

# Controlled medicines: the access gap between the Global North and South

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# Before essential medicines, the world agreed on medicines for pain

*1961 – The Single Convention on Narcotic Drugs*

Opioids were the first medicines the world agreed were necessary across countries — years before the first WHO Model List of Essential Medicines.

The original promise was care and protection: **to ensure availability for medical use, while preventing misuse and diversion.**



# We have failed on both sides of the mandate

Harmful use and untreated suffering often coexist in the same countries, communities, and health systems. Both reveal profound health, social, and political failures.

Worldwide:

- Around 64 million people live with drug-use disorders. Yet fewer than 10% receive treatment
- Around 70 million people experience serious health-related suffering each year. Yet only about 14% of people in need of palliative care receive it.

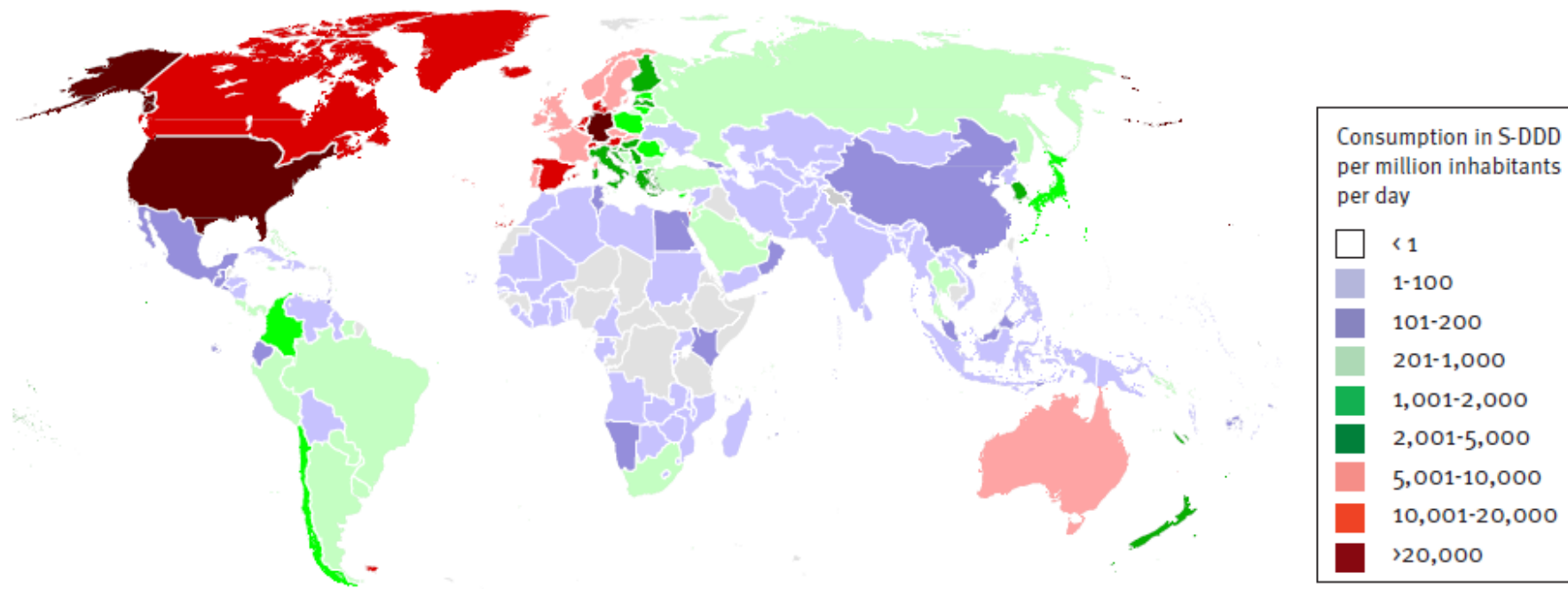


# Pain relief remains one of the clearest failures of global health equity

*More than 95% of opioids in morphine-equivalent doses are distributed to high-income countries.*

*Only 0.03% reach low-income countries*

Map 3. Availability of opioids for pain management, average for the period 2018–2020



# This is broader than morphine

- Controlled essential medicines are essential for UHC, emergency care, mental health, epilepsy care, palliative care, and harm reduction.
- Access barriers are well known.
- Beyond 'usual' access barriers, controlled medicines face additional obstacles:
  - disproportionate regulatory measures
  - burdensome administrative procedures
  - inadequate clinical guidance
  - fear of sanctions and 'professional scrutiny'
  - stigma surrounding both medicines and people in need
- Children are among disproportionately affected by the access gap.



# Accelerating access is urgent

- At current pace, it would take around 230 years for low-availability countries to reach even half availability level of high-income countries.
- Challenge for the next decade: make governments accountable not only for preventing diversion, but equally for ending avoidable suffering.
- Improving essential medicines systems does not automatically translate into access to controlled medicines → specific barriers must be explicitly identified, measured and addressed
- Children access requires dedicated focus

## Children's access to controlled medicines: policy lessons, intervention priorities, and a framework for action



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Children face multiple challenges in accessing controlled medicines—defined here as any pharmaceutical product whose active principles are listed under the international drug Conventions—particularly in low-income and middle-income countries. Although many barriers to accessing controlled medicines for children are known, there is a need for comprehensive, policy-driven, and system-level responses to address this global inequity. With a paucity of research on effective policy strategies for improving access to paediatric controlled medicines, transferrable policy lessons and expert guidance are crucial for informing such responses. This Health Policy purposefully reviews relevant policy guidance and resources and highlights policy lessons from three low-income and middle-income countries (Uganda, India, and Costa Rica). Guided by key literature and the multidisciplinary expertise of the authors, it proposes research and intervention priorities and formulates a functional framework that outlines actionable levers for improving appropriate access to controlled medicines for children.

### Introduction

Controlled medicines have been defined<sup>1</sup> as pharmaceutical products whose active principles are listed under the international drug Conventions<sup>2–4</sup> (see Maser and colleagues<sup>5</sup> for further definitions and distinctions relevant to controlled medicines). Controlled medicines are essential for managing multiple symptoms and conditions in children, including severe pain, seizures, neonatal abstinence syndrome, opioid use disorders, attention-deficit hyperactivity disorder, sickle cell disease, as well as for surgery, anaesthesia, and palliative care, including end-of-life dyspnoea (appendix pp 2–5).<sup>5</sup> Due to multiple complex and inter-related barriers, access to controlled medicines is poor in many settings, particularly in low-income and middle-income countries (LMICs).<sup>6</sup>

Access to medicines for children (defined here as those aged 0 to <18 years) is hindered by multiple barriers, including a systematic neglect in resource allocation, policymaking, research, and monitoring and evaluation.<sup>6–9</sup> For controlled medicines, in addition to the complex regulatory and sociocultural factors unique to these substances, access for children is constrained by child-specific factors. For example, children have been historically neglected in pharmaceutical research and development, and in efforts to monitor and quantify access to medicines.<sup>10</sup> Child-appropriate formulations are often omitted from essential medicine lists and standard treatment guidelines, causing additional challenges for procurement and supply.<sup>6,7,11</sup> Even when available in adequate formulations, the appropriate use of controlled medicines in children is hindered by provider and family knowledge gaps and fears of addiction and harm.<sup>6,12</sup>

Insufficient access to controlled medicines is harmful to children at multiple levels. At an individual level, it leaves children with a high burden of inadequately treated pain and suffering, and families face a sense of powerlessness and distress. At a population level, it

impedes global efforts to alleviate serious health-related suffering (an established measure of palliative care need) in children,<sup>13</sup> to improve outcomes across multiple health conditions, and to achieve Universal Health Coverage (UHC).<sup>5</sup> Moreover, the inaccessibility of controlled medicines is a violation of the human right to health,<sup>14,15</sup> and a failure of obligations to protect people from cruel, inhumane, and degrading treatment.<sup>16,17</sup> Although barriers to accessing controlled medicines for children are well known, the problem remains insufficiently understood in its complexity, highlighting the need for comprehensive, policy-driven, and system-level responses. This Health Policy provides a narrative review to summarise available guidance and resources:

### Key messages

- Current research and policy efforts insufficiently address the urgent needs of children requiring controlled medicines
- Global and national access agendas overlook the distinct therapeutic, developmental, and ethical dimensions relevant to children
- The WHO Guideline on balanced national controlled medicines policies (2025) calls for explicit attention to children's needs; translating it into practice requires placing children at the centre of policy design and implementation, with active participation from children and adolescents, families and caregivers, and frontline health workers
- Existing pharmaceutical, paediatric, and health-policy instruments and strategies are scattered and underused, and this is even more true for controlled medicines; there is a pressing need to consolidate these resources and adapt them to children, and to fill crucial research gaps to generate child-specific evidence on access, safety, and use
- Making controlled medicines available and accessible to children requires substantial and coordinated efforts by multiple stakeholders to fund essential activities that range from research and development and production of paediatric formulations to their inclusion in health insurance packages
- Equitable access to controlled medicines for children is grounded in the principle of human dignity and in the human right to health—addressing this long overdue injustice is feasible, urgent, and essential for achieving Universal Health Coverage and the right to health



## ***We cannot normalize avoidable pain and suffering***

***When severe pain is left untreated despite available means to relieve it,  
this is not only a clinical failure,  
it becomes a violation of human dignity and  
protection from cruel, inhuman or degrading treatment.***

