Italy reforms national policy for cancer pain relief and opioids

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Treatment of pain caused by cancer in Italy has been reported to be inadequate for more than a decade. The problem has been documented in the literature by International Narcotics Control Board (INCB) reports that show Italy’s low consumption of morphine, and by INCB statements reflecting concern that pain medications are not adequately available to suffering cancer patients. The reasons for undertreatment include lack of physician education, low public awareness about pain management and overly restrictive regulations that inhibit the prescribing of opioid analgesics. In 1999, a workgroup appointed by the Ministry of Health began to address inadequate cancer pain management. In 2000, the workgroup issued a proposal to reform national policy, including simplification of opioid prescribing requirements. The proposal was adopted by Parliament in January 2001 and was effective from March 6th. Distribution of a new opioids prescription form to selected regions in Italy began in December 2001. The change, when fully implemented, will be an important step toward relieving cancer pain.

Keywords: cancer pain, Italy, legislation, opioid analgesics, opioid availability, triplicate prescriptions.

INTRODUCTION

It is estimated that there are about 300,000 new cases of cancer per year in Italy (Zurrada & Costa 1997). Many of these patients, especially those in the late-stage, will suffer from moderate to severe pain. The World Health Organization (WHO) has established a public health goal to relieve cancer pain and has made recommendations to governments (World Health Organization 1986, 1990).

Opioid analgesics are essential for the relief of cancer pain but often are not available for a variety of reasons including excessively strict national narcotic regulations (World Health Organization 1996). The International Narcotics Control Board (INCB) has asked governments to evaluate their national policies to ensure the availability of opioids for medical purposes, in accordance with the United Nations 1961 Single Convention on Narcotic Drugs. The Single Convention recognizes explicitly that opioid analgesics (narcotic drugs) are indispensable for the relief of pain and suffering, and that national governments are obligated to ensure their adequate availability for medical and scientific purposes (United Nations 1973).

Experts have reported that management of cancer pain is inadequate in Italy (De Benedittis & Lorenzetti 1989,
Garattini 1993], especially when compared to many other developed countries in the world (Zenz & Willweber-Strumpf 1993). The reasons offered for inadequate pain management include lack of physician education and public awareness of the importance of using opioid analgesics (including morphine) to treat cancer pain (De Benedictis & Lorenzetti 1989; Garattini 1993; Mercadante & Salvaggio 1996), cultural prejudices about opioid analgesics (Garattini 1993), and overly restrictive prescription regulations (Minotti & Betti 1997), in particular the complex Special Prescription Forms (SPF), which inhibit the prescribing of opioid analgesics (Ripamonti et al. 1996; Simini 1996; Mercadante 1998). Overprescribing of weak analgesics in Italy has been attributed to the burdensome requirements of the SPF, which is required for strong analgesics (Blengini & Ventafridda 2000).

Italy’s per capita morphine consumption for 2000 ranks among the lowest of European countries (see Figure 1). Indeed, very low medical use of morphine in Italy has been reported (Garattini 1993; Simini 1996; Blengini et al. 1998; Mercadante 1998; International Narcotics Control Board 1996a; 2001). The INCB has expressed concern about opioid availability in Italy, stating ‘Some countries with relatively high per capita income [such as…Italy…] continue to have low consumption levels’ (International Narcotics Control Board 2000, p. 5). ‘The Board remains concerned about the low level of consumption of morphine for medical purposes in Italy, which may be indicative of insufficient availability of the drug for pain management purposes’ (International Narcotics Control Board 2000, p. 61).

There have been numerous efforts by healthcare professionals and pain relief organizations to address the educational and regulatory barriers on a national level, but with little success until recently.

METHODS

The methods used to change policy involved leadership and co-operation from governmental and non-governmental organizations and experts who used available data to define the problems and then devise measures to address them. Beginning in 1998, the Italian Society of General Practice (SIMG) devoted two issues of its journal to the topic, ‘Cancer patients, pain and palliative care’ (S.I.M.G., 1998a, b), which presented statistics about medical use of opioids and reviewed the regulatory and healthcare system barriers to adequate cancer pain management. One issue contained a request by numerous healthcare organizations to Italian governmental and non-governmental bodies (including the Ministry of Health) to modify the Italian law on opioids prescribing (Federazione Nazionale

![Figure 1](Image.png)

Ordini dei Medici Chirurghi e Odontoiatri et al. 1998. Shortly thereafter, the Drug Department of the Ministry of Health (MOH) appointed a specific workgroup ("Ministerial workgroup") of the Commissione Unica del Farmaco (CUF) to develop a proposal and recommendations to address inadequate pain management.

The members of the workgroup (a multidisciplinary team of practitioners, pharmacists, members of the Health Ministry, and a veterinarian) have expertise in oncology, pain management, palliative care, opioid legislation and pharmacology. The Ministerial workgroup began meeting in the spring of 1999 with three main objectives: [i] to recommend changes to the national narcotics law that governs opioid prescriptions; [ii] to identify and render available in the market, without costs for the patients, the drugs that are essential for pain; and [iii] to produce information for patients and the public on cancer pain management, as well as materials which can be used to train all Italian healthcare workers about cancer pain management.

Information and technical assistance was requested by an individual member of the Ministry of Health workgroup from the WHO Collaborating Center for Policy and Communications in Cancer Care at the University of Wisconsin Comprehensive Cancer Center in the USA. The Collaborating Center assisted with a study of the Italian opioid situation, comparing Italy’s morphine use trends to the rest of Europe and the world, provided consultation on the reasons for inadequate use of opioid analgesics, helped to diagnose regulatory barriers, and provided videotape testimony for a meeting sponsored by the Italian Ministry of Health and the Italian Society of General Practice (Joranson 2000). The approach to evaluating Italian opioids control policy was informed by the concurrent participation of the authors in the development of recently issued WHO guidelines. These important guidelines aid health professionals and governments to examine their national opioid control policies to ensure the availability of opioid analgesics for medical purposes while preventing abuse and diversion (World Health Organization 2000). English, French, Italian and Spanish translations available at http://www.medsch.wisc.edu/painpolicy/publicat/00whoabi/00whoabi.htm.

RESULTS

The workgroup’s efforts to identify and address barriers in Italy culminated in new legislation and drug registration procedures (adopted by Parliament in January 2001) that met all of the Ministerial workgroup’s objectives (Official Gazette of the Italian Republic 2001). First, through the legislation, the requirements for prescribing opioid analgesics were modified. The changes include: [i] replacing the previous complex, three-part prescription form (see Figure 2) with a simplified prescription form (see Figure 3) so that physicians must complete the required information only once, not three times. (The new opioid prescription form became available to some regions in Italy in December 2001); [ii] the new form is more similar to the standard prescription form used for all drugs reimbursable by the Italian Health System (see Figure 4). This is a significant change in Italy because it lessens the stigma that has existed historically against prescribing opioid medications for pain. Treating pain, which is a frequent and expected symptom of cancer, no longer requires a vastly different and complex prescription form than is required for treating any other usual cancer symptoms; [iii] the amount that can be prescribed on a form has been increased from only an 8-day supply to a one-month supply; [iv] physicians are allowed to prescribe two drugs or two dosage units (instead of one) on a single prescription form; and [v] sanctions for inadvertent technical errors made by physicians and pharmacists have been lessened; administrative sanctions for physicians have been eliminated, and sanctions for pharmacists have been reduced from penal to monetary. With the new law, prescribing opioid analgesics is simplified and some of the fears associated with prescribing and dispensing opioids are addressed. In addition, healthcare workers and family members are now allowed to deliver opioids to patients in their homes as long as they have a signed declaration by a physician describing the amounts and doses of drugs to be used to treat severe pain for cancer or degenerative diseases, but not for the home treatment of drug dependence. Finally, the law clarified that physicians and veterinarians may, by written prescription, obtain an office supply of opioid analgesics for dispensing to patients in emergencies, and that physicians and veterinarians may possess and transport necessary quantities of opioid analgesics in the case of an emergency. They are required to keep a copy of such prescriptions for two years and to maintain a dispensing record. These changes may have a positive impact on physicians’ prescribing for pain, and therefore patient’s ability to have their pain treated.

Pain medications have been added to the list of reimbursable drugs in the national healthcare system (with others to follow), and previously unavailable opioid analgesics will become available for prescription. Recently, the fentanyl patch has become free-of-charge for patients, and the first form of pharmaceutical immediate-release morphine (syrup) became available free-of-charge in April
2001. [In the past, pharmaceutical morphine syrup was completely absent from the Italian pharmaceutical market.] The simplified prescribing applies to a group of 10 drugs: buprenorphine, codeine, dihydrocodeine, fentanyl, methadone, morphine, oxycodone, hydrocodone, hydromorphone, and oxymorphone (the last three are not yet available on the Italian market).

Hydrocodone, hydromorphone, oxymorphone, and the pharmaceutical formulation of oxycodone will be available shortly on the Italian market. The Drug Department, which grants permission for drug registration, will help to expedite registration requests for these drugs. The Ministerial workgroup's proposal suggests registering the drugs and then making most, if not all, the strong opioid formulations available free-of-charge to patients. The overriding goal of these combined efforts is to achieve a pricing system that allows the pharmaceutical companies to provide the drugs to the public health system at prices acceptable to both parties, such that the public health system can provide reimbursement to patients.

Third, the Drug Department of the Italian Ministry of Health has allocated funds (one billion lira for 2001; U.S. $475 thousand) to coordinate physician education and to increase public awareness of cancer pain management. The Ministerial workgroup will propose guidelines to the Italian regions for pain management training of physicians, pharmacists, and other healthcare workers. The regions will decide independently what educational initiatives they will take, depending on their own local needs. Media coverage of the proposed legislative changes has already played a major role in increasing the
awareness of the Italian public. The Italian media cooperated with the workgroup to educate citizens about the importance of opioid analgesics for pain management. There have been 'signature campaigns' promoted by general practitioners to show the Italian Parliament the growing sentiment in the population for reform of the opioid control law.

Recognizing the need to implement the changes brought about by the new law, the Italian Ministry of Health extended the appointment of all the members of the workgroup for two years, so that they can continue to recommend registration of new drugs, co-ordinate educational information for healthcare professionals and the public, and monitor changes in opioid prescribing.

**DISCUSSION**

Although the government of Italy reported to the INCB in 1995 that its drug control policies contained no provisions that unduly inhibit the availability of opioid analgesics (International Narcotics Control Board 1996b), regulatory barriers have nevertheless been identified (Zenz & Willweber-Strumpf 1993; Ripamonti et al. 1996; Simini 1996; Mercadante 1998); some have now been addressed by the new legislation. The regulatory changes and educational efforts are an important step forward. As the Ministerial workgroup on pain management monitors the resulting changes over the next two years, it will be important to determine whether additional changes are necessary to achieve adequate pain management in Italy. The new WHO guidelines for evaluating national opioid control policies (World Health Organization 2000) could provide a framework for deciding the next steps.

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REFERENCES


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