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WHO Expert Committee

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Geneva, 3–10 July 1989

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CANCER PAIN RELIEF AND PALLIATIVE CARE

Report of the WHO Expert Committee on Cancer Pain Relief and Active Supportive Care

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care met in Geneva from 3 to 10 July 1989. The meeting was opened on behalf of the Director-General of WHO by Dr Hu Ching-Li, Assistant Director-General.

1. INTRODUCTION

Pain and symptom control is one of the priorities of the cancer control programme of WHO; others include prevention of cancer, early diagnosis and curative treatment, and implementation of national cancer control programmes.

For many years to come, in the absence both of totally effective measures for prevention, early diagnosis and curative treatment of cancer, and of sufficient health facilities and trained health care workers, active supportive care will be the only realistic humane approach for many patients. Nothing would have a greater impact on the quality of life of these patients than the dissemination and implementation of knowledge already available in relation to pain and symptom management.

The purpose of the Expert Committee was to review the current status of cancer care and pain relief and to produce recommendations and guidelines for improving the quality of life of cancer patients.

1.1 Development of the method for relief of cancer pain

In 1982, a WHO consultation in Milan, Italy, brought together a group of experts in the management of cancer pain. The experts, who came from the fields of anaesthesiology, neurology, neurosurgery, nursing, oncology, pharmacology, psychology and surgery, prepared draft guidelines on the relief of cancer pain, which expressed the consensus that, through the use of a limited number of

drugs, pain relief was a realistic target for the majority of cancer patients. Studies on the applicability and effectiveness of these guidelines have since been carried out in a number of countries with different health care systems, under the direction of WHO and the WHO Collaborating Centre for Cancer Pain Relief at the National Cancer Institute, Milan (1-5).

In 1984, a WHO meeting on the comprehensive management of cancer pain was held in Geneva. Among the participants were experts in the management of cancer pain, in national and international legislation concerning the regulation of opioid drugs, in health care delivery, in health education, and in pharmaceutical research and manufacturing, as well as representatives of several international nongovernmental organizations. This meeting resulted in the publication in 1986 of *Cancer pain relief* (6), which included a modified version of the 1982 draft guidelines, in the form of an annex entitled "Method for relief of cancer pain".

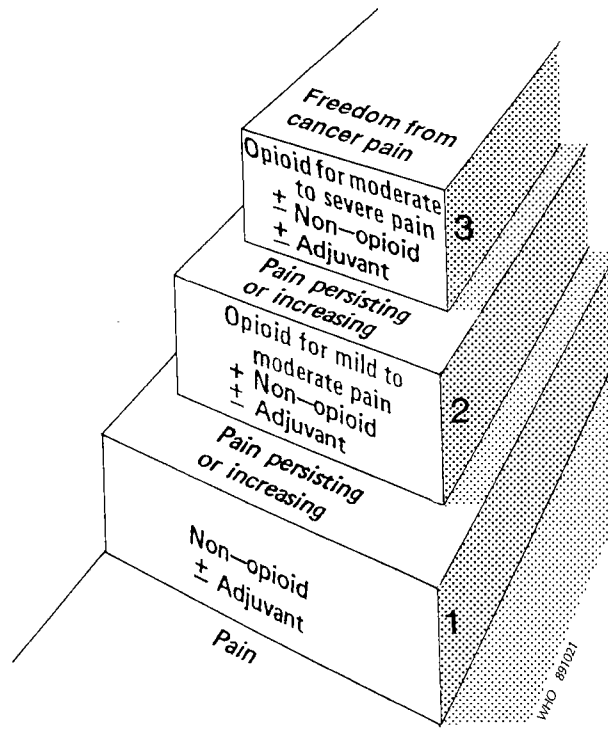
The success of that publication, of which over 160 000 copies have been printed in some 12 languages, demonstrated clearly that it fulfilled, and continues to fulfil, a need. Its success also reflects the fact that, previously, cancer pain had been commonly undertreated and frequently neglected as a public health problem. Health care workers in all parts of the world are now increasingly endeavouring to correct this. An extensive network of individuals, centres and organizations are linked with WHO in a global attack on cancer pain, whose goal is "freedom from cancer pain" as soon as possible (7).

1.2 Recent developments

Other major developments since 1986 include:

- the adoption of a policy for care of the terminally ill by the governments of France (8) and Japan (9);
- the adoption of a policy for pain control by the governments of Australia (10), France (8), Japan (9) and Sweden (11);
- the issue in Italy of a decree that allows the prescription of opioid drugs for oral administration (12);
- as a result of the National Cancer Control Plan for India (13), the introduction of a policy for cancer pain relief in the Indian states of Gujarat, Karnataka, Kerala (14), Maharashtra, and Tamil Nadu; this policy includes provision for training professional health care workers, and will make morphine available for oral administration for the first time in these states;

Fig. 1. The WHO three-step analgesic ladder



- the establishment in the USA of the Wisconsin Cancer Pain Initiative, to serve as a WHO demonstration project (15), followed by similar initiatives in at least nine other states;
- the publication of a quarterly newsheet, *Cancer pain release*, by the WHO Collaborating Center for Symptom Evaluation in Cancer Care, Madison, Wisconsin.

In addition, key international scientific conferences and workshops have been addressed by WHO staff and have included discussion of the WHO cancer pain relief programme. These have included 14th International Cancer Congress, Budapest 1986; Fifth World Congress on Pain, Hamburg 1987; Third Annual Symposium of the International Hospice Institute, Granby, Colorado 1987; Second and Third Congresses of Indian Society of Oncology, Bombay 1986 and Bangalore 1988; Fourth and Fifth International Conferences of Cancer Nursing, New York 1986 and London 1988;

Second International Congress on Cancer Pain, Rye, New York 1988; Canadian Cancer Society Conference on Supportive Care, Montebello, Canada 1988; Seventh World Congress on Care of the Terminally Ill, Montreal 1988, and national workshops sponsored by WHO to establish National Cancer Control Programmes (India 1986, Indonesia 1988, United Arab Emirates 1989).

WHO Collaborating Centres have been established to carry out research, training and implementation of the method of pain relief recommended by WHO. These centres cover quality of life (Amsterdam), cancer pain and palliative care (Milan), palliative care (Oxford), and symptom evaluation (Wisconsin). Preliminary steps have also been taken to designate three other centres—on cancer pain research and education (New York), on cancer pain relief and quality of life (Saitama), and on quality of life in cancer care (Winnipeg).¹

Teaching faculties are being developed jointly with the International Association for the Study of Pain (IASP), the International Society of Nurses in Cancer Care (ISNCC) and the International School for Cancer Care (ISCC). Collaboration on opioid availability has been established with the United Nations International Narcotics Control Board (INCB), Vienna. A survey on drug availability and existing obstacles has been conducted together with the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The International Union Against Cancer acknowledges the importance of cancer pain relief by devoting time to this topic in its international meetings. In consultation with INCB, WHO has prepared guidelines on availability of opioids for medical purposes, for drug regulatory authorities and health care workers.

National and international leaders in cancer pain relief have been identified as “focal points” for implementing the WHO method. Close collaborative ties (“twinning”) have been developed between centres in countries where cancer pain relief is well established and countries where it is still rudimentary.

1.3 Future challenges

Freedom from pain should be seen as a right of every cancer patient and access to pain therapy as a measure of respect for this

¹ While this report was in preparation for publication, these three centres were designated as WHO Collaborating Centres.

right. However, cancer pain relief cannot be considered in isolation. For most patients, suffering is not purely physical and pain is only one of several symptoms. Pain relief should therefore be seen as part of a comprehensive pattern of care which encompasses the physical, psychological, social and spiritual aspects of suffering (16) and which has come to be known as *palliative care*.

2. PALLIATIVE CARE

2.1 Introduction

Palliative care is the active total care of patients whose disease is not responsive to curative treatment. Control of pain, of other symptoms, and of psychological, social and spiritual problems is paramount (17). The goal of palliative care is achievement of the best possible quality of life for patients and their families.¹ Many aspects of palliative care are also applicable earlier in the course of the illness, in conjunction with anticancer treatment. Palliative care:

- affirms life and regards dying as a normal process;
- neither hastens nor postpones death;
- provides relief from pain and other distressing symptoms;
- integrates the psychological and spiritual aspects of patient care;
- offers a support system to help patients live as actively as possible until death;
- offers a support system to help the family cope during the patient's illness and in their own bereavement.

Radiotherapy, chemotherapy and surgery have a place in palliative care, provided that the symptomatic benefits of treatment clearly outweigh the disadvantages (18, 19). Investigative procedures are kept to a minimum.

Palliative care has its origins in the hospice movement. In recent years, palliative care has become established in an increasing number of countries and is now a recognized medical speciality in the United Kingdom. Academic posts have been established in several countries, notably Australia, Canada and the United Kingdom. There are now several national associations for palliative care and journals devoted to the subject.

¹ In this report, "family" refers to either actual relatives or other key people important to the patient.

Programmes of palliative care stress that illness should not be regarded as an isolated aberration in physiology but considered in terms of the suffering that it causes and the impact it has on patients' families. The "unit of care" is thus the family rather than the patient alone. This setting is regarded as most important; enquiries from the family are encouraged and the family's active participation in care is expected.

Palliative care requires a team approach, which recognizes that all health care workers have roles to play. Leadership of the team may vary according to the patient's particular problems and local factors. Team members should respect the need for confidentiality regarding the patient: sensitive personal information should not be shared unless there are compelling reasons for doing so, or unless the patient gives specific permission for the information to be passed on.

Nurses have a major role to play in palliative care, with particular responsibilities for providing information, for counselling and education of patients and families and for facilitating continuity of care between home and hospital. Because of their proximity to patients, nurses are ideally placed to monitor and evaluate pain and symptom control. To ensure that control measures are as effective as possible, nurses must have the authority to adjust drug doses within prescribed ranges to meet the needs of patients at any given time.

2.2 Present situation

Cancer is a major world problem. Every year about 7 million new cases are diagnosed, half of them in developing countries, and about 5 million people die (20, 21). Prevalence data indicate that there are currently about 14 million people with cancer (21-23).

In developed countries, 67% of male and 60% of female cancer patients will die of their disease (see Table 1); in developing countries, the figures are much higher. Of the eight most common forms of cancer, five are more prevalent in developing countries. Even if diagnosis is made at an early stage, treatment is curative in only three types; palliative care is needed in all eight (see Table 2). Globally, 8% of all deaths are caused by cancer (24). In developed countries, however, the proportion of deaths due to cancer is higher; in Europe for example, it is over 22% (25).

Table 1. Percentage cancer mortality in 20 developed countries in 1980^a

Site or type of cancer	Male	Female
Cervix uteri	—	33
Oral cavity	33	42
Corpus uteri	—	42
Breast	—	43
Bladder	38	45
Prostate	48	—
Larynx	50	48
Colon/rectum	59	59
Lymphoma	63	67
Ovary	—	71
Leukaemia	77	77
Stomach	83	83
Liver	83	91
Oesophagus	91	91
Bronchus	91	91
Pancreas	100	100
Total	67	59

^aDerived from estimated regression coefficients of crude incidence and mortality (20).

Table 2. Cancer control—priorities and strategies for the eight most common cancers (7)

Site of cancer	Primary prevention	Early diagnosis	Curative treatment ^a	Palliative care
Stomach	+ ^b	—	—	++
Lung	++	—	—	++
Breast	—	++	++	++
Colon/rectum	+	+	+	++
Cervix	+	++	++	++
Mouth/pharynx	++	++	++	++
Oesophagus	—	—	—	++
Liver	++	—	—	++

^aCurative for majority of cases with a realistic chance of early diagnosis.

^b++ = effective; + = partly effective; — = not effective.

2.3 Future need

Globally, the number of cancer patients and overall cancer mortality are increasing (20, 26, 27). Mortality rose significantly in developed countries between 1960 and 1980 (28) and the increase in some developing countries was even more marked. In the city of Shanghai, for example, cancer was the sixth most common cause of death in 1960 but the prime cause in 1980.

If current trends continue, cancer mortality can be expected to rise in nearly all regions of the world. The major reasons for this are a general increase in the average age of the world population, control

of other major health problems, and an increasing use of tobacco. Tobacco consumption is increasing by more than 2% a year in developing countries. By the year 2000, there are likely to be 1.5 million additional cases of lung cancer each year as a result of increasing tobacco use, and 90% of these patients will be incurable (29).

Table 3 shows the expected changes in deaths from cancer in four developed countries between 1980 and 2000. In all four cases the aging factor makes a positive contribution to the figures. In France, however, the effect of aging in women is outweighed by a reduction in the incidence of cancer. These figures provide evidence that national health plans must include provision for palliative care for the millions of people who would otherwise suffer considerably in the weeks and months before death.

Table 3. Projected percentage changes in cancer deaths between 1980 and 2000 in four countries (30)

Country	Male	Female
Japan	+80	+40
USA	+50	+30
France	+40	-6
United Kingdom (England and Wales only)	+20	+12

2.4 Obstacles to implementation

The greatest improvements in quality of life for cancer patients and their families could be effected by implementation of existing knowledge of pain and symptom control. In a number of countries, the situation has improved considerably over the past 20 years for reasons that include:

- the development of palliative care centres;
- a greater understanding of the use of analgesic drugs;
- demands from patients and families for better symptom control;
- a consensus that adequate symptom control and a good quality of life are particularly important in patients with advanced disease.

Globally, however, palliative care is still a neglected area and several million cancer patients suffer needlessly every day as a result. The major obstacles to the implementation of palliative care appear to be:

- absence of national policies on cancer pain relief and other aspects of palliative care;
- lack of education for health care workers, policy-makers, administrators and the general public;
- concern that the medical use of morphine and related drugs will fuel the problem of drug abuse in the community and result in increased restrictions on prescribing and supply;
- limitations on supply and distribution of the drugs needed for the relief of pain and other symptoms, particularly in developing countries;
- restrictions imposed by the adoption of regional, district or hospital formularies, which do not contain sufficient drugs for the control of pain and other symptoms;
- shortage of professional health care workers empowered to prescribe analgesics and other drugs;
- lack of financial resources for research and development in palliative care.

2.5 Resource allocation

Although more than half of the world's cancer patients live in developing countries, less than 10% of the resources committed to cancer control are available to them. This poverty extends to manpower. In sub-Saharan Africa (excluding South Africa), there are fewer than 100 cancer specialists of every kind (cancer nurses, radiotherapists, chemotherapists, etc.) for a population of 300 million.

Although it is the only realistic option for most cancer patients, palliative care attracts few of the available cancer control resources. Most of the resources are devoted to curative treatment, at a relatively high cost but with limited effect. Moreover, there is generally little or no training of health care workers in this type of care. Quality of life and comfort before death could be considerably improved through the application of current knowledge on palliative care, which is all too often ignored or regarded as a type of "waste-paper basket alternative" among treatment options (Fig. 2). Instead, palliative care needs to be seen in both developed and developing countries as an integral part of cancer care (Figs. 3 and 4). Curative care and palliative care are not mutually exclusive, but for most cancer patients no curative treatment exists. The quality of life in these patients would be greatly improved by access to palliative care throughout the course of their illness.

Fig. 2. Present allocation of cancer resources

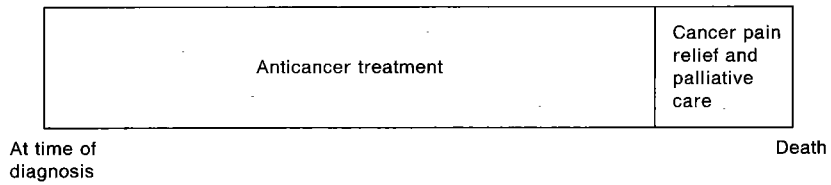


Fig. 3. Proposed allocation of cancer resources in developed countries

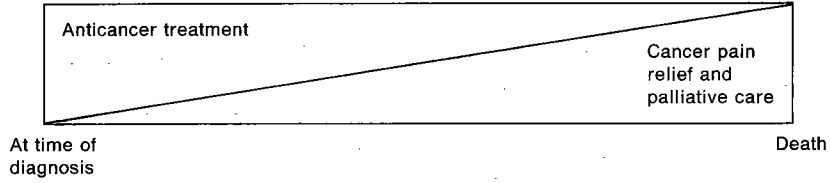
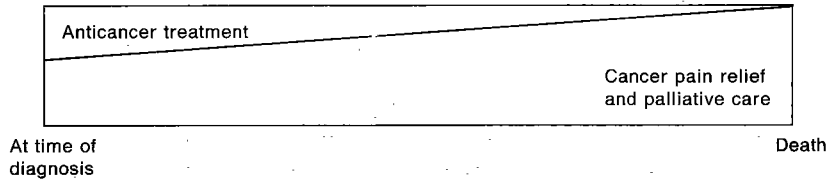


Fig. 4. Proposed allocation of cancer resources in developing countries



2.6 Organization of palliative care

Palliative care centres were among the first to demonstrate the value of regular “round-the-clock” administration of analgesics, notably orally administered morphine. In a few countries, demonstration centres have been established but have often had to battle against medical, nursing, pharmaceutical, and community ignorance, and sometimes antagonism. With the passage of time, the educational impact of these centres is likely to be considerable; studies have already demonstrated that the existence of a palliative care centre results in improved standards of care in neighbouring general hospitals (31, 32).

Fully developed palliative care programmes include the following components:

- *Home care.* Traditional medical care and funding are based on an institutional model whereas palliative care stresses the home as

the primary setting for care. Institutions are seen as back-up resources rather than as the focal points of the programmes.

- *Consultation service.* Health care workers who are trained in palliative care provide a consultation service for patients in hospital and in the community. Such a system also provides an educational opportunity for other health care workers.
- *Day care.* Patients who live alone or who are unable to get out on their own may benefit from attending a palliative care day centre two or three times a week. In addition, day care may do much to alleviate the demands that home care makes on patients' families.
- *Inpatient care.* Inpatient care concentrates on controlling pain and other manifestations of physical and psychosocial distress.
- *Bereavement support.* Some people need extra help to enable them to cope with their bereavement. Support by trained health care workers or volunteers may provide this.

In essence, however, palliative care is a concept: while some of the organizational structures listed above may be helpful, they are not essential for the delivery of good palliative care. Palliative care treatments are cost-effective, simple to apply and readily implemented in the home.

The basis of care in the community is continuing professional supervision. Palliative care requires the involvement of a variety of health care workers trained to evaluate patients' needs and resources, advise patients and families, understand the principles underlying the use of drugs in pain and symptom control, and provide psychological support for both patients and families.

Voluntary helpers, including neighbours, may need to be recruited to provide sufficient care for patients with little or no family. Equally important is the referral of patients to the agencies that, in some countries, offer financial assistance to patients with advanced cancer.

Ideal home care requires a continuum of care between home and hospital. The main burden of home care for the patient with advanced cancer falls on the family. Members of the family should therefore be trained to select and prepare suitable meals, administer analgesics and other necessary drugs, and deal with specific medical problems, such as paraplegia and incontinence.

Ignorance or anxiety within the home can be a principal cause of the failure of an otherwise well-established system of care.

2.7 Quality of life

Palliative care aims to maintain or improve the quality of life of patients with an incurable illness, and its impact may be evaluated by “measuring” quality of life. The starting point for such an evaluation is arbitrary. However, measures should assess reduction in suffering (“ill-being”) and changes in positive feelings and happiness (“well-being”) (33). The subjectivity of most measures of quality of life is often considered a limiting factor in their use (34), but some recently developed scales have a high degree of reliability. The components evaluated usually include physical symptoms, physical performance, psychological state, and social interaction.

Information provided by application of these measures in the context of palliative care is generally incomplete, because many important issues are not covered. Areas of omission include sexuality, the impact of illness on family structures, the “meaning” of illness to the patient, and the resolution of spiritual conflicts.

Development of further methods for measuring quality of life will help convince policy-makers to set more balanced priorities in cancer care and to reallocate national resources. Moreover, results from reliable and valid measurements of quality of life could lead to important changes in cancer control policy (35). For these reasons, any tests for assessing quality of life should ideally have cross-cultural validity.

Length of survival is frequently taken as the only measure of treatment success: for example, a recent review of chemotherapy studies in patients with incurable cancers could not identify any data on pain relief or other aspects of quality of life (35*a*). Yet, how are a few months of additional life, involving treatment at high cost and with major adverse effects, to be evaluated? During this time the patient may have no capacity to enjoy life and may suffer pain, despair and isolation from family and friends. Given reliable guidance on what can be expected, physicians and patients can make more rational choices of approach. Increasingly these choices will include coordinated elements of anticancer and palliative treatments evaluated biologically, socioeconomically and spiritually. At present, however, physicians find it difficult to avoid the use of frequently ineffective anticancer treatments.

3. CANCER PAIN

3.1 Extent of the problem

Published reports indicate that between 30% and 50% of cancer patients are experiencing pain or being treated for it (36–39). It is also conservatively estimated that at least 4 million people are currently suffering from cancer pain, with or without satisfactory treatment. The prevalence of pain increases as the disease progresses (36, 37) with significant variation according to the primary site of the cancer (36, 40, 41). It is likely that the primary site is only one of several factors that determines whether or not a patient has pain; it is probably less important as a determinant of pain than the stage of disease, presence of metastases, tendency to bone involvement, proximity of the tumour to neural structures, generation of pain-producing substances by the tumour, and patient variables such as anxiety and depression. Certainly all these factors are important in determining the *severity* of pain. As it is severity, rather than simply the presence, of pain that determines the need for treatment, primary site alone is an unreliable predictor of the need for pain relief.

Numerous published reports indicate that cancer pain is often inadequately treated. An analysis of 12 surveys covering nearly 2600 patients in developed countries suggests that more than 50% of patients suffer unrelieved pain (41). (There are no available estimates concerning relief of cancer pain in developing countries.) In addition to the obstacles to the implementation of palliative care listed in Section 2.4, cancer pain relief may be inadequate because of:

- a widespread lack of recognition by health care workers of the fact that established methods already exist for the relief of almost all cancer pain;
- legal and other constraints on the medical use of analgesic drugs, notably morphine.

3.2 Types of cancer pain

Pain in cancer may be:

- caused by the cancer itself (which is by far the most common type of pain);
- related to the cancer (e.g. muscle spasm, constipation, bedsores);

- related to treatment (e.g. chronic postoperative scar pain, stomatitis resulting from chemotherapy);
- caused by a concurrent disorder (e.g. spondylosis, arthritis).

Many patients with advanced cancer have multiple pains that relate to several of these categories (42).

Pain caused by the cancer itself arises from extension into soft tissues, visceral or bone involvement, nerve compression and destruction, and raised intracranial pressure.

It is important to determine as accurately as possible the cause of the pain because this often has major implications for treatment (43). Fortunately, most cancer-related pain responds to analgesics.

3.3 Nature of cancer pain

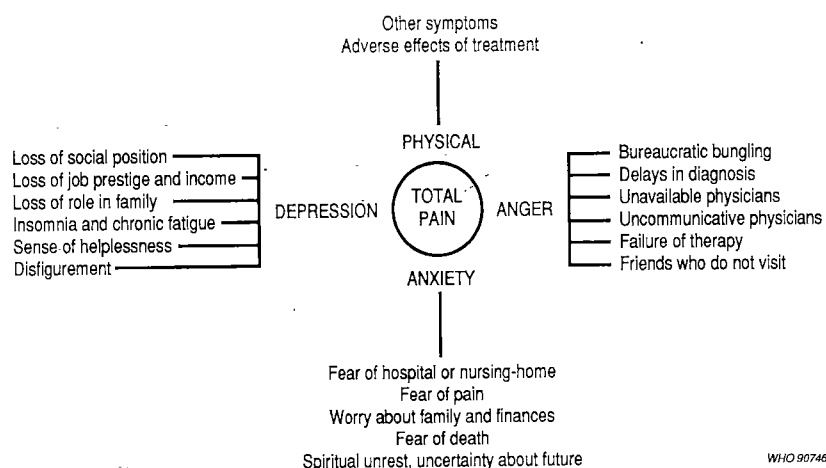
The definition of pain proposed by the International Association for the Study of Pain (44) is a useful starting point for discussing the nature of cancer pain:

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage. Pain is always subjective. Each individual learns the application of the word through experiences related to injury in early life. It is unquestionably a sensation in a part or parts of the body but it is also always unpleasant and therefore an emotional experience.

Several studies have evaluated the psychological factors that influence the severity of pain in patients with cancer (45–47). These factors are a major determinant of severity of pain in patients with advanced disease. A sense of hopelessness and the fear of impending death add to the total suffering of patients and exacerbate their pain. Identification of both the physical and the non-physical components is essential to the provision of appropriate treatment. The concept of “total pain” to encompass all relevant aspects is useful (Fig. 5); it includes the noxious physical stimulus and also psychological, social and spiritual factors (48, 49).

Recognition of the complex nature of cancer pain makes it easier to understand why some patients continue to experience intolerable pain even when given increasing amounts of analgesic medication. Unrelieved severe pain is often associated with a series of other symptoms, including disturbed sleep, reduced appetite, impaired concentration, irritability and depression.

Fig. 5. Factors influencing a patient's perception of pain (49)



3.4 Method for relief of cancer pain

Since the preparation of the draft interim guidelines in 1982 and the publication in 1986 of *Cancer pain relief* (6), there has been a rapid increase in the number of professional health care workers who are competent in cancer pain management. Such competence appears to be readily transferable to a wide variety of situations (1-5, 50), and adequate pain relief is therefore not dependent on the provision of a specialist palliative care service. With professional determination, administrative support and governmental encouragement, the concepts of care embodied in a specialist centre can be applied successfully elsewhere.

3.5 Field-testing of the method

Since 1985, five centres in five different countries have published the results of field tests of the method for cancer pain relief described by WHO (1-5). The number of patients treated ranged from 20 in one study to 1229 in another, with a total of 2608 cases being reported. In each of the studies it was demonstrated that, for the majority of cancer patients, pain could be either reduced considerably or completely controlled by the use of analgesics alone or in combination with adjuvant drugs.

In addition, a large multicentre study of the method has been coordinated by the WHO Collaborating Centre for Cancer Pain Relief at the National Cancer Institute in Milan. Details of current practice were requested from centres that were interested in cancer pain relief but that had minimal exposure to the method. Data from patients with pain were recorded from the time of their initial referral until death. Comparable data were requested from centres that had already used the method (including three of the five centres that published individual reports).

The study included 110 patients from centres previously unfamiliar, and 261 from centres previously familiar, with the method, from a total of 25 countries. Those centres previously exposed to the method reported significantly better pain relief at the end of 4 weeks' treatment. Pain was controlled (judged as absent or slight on a 4-point scale) in 75% of patients treated in centres trained in the use of the method. A similar level of pain control was obtained in only 50% of patients treated in the centres not previously exposed to the method. One reason for the better results was a significantly greater use of orally administered morphine and related drugs (Step 3 of the analgesic ladder). Adverse effects were infrequent in both groups. These results indicate that professional and public expectations about the successful management of cancer pain can be raised considerably.

3.6 The way forward

The field tests confirm that treatment with non-opioid, opioid, and adjuvant drugs is the mainstay of cancer pain management. Effective use of these drugs requires an understanding of their pharmacological characteristics, the selection of a particular drug being related to the needs of the individual patient (16, 51, 52).

In a small minority of patients, neurolytic and neurosurgical (51, 53) techniques are useful. The following are examples:

- coeliac axis plexus block for drug-resistant pancreatic pain;
- percutaneous spinothalamic tractotomy (cordotomy) for unilateral drug-resistant pain in the lower limb;
- intrathecal saddle block for drug-resistant perineal pain.

However, the effects of these procedures, which are often unrepeatable, generally last for no more than a few months. Their value is therefore limited, except in patients whose life expectancy is

three months or less. The main benefit of such techniques, if used more generally, is to procure maximum relief more quickly. In one study, pain relief in two groups of patient treated either with drugs alone or with a combination of drugs and neurolytic procedures showed no significant difference after six weeks (54).

It is encouraging that a number of medical groups and national committees have published helpful explanatory documents on drug treatment in cancer pain management (8–11, 55–59). All have emphasized the importance of providing adequate pain control and supportive care so that patients can enjoy a better quality of life and eventually die in as much comfort as possible. These reports have also stressed the need to educate physicians and other professional health care workers in the use of opioid analgesics in the care of cancer patients.

There is, however, a need for more research into, and further evaluation of, for example:

- non-opioid analgesics;
- opioids for mild to moderate pain;
- more selective opioid analgesics;
- diphosphonates for metastatic bone pain;
- local anaesthetic congeners in pain control;
- pain mediated by the sympathetic nervous system.

It is essential that the pharmaceutical industry and national cancer societies play leading roles in all these areas.

4. OPIOID AVAILABILITY

In many countries, morphine and codeine are not available for treatment of cancer pain, or are available but underused. As a result, many cancer patients suffer pain needlessly. WHO is attempting to address these problems by promoting wider knowledge among health care workers of the importance of orally administered opioids in the management of cancer pain, and by encouraging drug regulatory authorities to make sufficient quantities of these substances available to treat patients in their own countries.

4.1 Use of the term “opioid”

In this report, the word “narcotic” is used only in relation to the Single Convention on Narcotic Drugs, 1961 (60), in which

“narcotic” is used in a legal, rather than a pharmacological, sense. Thus substances are included which are *not* narcotics from a pharmacological point of view, for example cocaine and marijuana. Similarly, certain other drugs which are pharmacological narcotics feature in the Convention on Psychotropic Substances, 1971, for example buprenorphine and pentazocine (61).

To avoid confusion between the legal and pharmacological meanings of “narcotic”, the generic term “opioid” is used in this report. This term refers to codeine, morphine, and other natural and synthetic drugs whose effects are mediated by specific receptors in the central and peripheral nervous systems.

4.2 Morphine consumption: present situation

Tables 5–9 and Figs 6–8 show the consumption of morphine for various countries expressed as daily defined doses (DDD) per million population per day. For statistical purposes the DDD of morphine is 30 mg. The number of DDD consumed is determined in the following ways (62):

- annual consumption is divided by 365 days;
- the result obtained is divided by the DDD of morphine (30 mg);
- this figure is then divided by the population, in millions, of the country or territory.

These statistics refer to morphine consumption by all routes. There are no separate statistics for orally administered morphine, which is given in higher doses than morphine by injection.

In the Single Convention on Narcotic Drugs, 1961, the term “consumption” refers to the transfer of a drug from the manufacturing and wholesale levels to the retail level. For statistical purposes, drugs held by retail pharmacists are therefore considered to have been “consumed”.

It is acknowledged that morphine consumption figures do not completely indicate the extent to which opioids are used for treatment of moderate to severe pain. In some countries, opioids such as methadone, hydromorphone, levorphanol and pethidine are also used to relieve cancer pain. Even so, morphine consumption is probably the best indicator. Codeine is the most widely consumed opioid; however, since it is used as an antidiarrhoeal agent and an antitussive, as well as an analgesic, statistics on codeine consumption offer little insight into the use of opioids in cancer pain treatment.

Table 4 shows the total global morphine consumption for the 16 years 1972–1987 and reveals that consumption has increased by about 2.5 times during this period. Most of the increase occurred from 1984 onwards, which is also the period in which WHO has emphasized drug treatment, particularly with orally administered morphine, as the mainstay of cancer pain management.

Table 4. Total global morphine consumption 1972–1987 *

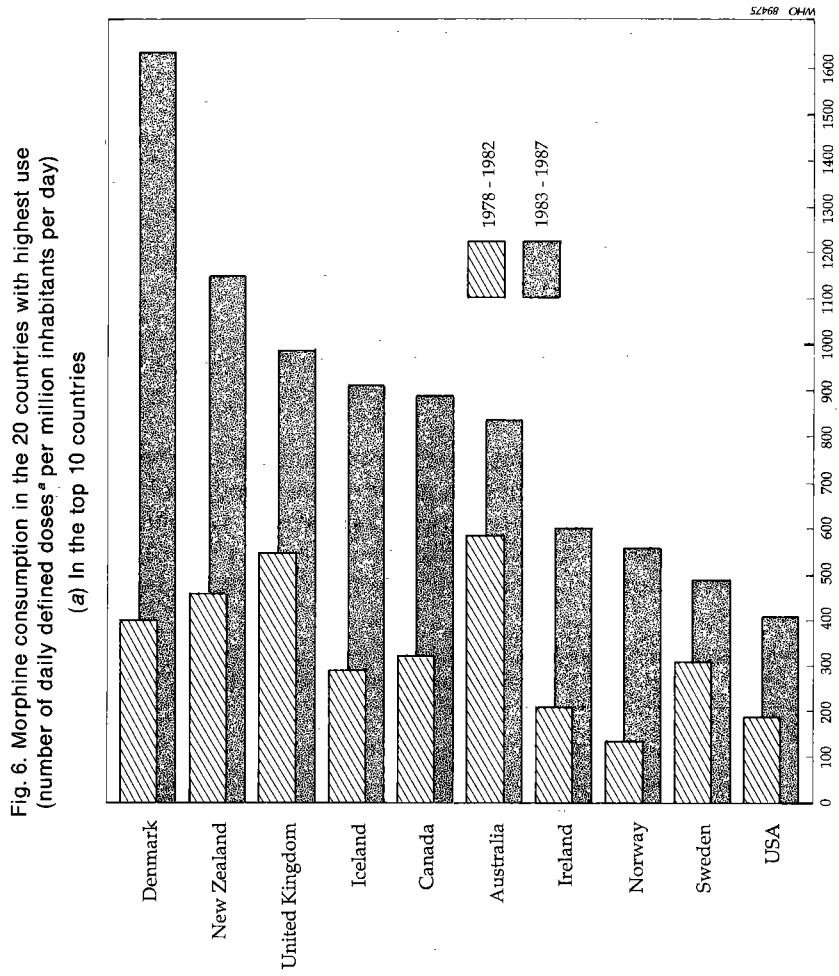
Year	Consumption (kg)	Year	Consumption (kg)
1972	1960	1980	2345
1973	2252	1981	2479
1974	1884	1982	2267
1975	2016	1983	2434
1976	1814	1984	2990
1977	1920	1985	3639
1978	2359	1986	4658
1979	1887	1987	4662

*Weight of morphine given here is that of morphine base, of which approximately 94% is pure anhydrous base. Morphine sulfate contains approximately 75% of the pure anhydrous base, while morphine hydrochloride contains approximately 76% of the pure anhydrous base.

Table 5 shows that the increase in morphine use is restricted to the 10 countries with the highest morphine consumption (expressed as DDD per million population per day), where morphine use has increased 4-fold since 1979. (See also Fig. 6a.) Consumption in the other countries is unchanged overall. Surprisingly, however,

Table 5. Total global morphine consumption (with and without the 10 countries showing highest consumption in the period 1983–87)

Year	Total consumption (kg)	Top 10 countries (kg)	Other countries (kg)
1972	1960	857	1103
1973	2252	987	1265
1974	1884	753	1131
1975	2016	752	1264
1976	1814	703	1111
1977	1920	754	1166
1978	2359	981	1378
1979	1887	778	1109
1980	2345	1117	1228
1981	2479	1233	1246
1982	2267	1178	1089
1983	2434	1249	1185
1984	2990	1812	1178
1985	3639	2112	1527
1986	4658	2862	1796
1987	4662	3486	1176



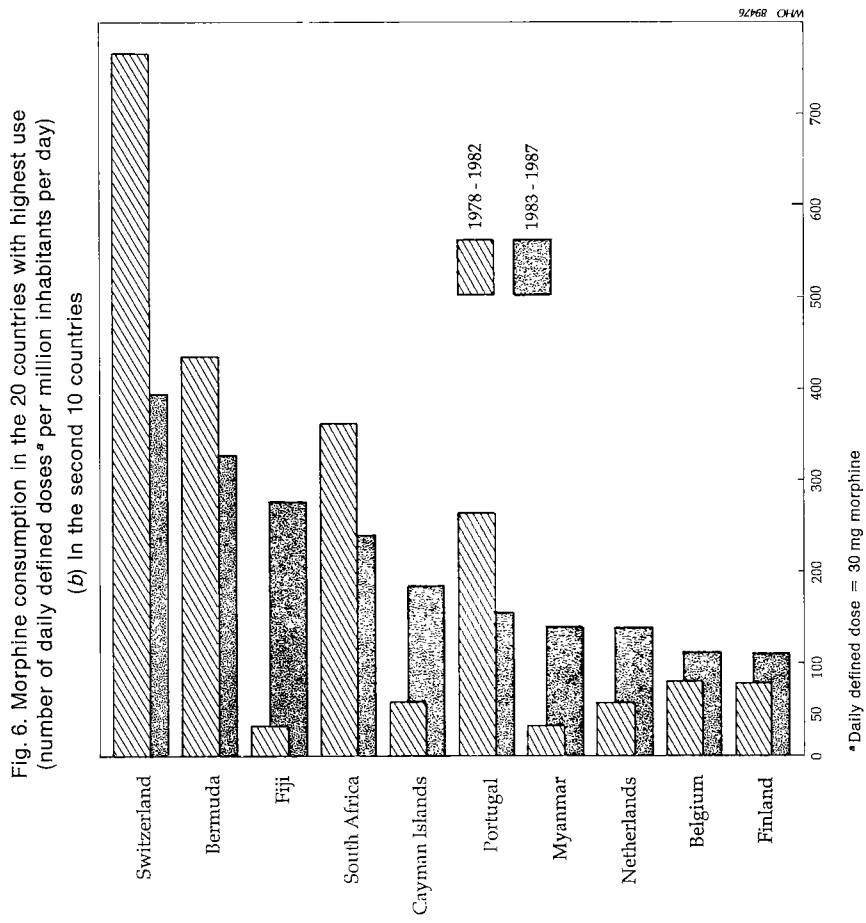
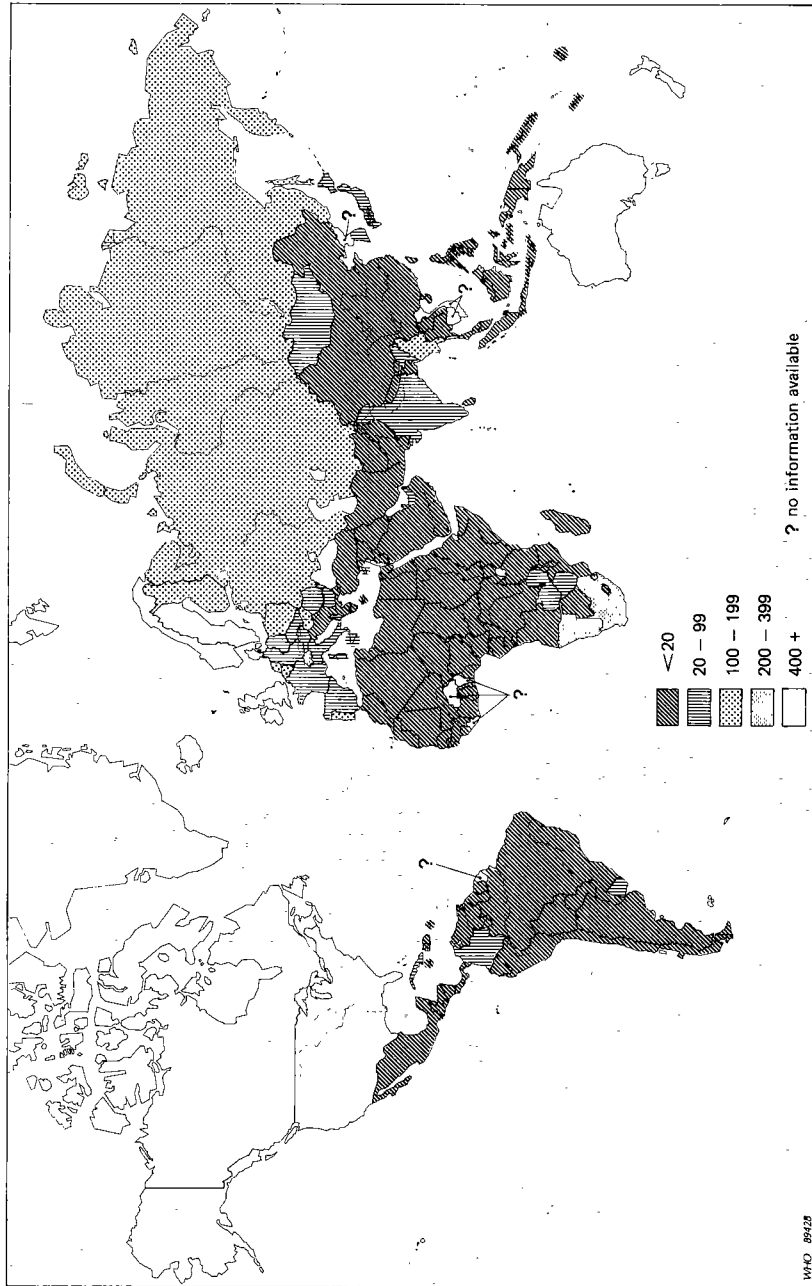


Fig. 7. Global morphine consumption 1983-1987 (number of daily defined doses per million population per day)



morphine consumption in four of the top 20 countries—Bermuda, Portugal, South Africa and Switzerland—has dropped significantly (see Fig. 6*b*). Part of this decrease may, of course, be due to an increased use of other opioids, such as hydromorphone or buprenorphine. It is worthy of note that current consumption of morphine in the top 10 countries accounts for 75% of global use; the remaining 25% is consumed in the other 133 countries for which data are available.

Table 6 shows the consumption of morphine in all countries for which there are available data, comparing figures for the period 1978–1982 with those for 1983–1987. Fig. 7 shows global morphine use, with countries divided into five categories according to consumption; since the figure is concerned only with morphine, there is no indication of overall opioid use.

Table 7 lists 54 countries, grouped by region, in which morphine use in the period 1983–1987 was higher, even if only slightly, than in the previous 5-year period; Table 8 similarly lists the 58 countries in which a reduction in consumption, however small, was recorded. The 51 countries for which there was no registered morphine consumption in the period 1983–1987 are listed by region in Table 9.

4.3 International Narcotics Control Board

It is central to any discussion of opioid analgesics to understand that the Single Convention on Narcotic Drugs, 1961 (as amended by the 1972 protocol), is the international treaty that regulates the production, manufacture, import, export and distribution of narcotic drugs for medical use, including the opioids. It also sets the framework for concerted international action against illicit manufacture and production, and against the diversion of narcotic drugs from licit to illicit markets. Simply stated, countries party to the Single Convention are required to control all aspects of the use of opioids within their territories and all international movement of opioids. Reports on production, manufacture, imports, exports, and consumption of opioids must be made to the International Narcotics Control Board (INCB) in Vienna, Austria.

The Economic and Social Council of the United Nations, in Resolution 1988/10, requested the INCB to review the available information on the supply of and demand for opioids for medical purposes and to develop practical and effective solutions to any problems that were identified (63). As a result of this resolution, the

Table 6. Consumption of morphine in 143 countries (expressed as number of daily defined doses per million population per day)

Country	1978-82	1983-87	Country	1978-82	1983-87
Denmark	394	1630	Saudi Arabia	27	12
New Zealand	455	1146	Yugoslavia	-	12
United Kingdom	543	988	Chile	13	11
Iceland	288	909	Dominica	12	11
Canada	323	885	Kuwait	15	11
Australia	586	837	Mauritius	7	10
Ireland	209	598	Suriname	17	9
Norway	136	558	Iraq	5	7
Sweden	308	485	Nicaragua	17	7
USA	187	404	Qatar	5	7
Switzerland	766	394	Oman	5	6
Bermuda	435	328	Syrian Arab Republic	7	6
Fiji	32	277	Thailand	7	6
South Africa	362	241	Turkey	3	6
Portugal	266	156	Costa Rica	4	4
Myanmar	33	141	Guatemala	4	4
Netherlands	58	139	Malawi	4	4
Belgium	81	112	Venezuela	6	4
Finland	76	110	Bangladesh	-	3
Hungary	121	106	Egypt	6	3
Israel	43	106	Tonga	6	3
Poland	104	104	Dominican Republic	1	2
USSR	106	100	Jordan	1	2
Austria	47	97	Mexico	4	2
German Dem. Rep.	73	87	Rwanda	1	2
Czechoslovakia	70	80	Sri Lanka	13	2
Germany, Fed. Rep. of	25	80	Afghanistan	-	1
Italy	89	80	Botswana	-	1
Bulgaria	56	76	Brazil	-	1
Seychelles	45	75	Democratic Yemen	2	1
Barbados	27	74	Ecuador	7	1
Singapore	178	71	Kenya	6	1
Cyprus	22	68	Libyan Arab Jamahiriya	2	1
Luxembourg	33	60	Papua New Guinea	79	1
Spain	14	60	Uganda	2	1
Zimbabwe	130	60	Zaire	-	1
Uruguay	126	59	Algeria	-	-
India	43	50	Angola	-	-
France	41	48	Belize	-	-
Malta	15	43	Benin	1	-
Bahamas	11	41	Bhutan	-	-
Japan	19	39	Bolivia	-	-
Republic of Korea	10	31	Burkina Faso	-	-
Cuba	20	29	Burundi	-	-
Albania	11	26	Cameroon	2	-
Andorra	5	26	Cape Verde	-	-
United Arab Emirates	29	26	Central African Rep.	-	-
Zambia	51	26	Chad	-	-
Colombia	25	25	China	-	-
Trinidad and Tobago	8	24	Congo	-	-
Romania	27	22	Côte d'Ivoire	-	-
Bahrain	5	16	Djibouti	11	-
Ghana	-	16	El Salvador	1	-
Argentina	5	15	Ethiopia	-	-
Greece	17	14	Gabon	-	-
Iran, Islamic Rep. of	63	14	Gambia	1	-
Malaysia	19	13	Guinea	2	-
Jamaica	13	12	Guinea-Bissau	-	-

Table 6 (continued)

Country	1978-82	1983-87	Country	1978-82	1983-87
Guyana	44	-	Pakistan	-	-
Haiti	-	-	Panama	-	-
Honduras	1	-	Paraguay	122	-
Indonesia	-	-	Peru	-	-
Lao People's Dem. Rep.	-	-	Philippines	1	-
Lesotho	10	-	Senegal	-	-
Madagascar	-	-	Sierra Leone	-	-
Maldives	9	-	Somalia	-	-
Mali	-	-	Sudan	3	-
Mauritania	2	-	Swaziland	5	-
Morocco	-	-	Togo	1	-
Mozambique	1	-	Tunisia	1	-
Nepal	2	-	United Rep. of Tanzania	1	-
Niger	-	-	Yemen	9	-
Nigeria	1	-			

INCB and WHO agreed to develop a joint working document for presentation to the INCB in October 1989. The document focused on the following issues:

- the medical need for codeine and morphine (the scope of the document was limited to these two substances because of their importance in medical treatment and the fact that they are the only opioids on the main list of the WHO Model List of Essential Drugs (64));
- the current situation in selected countries, plus an analysis of changes in consumption patterns;
- the obstacles to meeting medical needs for morphine and codeine;
- proposals/recommendations for overcoming the obstacles identified.

The INCB/WHO document identified the following obstacles to availability of morphine and codeine:

- interpretation of the Single Convention on Narcotic Drugs, 1961, by drug regulatory authorities;
- legislative, regulatory and administrative impediments that exist in various countries and that lead to underutilization of opioids;
- medical, nursing and pharmacy practices;
- the perception and knowledge of health care workers about the role of morphine and codeine in treatment and the availability and use of alternative treatments;
- shortage of health care workers and facilities (including the infrastructure for drug distribution);

Table 7. Countries showing increased morphine consumption in 1983–1987 compared with 1978–1982

Note: The order in which countries are listed reflects that used in Table 6.

<i>Europe</i> (23)	<i>Americas</i> (10)	<i>Africa</i> (7)
Denmark	Canada	Seychelles
United Kingdom	USA	Ghana
Iceland	Barbados	Mauritius
Ireland	Bahamas	Rwanda
Norway	Cuba	Botswana
Sweden	Trinidad and Tobago	Kenya
Netherlands	Argentina	Zaire
Belgium	Nicaragua	
Finland	Dominican Republic	<i>Western Pacific</i> (5)
Israel	Brazil	New Zealand
Austria		Australia
German Dem. Rep.	<i>Eastern Mediterranean</i> (7)	Fiji
Czechoslovakia	Cyprus	Japan
Germany, Fed. Rep. of	Bahrain	Rep. of Korea
Bulgaria	Iraq	
Luxembourg	Qatar	<i>South-East Asia</i> (2)
Spain	Oman	Myanmar
France	Jordan	India
Malta	Afghanistan	
Albania		
Andorra		
Yugoslavia		
Turkey		

- financial constraints of drug costs, both to the country and to the individual patient;
- structural constraints, particularly the reluctance of the drug industry to introduce opioids into a market;
- constraints on availability stemming from governmental action to combat drug abuse.

4.4 Background to opioid distribution

The WHO publication *Guidelines for the control of narcotic and psychotropic substances* (65) outlines the elements of drug control for national authorities, as follows:

A policy for drug supply and utilization is evidently an integral part of a national health care policy. Within this context the responsibility of the national authority is to ensure the needed supply of safe and effective drugs of good quality.

Specific provisions within a drug law

Registration

The essential feature of a drug law is a system of registration, without which it is not possible for a country to control the supply and utilization of the drugs

Table 8. Countries showing decreased morphine consumption in 1983–1987 compared with 1978–1982

Note: The order in which countries are listed reflects that used in Table 6.

<i>Africa</i> (16)	<i>Americas</i> (14)	<i>Eastern Mediterranean</i> (11)
South Africa	Bermuda	United Arab Emirates
Zimbabwe	Uruguay	Iran, Islamic Rep. of
Zambia	Jamaica	Saudi Arabia
Uganda	Chile	Kuwait
Benin	Dominica	Syrian Arab Republic
Cameroon	Suriname	Egypt
Gambia	Venezuela	Democratic Yemen
Guinea	Mexico	Libyan Arab Jamahirya
Lesotho	Bolivia	Djibouti
Mauritania	Ecuador	Tunisia
Mozambique	El Salvador	Yemen
Nigeria	Guyana	
Sudan	Honduras	<i>South-East Asia</i> (5)
Swaziland	Paraguay	Thailand
Togo		Bangladesh
United Rep. of Tanzania	<i>Europe</i> (7)	Sri Lanka
	Switzerland	Maldives
<i>Western Pacific</i> (5)	Portugal	Nepal
Singapore	Hungary	
Malaysia	USSR	
Tonga	Italy	
Papua New Guinea	Romania	
Philippines	Greece	

available within its jurisdiction. There are various possible types of registration system. The operation of such a system may be facilitated by collaboration or mutual consultation between countries at a regional or wider international level. An ideal registration system includes:

- evaluation of safety, efficacy and quality of pharmaceutical products;
- licensing, including the renewal, withdrawal and supervision of licences,
- allocation of drugs to different categories to provide for different levels of control, e.g. dispensing on prescription only, sale through pharmacies or other licensed retailers only, or general sale without prescription;
- supervision of the labelling of containers and outer packaging, and of the content of package inserts;
- post-registration surveillance.

Control of manufacture and importation

The drug law will also provide the legal basis for the control of manufacture and importation. Appropriate regulations should be introduced to govern the suitability of premises and equipment, the professional and technical qualifications of the personnel engaged in manufacture and quality control, good practices in the manufacture and quality control of drugs, the maintenance of proper hygienic standards in manufacture, distribution and storage, the adequacy of storage conditions with particular reference to orderliness, temperature and humidity conditions, the keeping of records, and where necessary, the taking of appropriate measures to prevent theft or diversion into illicit channels. Such

Table 9. Countries with no registered morphine consumption in the period
1983-87

<i>Africa</i> (27)	<i>Americas</i> (9)	<i>Eastern Mediterranean</i> (8)
Angola	Belize	Algeria
Benin	Bolivia	Djibouti
Burkina Faso	El Salvador	Morocco
Burundi	Guyana	Pakistan
Cameroon	Haiti	Somalia
Cape Verde	Honduras	Sudan
Central Afr. Rep.	Panama	Tunisia
Chad	Paraguay	Yemen
Congo	Peru	
Côte d'Ivoire		<i>Western Pacific</i> (3)
Ethiopia	<i>South-East Asia</i> (4)	China
Gabon	Bhutan	Lao People's Dem. Rep.
Gambia	Indonesia	Philippines
Guinea	Maldives	
Guinea-Bissau	Nepal	<i>Europe</i> (0)
Lesotho		
Madagascar		
Mali		
Mauritania		
Mozambique		
Niger		
Nigeria		
Senegal		
Sierra Leone		
Swaziland		
Togo		
United Republic of Tanzania		

regulations should be enforced by suitably qualified inspectors, whose authority should be defined by the law. . . Many drugs will not be manufactured within the country but will be imported. In such cases much of the information will have to be obtained either direct from the manufacturer, or through the drug administration of another country. . .

Control of exports

The export of drugs is not usually made subject to specific control under the general drug legislation. However, countries may, if they so desire, adopt a general provision in their national drug law requiring exported drugs to satisfy either domestic requirements or the requirements of the country of destination. . .

Control of distribution at the national level

In order to ensure the supply of drugs of good quality to the consumer or patient, control of the distribution chain is necessary. Wherever possible, the wholesale and retail distribution of drugs should therefore be restricted to those persons and enterprises having adequate storage facilities at their disposal. Training consistent with the level of service to be given is essential, including knowledge of how to store, handle and dispense or distribute drugs. Whenever regulations call for dispensing on medical prescription only, or sale through pharmacists or other licensed retailers only, control of the national distribution

network is an obvious prerequisite. Many drugs, indeed the majority, are not suitable for self-medication because of their therapeutic and toxic properties while, with psychoactive drugs, the risk of abuse exists. If practical considerations preclude effective government surveillance of the national distribution network, it may be desirable to provide such drugs only through hospital pharmacies or clinics with dispensing facilities. In rural areas without hospitals or clinics with dispensing facilities, a limited assortment of drugs for primary health care may be made available through medical or health workers.

The conventions require all persons and enterprises engaged in the manufacture, trade and distribution of the controlled substances to be licensed, and the establishments and premises where such activities take place to be controlled through inspections.

Drug control administration

Of central importance to all the above is the drug control administration itself, whose tasks will be determined by the scope of the general drug legislation. These will usually include registration and control of the manufacture, importation, exportation and wholesale and retail distribution of drugs. In some cases, this administration may also be responsible for pricing. The availability of analytical chemical services, preferably in the form of an official quality control laboratory working in conjunction with a university faculty, is a virtual necessity. Where registration and selection of drugs for use in the public sector involve an independent national scientific evaluation of efficacy and safety, expertise of academic level in internal medicine and other medical specialities, pharmacology and toxicology should be available to the administration, whenever possible in the form of an advisory panel, board or committee. In order to promote cooperation between the government and the medical and pharmaceutical professions, the active involvement of the corresponding professional societies in the implementation of national drug policies should be sought.

Special legislation relating to the Conventions

. . . In the context of the Conventions, special legislation will be needed in the following areas:

- (1) Insertion of the complete list of substances (drugs) in the schedules of the conventions into the relevant provisions on the control of pharmaceutical products (Single Convention, Article 1 and Psychotropic Convention, Article 1).
- (2) Licensing and inspection of all persons and enterprises in respect of all controlled substances in manufacture, production, trade and distribution.
- (3) Control of international trade, including the requirement for import and export authorizations for a number of the controlled substances.
- (4) The keeping of records on various aspects of manufacture, trade, distribution and use of the controlled substances as a basis for reports to the [United Nations] Secretary-General and the International Narcotics Control Board.
- (5) The use of medical prescriptions in dispensing the controlled substances.
- (6) The labelling of controlled substances and the control of advertising.
- (7) Penalties for actions contrary to the provisions of the conventions.

Sales categories of drugs

The control of pharmaceutical products used for the prevention, diagnosis and treatment of diseases should be the subject of a special drug law. . . The legislation must be introduced in stages, possibly in the following manner:

- (1) Make provision in the drug law for the administrative authority (or the minister or his delegate) to have the power to make regulations for the control of pharmaceuticals and other hazardous substances at the point of sale to the consumer.
- (2) Include in the regulations an appropriate list of schedules, defining the controls to be applied at each level.
- (3) Allow also for additions to, or removals from these schedules by administrative order of the responsible officer (normally a senior official at the ministry).

4.5 Diversion of medically prescribed opioids

Much has been written about the implications of international control of opioids. Indeed, the Single Convention on Narcotic Drugs, 1961, a concise document of 57 pages, has a companion *Commentary* of 489 pages (66). This underlines the point that any effort to simplify availability must recognize that many years and much effort have gone into developing an international system to prevent diversion from licit to illicit channels, with emphasis on combating illicit traffic. Even so, the international treaty does not aim to reduce the use of opioids that are needed for medical use. The following quotation comes from the Preamble to the Single Convention: "The medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and . . . adequate provision must be made to ensure the availability of narcotic drugs for such purposes."

4.5.1 Risk of diversion

Fear of diversion of opioids into illicit channels is often ill-founded, since only a very small percentage of illicit drugs comes from the health care system. In particular, orally administered morphine is not a drug of choice for opioid-dependent persons.

Nevertheless, concern about illicit drug use and its social consequences has curtailed the availability of opioid drugs to patients with cancer pain. It is therefore necessary to examine what has happened in countries where oral preparations of opioids for moderate to severe pain have been made available for such patients. Sweden provides a good example. The oral use of opioids for moderate to severe pain did not gain widespread acceptance in

Sweden until the late 1970s because oral administration was considered less efficacious than parenteral administration. Now, however, the regular use of orally administered morphine is considered the mainstay of the management of chronic cancer pain when non-opioid analgesics and weak opioids fail. This is reflected in the increased use in Sweden of morphine and methadone preparations for oral administration; between 1975 and 1982 use of these preparations increased 17-fold (67). The greater availability of strong opioids has allowed more cancer patients to be cared for at home. Equally important is the fact that there has been no associated increase in illicit drug use or diversion of drugs to established addicts.

4.5.2 *Risk of psychological dependence from medically prescribed opioids*

There is very little published information assessing drug abuse and the risk of psychological dependence (“addiction”) for patients who receive opioid analgesics for any type of painful chronic illness. However, the incidence of opioid dependence in some 40 000 hospitalized patients has been monitored in a prospective study (68). Among nearly 12 000 patients who received at least one opioid preparation for moderate to severe pain, there were only four reasonably well-documented cases of dependence in patients who had no history of drug abuse. These data suggest that the medical use of opioids is rarely associated with the development of psychological dependence.

A series of studies reporting the abuse of analgesics in patients with chronic illness found that abuse of non-opioid analgesics or combinations of weak opioids and non-opioids was more common than abuse of more potent opioids (69–71). Several recent studies, describing opioid therapy in patients with pain of nonmalignant origin, report that long-term use of opioids is not associated with either drug abuse or psychological dependence (72, 73). These studies support the view that drug use alone is not the major factor in the development of psychological dependence, and that other medical, social, psychological, and economic factors play an important role.

4.5.3 *Tolerance to opioids*

There is evidence to suggest that patients receiving opioids on a continuing basis develop some degree of tolerance to the analgesic effect of these drugs (74). Physical dependence also occurs, as demonstrated by the appearance of withdrawal symptoms following the administration of an antagonist such as naloxone, and by reports of acute withdrawal symptoms in patients who stop drug therapy abruptly after pain-relieving neurolytic or neurosurgical procedures (75). However, in studies of patterns of drug use in cancer patients, it was found that progression of metastatic disease causing increasingly severe pain was the major factor determining the need to increase analgesic dosage (75, 76). Reduction of drug intake was associated with specific therapy directed at the cause of the pain. Another study that has been reported was unable to find instances of drug overdose, substance abuse, or psychological dependence (77). It should also be pointed out that tolerance to the different opioid effects develops at different rates. In volunteer studies, for example, tolerance to respiratory depression develops rapidly whereas tolerance to the constipating effects develops slowly, if at all. When orally administered strong opioids are used in the manner described by WHO (6), tolerance is only rarely a practical problem. Similarly, physical dependence does not represent a clinical problem. Opioid drugs should not be stopped abruptly but withdrawn slowly to prevent the onset of the signs and symptoms of withdrawal. In short, tolerance and physical dependence are pharmacological effects that occur with repeated drug administration. They are to be distinguished from psychological dependence ("addiction"), which is a behavioural pattern characterized by compulsive drug-seeking behaviour leading to an overwhelming involvement with the use and procurement of the drug.

4.6 **Drug legislation and administrative requirements**

In order not to impede the availability of opioids, particularly morphine and codeine, for the treatment of pain, national, provincial and state drug legislation and administrative requirements should respect the following principles:

- Physicians should be legally empowered to prescribe, pharmacists to stock and dispense, and nurses to administer opioids for medical purposes.¹
- Government authorities and other bodies responsible for evaluating and ruling on professional conduct of health care workers should recognize the medical need for the use of opioids to treat pain.
- Manufacturers and/or distributors should be empowered to import, manufacture, stock and distribute opioids in keeping with the international drug conventions and good medical practice.

Record-keeping and authorization requirements should not be such that, for all practical purposes, they eliminate the availability of opioids for medical purposes. Multiple-copy prescription programmes are cited as means of reducing careless prescribing and “multiple doctoring” (patients registering with several medical practitioners in order to obtain several prescriptions for the same, or similar, drugs). There is some justification for this, but the extent to which these programmes restrict or inhibit the prescribing of opioids to patients who need them should also be questioned.

Health care workers may be reluctant to prescribe, stock or dispense opioids if they feel that there is a possibility of their professional licences being suspended or revoked by the governing authority in cases where large quantities of opioids are provided to an individual, even though the medical need for such drugs can be proved.

Although a country’s law may in theory permit the importation and distribution of opioids, in practice it may be that the necessary permits will not be granted by the regulating authority. Each country must supply to the INCB a realistic estimate of drug consumption, sufficient to meet the probable demand for medical use.

4.7 Facilitating opioid availability for medical purposes

The Expert Committee took note of a document currently being prepared by WHO in consultation with the Secretariat of the INCB, entitled *A guide to opioid availability for medical purposes*. While not specifically addressing the obstacles outlined in the joint INCB/WHO working document (see section 4.3), the guide will help drug

¹ Similar authorization may be extended to other health care workers according to local needs.

regulatory authorities and health care workers to overcome some of the interpretive and legislative barriers to the availability of opioids.

4.7.1 Availability of other drugs for the relief of cancer pain

Previous sections of this report refer to the specific factors affecting the availability of opioid analgesics that are under national and international control. Problems may also arise in the cases of buprenorphine, which is on the list of basic drugs for cancer pain relief (6) but which is controlled under the Convention on Psychotropic Substances, 1971, and diazepam. When implemented as intended, the Convention should not restrict the availability of therapeutically useful substances. In practice, however, impediments and disincentives to the prescription and supply of such medicines can occur if legal controls are unduly onerous and bureaucratic.

It is also recognized that many countries have additional problems of drug supply and distribution, which affect the availability of medicines in all therapeutic categories but which are not related to the international control of drugs. Non-availability of medicines in these countries is often due to a combination of factors such as inadequate funding of government health services, lack of health care infrastructure, and inadequate facilities for storage and distribution of medicines. These problems are being addressed by WHO, through its Action Programme on Essential Drugs. This programme recommends, among other measures, the establishment of national drug policies and the adoption of national lists of essential drugs, based on the WHO Model List of Essential Drugs (64). When such policies are formulated, it is important that they take into account the needs of cancer pain relief programmes. National and local formularies should include sufficient appropriate drugs to allow the guidelines on cancer pain relief to be implemented.

4.7.2 Availability of an opioid antagonist

Hyper-responsiveness to opioids or inadvertent overdose may lead to acute opioid intoxication, as may accidental ingestion of opioids by children in the home. It is therefore recommended that naloxone (an opioid antagonist) should be made available in all countries as an integral part of cancer pain relief programmes.

4.8 Conclusions

The following steps are necessary to ensure adequate drug availability:

- review of legislation with a view to permitting the importation, manufacture, prescription, stocking, dispensing, and administration of opioids for medical reasons;
- review of the administrative practices of opioid drug control with a view to their simplification so as not to impede legitimate use of opioids by patients;
- determination of the probable needs of the country, based on estimates of present consumption plus the “best guess” of needs for the likely number of cancer patients to be treated;
- review of legislation and practices that may affect the availability of other drugs.

5. OTHER COMMON SYMPTOMS OF CANCER PATIENTS

5.1 Physical symptoms

The most common symptom in patients with advanced cancer is asthenia (weakness), normally associated with anorexia and malnutrition. Problems of the skin and mouth and of respiration are also common. In addition, a number of neuropsychiatric syndromes, including anxiety, depression and confusion, create distress for both patients and families.

There is now considerable theoretical and practical knowledge about the control of these common symptoms as well of the pain experienced by cancer patients (49, 50, 78–82). The underlying mechanisms of some symptoms, however, such as the cachexia-anorexia-asthenia syndrome, remain poorly understood. There is a critical need to support research in this area in order to develop rational therapies based on sound physiological and psychological principles.

Pain, dyspnoea and other symptoms do not occur in isolation: they interact so as to produce a “crescendo” effect. For example, the dyspnoeic patient will experience increasing anxiety and rapid breathing, which may then exacerbate pain arising from metastases in the ribs and spine.

Treatment of multiple symptoms is demanding. Therapeutic efforts must consider the interaction of symptoms, the causal factors

involved, and maintenance of the delicate balance between relief, adverse drug effects, and patients' expectations. This task is best carried out by a palliative care team working with the patient-family group and other involved professional health care workers.

As in other areas of cancer care, the emphasis should be on prevention and early diagnosis. Many problems, such as mouth infections, skin ulcers, and constipation, can be prevented if the patient and care-givers have a plan for prophylactic treatment, which is subject to regular review.

5.2 Psychiatric symptoms

In one survey of more than 200 patients at three cancer centres, about half adjusted normally to the stresses of cancer with no diagnosable psychiatric disorder, while the other half had clinically apparent psychiatric complications (see Table 10). Among those in whom psychiatric problems were diagnosed, 39% had significant pain; only 19% of the psychiatrically normal patients had comparable pain (83). It is important to recognize that pain is a significant cause of psychiatric distress, which disappears when the pain is controlled.

Table 10. Psychiatric complications in 215 cancer patients

Category	Number	Percentage
Reactive anxiety or depression ("adjustment disorders")	69	32%
Major anxiety state	4	2%
Major depression	13	6%
Organic mental disorders	8	4%
Personality disorders	7	3%
Total	101	47%

Physicians, nurses and social workers experienced in palliative care should be able to identify and manage a wide range of psychiatric disturbances. A common error is to assume the existence of a functional problem such as depression, when the underlying problem is actually a confusional state, precipitated by a biochemical abnormality or toxicity. In one study, 85% of a group of terminally ill cancer patients developed a confusional state (84).

Psycho-oncology is developing rapidly as a subspeciality of psychology/psychiatry, and it is helpful to identify psychiatrists who

are willing to become familiar with the common problems of cancer patients. Articles and books in this area are relatively new, but they are beginning to offer more comprehensive reviews (85–90).

5.3 General strategy

Attention to detail and development of a specific plan for patient care are essential. After careful explanation of the problem, it is appropriate to discuss treatment options with the patient and to decide together on the immediate course of action. Few things are more damaging to a patient's self-esteem than to be disregarded in discussions concerning treatment.

Discussion with close relatives gives the opportunity to enlist their cooperation and to reinforce plans for symptom control; this is particularly important when the patient is at home. Their active participation is essential; they have a right to be informed, subject to the patient's approval. It is important, though, not to let relatives "take over": whenever possible, the patient's wishes must prevail.

In managing a persistent symptom, drugs should be administered regularly on a prophylactic basis. This principle is now generally accepted in relation to analgesics and pain management, but its application to the use of antiemetics and laxatives is not as fully appreciated. The use of drugs "as needed" instead of on a regular basis is often the cause of much unrelieved distress.

Whenever the prescription of an additional drug is considered, it is necessary to ask the following questions:

- What is the aim of treatment and how can it be monitored?
- What is the risk of adverse effects or drug interactions?
- Is it possible for the patient to stop one or more of the preparations he or she is already taking?

Simultaneous treatment with several drugs, although often necessary, can create added problems in a patient whose debilitated state has interfered with normal metabolism and excretion of drugs.

It is often impossible to predict the optimum dose of a drug used for symptom relief, and this is particularly true of opioids, laxatives and psychotropic drugs. Moreover, adverse effects may limit the likelihood of a patient complying with the treatment regimen. As adjustments in dose are likely to be needed, appropriate arrangements should be made for continuing supervision.

In addition to drug treatment, a wide variety of physical and behavioural approaches can enhance patient comfort. The skilful application of non-drug treatments complements pharmaceutical approaches, reduces the need for high doses of drugs, and thus reduces the risk of adverse effects.

Although many symptoms respond to a combination of drug and non-drug treatments, it is sometimes necessary to compromise in order to avoid unacceptable adverse effects. For example, anticholinergic effects such as dry mouth or visual disturbance are sometimes limiting factors. When there is intestinal obstruction, it is generally better to aim to reduce vomiting to once or twice a day rather than to seek complete control.

5.4 Sustaining hope

Hope can be sustained only if the patient continues to have a goal, and it is important to reassure the patient that everything will be done to relieve distressing symptoms. It is often necessary to proceed step by step, rather than to seek immediate and complete relief. If the overall goal can be approached via a series of smaller goals, the patient and the care-givers are more likely to remain hopeful (91).

Eventually, the patient's physical strength will diminish and it will become apparent that death is near. At this time, support and companionship are of particular importance. Health care workers should not feel powerless in the face of death. Continued attendance is an essential part of care in the last days of life, when technical expertise becomes less relevant and psychosocial and spiritual considerations are paramount. The skilful input of physicians and nurses who appreciate this will make the final hours of a patient's life more peaceful and help sustain the family in their bereavement.

6. PSYCHOSOCIAL ASPECTS

6.1 The patient

The psychological needs of patients with advanced cancer are considerable (Table 11) and unless these receive recognition and response, good pain control and symptom relief may prove impossible.

These needs are common to cancer patients in all cultures. Many patients, however, will not raise psychosocial concerns without

Table 11. The psychological needs of the patient with advanced cancer

Need	Comment
Safety	A feeling of security
Belonging	The wish to feel needed and not to feel a burden
Love	Expressions of affection; human contact (touch)
Understanding	Explanation of symptoms and the nature of the disease; the opportunity to discuss the process of dying
Acceptance	Regardless of mood, sociability and appearance
Self-esteem	Involvement in decision-making, particularly as physical dependence on others increases; the opportunity to give as well as to receive
Trust	Honest communication with family and care-givers, and confidence of receiving the best possible care

prompting. All too often, questions by health care workers about physical aspects determine treatment priorities, while time and lack of privacy preclude discussions of other matters. It is perhaps not surprising that serious problems of anxiety and depression commonly occur in cancer patients (83). A particularly difficult time follows disclosure of the diagnosis, when the patient first faces the prospect of incurability and death. This often induces a state of numbness and denial followed by a period of mental turmoil. Support is particularly necessary at this time.

When attempting to elicit personal information from patients and families which it may be difficult for them to discuss, health workers should use open-ended questions such as "How have things been with you lately?" or "Tell me, how have you been feeling in general?". It is important to allow time for patients to answer. They will provide information only if they feel trust for the questioner and can sense his or her genuine interest (92).

Regular visits and an empathic attitude to patients are essential for effective psychological care, as is good communication between health care workers, patients and families. Without these, patients often experience unnecessary added distress. Other necessary attributes in the care-givers include honesty, humility, and sensitivity to the patient.

6.2 The family and close friends

The person closest to the patient may not be the next of kin, or even a relative. Health workers need to recognize and appreciate that the nature of close relationships varies widely. Lack of support for

those caring for a patient at home is often the precipitating factor in the admission to hospital of a dying patient. The social worker should be an integral member of the palliative care team, providing additional psychological support for both patient and family and helping to identify and resolve practical, social and financial problems. Good support should include the following elements:

- *Practical support.* This should include, when indicated, instruction in skin care and the prevention of bedsores, how to lift a paralysed patient and how to cope with incontinence. Support of this kind can be provided by general medical practitioners, community nurses, physiotherapists, occupational therapists and social workers, or welfare officers.
- *Emotional support.* Family care-givers should be the patient's main source of psychological support; they can be helped in this role by appropriate counselling. They should be made aware of the patient's psychological needs (see Table 11) and of common reactions to life-threatening illness. Nurses, social workers and physicians will usually be responsible for this aspect of family support, but trained volunteers and community groups can effectively supplement family and professional support.
- *Day care and inpatient beds for respite care.* In some cases, a patient's attendance at a day centre and/or admission to a palliative care centre or hospital as an inpatient may be necessary to provide respite for family care-givers.
- *Farewell leave.* In developing countries, most patients die at home in the care of the family. In developed countries, by contrast, death more often occurs in an institution although much of the terminal care could be provided as effectively—and more economically—by the family. Countries with a health care structure that allows, for example, paid maternity leave should consider establishing paid leave for those who care for the terminally ill. Denmark has already introduced this concept: when a physician has judged that further anticancer treatment is futile, paid leave is granted to a close relative to care for the patient at home when possible and desirable. In 1989, Sweden introduced 30 days' paid leave for the principal care-giver. In Norway, although no official mechanism for paid leave has yet been established, a similar system frequently operates: the physician declares that a close relative or friend is the key care-giver and then arranges for standard sick-leave compensation.

- *Bereavement support.* There is evidence that those who lack support in their bereavement have a higher rate of morbidity (93–95). All relatives and friends will need to discuss the events surrounding the death of the patient. This can be encouraged by attentive listening by a professional health care worker or suitably trained volunteer (96). There may need to be follow-up for several months, sometimes much longer, and this is particularly true for bereaved people with limited social support (97). To be effective, a bereavement programme must have defined goals and a consistent method of follow-up, and must concentrate its efforts on those individuals at greatest risk (96).

6.3 Patients with AIDS

Patients with acquired immunodeficiency syndrome (AIDS) face many psychosocial stresses, which may be more marked than those in cases of cancer because the patients:

- are generally younger;
- experience stresses particular to their risk group (e.g. social ostracism);
- often suffer from organic mental disorders (confusion, dementia, organic mood syndromes) caused by HIV (human immunodeficiency virus) infection of the central nervous system or by complications of the underlying immunodeficiency such as opportunistic infections and tumours.

In principle, there is no difference between the care of the patient with AIDS and the care of the patient with advanced cancer. Psycho-oncologists and professional mental health workers working in oncology have experience not only in dealing with the psychological impact of life-threatening diseases, but also in the field of organic psychiatry. They are, therefore, well prepared to deal with patients with AIDS. In 1988, the American Society of Psychiatric Oncology/AIDS (ASPOA) was established as a national organization representing psychiatrists working in the areas of cancer and AIDS.

6.4 Staff support

Good palliative care depends on well trained health care staff who feel that they have sufficient psychological support to undertake

emotionally demanding tasks. The following considerations are important in this respect:

- *Selection of staff.* Interviewing panels should include someone who is already involved in palliative care and who is therefore aware of the personal qualities, as well as the professional qualifications, needed for this type of work.
- *Good communication.* Much job stress is related to inter-professional conflict (97). A clear operational policy, defining the roles of members of the care team, will help to reduce the risk of gaps or excessive overlap in the various elements of care, and will also reduce staff stress.
- *Staffing levels.* Palliative care is time-consuming and adequate staffing levels are therefore necessary, particularly in the terminal stages of cancer. The counselling role of staff is essential but difficult to quantify. Administrators should take this essential component of palliative care into account when deciding on staff levels.
- *Emotional support.* Health care staff are most likely to find emotional support in a unit where they also enjoy a high degree of mutual respect, have clearly defined and commonly supported goals, and where authority matches responsibility.

6.5 Teaching psychological skills to health care workers

If the psychosocial care of cancer patients is to be satisfactory, professional health care workers must be trained in psychological assessment and counselling skills. Few physicians and nurses involved in cancer care receive any formal training in these areas and often have little time available in the working day for their application.

6.5.1 Basic training

Basic skills that should be taught to and mastered by all physicians, nurses and social workers include:

- recognition of the nature and prevalence of the psychosocial distress associated with cancer and its treatment;
- knowledge of the signs and symptoms that distinguish morbid reactions requiring special intervention from normal reactions;

- ability to acknowledge, clarify and organize key verbal and nonverbal cues that patients and relatives give about their problems;
- ability to maintain the focus of an interview, helping patients and relatives stick to the point without alienating them;
- ability to explore highly emotive topics, e.g. worry about the future or the impact of illness on a personal relationship, in a way that is constructive yet allows the expression of feeling;
- the use of open-ended (“How are you feeling?”) and non-directive questions (“How did you feel about having a stoma?”).

These skills can be improved through the provision of written and visual materials that make the methods more explicit. In addition, practice through role-play with videotape feedback of performance will enhance learning (98). Situations that are most commonly practised in role-play include:

- basic psychological assessment;
- breaking bad news;
- coping with a patient who has been misled about his or her prognosis;
- handling difficult questions;
- dealing with anger;
- challenging denial;
- establishing dialogue with a withdrawn patient;
- facing relatives after the death of the patient.

Published data indicate that the acquired skills persist (99), but follow-up workshops within 6–12 months of the original teaching sessions would help consolidate learning and facilitate the discussion of difficulties encountered in clinical practice. Participants could then move on to more advanced counselling tasks.

6.5.2 *Training at work*

Training within the working environment is an alternative approach (100, 101). Ideally, it should be possible to offer training to staff at all major cancer centres with the help of suitably trained and experienced tutors.

More teachers will be needed if training in assessment and counselling is to be improved. Cancer specialists, psychiatrists, psychologists, specialist nurses and social workers already committed to improving psychological and social care are clearly

valuable resources. Most of them, however, need training in the use of appropriate teaching methods (102).

6.6 Research

Research in the psychosocial aspects of cancer care has suffered from lack of long-term funding, but the problem has been recognized and several initiatives have been taken. In the United Kingdom, for example, two cancer societies have jointly established two psychosocial research units that are concentrating on longer-term research. Both the American Cancer Society and the Dutch Cancer Foundation are also fostering research in this area.

Some major cancer centres, such as the Memorial Sloan-Kettering Cancer Center in New York, have established academic departments of psychiatry that offer formal clinical and research training, as well as conducting clinical research that addresses key questions in psychosocial oncology. Others, like the Institut Jules Bordet in Paris, have departments of psychosocial oncology. These institutions are resources for those wishing to obtain training in research methodology.

7. SPIRITUAL ASPECTS

Because palliative care is concerned with the well-being of the whole person, it should acknowledge and respect the spiritual aspects of human life. Thus, all programmes of palliative care should respect and incorporate the basic values of spiritual and religious diversity that are enshrined in the United Nations' *Declaration on the elimination of all forms of intolerance and of discrimination based on religion and belief* (103):

Everyone shall have the right to freedom of thought, conscience and religion. This right shall include freedom to have a religion or whatever belief of his choice, and freedom, either individually or in community with others and in public or private, to manifest his religion or belief in worship, observance, practice and teaching.

7.1 Definition of "spiritual"

"Spiritual" refers to those aspects of human life relating to experiences that transcend sensory phenomena. This is not the same as "religious", though for many people the spiritual dimension of

their lives includes a religious component. The spiritual aspect of human life may be viewed as an integrating component, holding together the physical, psychological and social components (104). It is often perceived as being concerned with meaning and purpose and, for those nearing the end of life, this is commonly associated with a need for forgiveness, reconciliation and affirmation of worth.

7.2 Assessment of spiritual needs

Patients should be asked about the spiritual aspects of their lives. Some find these areas vague, or even threatening, and questions must be asked gently, with full respect for patients' rights to their own values and beliefs, and acceptance of their right to remain silent about them (105).

Information about patients' concepts of deity may be elicited by asking whether religion or God is significant to them and, if so, by asking for a simple description (106). Questions that focus on sources of hope and strength may also open up this area of care, e.g. "To whom do you turn when you need help?"

It is important to enquire about religious practices with special attention to those that impinge upon hospital life or health care. Questions that focus on the relation between spiritual beliefs and health may also be helpful, for example "Has being sick made any difference to your beliefs or to the practice of your religion?"

7.3 Offering spiritual help and support

Patients have the right to expect that their spiritual experiences will be respected and listened to with attention (107, 108). The relating of such experiences, and the reflection on their meaning, frequently offer a kind of inner healing. When patient and care-giver have a relationship based on mutual respect and trust, there can be a place for the sharing of stories, conversations about the meaning of life and the purpose of suffering, and even participation in religious rituals. A caring relationship that is able to incorporate spiritual aspects has added potential for inner healing. Two premises must be borne in mind:

- Respect for people's beliefs is imperative (104). Care-givers do not have to agree with people's beliefs or practices in order to take them seriously. Non-believers can affirm their contribution to a sense of well-being and integrity in others.

- Supportive interventions in this area must be offered in ways that are non-sectarian, non-dogmatic and in keeping with patients' own views of the world.

Patients who wish to participate in private or communal spiritual or religious activities must be enabled to do so. At times, however, they will need privacy and access to spiritual advisers.

8. ETHICAL CONSIDERATIONS

Two cardinal principles of clinical care are to do good and to minimize harm. In practice, this means seeking an acceptable balance between the advantages or benefits and the disadvantages or burdens of treatment. These principles are applied in conjunction with at least three others:

- respect for life;
- respect for patient autonomy;
- fairness in the use of limited resources.

In palliative care, the same principles apply. Moreover, in a situation where there is uncertainty about the most appropriate treatment for an individual patient, the dilemma may be resolved by a consideration of the patients' total circumstances (109).

8.1 The ethics of pain control

The ethical and legal distinction between killing the pain and killing the patient is clear in principle, but may not always be so clear in practice. If perceptions are out of phase with principles, some may feel that in killing the pain they have also killed the patient. However, patients have a right to demand, and physicians a duty to administer, sufficient analgesic medication to control pain:

A physician cannot be held criminally liable for undertaking or continuing the administration of appropriate palliative care in order to eliminate or reduce the suffering of an individual, only because of the effect that this action might have on the latter's life expectancy. (110)

One of the essential elements of a "good death" is freedom from the pain that dominates consciousness and may leave the patient physically and mentally incapable of reaching whatever goals he or she may want to achieve before death. There is thus no excuse for failure to use available methods to control pain adequately.

If shortening of life results from the use of adequate doses of an analgesic drug, this is *not* the same as intentionally terminating life by overdose. Any hastening of death that is linked to adequate pain control measures simply means that the patient could no longer tolerate the therapy necessary for a bearable and dignified life.

8.2 The ethics of life-prolonging treatment

Doctors and nurses have a professional and moral responsibility to ensure that a patient's refusal of life-sustaining measures is not the expression of feelings dominated temporarily by hopelessness, guilt, or depression. Conversely, preservation of life at all costs is not necessarily the right course, particularly when the personal cost is such that the patient finds it unacceptable (111, 112).

Human dignity and self-esteem come to mature expression when a person's considered and cherished intentions are respected by others. Patients surviving on life-support machines are not always able to act in accordance with their intentions. The help that they then need, but cannot always obtain, includes attention, understanding, and respect from others for a choice that seemingly contradicts a basic purpose of medicine, that is, the saving of life (113).

In many countries, people have come to accept the notion that aggressive life-support, at intolerable personal cost, is not the right course to take. From this has evolved the ethic of allowing terminally ill people to die peacefully, which may involve withholding or discontinuing such interventions as respiratory support, chemotherapy, surgery, and assisted nutrition. The ethic rests upon the considerations outlined below (114).

8.2.1 The patient's will as norm

Provided that a patient's mental competence is not in doubt, most people would agree with the principle that "the will of the patient, not the health of the patient, should be the supreme law" (115). The Law Reform Commission of Canada, for example, has proposed an amendment to the Criminal Code to prohibit any relevant paragraph of the code from being interpreted as requiring a physician "to continue to administer or to undertake medical treatment against the expressed wishes of the person for whom such treatment is intended" (110).

One of the several religious organizations that have addressed this issue also supports self-determination and stresses that refusal of life-prolonging treatment is not equivalent to suicide (116). The relevant passage states:

One cannot impose on anyone the obligation to have recourse to a technique which is already in use but which carries a risk or is burdensome. Such a refusal is not the equivalent of suicide; on the contrary, it would be considered as an acceptance of the human condition, or a wish to avoid the application of a medical procedure disproportionate to the results that can be expected or a desire not to impose excessive expense on the family or the community.

Occasionally, a patient may choose to suffer unrelieved pain because of deeply held beliefs. This decision must be respected, however difficult the experience for the family and professional caregivers.

8.2.2 *The principle of proportion*

The principle of proportion affirms that life-prolonging treatments are contraindicated when they are the source of more suffering than benefit. Dogmatic adherence to a "life is sacred" principle may result from failure to recognize the limits of medicine and particularly of a patient's physical and moral resources. Medicine reaches a limit when all it can offer is an extension of function, which is perceived by the patient to be a prolongation of dying rather than an enhancement of living. It is therefore ethically justifiable to discontinue the use of life-prolonging techniques when their application imposes strain or suffering on the patient out of proportion to the benefits that may be gained from them (111, 116).

8.2.3 *The equivalence principle*

Some health workers find it easier to withhold life-prolonging treatment than to discontinue such treatment once it is started. However, the decision in each case is governed by the same ethical considerations: in other words, "stopping treatment is ethically no different from never starting it" (115).

8.2.4 *The relativity principle*

The preceding considerations rest on the premise that life is not an absolute good and that death is not an absolute evil. A moment arrives, at different times for different patients, when technologically

aided efforts to extend life may interfere with higher personal values. In this circumstance, life-prolonging efforts should give way to other forms of care.

8.3 Euthanasia

If decisions to stop all life-prolonging treatment and to allow “nature to take its course” are morally and legally justifiable, the question arises as to whether society should allow doctors to help nature take its course more quickly. If the patient is bound to die, it may be asked, of what good to the patient or family is an interim period of slow decline into death? Why should patients, families and care-givers be obliged to await death passively? Would not active acceleration of death—euthanasia—be preferable?

Many would argue that it is essential for euthanasia to remain illegal because of the most basic of all principles, namely, that no one has dominion over the life of another. Religious leaders, philosophers and judges have reiterated this principle in various ways over the ages. Others have argued that the “no dominion” principle cannot be justified if euthanasia appears desirable in some circumstances, from certain points of view, or to everyone involved in a particular case. These and other related points of view have been raised time and again and debated vigorously in several countries.

The Committee adopted the position that, with the development of modern methods of palliative care, legalization of voluntary euthanasia is unnecessary. Now that a practicable alternative to death in pain exists, there should be concentrated efforts to implement programmes of palliative care, rather than a yielding to pressure for legal euthanasia.

The Committee reached the following conclusions:

- It is ethically justifiable to withhold or discontinue life-support interventions that do not accord with a patient’s wishes when such interventions cannot reverse the course of disease, but only prolong the process of dying.
- It is also ethically justifiable for doctors, after consultation with family members, guardians or proxies previously appointed by a patient, to take such decisions on behalf of unconscious or incompetent patients.
- Drugs in the doses required to control pain and other symptoms should not be withheld solely because they may shorten a patient’s life.

- Euthanasia (active acceleration of death with drugs) should not be legalized.

8.4 Fairness in the use of limited resources

8.4.1 Home care

Increased emphasis on home care raises the issue of fair allocation of available health care resources. It is usually in the patient's best interests to return home if adequate health care support is available: discharge from an institution enhances the patient's autonomy and therefore self-esteem. However, existing funding arrangements in many countries do not always allow the equitable distribution of appropriate resources.

While the overall costs to the health care services may be reduced by home care, those to the family are usually increased. Costs include direct financial costs, such as for drugs and dressings, loss of care-givers' earnings through absence from work, and payments for additional nursing, support services and sometimes building alterations. In addition, there is an emotional price to pay for lost sleep and a constant association with the suffering of a loved one. The patient's illness creates new burdens for the care-givers and considerably limits their freedom. For some, this can become very tiring, and the desire to be loving and giving may be replaced by a sense of onerous duty (117).

It is easily assumed that families should provide home care, but the dedication of care-givers should not be taken for granted. If a society encourages home care, it also has an ethical responsibility to look after both the patient and the family care-givers. The tangible expression of this philosophy would be the expansion of home nursing services and the provision of public financial support for care-givers.

8.4.2 Misuse of cancer control resources

The aggressive use of expensive chemotherapeutic agents when there is no prospect of cure is an example of the misuse of resources (118, 119). In many countries, the resources available for cancer services would be better utilized if a sizeable proportion were redirected to the development of programmes of prevention, early diagnosis and palliative care.

9. EDUCATION AND TRAINING

9.1 Professional health care workers

Several reports emphasize that professional health care workers lack education in the management of cancer pain (40, 55, 120, 121). The same is true of palliative care in general, and education is a priority for ensuring the effective implementation of a palliative care programme. The success of palliative care in several countries indicates that education in palliative care can be transferred to, and incorporated into, existing health care systems (1–3); the creation of a separate system for palliative care is therefore not essential.

9.2 Multiprofessional education

Multiprofessional team-work is necessary for optimum pain relief and palliative care, and multiprofessional education may therefore sometimes be appropriate. Subjects suited to such an approach include:

- attitudes in society to terminal disease and death;
- aims and scope of palliative care;
- general principles of the management of pain and other symptoms;
- psychological assessment and counselling skills;
- general principles of psychological and family support;
- spiritual aspects of care;
- loss and grief;
- ethical and legal aspects;
- staff support.

9.3 Multidimensional education

Education is concerned with the following three interrelated aspects of palliative care:

- attitudes, beliefs and values;
- knowledge base;
- skills.

The lists that follow are intended as a guide and are not comprehensive. If educational objectives are to be achieved, other issues will also need to be addressed, such as the management of change and the development of health policy.

- *Attitudes, beliefs and values.* Minimum learning in this area should include the following topics:
 - the philosophy and ethics of palliative care;
 - personal attitudes towards cancer, pain, dying, death and bereavement;
 - illness as a complex state with physical, psychological, social and spiritual dimensions;
 - multiprofessional team-work;
 - the family as the unit of care.
- *Knowledge base.* As a minimum, learning in this area should include the following topics:
 - principles of effective communication;
 - pathophysiology of the common symptoms of advanced cancer;
 - assessment and management of pain and other symptoms;
 - psychological and spiritual needs of seriously ill and dying patients;
 - treatment of emotional and spiritual distress;
 - psychological needs of the family and other key people;
 - availability of community resources to assist patients and their families;
 - physiological and psychological responses to bereavement.
- *Skills.* Opportunities should be provided for the application of learned knowledge through practice in the classroom, making use of role-play and discussion of real case-histories. Important areas for practice include: goal-setting in physical, psychological, social and spiritual dimensions; development of a family care plan; and monitoring of pain and symptom management.

9.4 Educational material

There is a lack of suitable educational material in many parts of the world. The situation is improving, however, and there are signs that health care workers are increasingly aware of the need for palliative care and for higher standards (122).

In relation to pain control, the WHO publication *Cancer pain relief* (6) has served as an excellent primer. The Committee noted that WHO intended to revise the method for relief of cancer pain and to produce guidelines on relief of other symptoms. In addition, several leading medical societies and governments have issued reports on the management of cancer pain in recent years (8–11,

55–57), which strongly urge the implementation of programmes of cancer pain management based on drug treatment.

A number of reference works on palliative care are now available (49, 50, 79, 81). In France, an official Government document entitled *Soigner et accompagner jusqu'au bout* [*Caring and accompanying to the end*] (8) was recently published, and in Japan the Ministry of Health and Welfare and the Japanese Medical Association have jointly issued a manual of care for terminally ill cancer patients (9). In addition, several palliative care journals have been established in the past few years, for example, *American hospice journal*, *Journal of palliative care*, *Journal of pain and symptom management*, and *Palliative medicine*.

9.5 Integrated education

To maximize the impact of an educational programme on pain relief and palliative care, the subject should be:

- included as compulsory in courses leading to a basic professional qualification;
- accepted as suitable for testing by examination boards;
- recognized by universities and professional bodies as appropriate for study, dissertations, certificates, diplomas, and advanced degrees;
- included in postgraduate programmes of continuing professional education;
- recognized as an appropriate basis for scholarships, fellowships, and grants by academic institutions and research-funding bodies.

Progress is more likely if steps are also taken to:

- encourage and help societies and institutions interested in professional education (e.g. International Union Against Cancer, International Society of Nurses in Cancer Care, European School of Oncology, International School for Cancer Care, International Association for the Study of Pain, other health care associations, postgraduate colleges, cancer societies and foundations) to sponsor relevant conferences, seminars and meetings at local, national, and regional levels;
- provide a comprehensive list of suitable instructional material on cancer pain and symptom management, and facilitate access to such material through existing educational systems;

- encourage support for funding educational programmes for health care workers and the public in the goals and practical application of palliative care.

9.6 Public education

It is essential that the public be made aware that:

- palliative care will improve a patient's quality of life, even if the cancer is incurable;
- cancer is not always painful;
- treatment exists that can relieve pain and many other symptoms in advanced cancer;
- drug therapy is the mainstay of cancer pain management;
- there is no need for patients to suffer prolonged and intolerable pain or other distressing symptoms;
- drugs for the relief of pain can be taken indefinitely without losing their effectiveness;
- psychological dependence (“addiction”) does not occur when morphine is taken to relieve cancer pain;
- the medical use of morphine does not lead to abuse.

9.7 Education of patients and families

In addition, patients and families need to know how to obtain support from a palliative care service, and where and whether home care support is available.

10. IMPLEMENTATION OF PALLIATIVE CARE AT THE NATIONAL LEVEL

10.1 Prerequisites for a national policy

After formulation of guiding principles as a foundation, the first prerequisite in establishing a national policy on cancer pain relief and palliative care is the recognition that cancer pain and other common cancer symptoms are undertreated, and that this is a neglected public health problem. Other prerequisites include:

- a commitment to train health care workers in managing pain and other common symptoms of cancer;

- a commitment to ensure the availability of both opioid and non-opioid analgesics; and,
- a commitment to ensure that laws and regulations governing the professional conduct of health care workers permit the adequate treatment of cancer patients in pain.

10.2 A national policy for palliative cancer care

A national policy need not be elaborate. In addition to the prerequisites listed above, it should outline a step-by-step plan for implementation of a palliative care programme. For example, a national policy document may project a phased introduction of the programme, beginning with the major cancer treatment centres, followed by provincial hospitals and then community health centres. This will facilitate the development of a structured and coordinated national system for educating health care workers in the management of pain and other common symptoms of cancer, at the same time making available the necessary drugs, especially opioid analgesics.

10.3 Monitoring, evaluation and indicators

Monitoring and evaluation should form an integral and essential part of all activities in a palliative care programme; the results should be used for reformulation and strengthening of activities. Proposed indicators for monitoring and evaluating the effective implementation of cancer pain relief and palliative care programmes include the following:

- adoption of an official policy;
- availability of appropriate drugs, especially morphine for oral administration;
- programmes of education for health care workers on cancer pain relief and palliative care;
- the level of morphine consumption;
- implementation of guidelines on cancer pain relief and palliative care.

Changes in these indicators will reflect the degree of success in implementing the programme, but the ultimate indicator of success will be the level of application of pain relief and palliative care for cancer patients in rural community health clinics.

The Expert Committee noted with approval that, at the global level, WHO will regularly monitor and evaluate progress made in each Member State, stimulating the work and providing technical support at regional and/or country level. The global monitoring of programmes for cancer pain relief and palliative care is part of WHO's cancer control programme.

11. RECOMMENDATIONS

11.1 Recommendations to WHO

1. WHO should support the concept of palliative care, which integrates pain relief into a comprehensive approach to care at all stages of cancer, and should take into consideration the management of all problems affecting dying cancer patients and their families.
2. The policies and guidelines recommended for cancer pain relief and palliative care are also relevant to the management of AIDS and could be employed in improving the care of patients with AIDS.
3. The expertise that WHO gains through its work in the area of cancer pain relief and palliative care should ultimately be applicable to broader-based programmes directed at the needs of all dying patients.
4. WHO should urge Member States to establish cancer pain relief and palliative care programmes within their existing health care systems and should provide expert guidance on this, based on WHO policies.
5. WHO should consider organizing regional and interregional workshops to facilitate the introduction and progress of cancer pain relief and palliative care policies and programmes in all Member States.
6. WHO should ensure the widest possible distribution of guidelines on relief of cancer pain, and other symptoms, and on availability of opioids for medical purposes.
7. WHO should produce guidelines that will assist family caregivers to provide palliative care for cancer patients in the home.
8. WHO should arrange for the preparation of material on psychosocial aspects of palliative care, to complement the existing guidelines for health care workers.

9. WHO should encourage international development agencies to support and assist in the establishment of cancer pain relief and palliative care programmes in Member States.

10. WHO should regularly review the agents available for relief of cancer pain and make recommendations for their inclusion in the Model List of Essential Drugs.

11. WHO should promote the interest and involvement of appropriate nongovernmental organizations in the development and support of cancer pain relief programmes and palliative care initiatives.

12. WHO should encourage international nursing organizations to review *A core curriculum for a post basic course in palliative nursing care* and to promote implementation of its recommendations.¹

13. WHO should cooperate with both public and private research agencies in an effort to establish “quality of life” scales for application in a palliative care setting.

14. WHO should encourage public and private research agencies in the development of more selective opioids and novel analgesic agents that might further improve the management of pain in cancer patients.

15. WHO should encourage governments, nongovernmental organizations and voluntary agencies to promote the formation of multi-institutional networks for palliative care research.

16. WHO should encourage national research bodies, non-governmental cancer agencies and other cancer organizations: (a) to adopt pain control and palliative care as priority interests, (b) to establish programmes for the development and support of research in the area of cancer pain and symptom control, and (c) to provide funding for palliative care research in fairer proportion to the magnitude of the existing problem.

17. Given the need to raise the level of awareness about the potential benefits of palliative care and the availability of methods to control cancer pain and other symptoms, WHO should encourage the media to inform the public that:

- patients should insist on their rights to good palliative care and to freedom from cancer pain;
- palliative care will improve the quality of life of patients with cancer, even though the disease may be incurable;

¹ Available from the International Society of Nurses in Cancer Care, Royal Marsden Hospital, London SW3 6JJ, England.

- cancer is not always painful;
- treatments exist that will relieve pain and many other symptoms in advanced cancer;
- drug therapy is the mainstay of cancer pain management;
- there is no need for patients to suffer prolonged and intolerable pain or other distressing symptoms;
- psychological dependence (“addiction”) does not result from the use of opioids to relieve cancer pain;
- the use of opioid analgesics in cancer patients does not lead to abuse or to the diversion of the drugs into illicit markets;
- family members or friends can undertake most aspects of palliative care in patients’ homes.

18. WHO should collaborate with the INCB in extending and intensifying its training activities, to include coverage of opioid availability to health care workers when appropriate, and in its dialogue with drug regulatory authorities to ensure execution of the provisions of the Conventions and to simplify the supply and distribution of opioids for medical purposes.

19. WHO should encourage international and national non-governmental health agencies to establish and fund demonstration teams to train health care workers in cancer pain relief and palliative care.

20. WHO should encourage nongovernmental organizations and voluntary societies to consider fellowship support for trainees studying cancer pain relief and palliative care.

21. WHO should urge those institutions and organizations responsible for training and certifying health care workers to ensure that cancer pain relief and palliative care are:

- included compulsorily in courses leading to a basic professional qualification;
- accepted as suitable subjects for testing by examination boards;
- recognized by universities and professional bodies as appropriate subjects for study, dissertations, certificates, diplomas and advanced degrees;
- included in postgraduate programmes of continuing professional education;
- recognized as appropriate subjects for scholarships, fellowships and grants by academic institutions and research-funding bodies.

11.2 Recommendations to Member States

Implementation of the following recommendations, which could have a major impact on the quality of life of cancer patients, will require strong political motivation and leadership but can be undertaken without high expenditure.

1. Governments should establish national policies and programmes for cancer pain relief and palliative care.

2. Governments of Member States should ensure that cancer pain relief and palliative care programmes are incorporated into their existing health care systems: separate systems of care are neither necessary nor desirable.

3. Governments should ensure that health care workers (physicians, nurses, pharmacists, or other categories appropriate to local needs) are adequately trained in palliative care and the relief of cancer pain.

4. Governments should review their national health policies to ensure that equitable support is provided for programmes of palliative care in the home.

5. In the light of the financial, emotional, physical and social burdens carried by family members who are willing to care for cancer patients in the home, governments should consider establishing formal systems of recompense for the principal family care-givers.

6. Governments should recognize the singular importance of home care for patients with advanced cancer and should ensure that hospitals are able to offer appropriate back-up and support for home care.

7. Governments should ensure the availability of both opioid and non-opioid analgesics, particularly morphine for oral administration. Further, they should make realistic determinations of their opioid requirements and ensure that annual estimates submitted to the INCB reflect actual needs.

8. Governments should ensure that their drug legislation makes full provision for the following:

- regular review, with the aim of permitting importation, manufacture, prescribing, stocking, dispensing and administration of opioids for medical reasons;
- legally empowering physicians, nurses, pharmacists and, where necessary, other categories of health care worker, to prescribe, stock, dispense and administer opioids;

—review of the controls governing opioid use, with a view to simplification, so that drugs are available in the necessary quantities for legitimate use.

9. With pressure for the legalization of euthanasia likely to increase, governments should make strenuous efforts to keep fully informed of all developments in the fields of cancer pain relief, palliative care and management of terminal cancer.

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