Special Article

Improving Availability of and Access to Opioids in Colombia: Description and Preliminary Results of an Action Plan for the Country

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Abstract

Latin America consumes less than 2.7% of the morphine in the world, as reported by the governments to the International Narcotics Control Board. Methods to improve access to opioids for the treatment of pain have been developed by the Pain & Policy Studies Group (PPSG), a World Health Organization Collaborating Center at the University of Wisconsin. This article describes the preparation and implementation of an action plan in Colombia as a part of an international fellowship program on opioid policy developed by the PPSG and funded by the Open Society Institute. The action plan for Colombia included three steps: 1) a survey of regulators and health care providers to identify the current situation and their perceptions of opioid availability in the regions of the country; 2) a workshop with representatives of the Ministry of Health, the national and state competent authorities, pain and palliative care physicians, and international leaders; and 3) implementation workshops at the local level throughout the country. For the survey, response rates of 47% and 96% were registered among physicians and competent authorities, respectively. The survey identified significant regional differences in perceived opioid availability between physicians and regulators. Focus group discussions during the workshop identified several reasons leading to limited availability of opioids in the country, including deficiencies in the procurement process, insufficient human resources, excessive bureaucratic tasks, insufficient number of pharmacies authorized to dispense controlled medications in the country, lack of training in the health care professions, and overly restrictive laws and regulations governing

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opioid availability. The third step of the action plan has not been implemented. Additional and continuous monitoring needs to be implemented to measure the progress of this project. J Pain Symptom Manage 2009;38:758–766.

Key Words
Opioid analgesics, drug availability, Colombia, barriers, opioid legislation, education

Introduction

The World Health Organization (WHO) and other organizations have designated morphine and codeine as essential analgesics for the treatment of pain;[1] their safety and efficacy have been proven in many studies. Morphine consumption has been used for several years as one general indicator of the availability of pain treatment in countries of the world. Unfortunately, the use of morphine in Latin America accounts for less than 3% of the amount used at a global level according to the International Narcotics Control Board (INCB).[2] Colombia reports a per capita consumption (1.09 mg/capita) significantly lower than the global average (5.98 mg/capita).[3]

There are several initiatives to improve availability of opioids in the world—many of them under the leadership and guidance of the Pain & Policy Studies Group (PPSG), a WHO Collaborating Center for Policy and Communications in Cancer Care. Among these are specialized opioid availability workshops between health care providers, regulators, and other stakeholders using the WHO Guidelines for Achieving Balance in National Opioids Control Policy.[4,5] The importance of involving leadership from governmental entities, nongovernmental organizations, and between the stakeholders and health professionals has been emphasized to encourage communication and collaboration and to identify solutions to the problems.[6]

Recent experiences following this model have been described in Romania, India, Uganda, Italy, and Vietnam, with significant improvements in policies.[7–12] Availability of opioids in Latin America has also been reported in several meetings and publications. Restrictive laws and regulations, exaggerated fears of addiction, the lack of education among health care professionals, and the lack of political support have been consistently identified as the most significant barriers in the availability of opioids in the region.[13–15] Resolution 5261 from the Colombian Ministry of Health, which regulates the access to health services in Colombia, fails to recognize pain treatment and palliative care as priorities.[16]

In Colombia, the importation, procurement, distribution, and supervision of controlled substances, including opioids, fall under a monopoly controlled by the state.[17] According to the law, the state establishes the guidelines for supervision and distribution of all the controlled medications throughout the country. The chain of distribution of opioids starts at the Fondo Nacional de Estupefacientes (National Competent Authority [NCA]), an entity attached to the Ministry of Health, from where they are distributed to the 32 different states (Departamentos) in the quantities requested by each. The NCA is the governmental entity responsible for determining the national quotas and maintaining communication with the INCB, the independent and quasi-judicial body responsible for implementing the United Nations' international drug conventions. Each state, under the responsibility of the Secretary of Health, has an office in charge of controlled medications called Fondos Rotatorios de Estupefacientes (Regional Competent Authorities [RCAs]), which are responsible for procuring the medications from the NCA in Bogota and then distributing them in each state. The state secretary of health reports directly to the governor of the state.

For several years, a group of individuals from the National Cancer Institute, Universidad de la Sabana in Bogota, representatives of the Colombian Palliative Care Association (ACCP), and the Colombian Chapter of the International Association for the Study of Pain (Asociacion Colombiana para el Estudio del Dolor [ACED]) have served as advisers to the

NCA in its effort to improve the availability of opioids for medical use in the country. Through the work of this group, important changes, such as increasing the maximum number of days allowed for the prescription of opioids from 10 to 30 days, were achieved in 2006.[17]

A program called International Pain and Policy Fellowship was developed by the PPSG and funded by the Open Society Institute to accelerate the rate of change in low- and middle-income countries. One of the coauthors (M. X. L) was selected as a grantee of this program. The program includes the identification of the main policy and system barriers that hinder availability and access to opioids in the grantee's country, as well as the development of an action plan to minimize or eliminate those barriers. The fellowship included a week of face-to-face meetings in Madison, Wisconsin, with expert representatives from the PPSG, the program for Access to Controlled Medications from WHO in Geneva, Switzerland, faculty members from the University of Wisconsin, international experts who assumed the role of mentors for the fellows, and representatives of other organizations. During this week, the coauthor, in collaboration with her mentor (L. D. L) and under guidance from the PPSG, carried out an analysis of the situation in Colombia and identified problems in the procurement process as the main barrier in the availability of opioids in the country. An action plan with the aim to solve this problem was developed and presented to the whole group at the end of the week. Subsequent reports were sent and constant communication with the mentor and staff from the PPSG was maintained during the process. This article describes an action plan, developed and put in place in Colombia as part of the international fellowship program on opioid policy, developed by the PPSG.

Action Plan

The action plan for Colombia was divided into three parts: the first included a survey to identify the perception of the availability of opioids in Colombia by pain and palliative care physicians and the RCAs; the second included a workshop in Bogota (the capital of Colombia) to jointly review with physicians and regulators the barriers in their regions and identify possible solutions and the steps needed to eliminate those barriers; and the third included the implementation workshops at the local level throughout the country.

Methodology

Survey. A review of the literature did not reveal any existing instruments to gather data related to the availability of opioids at the state level. Two instruments were designed by 10 physicians who prescribe opioids regularly: one for pain and palliative care physicians and another for the state RCAs. The questionnaires were sent to a list of pain and palliative care practitioners around the country, selected from the membership lists of ACED and ACCP ($n = 192$). Based on their own experience, each participant was asked to grade the availability of opioids in their region. Additionally, they were asked to identify the barriers to opioid availability at a regional and institutional level.

To carry out this study and to allow for the coordination and handling of the information, the country was divided into six geographical regions. Between January and October 2007, 32 pain and palliative care physicians were preliminarily contacted by phone and the questionnaires were sent by e-mail. Officers from all the RCA offices of the country were also contacted, and the questionnaire was delivered to them as well.

Workshop. A national opioid availability workshop was planned in Bogota to jointly review with physicians and regulators the barriers in their regions and identify possible solutions and the steps needed to overcome those barriers.

The objectives of the workshop were:

1. To identify the main barriers in the availability of opioids in the six regions and possible solutions to eliminate or reduce those barriers;
2. To inform regulators about the challenges encountered by the treating physicians in the prescription process;
3. To inform the treating physicians about the legal, administrative, and regulatory limitations to which the RCAs are subject.

Table 1
Opioid Availability Reported by RCAs

Opioid Formulations	Excellent (%)	Good (%)	Average (%)	Poor (%)	None (%)	Total (%)
Morphine 10 mg/mL ampoules	62.5	34.5	3	0	0	100
Morphine 30 mg/mL oral solution	54.8	32.3	3.22	3.18	6.5	100
Morphine 30 mg/mL ampoules	46.8	25	3.1	3.1	22	100
Methadone 10 mg tablets	28.5	32.15	10.7	3.65	25	100
Methadone 40 mg tablets	23.3	40	10	0	26.7	100
Hydromorphone 2.5 mg tablets	26.1	11.1	11.1	8.9	42.8	100
Hydromorphone 5 mg tablets	39.2	14.2	3.5	0	43.1	100
Pethidine 50 mg/mL ampoules	56.4	40.5	0	0	3.1	100
Hydromorphone 2 mg/mL ampoules	33.3	3.7	11.1	0	51.9	100

An organizing committee identified and selected the participants to be invited to the workshop. Participants were selected based on their level of involvement with pain and palliative care activities and their demonstrated leadership in their corresponding regions. The workshop was conducted in the Universidad de la Sabana on November 27–29, 2007. Facilitators and presenters included individuals from national and international nongovernmental and professional organizations as well as representatives of other governments. The Appendix includes a list of the organizations and institutions represented in the workshop.

The workshop was divided into two parts: The first part included presentations of the international and the national policy and system of control for opioid medications, clinical aspects of pain management, and the use of opioids. During the second part of the workshop, participants were divided in six working groups according to geographical regions. Each group included a physician, representatives of the corresponding RCAs, an international adviser, an officer from NCA, a representative of the scientific association, and a distributor. A diagnosis of the situation for each region was carried out, identifying difficulties in the distribution chain from the perspective of the professionals and the distributors. Each group presented its analysis to all the participants, and those barriers that were common to each group were identified and selected as the priorities. Based on these results, a series of recommendations at the national level were made by the whole group to present to the Ministry of Health (MOH) through the NCA.

Results

Survey

Fifteen questionnaires were received from the physicians and 31 from the RCAs (with response rates of 46.8% and 96.9%, respectively). The RCAs rated the availability of morphine in its three pharmaceutical formulations and pethidine (meperidine) (62.5%, 54.8%, 46.8%,

Table 2
Opioid Availability Reported by Physicians

Opioid Formulations	Excellent (%)	Good (%)	Average (%)	Poor (%)	None (%)	Did Not Know It Was Available (%)	Does Not Prescribe (%)	Total (%)
Morphine 10 mg/mL ampoules	66.6	20	6.8	0	0	0	6.6	100
Morphine 30 mg/mL oral solution	46.6	33.3	6.6	6.9	0	0	6.6	100
Morphine 30 mg/mL 3% ampoules	25	28.4	20	6.6	0	0	20	100
Methadone 10 mg tablets	13.3	26.9	40	6.6	6.6	0	6.6	100
Methadone 40 mg tablets	0	25	20	28.4	13.3	0	13.3	100
Hydromorphone 2.5 mg tablets	6.6	26.9	33.3	13.3	6.6	0	13.3	100
Hydromorphone 5 mg tablets	0	20	28.4	25	13.3	0	13.3	100
Hydromorphone 2 mg/mL ampoules	13.3	40	20	6.6	13.3	0	6.8	100
Pethidine 50 mg/mL ampoules	20	33.4	0	0	0	0	46.6	100

and 56.4%, respectively) as excellent. The vast majority of the RCAs rated the availability as good, except for hydromorphone. These results are summarized in Table 1.

Sixty-six percent of the physicians reported excellent availability of morphine 10 mg/mL ampoules. For methadone 40 mg tablets, 41.7% of the respondents reported either poor or no availability. For hydromorphone 5 mg tablets, 38.3% of the respondents reported either poor or no availability. For methadone 10 mg tablets and hydromorphone 2.5 mg tablets, 46% of the respondents reported either average or poor availability. These results are presented in Table 2.

Based on the information supplied by the RCAs, the most requested medication is morphine 10 mg/mL ampoules (58.06%), followed by pethidine (45.16%) and morphine 30 mg/mL oral solution (9.6%). According to the physicians, the most prescribed medication is tramadol oral drops, followed by morphine 30 mg/mL oral solution and morphine 10 mg/mL ampoules. Pethidine ampoules, hydromorphone 5 mg tablets, and methadone 40 mg tablets are not prescribed by most of the physicians who responded to the survey.

Most of the RCAs identified the barriers for availability of opioids as insufficient human resources (46.9%), deficiencies in filling out official forms (46.9%), fear of expiration of the medication (43.7%), not enough safety conditions to store the medications (40.6%), administrative procedures (37.5%), transportation of medication (21.9%), and communication difficulties (21.9%).

The main difficulties reported by physicians were cumbersome procedures to authorize medications by the Health Maintenance Organizations (HMOs) (73.3%), followed by poor accessibility in hospitals/pharmacies because of limited hours for dispensing the medication. The least relevant difficulties identified were those related to filling out the special prescription form and understanding the regulations.

Workshop

During the workshop, the following problems were identified throughout the regions:

1. Low availability of opioid medications and limited hours in pharmacies that stock the medications.
2. Little information about what occurs at the Colombian HMOs (at the time the workshop was held).
3. Excessive administrative procedures and unduly strict requirements for the RCAs.
4. Insufficient and overburdened RCA personnel.
5. Inadequate communication between RCAs and the NCA, and between RCAs and physicians.
6. Insufficient knowledge about the laws and regulations among physicians and health workers and about the basics of pain management and the use of opioids among regulators.
7. Several problems with official prescription forms include the following: physicians have to pay for the forms, forms are not always available, and sometimes, physicians do not complete the forms correctly.

Local Workshops

A series of local workshops were planned to be conducted as follow-up to the workshop in Bogota, which would include representatives from the NCA, the corresponding RCAs, and physicians for each region. These workshops were initially planned to be conducted throughout 2008, but the NCA canceled them for reasons unknown to the authors. At the time this article was submitted, new dates for the workshops had not been assigned.

Discussion

Survey

The lack of human resources as one of the main barriers identified by the RCAs may be because of the fact that government personnel have many functions assigned to their jobs, such as following up on canine sterilization and verifying health conditions in slaughterhouses among many others. The problems in filling out official forms may be attributed to the ignorance of the physicians about good practices regarding prescription of opioids, shown in errors in the prescriptions. The reasons behind RCA fear of expiration date of medication include lack of trained physicians, administrative and financial costs related to expired stocks of medications, and the possibility

of sanctions by the NCA. The administrative procedures that were identified by RCAs as barriers may be related to the need to establish interinstitutional agreements that would require central approval, a lack of agreements for transporting the medication throughout Colombia, and frustrating delays in communications because of the heavy workload of the officers. Several factors and perceptions contribute to the difficulties expressed by physicians. For example, some opioids are not included in the obligatory health plan, many pharmacies have limited and insufficient hours for dispensing medications, and physicians perceive that the NCA and the RCA are more interested in strict control to prevent misuse than in allowing availability.

A possible explanation for the difference between the responses from physicians and the RCAs on the most commonly prescribed opioids may be that the physicians responding to the survey included only those working in chronic pain and palliative care. Pethidine is still used widely in acute pain management, and the responses of the RCAs may represent this. According to the results, the most common medication sold by the NCA is 10 mg/mL ampoules of morphine for hospital use. This shows that the main use of opioids in this country is for acute pain. It is interesting and also alarming that there is almost no sale of 30 mg/mL oral solution and injectable morphine, and codeine is not among the 10 medications most commonly prescribed. This may be explained by the fact that codeine is not included in the obligatory health plan, and hence, its cost is not covered by the insurance plans. Although the International Association of Hospices and Palliative Care includes extended-release morphine in the list of essential medications in palliative care, this pharmaceutical form is not available in Colombia.

Workshop

There were several striking regional differences in barriers. The worst availability was found in regional areas with low population density, which usually receive the lowest budget allocations from their state treasuries. Also, it became evident during the large group discussion that many of the RCAs were hesitant to voice their problems and opinions in front of the NCA authorities. Therefore, many of the problems that were discussed in the regional groups failed to be expressed or addressed in the general discussion.

Workshop participants stressed the importance of the following issues: increasing the dispensing hours of hospitals and pharmacies of main cities in each state to allow for the availability of opioids 24 hours a day, seven days a week, and implementing workshops at the local level throughout the country, and identified this as one of the primary goals to achieve. It was also clear that there had been very limited contact between the prescribers and the regulators, and in some cases where there was contact, it was during the critical moments of shortage of the medication. The priority of NCA and RCAs is focused on opioid surveillance and control over availability; this led to tensions between physicians and regulators, which resulted in additional barriers.

It is important to point out the lack of consensus related to the relevance of the use of the special prescription form. The regulating entities perceive it as an important tool to monitor medical usage, but the physicians perceive it as a barrier to opioid access. The special prescription form also has been reported as a barrier in several states in the United States in which it is implemented. This breach in consensus may be resolved by implementing an efficient information system, as recommended by leading experts from the field.[18] During the focus group discussions, the importance of involving the HMOs was identified, and the results of the questionnaires showed significant differences between availability as reported by the RCAs and the physicians. This may be the result of a procurement barrier among pharmacies and local hospitals and their corresponding RCAs or a barrier in the distribution chain that has not been identified yet. Additional studies are needed to identify all the barriers in the distribution chain and the procurement process.

As mentioned in the Results section, the local implementation workshops were canceled by the NCA. This may be the result of lack of political support at the regional level for what may be considered an invasion of the Bogota office in the states, lack of commitment by the NCA, poor communication between the NCA and the MOH, or lack of internal support to the NCA from within the MOH. The authors are aware that there are

many issues that remain unknown, political in nature, and beyond their ability to influence.

Limitations of the Study

The selection of the participants in the survey included only a fraction of the physicians in the country. Moreover, it included only physicians working in pain and palliative care, which may also affect their perception on availability. To assess the general perception of the clinicians in Colombia, we should survey physicians of different specialties who prescribe opioids (number and type of practice) to enable us to characterize the prescription customs and correlate them to the administrative problems in each of the states. Finally, to complete the general perception, we need to include patients' and HMOs' perspectives of the situation.

Improvements and Future Steps

As stated, after the workshop discussions, a series of recommendations were made by all the participants and delivered to the MOH by the NCA. The following includes the list of recommendations:

1. To modify Resolution 1478, to guarantee availability 24 hours a day, seven days a week, in the capital cities of the 10 main departments in the country and, as may be necessary, in all Colombian territories.
2. To contact the Colombian HMOs to involve them in the process and to obtain an optimum access to medications.
3. To include in the Obligatory Health Plan all essential analgesics in the WHO's list (immediate- and extended-release morphine and codeine tablets).
4. To require the department hospitals to provide opioid medications for outpatients.
5. To create advisory committees of the regional offices to establish educational programs and to detect early problems in the distribution chain.
6. To systematize the information on availability of opioids in real time.
7. To empower the regional officers so that they may dedicate their time exclusively to tasks leading to the availability and surveillance of controlled medications.

As a result of the recommendations from the workshops, the NCA issued a letter requesting the RCAs to establish agreements to guarantee availability and accessibility in each of the regional territories to the controlled medications.[19] An additional letter was sent to the Colombian HMOs, reminding them of the importance of timely dispensing of the special controlled medications included in the Mandatory Health Plan.[20] This resulted in new contracts with state hospitals and pharmacies by the RCAs in six states.

Conclusion

Our action plan to improve availability and accessibility to opioid analgesics demonstrated that the dialogue between different national entities is not always easy to achieve, but persistence and commitment can bring about the desired change. It is necessary to continue these efforts in all areas to turn the recommendations of the workshop into tangible results. The participation of clinicians, government representatives, and insurance companies is of the utmost importance to suggest changes in the legislation of opioid medications. As the efforts of regulators, physicians, and the public in general become integrated, improved accessibility of opioids should be attained, such as that repeatedly demonstrated by international efforts in other countries.

Improving availability and access to opioids in Colombia to ensure that national improvements in opioid availability endure public policies related to pain relief and palliative care must be drafted and adopted. Therefore, an important priority to achieve sustained improvement is consultation and open, ongoing communication between health professionals and governmental entities, supplemented by the participation of insurance companies and the patients.

In Colombia, our research demonstrates the success of recommendations issued by stakeholders to bring about important change in contracts between RCAs and state hospitals and pharmacies in six states and to establish future guidelines to improve the availability of opioid medications. It is critical now to systematize information on the distribution of opioids to allow for precise monitoring on the availability of opioids and to learn about the trends in prescription at a national level.

To guarantee access to medication, it is necessary to integrate pain management into existing

medical school curricula, thereby improving physician knowledge of good prescribing practices within the context of balance. Finally, to ensure permanent availability of opioids, it is critical that all the stakeholders continue the joint collaboration with the main goal of improving the quality of care of patients with pain in Colombia.

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Appendix

List of Organizations and Institutions Represented at the Workshop[a]

World Health Organization

Pain & Policy Studies Group, University of Wisconsin, WHO/Pan American Health Organization (PAHO) Collaborating Center for Policy and Communications in Cancer Care

French Health Products Safety Agency—Narcotics and Psychotropics Department

International Association for Hospice and Palliative Care

Pan American Health Organization

Collaborative Center of PAHO (COHAN)

Ministry of Health, Public Health Office

National Competent Authority

Thirty-one Regional Competent Authorities

Universidad de la Sabana

Colombian Association of Palliative Care

Colombian Chapter of the International Association for the Study of Pain

National Cancer Institute, Bogotá

Colsubsidio (Colombian distributor)

[a]Sixteen individual pain and palliative care physicians attended as well.