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Special Article

How Universal Is Palliative Care in Colombia? A Health Policy and Systems Analysis

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Abstract

Colombia's health sector reform has been recognized for its universal health (UHC) coverage scheme. However, this reform evolved without palliative care (PC), thereby omitting a core element of UHC. In this paper, we analyze the Colombian health system reform and health policies in relation to PC. We present the history, innovations, successes, and shortcomings of the reform and summarize the lessons learned to strengthen efforts leading to PC integration. Our analysis is based on the WHO public health framework for PC (policy, access to medicines, education, service provision). For several years and especially during the last decade, the government enacted laws and regulations to improve access to essential medicines and to integrate PC. Relative to other countries in Latin America, Colombia was the first to launch a PC service and to accredit palliative medicine as a specialty, the second to establish a national PC association and one of the few countries with a specific PC law. However, data shows that there are still too few services to meet the PC needs of approximately 250,000 adult patients annually. Our analysis shows that the country's failure to integrate PC most likely is a result of limited health worker education. Advocacy efforts should include deans of schools and provosts, in addition to policy makers and regulators. Other possible factors affecting uptake and implementation of existing national policies are civil unrest and limited collaboration between government offices. Additional research is needed to evaluate the impact of these and other related factors on PC integration in Colombia. J Pain Symptom Manage 2021;000:1−10. *© 2021 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.*

Key Words

Colombia, policy analysis, universal health care, essential medicines, education, service provision

Introduction

Colombia's health sector reform in 1990s (Law 100), has been recognized for its scheme to achieve universal health coverage (UHC).[1,2] This has been most dramatic for the poorest, as the reform managed to identify and provide a benefits package (referred to as *"paquete basico"*), to meet the most pressing and prevalent health needs of Colombians.

Although the World Health Assembly (WHA) adopted a PC resolution in 2014,[3] and the Astana Declaration from 2018[4] includes PC, the country's health reform evolved for many years without appropriate coverage of PC, omitting a core element of UHC,[5] resulting in no PC integration and inequities in access to care.[6] It is estimated that in Colombia, approximately 250,000 adults need PC annually, based on the Lancet Commission on Palliative Care and Pain Relief methodology to estimate serious health-related suffering (SHS).[7,8]

During the last decade, the government enacted laws, decrees and regulations to integrate PC but based on recent data of 1.6 services per million inhabitants, there are still too few services to meet population need.[9]

In this paper, we analyze the Colombian health system reform in relation to PC, presenting its history,

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innovations, successes, and shortcomings, and summarizing lessons learned to strengthen efforts leading to PC integration. Our research and findings are based on analysis of secondary literature and publicly available data, using the WHO Public Health Model as framework (access to medicines, health policies, education, and service provision)[10] and input from leaders from the national PC associations as well as key experts from the field, and government authorities in relevant offices. As far as we know, this the first in-depth analysis of health reform and PC for a specific country. We hope that this analysis will generate robust advocacy initiatives in the country and motivate decision makers in Colombia as well as others worldwide, to adopt the necessary steps to ensure access to PC for persons in need.

Access to Pain Relief Medications

Colombia's first law controlling the use of substances with "abuse potential" dates back to Law 11[11] adopted in 1920's, which regulated the importation, sale and prescription of opium, laudanum, morphine, codeine, and heroin. Law 11 did not prohibit consumption of these substances but restricted their sale and use to medical needs.

More legislation followed after Law 11, imposing new controls and restrictions while consistently recognizing the medical use of the substances.[12−14] In 1939, Law 36 [15] created a government monopoly to import and sell "narcotics" for medical use in clinics and hospitals. In 1940, ~~6~~a decree[16] allocated a budget to operate this monopoly and required the entities and individuals that manufactured or imported these substances to register with the Ministry of Health and Social Protection (MSPS). In 1969, another decree established a special unit [later renamed *Fondo Nacional de Estupefacientes (FNE)*][17] in the MSPS to manage the importation of these substances and prevent illicit traffic, while supporting treatment for dependency.[17]

In 1975, Colombia became party to the Single Convention on Narcotic Drugs[18] thus joining other countries in a unified legal framework to prevent narcotrafficking and diversion of controlled substances. The Single Convention also listed in different schedules − based on their abuse potential − the substances to be placed under international control.

A law was adopted in 1986 (Law 30) which still stands, and covers both the use of controlled substances for licit purposes and the prevention of trafficking and diversion.[19] It describes the rights and obligations of physicians, manufacturers, pharmacists, and administrators, specifying all licit activities related to the medical use of opioids and the penalties for contravening its provisions. It also describes the role of the FNE and its partner offices in each state, called *Fondos Rotatorios de Estupefacientes* (FREs). The FNE collects data from the FREs, on quantities distributed by wholesalers and pharmaceutical companies to retail pharmacies and hospitals. It reports these annually to the International Narcotics Control Board (INCB) as "consumed," and provides an estimate of expected demand for the subsequent year. In 2016 the MSPS issued a directive requiring all distributors, pharmacies and health institutions to take the necessary steps to ensure availability of opioids for pain relief and PC 24 hours a day, seven days a week.[20]

The FNE monopoly covers the importation or manufacture of codeine, morphine, hydromorphone, methadone, and pethidine. It also holds the exclusive right for the sale of these generic opioid medications at affordable prices.[21] From the FNE storage, the medications may be distributed to the FREs of all 32 states in the quantities requested and paid for by each, as well as to wholesale pharmacies and approved hospitals and clinics. Other controlled substances under patent protection, including fentanyl, buprenorphine transdermal patches, and oxycodone tablets, are licensed to private companies and sold at market prices. Table 1 lists the strong analgesics registered in the country.

Following the methodology of the Lancet Commission[8] we analyzed the evolution of selected distributed opioids in morphine equivalence (DOME) (morphine, codeine, fentanyl, hydromorphone, pethidine, and oxycodone). We included all opioid analgesics included in Section 2 the WHO List of Essential Medicines plus pethidine, which was widely used in the 90s for pain relief in both acute and chronic conditions, and although not recommended for long term use, it is still used for acute pain relief. We excluded methadone, whose use for pain relief is still limited in the country. Colombia shows a sustained increase in DOME, from 1.4 mg (1990) to 2.3 mg (2000), 6.0 mg

Table 1
Strong Analgesics Available in Colombia (in Alphabetic Order)

Substances	Formulations
Buprenorphine	Transdermal patch
Codeine	Oral solid (with paracetamol or diclofenac)
Fentanyl	Injectable Transdermal patch
Hydrocodone	Oral solid (with paracetamol or ibuprofen or naproxen)
Hydromorphone[a]	Oral solid, injectable
Pethidine[a]	Injectable
Methadone[a]	Oral solid
Morphine[a]	Oral liquid, injectable
Oxycodone	Oral solid SR and IR Oral SR with naloxone Injectable
Tapentadol	Oral solid SR and IR
Tramadol	Oral liquid, oral solid SR and IR Injectable (with diclofenac and ibuprofen) Oral liquid (with paracetamol)

[a]FNE Monopoly

(2010) to 11.2 mg (2017). The data also shows an increase of fentanyl and oxycodone relative to the DOME, compared to cheaper generic morphine (Fig. 1).

We estimate that this DOME could have covered 23% of the requirements for PC in 1990, 34% in 2000; 80% in 2010 and 137% in 2017, respectively. But opioids are also essential for other areas of health care, including surgery and acute pain, which explains why, compared to a benchmark of countries of Western Europe, Colombia falls short of meeting its pain relief needs (16%).

Each state in Colombia has its own budget allocation process, including for the purchase of controlled medicines under the government monopoly. The FNE has no operational mandate over the FREs and only state secretaries of health can determine if, and how much to purchase. So, if pain relief is not considered a priority, the result is unavailability of inexpensive medications for patients in pain in those states. The central government recently took steps to solve these inequities, adopting a regulation allowing licensed care providers to purchase the medicines directly from the FNE if the state where they are located fails to budget for their procurement.[22] However, even with the laws promoting health equity, the distribution of opioids throughout the national territory is extremely uneven, with some states and rural areas having no or very little availability (Fig. 2).[23] States with the highest DOME have major cities and large hospitals that provide acute care. These are also where most pain relief and PC services are located (Bogota, Medellin, Cali, Barranquilla among others).

Special prescription forms that vary from state to state are another regulatory barrier to opioid access. PC organizations have been advocating for a uniform electronic prescription that would allow physicians to assess and treat patients who live in remote catchment areas where there are no medications available or no physicians with the required training. These would also allow patients to travel to a nearby state to purchase the medication if it is not available in a pharmacy in their state. Other barriers include an insufficiently trained health workforce to appropriately prescribe, dispense and administer opioids, further discussed below.[24] An analysis from 2009 identified barriers to the availability of controlled medicines and initiated an advocacy campaign, leading to collaboration between the government and PC and pain relief experts as advisers.[25]

Colombia's Health Reform and Palliative Care

The implementation of Law 100 from 1993, resulted in financial protection from catastrophic health expenditures and improved access to services, especially for workers in the informal sector. Health insurance coverage increased from 23.5% of the population in 1993 to 97.8% in 2020,[26,27] while out-of-pocket spending decreased from 45% to less than 15%.[27,28] In comparison with 191 countries, Colombia's health care system ranked 22th in 2000.[29]

Congress passed Law 1384 in 2010, guaranteeing PC as a component of comprehensive cancer care for patients and their families and ensuring availability of opioids.[30] In 2012, the MSPS launched the *10-Year Public Health Plan* that aims to address the burden of rising NCDs with differential approaches for vulnerable groups, including PC for the ageing population.[31] The MSPS updated the health benefit plan to cover outpatient and inpatient care of patients in terminal stage with any condition or disease.[32]

In 2014, Congress enacted Law 1733,[33] to expand PC to patients with other chronic, degenerative or irreversible conditions, covering those left out by Law

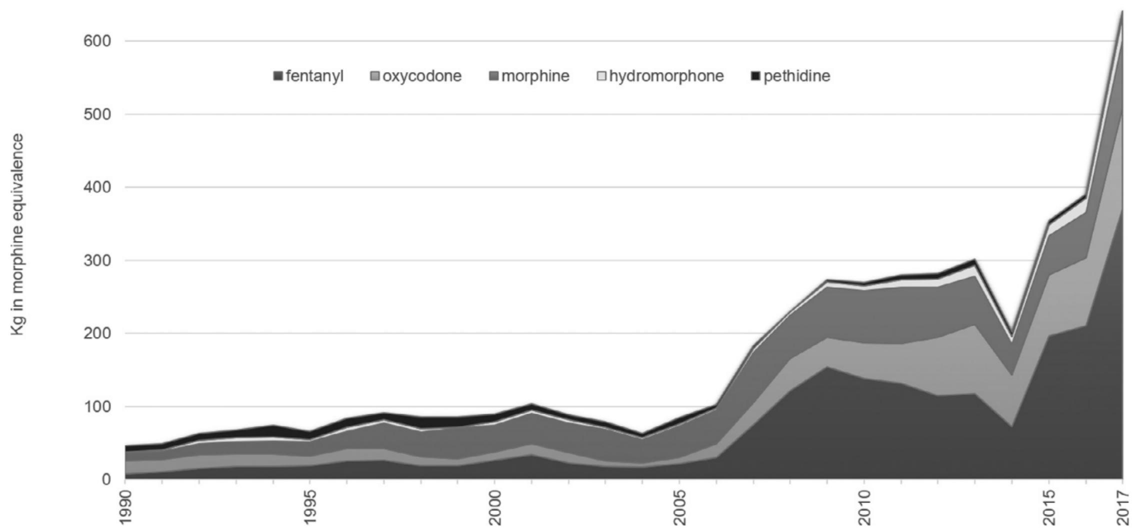

Fig. 1. Trend of distributed opioids in Kg of morphine equivalence in Colombia (1990−2017).

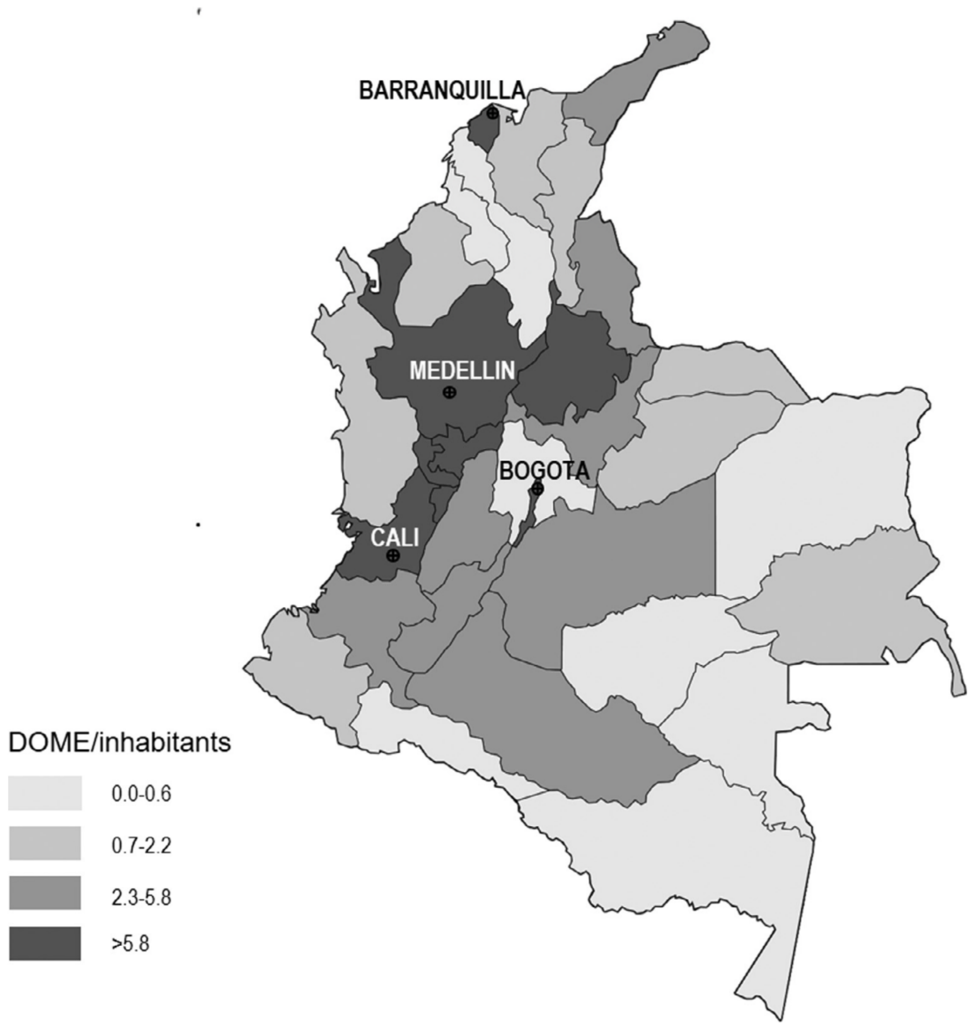

Fig. 2. Average distributed opioids in Kg of morphine equivalence per capita in Colombia by state (25th, 50th and 75th percentiles)*.

* San Andres and Providencia Islands are not visible due to map scale. Their DOME/inhabitant falls within the 0.0−0.6 interval.

1384, regulating the provision of these services. The Statutory Health Law[34] was passed in 2015 to complement Law 100, establishing a link between the fundamental right to health for all citizens and essential public health interventions that aim to address social determinants of health. The law presents a model for comprehensive, integrated health care delivery (*Modelo de Atención Integral en Salud)*, from promotion of healthy behaviors to prevention, treatment, rehabilitation and palliation.[35] This law also allocated the funds to support human resources in the MSPS office to coordinate the PC initiatives. This desk is currently located under the NCDs office with a broad mandate that extends to older persons and acute and communicable conditions, including COVID-19.

In 2016, a directive exhorted all health institutions to take steps to ensure that they respect the rights of patients requiring PC.[36] Publication of the first national clinical practice guidelines on PC[37,38] and a statement by the MSPS to all service providers, professionals, and regional authorities with the list of minimum requirements for accreditation of PC services, signaled further progress in 2016.[39] A 2018 law, based on the national PC law 1384, recognized patients' rights to write living wills and advance directives rejecting futile care.[40]

Fig. 3 presents a timeline of enacted laws, decrees, resolutions, and official memos relevant to PC.

The *paquete basico* covers all the medicines in the Essential Package of the Lancet Commission on PC and Pain Relief,[7] 238 medications included in the WHO Model List of Essential Medicines, and over 50% of all the medications sold in the country.[41] In addition to medications, the *paquete basico* also covers over 100 health interventions. Tables 2 and 3 compare the *paquete basico* with the Lancet Essential Package and the WHO Model List of Essential Medicines.

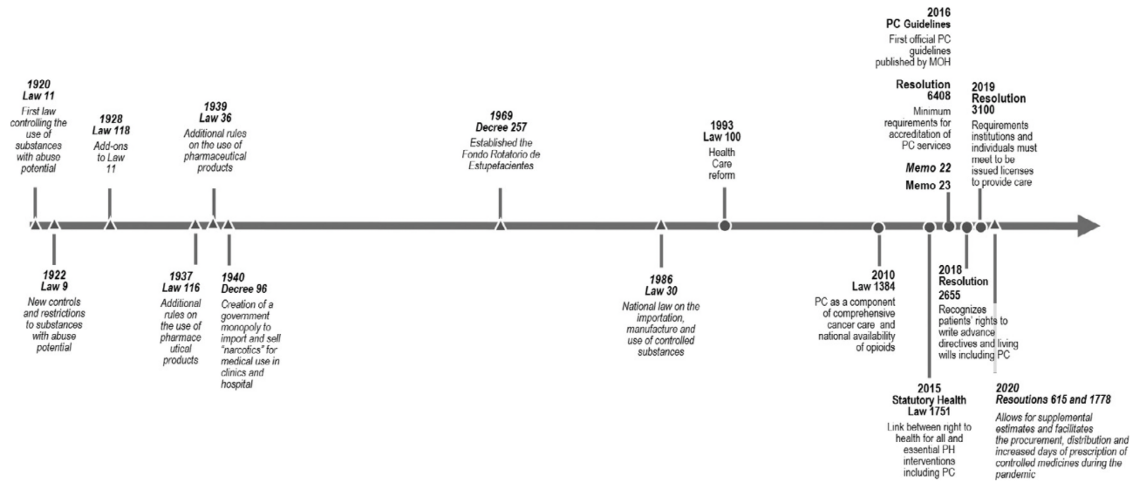

Fig. 3. Timeline of laws, decrees, resolutions, and official memos relevant to palliative care*.
* ▲ Relevant to opioids (*cursive text*); □Relevant to health systems, certification, care provision, and patients' rights (block text).

Unfortunately, the inclusion of medications and supplies in the *paquete basico* does not guarantee access. Many factors impact availability and access, including barriers in the procurement and distribution of medicines and supplies, absence of competition, complex reimbursement schemes and legal paperwork, and a cumbersome and complicated system through which all patients must navigate.[42]

Palliative Care Education

Lack of appropriate health worker education has been identified as a major barrier to achieving universal access to PC. Recommendations to close this gap include compulsory undergraduate courses for all health professionals and the establishment of formal graduate training programs. An initiative led by international organizations (ITES for its Spanish acronym)

Table 2

The "paquete basico" Compared to the Lancet Essential Package and the 19th WHO Model List of Essential Medicines

Medicines in the Lancet Essential Package for Pain Relief and PC	Included in the WHO EML?	Included in the paquete basico?
Amitriptyline	Yes	Yes
Bisacodyl (Senna)	Yes	Yes
Dexamethasone	Yes	Yes
Diazepam	Yes	Yes
Diphenhydramine (chlorpheniramine, cyclizine, or dimenhydrinate)	Yes	Yes
Fluconazole	Yes	Yes
Fluoxetine or other selective serotonin-reuptake inhibitors (sertraline and citalopram)	Yes	Yes
Furosemide	Yes	Yes
Hyoscine butylbromide	Yes	Yes
Haloperidol	Yes	Yes
Ibuprofen (naproxen, diclofenac, or meloxicam)	Yes	Yes
Lactulose (sorbitol or polyethylene glycol)	Yes	No - Other medications with similar properties (Bisacodyl) are included)
Loperamide	Yes	Yes
Metoclopramide	No	Yes
Metronidazole	Yes	Yes
Morphine (oral immediate-release and injectable)	Yes	Yes- In addition, other opioids are also covered (hydromorphone, methadone, codeine, and pethidine)
Naloxone parenteral	Yes	Yes
Omeprazole	Yes	Yes
Ondansetron	Yes	Yes
Paracetamol	Yes	Yes
Petroleum jelly	No	No

Table 3
Medical Equipment and Supplies of the "paquete basico" Compared to the Lancet Essential Package

Lancet Essential Package	Included in the paquete basico?
Pressure-reducing mattress	No, but it may be accessed by other means, including as a component of rehabilitation and physical therapy.
Nasogastric drainage or feeding tube	Yes
Urinary catheters	Yes
Opioid lock box	No
Flashlight with rechargeable battery (if no access to electricity)	No
Adult diapers (or cotton and plastic, if in extreme poverty)	No, but may be accessed by other means, through a MSPS fund.
Oxygen	Yes

aimed to include PC in the undergraduate curricula of medical and nursing schools.[43] Currently, fewer than one tenth of all medical schools (five out of 55) offer PC as an independent subject at the undergraduate level.[9]

At the postgraduate level, Colombia was the first country in Latin America to recognize palliative medicine as a medical specialty with the title "Specialist in Pain Medicine and Palliative Care.[44] In 2019, the MSPS issued a regulation outlining the many licensing requirements for institutions and individuals providing PC. One of many requirements is a specialist degree in PC for physicians providing outpatient care.[45] This requirement has generated controversy as many feel that general practitioners with basic PC training can provide outpatient care, and that such restrictions should be reserved for more complex cases and patients with refractory symptoms.

Colombia has achieved important progress in postgraduate level but has still a long way to go for the inclusion of PC in the curricula of undergraduate careers. Academic institutions and civil society organizations have created a collaborative network called *Red Colombiana de Educación en Cuidados Paliativos* to advocate for government reform of PC education and expand its adoption through all health curricula.

Palliative Care Delivery

Medellin launched the country's first PC service in the early 1980s at the Hospital Universitario San Vicente de Paul, anchoring it within the pain clinic, mirroring a similar trend in other countries.[9] *Fundación Omega* was launched in Bogota in the late 1980's, focusing on the psychosocial aspects of care and bereavement support to patients and families, as was the multidisciplinary hospice *La Viga* in Cali, the first free standing hospice facility in Latin America. [9] Three pediatric PC services were started almost ten years later: *Clínica Infantil Colsubsidio* and *Fundación Hospital la Misericordia* in Bogota, and *Fundación Valle del Lili* in Cali.

There are currently 79 PC services operating in Colombia (equivalent to 1.6 services per million inhabitants) nine of which are focused on pediatrics (less than one service per million for children).[9] The highest level of PC provision is found in large urban areas having specialized hospital services, with very little provision at the community level.[6]

Using the number of PC services as an outcome indicator reflecting appropriate steps and measures taken in other domains (policies, access to medicines and education) shows that Colombia has too few PC services to meet population need.

Civil Society and Academic Initiatives

The first civil society PC organization (*Asociacion Colombiana de Cuidados Paliativos - ACCP*) was created in the early 1990s and focused mainly on education of specialists. The ACCP registered as a scientific society with the MPSP in the early 2000s, gaining recognition for PC as medical specialty, a designation that limits eligibility for positions on the board of directors to professionals with specialist degrees, leading to dissension among members who lacked those credentials. A group of psychologists and nurses created the *Asociacion Cuidados Paliativos de Colombia (ASOCUPAC)* in 2014 and decided not to register as a scientific organization to ensure inclusivity. Both organizations now have specific niches and collaborate effectively to advocate for PC with the MSPS.

Two other initiatives have augmented the positive effect of the civil society organizations: the Colombian Observatory of PC, monitors and reports data assessing policies and advances in education, public policy, and access to essential medicines that are paving the way for PC integration.[23] And in 2014, New Health Foundation launched "Project Lucy", to develop and implement a national model for end-of-life care by creating programs and resources for PC providers, redesigning financial models for insurers, training professionals, and generating social awareness. Since its inception, the number of Health Management Organizations offering PC coverage has increased and the number of patients insured now exceeds 15 million.[46]

Recent Developments

The first case of COVID-19 in Colombia was reported March 2020. At the time of writing, the country has reported over 3 million cases, and more than 84,000 deaths.[47] In response to the extensive additional demands on supplies of essential medicines, the government declared a state of emergency. This allows the MSPS to adopt regulations facilitating procurement and distribution of controlled medicines, including allowing home delivery and increasing prescription validity to 90 days (until the emergency decree is revoked, whereupon it will return to the 30-day statutory limit).[48,49] The FNE reports that it is following the recommendations of the WHO-INCB-UNODC Joint Statement[50] and in 2020 requested supplementary estimates to cover the need for controlled substances to treat COVID-19 patients (midazolam, ketamine, fentanyl) doubling the 2019 estimate. Although these medications are not covered by the FNE monopoly, the office is still responsible for submitting the supplementary requests to the INCB.

Main Findings and Recommendations

The decision Colombia took over a century ago to guarantee access to pain relief by subsidizing opioids and other controlled medicines resulted in a unique method of facilitating access to essential analgesics for patients with legitimate medical needs. We are unaware of any other LMIC with such a procurement and financing model for pain relief medications, even in 2021. Furthermore, relative to other countries in the region, Colombia was the first to launch a PC service, the first to accredit palliative medicine as a specialty, the second to establish a national PC association and one of the few countries with a specific PC law, along with a record of multiple policies, decrees, and campaigns to advance PC. Notwithstanding, the number of services per capita and DOME are insufficient to meet population need. The reason for this stagnation is probably multifactorial. Our analysis using the components of the WHO public health model for PC (policy, education, medicines, and service provision) has revealed the most significant gap is in professional education of health workers. Although the government took steps to improve provision of and access to medicines for an entire decade and insurance entities adopted PC in their coverage, graduating cadres of medical, nursing and pharmacy school professionals, lacked the necessary PC competencies to operationalize those official initiatives. Many entered careers in politics, administration, or regulatory offices, unaware of the systemic shortcomings. Since academic institutions are independent, the government cannot mandate curricula. Changes in the academia are slow, and advocacy efforts from PC organization, which have mostly focused on government, should also include academia, and building constructive relations with deans and provosts.

Aligned with the recommendations included in the WHA PC Resolution[3] and consistent with the recommendations adopted by the IAHPC in a consensus based process to define PC,[51] we offer a set of recommendations to governments and civil society organizations (Box 1) in their efforts to achieve palliative care integration. These recommendations are applicable in all countries including Colombia.

Box 1 Recommendations for the integration of Palliative Care

- Adopt adequate policies and norms that include palliative care in health laws, national health programs and national health budgets;
- Ensure that insurance plans integrate palliative care as a component of programs;
- Ensure access to essential medicines and technologies for pain relief and palliative care, including pediatric formulations;
- Ensure that palliative care is part of all health services (from community health-based programs to hospitals), that everyone is assessed, and that all staff can provide basic palliative care with specialist teams available for referral and consultation;
- Ensure access to adequate palliative care for vulnerable groups, including children and older persons;
- Engage with universities, the academia and teaching hospitals to include palliative care research as well as palliative care training as an integral component of ongoing education, including basic, intermediate, specialist, and continuing education.

Aside from the WHO model components (policy, education, access to medicines and service provision), civil unrest may also be an additional factor affecting policy implementation and health care provision, as violence impacts service delivery and medicines availability, especially in remote areas and informal settlements. Colombia has endured 70 years of internal conflict, and violence continues to be significant, even after the 2016 peace treaty. Finally, there seems to be limited collaboration between government offices responsible for NCDs, the FNEs and the FREs. Additional research and analysis are needed to evaluate the impact of these and other related factors in achieving PC integration in Colombia.

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