeine and dihydrocodeine
  - dextropropoxyphene
  - combination analgesics containing any of these.
- Barbiturates have no place in the treatment of tension-type headache.
- As the frequency of headaches increases, so does the risk of medication overuse.

### Prophylaxis

- Amitriptyline, 10-100 mg at night, is the drug of choice for frequent episodic or chronic tension-type headache.
- Nortriptyline causes fewer anticholinergic side-effects but has less good evidence of efficacy (amitriptyline can be replaced by nortriptyline at the same dose).

### *Principles of prophylaxis*

- Intolerance is reduced by starting at a low dose (10 mg) and incrementing by 10-25 mg each 1-2 weeks.
- A calendar should be kept to assess efficacy and promote compliance.
- Prophylaxis that appears ineffective should not be discontinued too soon; 2-3 months may be the minimum to achieve and observe efficacy.
- Tapered withdrawal may be considered after 6 months of good control, but prolonged treatment is sometimes indicated.

### Follow-up

Every patient to whom treatment is offered, or whose treatment is changed, requires follow-up in order to ensure that optimum treatment has been established. Use of a calendar is recommended to monitor acute medication use or overuse, or to encourage compliance with prophylactic medication, and to record treatment effect. The use of an outcome measure is recommended. The HART index (Appendix 1) is expressly to guide follow-up in primary care.

### *If prophylaxis fails*

- failure may be due to subtherapeutic dosage or insufficient duration of treatment
- review the diagnosis
- review compliance (patients who are not informed that they are receiving medication often used as an antidepressant, and told why, may default when they find out)
- review other medication, especially for overuse
- when prophylaxis still fails to have clear benefit, discontinue it
- if all options fail, specialist referral is indicated.

### Pain management

Despite best efforts, chronic tension-type headache is often refractory to medical treatment.


Patients in this situation require a pain management programme with emphasis on psychological approaches.

## Information for patients

*Lifting The Burden* has produced an information leaflet on tension-type headache and its treatment (Appendix 2). This is currently available in Danish, Dutch, English, French, German, Italian, Portuguese and Spanish.

*Botulinum toxin (Botox)*

Patients may ask about this treatment. There is insufficient evidence to support the efficacy of Botox in tension-type headache. This treatment is not currently recommended.

	in conjunction with	<b><i>Lifting The Burden</i></b>
	<b>European principles of management of common headache disorders in primary care</b>	

## 10. Medical management of cluster headache

Cluster headache management is usually better left to experienced specialists who see this disorder frequently. Recognition in primary care is crucial to ensure prompt referral. The objective in both episodic and chronic cluster headache is total attack suppression. This is not always achievable. Both acute medication and prophylaxis have a role in management, but preventative drugs are the mainstay of treatment in most cases.

### Acute therapies

- Sumatriptan 6 mg subcutaneously is the only proven highly-effective acute treatment, but cannot be recommended for use more than twice a day.
- Oxygen 100% at  $\geq 7$  l/min for up to 15 min (requires a non-rebreathing mask and regulator) helps some people and may be used as frequently as needed.
- Analgesics, including opioids, have no place in treating cluster headache.

### Prophylaxis

#### *Principles*

- drugs in the table are used by specialists, balancing efficacy against toxicity
- prophylaxis of episodic cluster headache should begin as early as possible after the start of a new cluster bout and (except for prednisolone, which is used in short courses only) should be discontinued by tapering 2 weeks after full remission
- for chronic cluster headache, treatments may need to be continued long-term
- failure of one drug does not predict failure of others
- combinations may be tried, but the potential for toxicity is obviously high.

### Drugs used by specialists in cluster headache prophylaxis (all are potentially toxic: refer to pharmacopoeia)

verapamil 240-960 mg daily	ECG monitoring is advised
prednisolone 60-80 mg od for 2-4 days, discontinued by dose reduction over 2-3 weeks	may need repeating because of relapse during dose reduction
lithium carbonate 600-1600 mg daily	levels must be monitored
ergotamine tartrate 2-4 mg daily per rectum	usually omitted every 7th day may not be used concomitantly with sumatriptan
methysergide 1-2 mg tds	usage interrupted for at least 1 month in every 6 months not recommended to be used concomitantly with sumatriptan

### Follow-up

Every patient with active cluster headache requires frequent follow-up both to ensure that optimum treatment is maintained and to monitor for treatment toxicity.

### Information for patients

*Lifting The Burden* has produced an information leaflet on cluster headache and its treatment (Appendix 2). This is currently available in Danish, Dutch, English, French, German, Italian, Portuguese and Spanish.

	in conjunction with	<b><i>Lifting The Burden</i></b>
	<b>European principles of management of common headache disorders in primary care</b>	

### 11. Management of medication-overuse headache

Medication-overuse headache is an aggravation of a prior primary headache by chronic overuse of medication taken to treat it.

Once this condition has developed, early intervention is important. The long-term prognosis depends on the duration of medication overuse.

#### Management

- Prevention, through education, is better than cure.
- The only effective treatment of established medication-overuse headache is withdrawal of the suspected medication(s).

#### Objectives

There are four separate objectives in the complete management of MOH, and all are important:

- the first is to achieve withdrawal from the overused medication
- the second, which should follow, is recovery from MOH
- the third is to review and reassess the underlying primary headache disorder (migraine or tension-type headache)
- the fourth is to prevent relapse.

#### Principles

- clear explanation that the “treatment” a patient is taking for headache is actually the *cause* of it is vital to success
- patients may be reassured that the outcome of withdrawal is usually good
- with forewarning, withdrawal is most successfully done abruptly; admission to hospital is rarely necessary.
- withdrawal leads initially to worsening headache, so

should be planned to avoid unnecessary lifestyle disruption (1-2 weeks’ sick leave may be needed)

- after 1-2 weeks, usually, headache shows signs of improvement
- recovery continues slowly for weeks to months.

#### Follow-up

- every patient withdrawing from medication requires follow-up in order to provide support and observe outcome
- first review is advised after 2-3 weeks to ensure withdrawal has been achieved
- use of a calendar is strongly recommended to record symptoms and medication use during withdrawal, and to record changing headache pattern
- most patients revert to their original headache type (migraine or tension-type headache) within 2 months; this will need review and appropriate management
- further follow-up is important to avoid relapse, and most patients require extended support: the relapse rate is around 40% within five years.

#### Re-introducing withdrawn medication

- withdrawn medications should subsequently be avoided as far as is possible
- when needed, they may be cautiously reintroduced after 2 months
- frequency of use should never exceed 2 days/week on a regular basis.

#### Information for patients

*Lifting The Burden* has produced an information leaflet on medication-overuse headache and its management (Appendix 2). This is currently available in Danish, Dutch, English, French, German, Italian, Portuguese and Spanish.

	in conjunction with	<b><i>Lifting The Burden</i></b>
	<b>European principles of management of common headache disorders in primary care</b>	

## 12. Headache management in primary care: when to refer

Most primary headaches, and medication-overuse headache, can best be managed in primary care.

Reasons for specialist referral:

- diagnostic uncertainty after due enquiry
- diagnosis of cluster headache (most cases are best managed by specialists)
- suspicion of serious secondary headache, or cases where investigation may be necessary to exclude serious pathology (referral may need to be immediate):
  - any headache that is new or unexpected in an individual patient, but especially:
    - newly-occurring thunderclap headache (intense headache with abrupt or “explosive” onset)
    - new headache in a patient older than 50 years
    - new headache in a pre-pubertal child

- new headache in a patient with a history of cancer, HIV infection or immunodeficiency
- unusual migraine aura, especially:
  - aura with duration >1 hour
  - aura featuring motor weakness
  - aura without headache in the absence of a prior history of migraine with aura
  - aura first occurring with use of combined oral contraceptives
- progressively worsening headache over weeks or longer
- headache associated with postural change indicative of high or low intracranial pressure
- headache associated with unexplained fever
- headache associated with unexplained physical signs
- persistent management failure
- comorbid disorders requiring specialist management
- presence of risk factors for coronary heart disease may warrant cardiological referral prior to use of triptans.

T.J. Steiner

**The HALT and HART indices**

T.J. Steiner  
Chairman: Global Campaign  
Committee *Lifting The Burden*

**Introduction**

Assessment of a headache disorder as a prelude to planning best management requires more than diagnosis: there should be some measure or estimation of the impact of the disorder on the patient's life and lifestyle.

There are many ways in which recurrent or persistent headache can damage life. Finding a simple measure that summarises these in a single index, and which is equally applicable for all of the common headache disorders, is quite a challenge. The MIDAS instrument developed by Stewart and Lipton [1] has proved extremely useful. The concept behind it is simple enough: it estimates active time lost through the disabling effect of headache, and the result is expressed by a number with intuitively meaningful units (hours).

The HALT index is a direct and close derivative of MIDAS. It was developed by *Lifting The Burden* to use wording that is more easily translated.

Whenever treatment is started, or changed, follow-up ensures that optimum treatment has been established or recognizes that it has not and identifies any further change to treatment that may be needed.

It is not always easy to know whether or not the outcome that has been achieved by an individual patient is the best that the patient can reasonably expect. For the non-specialist, one question that sometimes arises is: "What further effort, in hope of a better outcome, is justified?" A second question, which follows if it is thought

that more should be done, may be "What is it that needs changing?"

An international working group\* of *Lifting The Burden* is developing the Headache Under-Response to Treatment (HURT) index, an outcome measure that is designed to aid management by suggesting answers to these two questions. This index will be published later, elsewhere. The instrument that is included here is its forerunner, pending validation. To distinguish between them, it is referred to as the Headache and Assessment of Response to Treatment (HART) index.

**\*Lifting The Burden Working group on Outcome Measures:**

R. Lipton (chairman) (USA), M. Al Jumah (Saudi Arabia), B. Eggleston (Australia), M. Fontebasso (UK), L. Gardella (Argentina), R. Jensen (Denmark), H. Kettinen (Finland), M.J.A. Láinez (Spain), F. Mennini (Italy), M. Peters (Netherlands/UK), K. Ravishankar (India), F. Sakai (Japan), N. Sharma (India), T.J. Steiner (UK), W. Stewart (USA), A.D. Tehindrazanarivelo (Madagascar/France), D. Valade (France), M. Von Korff (USA), S.Y. Yu (PR China)

**Reference**

1. Stewart WF, Lipton RB, Kolodner K et al (2000) Validity of the Migraine Disability Assessment (MIDAS) score in comparison to a diary-based measure in a population sample of migraine sufferers. *Pain* 88:41–52

## *Lifting The Burden*

# **The Global Campaign to Reduce the Burden of Headache Worldwide**

A partnership in action between the World Health Organization, World Headache Alliance,  
International Headache Society and European Headache Federation

## **HALT Index\* (Headache-Attributed Lost Time)**

**Your doctor or nurse may give you this short questionnaire before starting treatment. Please answer the five simple questions. This will help your doctor or nurse understand how much your headaches are affecting your life, and guide your medical treatment.**

**Please answer these questions carefully**

- 1** On how many **days** in the **last three months** could you **not go** to work or school because of your headaches?
- 2** On how many **days** in the **last three months** could you do **less than half** your usual amount in your job or schoolwork because of your headaches? (Do not include days you counted in question 1 where you missed work or school)
- 3** On how many **days** in the **last three months** could you not do any household work because of your headaches?
- 4** On how many **days** in the **last three months** could you do **less than half** your usual amount of household work because of your headaches? (Do not include days you counted in question 3 where you did not do household work.)
- 5** On how many **days** in the **last three months** did you **miss** family, social or leisure activities because of your headaches?

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**Grading** (I-IV indicate, in order, increasing need for medical care; either III or IV indicates high need)

- |   |           |
|---|-----------|
| <b>0-5</b> Minimal or infrequent impact | Grade I   |
| <b>6-10</b> Mild or infrequent impact   | Grade II  |
| <b>11-20</b> Moderate impact            | Grade III |
| <b>20+</b> Severe impact                | Grade IV  |

**TOTAL**

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\* HALT is closely based on the first five questions of MIDAS, developed by R.B. Lipton and W.F. Stewart

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A partnership in action between the World Health Organization, World Headache Alliance, International Headache Society and European Headache Federation

## HART Index (Headache and Assessment of Response to Treatment)

Your medical treatment for your headaches may not be as good as it can be. By completing this short questionnaire, you will help your doctor or nurse improve it.

Please answer these questions carefully

**1** On how many **days** in the **last month** did you have a headache?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
none	1-2	3-5	6-15	16-30

**2** On how many **days** in the **last three months** did your headaches make it hard to work, study or carry out household work?

<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
none	1-5	6-10	11-20	21+

**3** On how many **days** in the **last three months** did your headaches spoil or prevent your family, social or leisure activities?

<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
none	1-5	6-10	11-20	21+

**Analysis** (these questions establish frequency of all headaches and of disabling headaches under current treatment; ticks towards the right suggest increasing need for treatment review)

All ticks in white area

Headache control is good: no review needed.

One or more ticks in lightly-shaded area

Better acute headache management is needed; review Qs 4-8 for guidance; prophylaxis may not be required.

One or more ticks in middle-shaded area

Headache control is not good; review Qs 4-8 to optimise acute medication; consider ways of reducing frequency (trigger avoidance and prophylactic medication).

One or more ticks in darkly-shaded area

Disabling headache, poorly treated; possibly chronic daily headache (acute medication should be avoided); review Qs 4-8 and consider ways of reducing frequency.



**4** On how many **days** in the **last month** did you take medication to **relieve** a headache?  
(Do not count preventative medication)

<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
none	1-4	5-9	10-15	16-30

**5** When you take your headache medication, does one dose get rid of your headache and keep it away?

<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
always	often	sometimes	rarely	never

**6** Are you able to take your headache medication without being bothered by side effects?

<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
always	often	sometimes	rarely	never

**7** Do you feel in control of your headaches?

<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
always	often	sometimes	rarely	never

**8** What have you been told is your headache diagnosis?

please write your diagnosis here:

<input type="checkbox"/>	<input checked="" type="checkbox"/>
yes	no

Do you feel you understand it?

**Analysis** (these questions suggest how current management might be improved)

**Q4:** Response should accord with Q1. When medication days are >10, there is risk of medication-overuse headache.

Advise patient about the risk and dangers of medication overuse. Consider ways to reduce frequency (trigger avoidance and prophylactic medication).

**Q5:** Ticks towards the right increasingly suggest poor efficacy

Consider treating earlier, changing medication, dose or route of administration, or using combination therapy, according to local guidelines.

**Q6:** Ticks towards the right increasingly suggest poor tolerability.

Consider changing medication or dose according to local guidelines.

**Q7:** This question relates to self-efficacy and to satisfaction. The response should be concordant with previous responses.

When the response is in the shaded area, look for the reason(s) in responses to Qs 1-6. If it is not evident, consider co-morbidities. When the response is not concordant, consider cognitive interventions and expectation management.

**Q8:** This question relates to education.

Always hand out the appropriate information leaflet. When the diagnosis is wrongly stated, or the answer "no" is given, further explanation may be necessary.

T.J. Steiner

T.J. Steiner  
Chairman: Global Campaign  
Committee *Lifting The Burden*

## Information for Patients

### Introduction

Headache management is facilitated if the patient understands his or her headache disorder and the treatment being proposed for it. Compliance is improved and a better outcome is likely. Explanation takes time, which is often not available, but it should not be omitted.

A writing group\* of *Lifting The Burden* is developing a series of Patient Information Leaflets to be handed to patients at time of diagnosis. These include leaflets on each of the four important headache disorders in primary care (migraine, tension-type headache, cluster headache and medication-overuse headache). A fifth leaflet explains some of the relationships between female hormones and headache, which commonly raise questions from patients. All of these are published in the following pages. The writing group includes an international review panel of headache specialists, primary care physicians and patient representatives whose task is to ensure cross-cultural relevance in these leaflets.

### **\*Lifting The Burden Writing and review group for Patient Information Leaflets:**

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## *Lifting The Burden*

# **The Global Campaign to Reduce the Burden of Headache Worldwide**

A partnership in action between the World Health Organization, World Headache Alliance, International Headache Society and European Headache Federation

## **Information for people affected by migraine**

**Headache disorders are real – they are not just in the mind. If headache bothers you, it needs medical attention. The purpose of this leaflet is to help you understand your headache, your diagnosis and your treatment, and to work with your doctor or nurse in a way that will get best results for you.**

### **What is migraine?**

**"When I get migraine it makes me very ill and really puts me out of action for the entire day or more. I can feel one coming on and then the full blown migraine emerges and I feel wretched and need to go to bed. As it progresses, I feel sick and eventually I am sick and then, finally, the pain begins to lessen. The next day I'm left with a vague pain and feel absolutely exhausted but otherwise okay."**

Migraine is a medical disorder. It takes place in attacks, once or twice a year in some people but up to several times a month in others. The main feature of these attacks is headache, which may be severe. Other common features are feeling sick (nauseated) or being sick (vomiting) and finding light and noise uncomfortable.

If you feel nauseated when you have a headache, or light and noise bother you, or if your headache makes it difficult to carry out your usual daily activities, it is quite likely that it is migraine.

### *What causes migraine?*

Migraine comes from the brain. It is a disorder of the parts of the brain that process pain and other sensations. You probably inherited it from one or other parent or from a grandparent.

### *Who gets migraine?*

About one in seven adults have migraine, so it is very common. Women are three times more likely to be affected than men. It often starts in childhood or adolescence. In girls in particular it may start at puberty. Because of inheritance, migraine runs in families.

### *What are the different types of migraine?*

The commonest is *migraine without aura* (aura is described later). About three-quarters of people with migraine have only this type; one in 10 have *migraine with aura*, and twice this many have both types from time to time. Much less common are attacks of aura alone, with no headache. This type of migraine tends to develop in older people. There are other types of migraine, but these are rare.

### *What are the symptoms of migraine?*

Symptoms are present during the attack, which has four stages, although not all of these always happen. Between attacks, most people with migraine are completely well.

The *premonitory* phase comes before any other symptoms of the attack. Only half of people with migraine are aware of this phase. If you are one of these, you may feel irritable, depressed or tired for hours or even one or two days before the headache begins. However, some people find they are unusually energetic during this time. Some have food cravings. Others "just know" that a migraine attack is about to start.

The *aura*, when it happens, is almost always the next phase. Only a third of people with migraine ever have aura, and it may not be part of every attack even for them. Aura is a signal from the brain, which is being temporarily (but not seriously) affected by the migraine process. It lasts, usually, for 10 to 30 minutes, but can be longer. It mostly affects vision. You may notice blank patches, bright or flashing lights or coloured zigzag lines spreading in front of your eyes, usually to one side. Less common are sensory symptoms – pins-and-needles or numbness – which generally start in the fingers of one hand, and spread up the arm to affect that side of the face or tongue. When these happen, there are

nearly always visual symptoms as well. Difficulty speaking or finding the right words can also be part of the aura.

The *headache phase* is the most troublesome for most people, lasting for a few hours or up to two or three days. Migraine headache is often severe. It tends to be one-sided, but can be on both sides, and although most commonly at the front or in the temple it can be anywhere in the head. It is usually a throbbing or pounding headache, very often made worse by movement. You probably feel nauseated, and may vomit (which seems to relieve the headache). You may also find light and noise unpleasant and prefer to be alone in the dark and quiet.

The *resolution phase* follows as the headache fades. During this time you may again feel tired, irritable and depressed, and have difficulty concentrating. It can take a further day before you feel fully recovered.

#### *What is my “migraine threshold”?*

Migraine is unpredictable. An attack can start at any time. However, some people are more prone to attacks than others. The higher your *migraine threshold*, the less likely you are to develop an attack, and the lower your threshold the more at risk you are.

So-called *triggers* play a part in this. A trigger will set off an attack (although we do not understand how this happens). It does this more easily if your migraine threshold is low. If your threshold is high, two or three triggers may need to come together for this to happen.

Separate from triggers are *predisposing factors*. These have the effect of lowering your threshold, so that triggers work more easily. Tiredness, anxiety and general stress have this effect, as can menstruation, pregnancy and the menopause in women.

#### *What are the triggers?*

Everyone wants to know what might trigger his or her migraine. This is often difficult and sometimes impossible to pin down because triggers are not the same for everybody, or even always the same for different attacks in the same person. Many people with migraine cannot identify any triggers. Possible triggers are many and varied.

**Diet:** some foods (and alcohol), but only in some people; more commonly, delayed or missed or inadequate meals, caffeine withdrawal and becoming dehydrated.

**Sleep:** changes in sleep patterns, both lack of sleep and sleeping in.

**Other life-style:** intense exercise, or long-distance travel, especially across time zones.

**Environmental:** bright or flickering lights, strong smells and marked weather changes.

**Psychological:** emotional upset or, surprisingly, relaxation after a stressful period.

**Hormonal factors in women:** menstruation; breaks in hormonal contraception or hormone-replacement therapy

(HRT).

The commonest trigger is hunger, or not enough food in relation to needs. This is particularly the case in young people – children prone to migraine should never miss breakfast. In women, hormonal changes associated with the menstrual cycle are important potential triggers.

These, and most other triggers, represent some form of *stress*, and suggest that people with migraine do not respond well to change.

#### *What treatment can I take?*

Medications that treat the migraine attack are called acute treatments. The right ones can be very effective, but need to be taken correctly and not overused. They include non-prescription painkillers, most of which contain aspirin, ibuprofen or paracetamol. Of these, paracetamol is least effective for most people. In all cases, soluble or effervescent preparations work faster and better.

You can also take medicine called an anti-emetic if you feel nauseated or likely to vomit. Some anti-emetics actually help the painkillers by causing your body to absorb them more quickly. You can have these as suppositories if you feel very nauseated during migraine attacks.

Your pharmacist can give you advice on the best non-prescription treatments to take. If none of these works for you, or you need more than the recommended dose, the pharmacist may suggest you should ask for medical advice.

Your doctor may prescribe one of the specific anti-migraine treatments. You should try these when painkillers and anti-emetics do not relieve your symptoms and get you back into action reasonably quickly. They work quite differently. They do not tackle pain but undo what is happening in your brain to cause an attack. They include ergotamine, widely used in some countries but not others, and a group of newer drugs called triptans. If your doctor advises it, you can use these drugs together with painkillers, anti-emetics or both.

There are some simple measures that can make medication more effective.

#### *Take medication early ...*

Always carry at least one dose of the medication that has been recommended by your doctor, nurse or pharmacist. Take it as soon as you know an attack is coming on. Medication taken early is more likely to work well. During a migraine attack the stomach is less active, so tablets taken by mouth are not absorbed as well into the bloodstream as they would be normally. Eat something if you can, or drink something sweet.

#### *... but not too often*

Always carefully follow the instructions that come with your medication. In particular, do not take acute treatment too often because you can give yourself a headache from the treatment. This is called *medication-overuse headache*, and

there is a separate leaflet on it which you can ask for if you are worried about it. To avoid this happening, never take medication to treat headache symptoms *regularly* on more than two or three days a week.

*What if these don't work?*

If frequent or severe attacks are not well controlled with acute treatment, so-called *prophylactic* medication is an option. Unlike acute treatment, you *should* take this daily because it works in a totally different way – by preventing the migraine process starting. In other words, it raises your migraine threshold.

Your doctor or nurse can give you advice on the choice of medicines available and their likely side-effects. Most were first developed for quite different conditions, so do not be surprised if you are offered a medication described as treatment for high blood pressure, epilepsy or even depression. This is *not* why you are taking it. These medications work against migraine too.

If you are taking one of these, do follow the instructions carefully. Research has shown that a very common reason for this type of medication not working is that patients forget to take it.

*What else can I do to help myself?*

Exercising regularly and keeping fit will benefit you. Avoiding predisposing and trigger factors is sensible, so you should be aware of the full range of possible triggers. You may be able to avoid some triggers even if there are others

that you find difficult or impossible to control.

*Keep a diary*

Diary cards can record a lot of relevant information about your headaches – how often you get them, when they happen, how long they last and what your symptoms are. They are valuable in helping with diagnosis, identifying trigger factors and assessing how well treatments work.

*What if I think I may be pregnant?*

You will need advice from your doctor or nurse. Some of the medications used for migraine are unsuitable if you are pregnant.

*Do I need any tests?*

Most cases of migraine are easy to recognize. There are no tests to confirm the diagnosis, which is based on your description of your headaches and the lack of any abnormal findings when your doctor examines you. A brain scan is unlikely to help. If your doctor is at all unsure about the diagnosis, he or she may ask for tests to rule out other causes of headaches, but these are not often needed.

*Will my migraine get better?*

There is no known cure for migraine. However, for most people with migraine, attacks become less frequent in later life. Meanwhile, doing all you can to follow the advice in this leaflet can make the change from a condition that is out of control to one that you can control.

**For more information, visit [www.w-h-a.org](http://www.w-h-a.org)**

## *Lifting The Burden*

# **The Global Campaign to Reduce the Burden of Headache Worldwide**

A partnership in action between the World Health Organization, World Headache Alliance, International Headache Society and European Headache Federation

## **Information for people affected by tension-type headache**

**Headache disorders are real – they are not just in the mind.**

**If headache bothers you, it needs medical attention. The purpose of this leaflet is to help you understand your headache, your diagnosis and your treatment, and to work with your doctor or nurse in a way that will get best results for you.**

### **What is tension-type headache?**

**"I get headaches that last for several days at a time and feel as though I'm wearing a hat that's too tight - more like a pressure than a real pain. It doesn't really stop me doing anything, but it's much harder to get through the day."**

Tension-type headache is the common sort of headache that nearly everyone has occasionally. Although never serious, it can make it difficult to carry on entirely as normal. In a few people, it becomes bothersome enough to need medical attention, usually because it has become frequent.

### *Who gets tension-type headache?*

Tension-type headache affects most people from time to time, but women more than men. It also affects children.

### *What are the different types of tension-type headache?*

*Episodic tension-type headache* is often referred to as "normal" or "ordinary" headache. It happens in attacks (*episodes*) that last for anything from half an hour to several days. The frequency of these varies widely between people, and in individual people over time.

In about three people in every 100, tension-type headache happens on more days than not. This is *chronic tension-type headache*, which is one of the chronic daily headache syndromes (there is a separate leaflet about these which you can ask for if you wish). In some cases, tension-type headache is always present – it may ease but never goes completely. This type of headache can be quite disabling and distressing.

### *What are the symptoms of tension-type headache?*

Usually, tension-type headache is described as a squeezing or pressure, like a tight band around the head or a cap that is too tight. It tends to be on both sides of the head, and often spreads down to or up from the neck. The pain is usually moderate or mild, but it can be severe enough to prevent everyday activities. Generally there are no other symptoms, although some people with tension-type headache dislike bright lights or loud noises, and may not feel like eating much.

### *What causes tension-type headache?*

Tension-type headache is generally thought of as a headache affecting or arising from muscles and their connections. Its causes appear to be many and varied. However, there are some factors that are more important than others:

**Emotional tension:** this can be anxiety, or stress;

**Physical tension** in the muscles of the scalp and neck: this may be caused by poor posture, for example when working at a computer, or by lifting a heavy object incorrectly.

### *What can I do to help myself?*

**Relax.** Taking a break, having a massage or a warm bath, going for a walk or taking exercise to get you away from the normal routine may help.

**Cope with stress.** If you have a stressful job, or are faced with a stressful situation that you cannot avoid, try breathing and relaxation exercises to prevent a possible headache. There are many audiotapes to guide you in these exercises.

**Take regular exercise.** Tension-type headache is more com-

mon in people who do not take much exercise compared with those who do. Try walking wherever possible, or take stairs rather than the lift, so that exercise becomes a routine part of your life.

**Treat depression.** If you feel that you are depressed more often than not, it is important to ask for medical advice and get effective treatment.

#### *Keep a diary*

Diary cards can record a lot of relevant information about your headaches – how often you get them, when they happen, how long they last and what your symptoms are. They are valuable in helping with diagnosis, identifying trigger factors and assessing how well treatments work.

#### *Take painkillers if needed ...*

Simple painkillers such as aspirin or ibuprofen usually work well in episodic tension-type headache. Paracetamol is less effective but suits some people.

#### *... but not too often*

Medication only treats the symptoms of tension-type headache. This is perfectly acceptable if you do not get many. To manage frequent headache over the long term, it is better to try to treat the cause.

Always carefully follow the instructions that come with your medication. In particular, do not take painkillers too often because you can give yourself a worse headache from the treatment. This is called medication-overuse headache, and a separate leaflet on it is available if you are worried about it. To avoid this happening, never take medication to treat headache regularly on more than two or three days a week.

#### *What other treatments are there?*

If you have frequent episodic tension-type headache, or more so if you have chronic tension-type headache, painkillers are not the answer. They will only make things worse over time. So-called *prophylactic* medications are an option. Unlike painkillers, you *should* take these every day because they work in a wholly different way. Their purpose is to make you less prone to headache and so prevent headache from even starting.

Your doctor or nurse can advise on the choice of medicines

available and their likely side-effects. Most were first developed for quite different conditions, so do not be surprised if you are offered a medication described as treatment for depression or epilepsy, or as a muscle relaxant. This is *not* why you are taking it. These medications work in tension-type headache too, as they do in other painful conditions.

If you are taking one of these, do follow the instructions carefully. Research has shown that a very common reason for this type of medication not working is that patients forget to take it. Because posture sometimes plays a role in tension-type headache, and because of the muscles involved, your doctor or nurse may suggest physiotherapy to the head and neck. This can help some people greatly.

Other non-drug approaches include transcutaneous electrical nerve stimulation (TENS) (which is a treatment for pain), relaxation therapy including biofeedback or yoga, and acupuncture. These are not suitable for everybody, do not work for everyone, and are not available everywhere. Again, your doctor or nurse will give you advice.

#### *Will these treatments work?*

If the cause is identified and treated, episodic tension-type headache rarely continues to be a problem. Very often, it improves on its own, or the cause goes away, and no further treatment is needed.

For some people, especially with chronic tension-type headache, these treatments do not help or only partially help. If all else fails, you may be referred to a pain clinic which uses a wider range of treatments.

#### *Do I need any tests?*

There are no tests to confirm the diagnosis of tension-type headache. This is based on your description of the headaches and the lack of any abnormal findings when you are examined. Be sure to describe your symptoms carefully. Also tell your doctor how many painkillers or other medications you are taking for your headaches, and how often you are taking them.

A brain scan is unlikely to help. If your doctor is at all unsure about the diagnosis, he or she may ask for tests to rule out other causes of headaches, but these are not often needed. If your doctor does not ask for any, it means they will not help to give you the best treatment.

**For more information, visit [www.w-h-a.org](http://www.w-h-a.org)**

## *Lifting The Burden*

# **The Global Campaign to Reduce the Burden of Headache Worldwide**

A partnership in action between the World Health Organization, World Headache Alliance, International Headache Society and European Headache Federation

## **Information for people affected by cluster headache**

**Headache disorders are real – they are not just in the mind.**

**If headache bothers you, it needs medical attention. The purpose of this leaflet is to help you understand your headache, your diagnosis and your treatment, and to work with your doctor or nurse in a way that will get best results for you.**

### **What is cluster headache?**

**"They often wake me in the middle of the night, a couple of hours after I've gone to bed. They build up in a matter of seconds and the pain is just excruciating. It's only in my right eye, like a red hot poker. I don't know where to put myself. I have to do something to distract from the pain. Sometimes I pace up and down the room holding my head, or just sit in the chair and rock."**

Cluster headache is the name given to short-lasting attacks of very severe one-sided head pain, usually in or around the eye. These usually start without warning, one or more times every day, generally at the same times each day or during the night. Quite often, the first one will wake the person up an hour or so after falling asleep.

Cluster headache is sometimes said to be a type of migraine, but this is not so. It is a quite distinct headache and needs different treatment from migraine.

### *Who gets cluster headache?*

Cluster headache is not common. It affects up to three in every 1,000 people. Men are five times more likely than women to have cluster headache, which makes it unusual among headache disorders. The first attack is likely to happen between the ages of 20 and 40, but cluster headache can start at any age.

### *What are the different types of cluster headache?*

*Episodic cluster headache* is more common. This type hap-

pens daily for limited periods (*episodes*) and then stops, a feature giving rise to the term "cluster". Usually these periods last from six to 12 weeks, but they can end after two weeks or go on for anything up to six months. They tend to come at about the same time each year, often spring or autumn, but some people have two or three episodes every year and others have gaps of two or more years between episodes.

In between, people with episodic cluster headache have no symptoms of the condition at all.

*Chronic cluster headache*, which accounts for about one in 10 cases of cluster headache, does not stop. Daily or near-daily attacks continue year after year without a break.

Episodic cluster headache can turn into chronic cluster headache, and vice versa.

### *What are the symptoms of cluster headache?*

There are a highly recognizable group of symptoms. Most importantly, cluster headache is excruciatingly painful. The pain is strictly one-sided and always on the same side (although in episodic cluster headache it can switch sides from one episode to another). It is in, around or behind the eye and described as searing, knife-like or boring. It becomes worse very quickly, reaching full force within five to 10 minutes, and when untreated lasts between 15 minutes and three hours (most commonly between 30 and 60 minutes). In marked contrast to migraine, during which most people want to lie down and keep as quiet as possible, cluster headache causes agitation. People with this condition cannot keep still – they will pace around or rock violently



backwards and forwards, even going outside. Also, the eye on the painful side becomes red and waters and the eyelid may droop. The nostril feels blocked, or runs. The other side of the head is completely unaffected.

*What causes cluster headache?*

Despite a great deal of medical research into the cause of cluster headache, it is still not known. Much interest centres on the timing of attacks, which appears to link to circadian rhythms (the biological clock). Recent research has highlighted changes in a part of the brain known as the hypothalamus, the area that controls the body clock.

Many people with cluster headache are or have been heavy smokers. How this may contribute to causing cluster headache, if it does, is not known. Stopping smoking is always a good thing for health reasons, but it rarely has any effect on the condition.

*What are the triggers?*

So-called *triggers* set off a headache attack. Alcohol, even a small amount, may trigger an attack of cluster headache during a cluster episode but not at other times. We do not understand how this happens. There do not appear to be other common trigger factors.

*Do I need any tests?*

Because of its set of symptoms, cluster headache is easy to recognize. There are no tests to confirm the diagnosis, which is based on your description of the headaches and other symptoms and the lack of any abnormal findings when your doctor examines you. Therefore, it is very important to describe your symptoms carefully.

If your doctor is not sure about the diagnosis, tests including a brain scan may be carried out to rule out other causes of headaches. However, these are not often needed. If your doctor does not ask for a brain scan, it means that it will not help to give you the best treatment.

*What treatments are there?*

There are a number of treatments for cluster headache which often work well. They all need a doctor's prescription. The most usual treatments for the attack are 100% oxygen, which needs a cylinder, high-flow regulator and mask from a supplier, or an injected drug called sumatriptan, which you can give to yourself using a special injection device.

Preventative medications are the best treatments for most people with cluster headache. You take these every day for the length of the cluster episode to stop the headaches returning. They are effective, but you do need rather close medical supervision, often with blood tests, because of the possible side-effects. You may be referred to a specialist for this. The referral should be urgent because, if you have this condition, we know you are suffering greatly.

*What if these don't work?*

There are a range of preventative medications. If one does not work very well, another may. Sometimes, two or more are used together.

*What can I do to help myself?*

Ordinary painkillers do not work – they take too long, and the headache will usually have run its course before they take effect. For effective treatment, you will need to ask for medical help. Do this at the start of a cluster episode, as treatment appears to be more successful when started then.

*Keep a diary*

You can use diary cards to record a lot of relevant information about your headaches – how often you get them, when they happen, how long they last and what your symptoms are. They are valuable in helping with diagnosis, identifying trigger factors and assessing how well treatments work.

*Will my cluster headache get better?*

Cluster headache may return for many years. However, it seems to improve in later life for most people, particularly those with chronic cluster headache.

**For more information, visit [www.w-h-a.org](http://www.w-h-a.org)**

## *Lifting The Burden*

# **The Global Campaign to Reduce the Burden of Headache Worldwide**

A partnership in action between the World Health Organization, World Headache Alliance, International Headache Society and European Headache Federation

## **Information for people affected by chronic daily headache**

**Headache disorders are real – they are not just in the mind.**

**If headache bothers you, it needs medical attention. The purpose of this leaflet is to help you understand your headache, your diagnosis and your treatment, and to work with your doctor or nurse in a way that will get best results for you.**

### **What is chronic daily headache?**

**"I began to get headaches which would come on in the middle of the afternoon. I could carry on working through them but it was hard to concentrate. I found that a couple of painkillers would ease the headache. The headaches started to get more frequent and now I take painkillers most days. My head never seems to clear completely."**

*Chronic daily headache* is not a diagnosis. It is a convenient description given to headache that happens on 15 or more days every month for more than three months.

#### *What are the different types of chronic daily headache?*

There are several different types of chronic daily headache, and they are generally defined by their causes. *Chronic tension-type headache* and *medication-overuse headache* are the most common. There is a separate leaflet on tension-type headache if you would like it. Medication-overuse headache (see below) can develop from migraine or tension-type headache.

#### *Who gets chronic daily headache?*

It is surprisingly common. About one in 20 people develop this problem at some time in their lives. It is more common in women than men, and it also happens in children.

#### *What are the symptoms of chronic daily headache?*

The main feature is very frequent headache. This varies, but is often a dull pain. Other common symptoms, along-

side headache, are feeling tired, feeling sick, being irritable and difficulty sleeping. Sometimes headache seems relentless, although it may change as you go through the day. Medication-overuse headache is often at its worst on waking in the morning.

#### *Will my chronic daily headache get better?*

How chronic daily headache is treated depends on the diagnosis and the cause. Getting the right treatment is very important, so medical care is usually necessary.

All types of chronic daily headache may be temporarily relieved by painkillers or anti-migraine treatments, but in many cases this relief is only partial and the effect diminishes over time. These treatments are not appropriate because they will make the condition worse.

If your headache is already being caused by overusing medication of this sort, then it is likely to improve once you stop taking the medication, and not otherwise.

#### *Do I need any tests?*

Whatever the type of chronic daily headache, there are no tests to confirm the diagnosis. This is based on your description of your headaches and the lack of any abnormal findings when you are examined. Therefore, it is very important that you carefully describe your symptoms and how they developed. It is also very important that you say how many painkillers or other medications you are taking for your headaches, and how often you are taking them. Your doctor should be able to tell quite easily whether you have an illness more serious than chronic daily headache. If he or she is not sure about the diagnosis, or there is any

sudden change in your headache, tests including a brain scan may be carried out to rule out other causes of your headache. However, these are not often needed. If your doctor does not ask for a brain scan, it means that it will not help to give you the best treatment.

#### *What is medication-overuse headache?*

Any medication you use to treat the symptoms of headache, when taken too often for too long, can cause medication-overuse headache. Aspirin, paracetamol, ibuprofen, codeine - in fact, all painkillers, even those bought over the counter - are associated with this problem. And it is not just painkillers. Drugs that specifically treat migraine headache also lead to this problem when used too often. These include triptans and, most of all, ergotamine.

A similar headache (although not strictly medication-overuse headache) can result from taking too much caffeine. The usual source of this is coffee, tea or cola drinks, but it can come from caffeine tablets or from caffeine included in many painkillers.

The exact way medication-overuse headache develops is not known, and may be different according to the nature of the medication. Triptans and ergotamine may cause a rebound effect, with headache returning after they wear off. Painkillers are believed to cause, over time, a change in pain-signalling systems in the brain. This means they become used to the effects of the medication so that you need more and more of it.

**For most people with occasional headaches, painkillers are a safe and effective treatment.** However, medication-overuse headache may develop in anyone taking headache treatments regularly on more than three days a week. Usually, the person with medication-overuse headache begins with occasional attacks of tension-type headache or (more commonly) migraine. For varying reasons, the headaches begin to happen more often. This may be through natural variation or because an extra headache has developed, perhaps due to stress or muscular pain. The increase in headache leads to use of more medication to try to control the symptoms, eventually until both happen every day.

Many people in this situation know that they are taking more medication than is wise, and try to reduce the amount. This leads them to have a withdrawal syndrome of worsening headache, for which they take more medication. It is easy to see how this results in a vicious cycle, which can be difficult to break. It makes not so much difference how *much* you take – if you regularly use the full dose of painkillers on one or two days a week only, you are unlikely to develop medication-overuse headache. However, take just a couple of painkillers on most days and you may well be making your headaches worse. It is *frequent* use over a period of time that causes the problem.

#### *What can I do to help myself?*

The **only** way of treating this condition is to stop the overused medication (*withdrawal*). Clinical studies show that most people who withdraw from overused medication improve greatly. However, it can take up to three months before you see the full benefit. Even if headaches continue after that time, despite stopping the medication, their cause usually becomes clear and they will respond better to correctly-prescribed specific treatment.

You can withdraw either by stopping in one go or by gradually reducing the amount taken over two to three weeks. Whichever way you choose, drink plenty of fluids while doing this (but avoid taking more caffeine). If you stop in one go, you will almost certainly have withdrawal symptoms – worsening headache, feeling sick, perhaps being sick, anxiety and difficulty sleeping. These symptoms will appear within 48 hours and may last, at worst, for up to two weeks. However, people who try to stop slowly seem more likely to fail, perhaps because it takes so much longer.

It makes sense to choose when to withdraw, and not begin shortly before an important event. Do warn your work colleagues that you may be unable to come into work for a few days.

#### *What if I just carry on as I am?*

If medication overuse is causing your frequent headaches, carrying on as you are is not an option. You will continue to have ever-more frequent headaches, which will not respond to painkillers or to preventative medicine. Eventually you may do yourself other harm as well, such as damage to your liver and kidneys.

#### *Are there other treatments I can take?*

There are medications, which a doctor can prescribe, that you can take every day to help you withdraw. They work only if you stop all other headache medication, and even then it is uncertain how much they help. You will also have to stop these at some point, and, for most people, it is better to do without them.

#### *How can I make sure it doesn't happen again?*

As it develops, medication-overuse headache largely replaces the original headache (migraine or tension-type headache) for which you took the medication in the first place. This means that, as your medication-overuse headache improves after withdrawal, you can expect your original type of headache to return.

There are separate leaflets on both migraine and tension-type headache. You may find one of these useful at this stage.

If you need to, you can cautiously restart using medication for this headache once the pattern of headache has returned to normal. This is likely to be after at least several weeks. Be careful, because there is a risk of following the same path as

before. To prevent this, avoid treating headaches on more than three days in a row or on a regular basis on three or more days in a week. Always read the leaflet and packaging that come with any medicine.

If a headache doesn't get better, or keeps returning, never continue taking medication without consulting your doctor or nurse.

**See your doctor or nurse if frequent headaches do not go, or if they return again in the future.**

*Keep a diary*

You can use diary cards to record a lot of relevant information about your headaches – how often you get them, when they happen, how long they last and what your symptoms are. They are valuable in helping with diagnosis and in assessing how well treatments work.

For people at risk of medication-overuse headache, diaries are especially important as they help keep track of just how much medication you are taking.

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## *Lifting The Burden*

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A partnership in action between the World Health Organization, World Headache Alliance, International Headache Society and European Headache Federation

## **Information on female hormones for women with headache**

**Headache disorders are real – they are not just in the mind.**

**If headache bothers you, it needs medical attention.**

**The changing pattern of hormones throughout a woman’s life, from puberty to the menopause, has an important effect on migraine and other headaches. Knowing what to expect can help women understand why headaches occur and, importantly, when to seek help.**

### **Headache and women’s hormones**

**Given the strong influence of hormones on headache in women, you may wonder why doctors do not do any hormone tests. The simple answer is that no tests are able to show doctors the cause of the problem.**

The relationships between female hormones and the processes that cause headaches, or make them better or worse, are very complex. Even when hormones are clearly a factor in headache problems, all the standard hormone tests are usually normal. Studies measuring hormone levels show no differences between women with headaches triggered by hormonal changes and women without a hormonal trigger.

#### *Headache, migraine and puberty*

Puberty is the time when a girl begins to produce hormones in a monthly cycle that leads to the start of menstruation. This is therefore the time when hormones may first influence headaches. Although migraine can start at any age, in the one in every six women who will have this disorder, puberty commonly brings about its onset.

#### *Headache and the menstrual cycle*

Many women notice a link between headaches and their menstrual cycle. Headaches are typically more frequent and more severe in the days around the menstrual period. At the same time, there may be mood changes, water reten-

tion and other premenstrual symptoms, which improve as the period starts.

Migraine is also affected by the menstrual cycle, and in some women is triggered by the natural drop in levels of the hormone estrogen that happens just around the time of the menstrual period. Other hormones that change with the menstrual cycle, such as prostaglandins, which are released just before and during a period, may also be an important trigger. This is particularly likely in women who get migraine only on the first or second day of bleeding. So-called “menstrual migraine” can be more severe than headaches at other times of the month, so take your migraine treatments early. Your doctor can give you prescription-only drugs to control the symptoms of migraine but, if necessary, consider options to prevent menstrual attacks. No drugs are sold specifically for prevention of menstrual migraine, but there are some that often work well. The choice of drug depends on any other period problems you have that may benefit from treatment, so this is something to discuss with your doctor or nurse.

#### *Headaches and contraception*

Hormonal contraception, such as combined hormonal contraceptives (pills, patches, rings and injectable preparations), is very safe for the majority of women who use it. This is equally true for most women with migraine. Many women find that combined hormonal contraceptives have no effect upon their headaches – or even help them. Even so, headaches are a commonly reported side-effect of these

medications. In most cases, headaches of this sort improve after a few months, and they are rarely a reason to stop contraception.

Women who have *migraine without aura* before they start the contraceptive pill often notice that they get their attacks during the pill-free interval. During the pill-free week, estrogen levels drop – just as they do for menstrual migraine, and with the same effect.

Combined hormonal contraceptives should not be given to women with *migraine with aura*. This is because the estrogen in the contraceptives can increase the risk of a stroke. If 100,000 women under the age of 35 who have migraine aura started using combined hormonal contraception, we would expect around 28 to have a stroke within the next year. If the same group did not have migraine and did not use combined hormonal contraception, only one woman would be expected to have a stroke within the next year.

Although the risk of a stroke is very low in women younger than 50, it is sensible not to increase it since there are many choices of other methods of contraception. Several of these are even more effective contraceptives than the combined hormonal methods, so the increased risk is entirely avoidable.

If a woman with *migraine without aura* starts to have *migraine with aura* after beginning combined hormonal contraceptives, she should stop taking them immediately. Furthermore, she should seek medical advice – particularly since she may also need emergency contraception. There is a separate leaflet explaining what migraine without aura and migraine with aura are. Ask your doctor or nurse if you would like to have this.

Progestogen-only methods (pills, implants, injectable preparations and intrauterine methods) do not increase the risk of a stroke but have varying effects on headaches. Most evidence suggests that, if the method “switches off” normal periods, headaches usually improve.

#### *Headaches, pregnancy and breastfeeding*

Fortunately, most women find that headaches improve during the latter part of pregnancy. This is especially likely for *migraine without aura*. The benefit may continue through breastfeeding.

In the first few months of pregnancy, however, headaches may be worse. One reason is that sickness, particularly when it is severe, can reduce food and fluid intake and result in low blood sugar and dehydration. If this happens to you, try to eat small, frequent carbohydrate snacks and drink plenty of fluids. Adequate rest is important to avoid over-tiredness. Other preventative measures that can safely be tried include acupuncture, biofeedback, massage and relaxation techniques.

Women who have *migraine with aura* before they become pregnant are more likely to continue to have attacks during

pregnancy. If migraine happens for the first time during pregnancy, it is likely to be *migraine with aura*.

There is no evidence that headaches or migraine, either with or without aura, have any effect on the outcome of pregnancy or on the baby's growth and development. It is, of course, important to make sure that any treatments taken for headaches are safe. Few drugs have been tested for safety in pregnancy and during breastfeeding. In fact, paracetamol (when used correctly) is the only medication shown to be safe throughout pregnancy and breastfeeding. Unfortunately this is not the most effective treatment, especially for migraine, and even paracetamol should not be taken too often. However, there are other medications that can be taken under medical supervision. If you feel you need to take any other drugs for headaches, check with your doctor first.

#### *Headaches, the menopause and hormone replacement therapy (HRT)*

In the years leading up to the menopause, the ovaries produce less and less estrogen. During this time of hormonal imbalance, migraine and other headaches often become more frequent or severe. For most women, they settle again after the menopause, possibly because the hormonal fluctuations stop and the concentration of estrogen stabilises at a lower level.

Few studies have looked at the effect of HRT on headaches, but the decision to take HRT or not can be made regardless of headaches. Unlike the synthetic estrogens in contraceptives, the natural estrogens in HRT do not appear to increase the risk of a stroke in women with *migraine with aura*. It is reported that migraine is more likely to worsen with oral HRT and improve with non-oral HRT such as patches or gels. Too high an estrogen dose can trigger migraine aura, which calls for a reduction in dose. Whichever type of HRT you start with, it is important to give it an adequate trial; the first three months are a time of imbalance as the body becomes used to the change of hormones.

Many women use non-prescription remedies to treat hot flushes. There is some evidence that dietary estrogens (isoflavones such as in soya products) help menopausal symptoms as well as migraine, so it is worth increasing intake of foods rich in soya.

#### *Headaches and hysterectomy*

Hysterectomy is of no benefit in the treatment of hormonal headaches. The normal menstrual cycle is the result of the interaction of several different organs in the body. These include organs in the brain in addition to the ovaries and the womb. Removing the womb alone has little effect on the hormonal fluctuations of the menstrual cycle even though the periods stop.

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*What can I do to help myself?*

If you think that your headaches are worse with hormonal changes, the first thing to do is to keep a record of the dates of the first day of each period and the dates of each day of headache. After a few months, look back over the records and see if you can establish any patterns. This will tell you if hormones are having an important effect.

Remember to look at the other causes of headaches. Think

about other possible trigger factors. These may still be part of the problem even if hormones are too – and you may be able to avoid them.

When you do start a headache, particularly migraine, do not delay taking treatment; if you leave it too late, it may be less helpful. If your treatments are not effective enough to allow you to continue your usual daily activities, take your diary to your doctor and discuss further options.

**For more information, visit [www.w-h-a.org](http://www.w-h-a.org)**

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## Translation protocols

### Introduction

As *Lifting The Burden* sets objectives and plans activities worldwide, the documents it develops, initially in English, must be made accessible in many languages. The importance of rigorous translation of written materials used in medical management is increasingly recognized and advocated [1,2]. Quality-controlled translations following standardized protocols increase the likelihood of linguistic and conceptual equivalence between the translated products, essential if they are to be comparable cross-culturally. Three different types of documents exist: lay documents (such as information leaflets for patients); technical documents (information for professionals, such as management guidelines); and hybrid documents (aimed at people with headache but to be used either in clinical practice or in research, such as the HALT and HART indices).

A working group\* of *Lifting The Burden* has designed translation protocols for each of these types. The members of the group either were translation specialists or were knowledgeable about translation issues and the Global

Campaign. Their task was to write protocols that would ensure the rigour and quality of translations and were pragmatic and suitable for use in different cultures. All translations of *Lifting The Burden* materials should follow one or other of these protocols as closely as possible.

### \**Lifting The Burden* Working group for translations:

M. Peters (chairman), UK; J.M. Bertolote, Switzerland; C. Houchin, UK; T. Kandoura, UK; T.J. Steiner, UK.

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### References

1. Peters M, Passchier J (2006) Translating Instruments for cross-cultural studies in headache research. *Headache* 46:82–91
2. Wild D, Grove A, Martin M et al (2005) Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: Report of the ISPOR task force for translation and cultural adaptation. *Value in Health* 8:94–104



## *Lifting The Burden*

# **The Global Campaign to Reduce the Burden of Headache Worldwide**

A partnership in action between the World Health Organization, World Headache Alliance, International Headache Society and European Headache Federation

## **Translation protocol for technical documents**

**These guidelines have been developed by the Translation Working Group for the translation of documents (hereafter called “technical documents”) produced by *Lifting The Burden* and aimed at health-care professionals.**

Translations of all technical documents should follow these guidelines to ensure a high quality of translation and to be approved by the Translation Working Group.

Translation should follow five steps.

### **1. Coordination of the translation**

A translation coordinator, who oversees but does not carry out the translation, is selected according to the following criteria:

- a headache expert;
- bilingual in English and the target language (ideally a native speaker and a resident of the country of the target language);
- has ability to mediate between different translators and to understand the points of view of lay and professional translators.

If the coordinator is not a native speaker, a referee (native speaker) must be nominated. The referee cannot be involved in the translation process, and is called upon to arbitrate should irreconcilable views amongst translators prevent the production of a consensus-based translation.

The tasks of the coordinator include:

- selecting the translators and assessors (and referee if necessary);
- organising and overseeing the translation, including meeting with the translators to produce a consensus-based translation;
- organising and overseeing the quality assurance of the translation;
- producing the report of the translation process.

### **2. Translation into target language**

Two independent translations into the target language of the original document must be produced.

The two translations may be carried out by two individual translators, by two pairs of translators (one translates and the second of the pair reviews the translation) or by two independent panels of translators (with 3-4 members in each panel). If a translator pair or a panel is used, one person should be named chairman and is responsible for liaising with the translation coordinator. The two individuals, pairs or panels may not confer with each other until each has produced their translation.

Translators are selected according to the following criteria:

- native speakers of the target language;
- at least one (individual, pair or panel) must be headache expert(s) or primary-care physician(s), according to the intended audience of the document;
- (ideally, the other is a professional translator or bilingual person, pair or panel skilled in language/linguistics, such as a teacher or journalist; if no such translator is available, then a second headache expert or primary-care physician [individual, pair or panel] may be used).

Translators are instructed to:

- keep translations professional, using technical language;
- make semantic and conceptual translations (rather than literal), so that the meanings of the words and phrases remain as in the original document;
- avoid invention (adding their own ideas to the text);
- keep a record of any parts that they found difficult to translate.

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### 3. Production of a consensus-based translation

The coordinator works with the two translators, or the named chairmen of the translation pairs or panels, to reconcile differences between the two translations and produce a consensus-based translation. There are three steps to this process:

- the translators each send their translations to the coordinator;
- the coordinator makes an initial comparison of the two translations and highlights and records any parts of them that are substantially different;
- the coordinator and translators (or chairmen) meet (or, alternatively, hold a teleconference) to discuss these parts and any other problem areas, agreeing through consensus on one translation.

If the translators cannot reach a consensus on any part, the coordinator, if a native speaker, makes the final decision. If the coordinator is not a native speaker, the referee is called upon to make the final decision.

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### 4. Quality assessment

Three assessors are selected according to the following criteria:

- either headache experts or primary-care physicians, according to the intended audience of the document;
- native speakers of the target language (and, ideally, residents of the relevant country) with good understanding of linguistic factors (such as grammar, readability) but not necessarily bilingual.

The assessors are instructed:

- that the document is to be utilized by health-care professionals (specified, when appropriate);
- to assess the consensus-based translation for readability, grammatical correctness, medical correctness and cultural suitability;

- to keep records of their comments and send these to the coordinator.

Each assessor reviews the consensus-based translation individually, without reference to the others, sending comments to the coordinator.

Minor changes suggested by the assessors may be implemented by the coordinator (in consultation if necessary with the referee).

When substantial changes are suggested, the coordinator must liaise with the translators (and referee if necessary) to agree on an alternative translation. If substantial changes are agreed, the quality of the new translation should be reassessed by the same processes.

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### 5. Report of the translation process

The coordinator should produce a report in English on the translation process, documenting the details (qualifications and experience) of the translators, referee and assessors. Furthermore, the report will contain:

- the original document;
- the two first translations, the consensus-based translation, any other intermediate versions and the final translation;
- a record of any substantial difficulties encountered during the translation (difficulties may include problematic words or parts of the document that were difficult to translate, points of disagreement and alternatives, or any aspects on which it was difficult to achieve consensus or that were highlighted during the quality assessment of the translation).

The report is sent to the chairman of the Translation Working Group.

#### *Resolving problems*

Any problems with or queries about this translation process should be addressed to the chairman of the Translation Working Group.

## *Lifting The Burden*

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## **Translation protocol for lay documents**

**These guidelines have been developed by the Translation Working Group for the translation of documents (hereafter called “lay documents”) produced by *Lifting The Burden* as information for lay people, including people with headache, the general public and lay media.**

Translations of all lay documents should follow these guidelines to ensure a high quality of translation and to be approved by the Translation Working Group.

Translation should follow five steps.

### **1. Coordination of the translation**

A translation coordinator, who oversees but does not carry out the translation, is selected according to the following criteria:

- bilingual in English and the target language (ideally a native speaker and resident of the country of the target language);
- has ability to mediate between different translators and to understand the points of view of lay and professional translators.

If the coordinator is not a native speaker, a referee (native speaker) must be nominated. The referee cannot be involved in the translation process, and is called upon to arbitrate should irreconcilable views amongst translators prevent the production of a consensus-based translation.

The tasks of the coordinator include:

- selecting the translators, assessor and review panel (and referee if necessary);
- organising and overseeing the translation, including meeting with the translators to produce a consensus-based translation;
- organising and overseeing the quality assurance of the translation;
- producing the report of the translation process.

### **2. Translation into target language**

Two independent translations into the target language of the original document must be produced.

The two translations may be carried out by two individual translators, by two pairs of translators (one translates and the second of the pair reviews the translation) or by two independent panels of translators (with 3-4 members in each panel). If a translator pair or a panel is used, one person should be named chairman and is responsible for liaising with the translation coordinator. The two individuals, pairs or panels may not confer with each other until each has produced their translation.

Translators are selected according to the following criteria:

- native speakers of the target language;
- at least one (individual, pair or panel) must be headache or medical expert(s);
- (ideally, the other is a professional translator or bilingual person, pair or panel skilled in language/linguistics, such as a teacher or journalist; if no such translator is available, then a second headache or medical expert [individual, pair or panel] may be used).

Translators are instructed to:

- keep translations simple, avoiding technical language, so that the documents can be understood by lay people of average reading ability;
- make semantic and conceptual translations (rather than literal), so that the meanings of the words and phrases remain as in the original document;

- keep a record of any parts that they found difficult to translate.

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### 3. Production of a consensus-based translation

The coordinator works with the two translators, or the named chairmen of the translation pairs or panels, to reconcile differences between the two translations and produce a consensus-based translation. There are three steps to this process:

- the translators each send their translations to the coordinator;
- the coordinator makes an initial comparison of the two translations and highlights and records any parts of them that are substantially different;
- the coordinator and translators (or chairmen) meet (or, alternatively, hold a teleconference) to discuss these parts and any other problem areas, agreeing through consensus on one translation.

If the translators cannot reach a consensus on any part, the coordinator, if a native speaker, makes the final decision. If the coordinator is not a native speaker, the referee is called upon to make the final decision.

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### 4. Quality assessment

#### *a) Linguistic review*

One assessor is selected according to the following criteria:

- a lay person (not medically qualified and not a researcher);
- a native speaker of the target language (and, ideally, a resident of the relevant country) with good understanding of linguistic factors (such as grammar, readability) but not necessarily bilingual.

The assessor is instructed:

- that the document is to be understood by lay people of average reading ability;
- to assess the consensus-based translation for readability, grammatical correctness and cultural suitability;
- to keep a record of his/her comments and send these to the coordinator.

#### *b) Target audience review*

A second quality assessment judges suitability for the intended audience. It is carried out by a review panel of six people selected according to the following criteria:

- affected by headache disorders;
- native speakers of the target language and not necessarily bilingual.

Each panel member assesses the consensus-based translation individually, without reference to the others, sending comments to the coordinator.

#### *c) Production of final quality-assured translation*

Minor changes suggested by the assessor or panel members may be implemented by the coordinator (in consultation if necessary with the referee).

When substantial changes are suggested, the coordinator must liaise with the translators (and referee if necessary) to agree on an alternative translation. If substantial changes are agreed, the quality of the new translation should be re-assessed by the same processes.

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### 5. Report of the translation process

The coordinator should produce a report in English on the translation process, documenting the details (qualifications and experience) of the translators, referee, assessors and review panel members. Furthermore, the report will contain:

- the original document;
- the two first translations, the consensus-based translation, any other intermediate versions and the final translation;
- a record of any substantial difficulties encountered during the translation (difficulties may include problematic words or parts of the document that were difficult to translate, points of disagreement and alternatives, or any aspects on which it was difficult to achieve consensus or that were highlighted during the quality assessment of the translation).

The report is sent to the chairman of the Translation Working Group.

#### *Resolving problems*

Any problems with or queries about this translation process should be addressed to the chairman of the Translation Working Group.

## *Lifting The Burden*

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## **Translation protocol for hybrid documents**

**These guidelines have been developed by the Translation Working Group for the translation of documents (hereafter called “hybrid documents”) produced by *Lifting The Burden* and aimed at people with headache but to be used either in clinical practice or in research (such as questionnaires, diaries, survey instruments).**

Translations of all hybrid documents should follow these guidelines to ensure a high quality of translation and to be approved by the Translation Working Group.

Translation should follow six steps.

### **1. Coordination of the translation**

A translation coordinator, who oversees but does not carry out the translation, is selected according to the following criteria:

- has technical knowledge (ie, understands the concepts underlying the questions or instrument being translated);
- bilingual in English and the target language (ideally a native speaker and a resident of the country of the target language);
- has ability to mediate between different translators and to understand the points of view of lay and professional translators.

If the coordinator is not a native speaker, a referee (native speaker) must be nominated. The referee cannot be involved in the translation process, and is called upon to arbitrate should irreconcilable views amongst translators prevent the production of a consensus-based translation.

The tasks of the coordinator include:

- selecting the forward- and back-translators, assessor and review panel (and referee if necessary);
- liaising when necessary with the document author;
- organising and overseeing the forward- and back-translations, including meeting with the translators first to produce

a consensus-based forward-translation and again (when necessary) to resolve discrepancies discovered during back-translation;

- organising and overseeing the quality assurance of the translation;
- producing the report of the translation process.

### **2. Translation into target language**

Two independent forward-translations into the target language of the original document must be produced.

The two translations may be carried out by two individual translators, by two pairs of translators (one translates and the second of the pair reviews the translation) or by two independent panels of translators (with 3-4 members in each panel). If a translator pair or a panel is used, one person should be named chairman and is responsible for liaising with the translation coordinator. The two individuals, pairs or panels may not confer with each other until each has produced their translation.

Translators are selected according to the following criteria:

- native speakers of the target language;
- at least one (individual, pair or panel) must be headache or medical expert(s);
- (ideally, the other is a professional translator or bilingual person, pair or panel skilled in language/linguistics, such as a teacher or journalist; if no such translator is available, then a second headache or medical expert [individual, pair or panel] may be used).

Translators are provided by the coordinator with an explanation of the purpose and concepts underlying the elements of the document (obtained, when necessary, from the document author).

Translators are instructed to:

- keep translations simple, avoiding technical language, so that the documents can be understood by lay people of average reading ability;
- make semantic and conceptual translations (rather than literal), so that the meanings of the words and phrases remain as in the original document;
- keep a record of any parts that they found difficult to translate.

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### 3. Production of a consensus-based translation

The coordinator works with the two translators, or the named chairmen of the translation pairs or panels, to reconcile differences between the two translations and produce a consensus-based translation. There are three steps to this process:

- the translators each send their translations to the coordinator;
- the coordinator makes an initial comparison of the two translations and highlights and records any parts of them that are substantially different;
- the coordinator and translators (or chairmen) meet (or, alternatively, hold a teleconference) to discuss these parts and any other problem areas, agreeing through consensus on one forward translation.

If the translators cannot reach a consensus on any part, the coordinator, if a native speaker, makes the final decision. If the coordinator is not a native speaker, the referee is called upon to make the final decision.

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### 4. Back-translation

One back-translation of the consensus-based forward translation is carried out by one translator selected according to the following criteria:

- a native speaker of English;
- either a headache or medical expert, or a professional or bilingual lay translator skilled in language/linguistic issues.

The back-translation is sent to the coordinator to forward to the original author with a request to compare the original and back-translated versions and assess their conceptual equivalence. If the author believes conceptual equivalence is not maintained, he or she should be asked to explain the reasons to the coordinator.

Following this conceptual comparison, minor amendments may be implemented by the coordinator (in consultation with the referee when appropriate).

When substantial discrepancies have been highlighted, the coordinator calls a second meeting (or teleconference) with the forward-translators and back-translator to locate their causes and eliminate them by making changes either to the consensus-based forward-translation or to the back-translation as appropriate.

This process produces the back-checked consensus-based translation.

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## 5. Quality assessment

### *a) Linguistic review*

One assessor is selected according to the following criteria:

- a lay person (not medically qualified and not a researcher);
- a native speaker of the target language (and, ideally, a resident of the relevant country) with good understanding of linguistic factors (such as grammar, readability) but not necessarily bilingual.

The assessor is instructed:

- that the document is to be understood by lay people of average reading ability;
- to assess the back-checked consensus-based translation for readability, grammatical correctness and cultural suitability;
- to keep a record of his/her comments and send these to the coordinator.

### *b) Target audience review*

A second quality assessment judges suitability for the intended audience. It is carried out by a review panel of six people selected according to the following criteria:

- affected by headache disorders;
- native speakers of the target language and not necessarily bilingual.

Each panel member assesses the back-checked consensus-based translation individually, without reference to the others, sending comments to the coordinator.

### *c) Production of final quality-assured translation*

Minor changes suggested by the assessor or panel members may be implemented by the coordinator (in consultation if necessary with the referee).

When substantial changes are suggested, the coordinator must liaise with the forward-translators (and referee if necessary) to agree on an alternative translation. If substantial changes are agreed, the back-translation process should be repeated and, subsequently, the quality of the new translation should be re-assessed.

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## 6. Report of the translation process

The coordinator should produce a report in English on the translation process, documenting the details (qualifications and experience) of the translators, referee, assessors and review panel members. Furthermore, the report will contain:

- the original document;
- the two forward-translations, the consensus-based translation, the back-translation, the back-checked consensus-based translation, any other intermediate versions and the final translation;
- a record of any substantial difficulties encountered during the translation (difficulties may include problematic words

or parts of the document that were difficult to translate, points of disagreement and alternatives, or any aspects on which it was difficult to achieve consensus or that were highlighted during the quality assessment of the translation).

The report is sent to the chairman of the Translation Working Group.

### ***Resolving problems***

Any problems with or queries about this translation process should be addressed to the chairman of the Translation Working Group.