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EXPERT OPINION

The Access to Oncology Medicines Coalition: Enhanced in-Country Coordination for Sustainable Access

Diogo de Sousa Neves[1,2], Shalini Jayasekar Zürn[2], Thuy Khuc-Bilon[2], Melissa Rendler-Garcia[2], Yehoda M Martei[3], Sumithra Krishnamurthy Reddiar[2]

[1]Independent Global Health Consultant, Paris, Ile-de-France, France; [2]ATOM Coalition Secretariat, Union for International Cancer Control, Geneva, Canton of Geneva, Switzerland; [3]Haematology - Oncology Division, University of Pennsylvania, Philadelphia, PA, USA

Correspondence: Melissa Rendler-Garcia, Email rendler@uicc.org

Abstract: The disparity in access to essential cancer medicines between less and more affluent countries is a major source of inequities in access to cancer care. In May 2022, the Union for International Cancer Control (UICC) launched a new initiative, the Access to Oncology Medicines Coalition (ATOM Coalition), bringing together over 40 organisations from the private and civil society sectors to cooperate and combine resources to address key barriers of access to cancer medicines in low- and lower-middle income countries. While the ATOM Coalition is engaged in global efforts to make cancer medicines more accessible, the initiative also includes a country-level support programme to enhance coordinated locally-led action and accelerate access. This is supported by a transparent governance and organisational structure as well as a working framework with governments and other key stakeholders to assess the current capacity and develop tailored responses that can lift and/or relax some of the identified barriers through joint collaborations with ATOM Coalition partners.

Keywords: access to medicines, cancer medicines, health systems strengthening, health inequities, capacity strengthening

Introduction

The contrast in access to cancer care between low- and middle-income countries (LMICs) and high-income countries (HICs) is stark. Every year, approximately 10 million lives are lost due to cancer, making it the sixth leading cause of death worldwide.[1,2] The global cancer burden is expected to rise by 50% by 2040, with close to 70% of all new cases expected to occur in LMICs.[3] Patients in LMICs typically have significantly lower chances of survival compared to those receiving a cancer diagnosis in HICs.[4] In addition, while population-based studies in HICs point to a steady improvement in cancer survival over the past decades, largely due to greater access to early diagnosis and timely and appropriate treatment,[5,6] LMICs continue to face limited access to cancer treatment, including surgery,[7] radiotherapy,[8] and systemic therapies with cancer medicines.[9] This disparity in access not only persists but is widening, further underscoring the deep health inequities between wealthier and less affluent countries.

In recent years, significant advancements have been made in cancer treatment and care. However, the journey from innovation to patient access on a global scale is often impeded by major challenges that both the public and private sectors have not yet been able to solve. A primary issue is the availability of medicines that satisfy the priority cancer care needs of any population, which are also defined as essential cancer medicines. The full list of the essential cancer medicines, as defined by the World Health Organization, accounts for over 60 medicines across all class types.[10,11] These medicines have been available and routinely used in HICs for decades with proven clinical benefits for cancer patients.[12] In many LMICs, however there is an inconsistent supply of these medicines, and even when they become available, their costs are prohibitive to individuals in need, including medicines such as doxorubicin, cisplatin and tamoxifen.[9] For novel medicines, there is limited or non-existent access in LMICs, perpetuating the underlying disparities in access and outcomes.

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The recent attention placed on Universal Health Coverage (UHC) which is centred around ensuring that all people can access health services without financial hardship, offers an important avenue to address the challenge of limited access to cancer medicines.[12,13] To achieve UHC however, a range of key stakeholders including governments, civil society, and the private sector must collaborate. In this context, sector counterparts such as pharmaceutical companies have committed to expanding the scope and number of access programmes in LMICs, including through donations, reduced prices, and other access mechanisms for their cancer medicines.[14,15] These programmes can play a decisive role for cancer patients who qualify to benefit from accessing such medicines. However, in the absence of appropriate coordination and long-term planning, these well-intentioned efforts are likely to act as temporary fixes rather than long-term sustainable access solutions. The proliferation of multiple access programmes by different companies and institutions often leads to overlapping or duplicated efforts, further straining health systems in LMICs that are already under pressure. Similarly, access programmes may benefit some geographies more than others and lack a plan for scale-up, thus exacerbating health inequities further.

Multiple stakeholders are becoming increasingly aware of the challenges posed by lack of harmonisation across access programmes and thus propose new ways of integrating and fostering alignment. The World Health Organization (WHO), for example, emphasises the importance of coordinating new access initiatives with already existing programmes.[16] In addition, the WHO stresses the importance of preparing health systems to enhance sustainability of access programmes. This includes addressing appropriate pricing by the pharmaceutical sector as well as improved regulatory capacity, efficient procurement practices, strengthened supply chains, pathology and diagnostic capabilities, and quality service delivery with a central focus on a patient-centred approach in countries.

Focusing on system-level improvements, prioritising the needs of those affected by cancer and supporting strengthened coordination, creates a strong foundation for a sustainable model for health and medicine access. This approach is at the heart of the Access to Oncology Medicines Coalition (ATOM Coalition), a global initiative led by the Union for International Cancer Control (UICC).[17] Since its launch in 2022, the ATOM Coalition has brought together over 40 organisations, from the private and civil society sectors to cooperate and combine resources to address key barriers that often inhibit the availability, affordability, and appropriate use of oncology medicines in low- and lower-middle income countries. The ATOM Coalition builds on UICC's long-standing advocacy for the global availability of essential cancer medicines, further leveraging the work and expertise of coalition partners coordinating, complementing, and maximizing existing access initiatives to reach more people living with cancer. This paper presents the governance structure of the ATOM Coalition and examines in detail one of its key workstreams: country-level support for strengthening sustainable access to cancer medicines.

The ATOM Coalition Governance and Organisational Structure

The ATOM Coalition's country-level support programme is designed as a multifaceted approach that facilitates the agile coordination of a diverse group of stakeholders, each bringing a unique perspective and expertise in ensuring access to essential cancer medicines. The approach aims to ensure that activities are aligned and focused on prioritised country needs, as well as effectively complementing and adding value to existing access programmes and capacity strengthening activities already in place at country level.

The ATOM Coalition takes a holistic stakeholder approach in partnership, recognizing each sector brings a different perspective to solve the challenges related to accessing cancer medicines. Partners join the Coalition through an agreement with the UICC. The UICC leads the secretariat, guiding the Coalition's strategy, fostering stakeholder and partner cooperation, and coordinating efforts and activities at the global and country levels. The majority of the Coalition's private sector partners are pharmaceutical and diagnostic companies. By joining the coalition, private sector partners commit to a results-oriented approach, focusing on the coalition's ambition to improve access to essential cancer medicines in LLMICs. This is done through the four ATOM Coalition sustainable pathways that are used to deliver medicines or diagnostics:

1. Non-exclusive voluntary licenses, facilitated by the Medicines Patent Pool,[18]
2. Indirect commercialisation, facilitated by the IDA Foundation,
3. Pooled purchasing through the NCDconnect platform led by the IDA Foundation,[19] and
4. Donations programmes, led by the Max Foundation.

The Coalition's partner engagement structure is operationalised via four key communication channels between the Secretariat and Coalition partners. An Executive Committee is responsible for providing the overall strategic direction to the Secretariat, formed by the founding organisations that conceived the Coalition (UICC, The Max Foundation, Project ECHO, and the American Society of Clinical Pathology), a representative of the private sector council, and observers from civil society organisations (Medicines Patent Pool and the Access to Medicines Foundation). A second-tier group, the ATOM Coalition Council, comprises representatives from partner civil society organisations and cancer centres. Council members provide insights from their first-hand experiences in strengthening capacity related to access to cancer medicines in LMICs. The council serves as a platform for exchanging information and advice regarding implementation strategies in countries. A third group, the private sector council, includes representatives of all private sector partners. This council is an organised forum to bring private sector expertise to bear for greater impact on improving access to cancer medicine and care across the value chain in ATOM Coalition target countries. Finally, the Coalition harnesses expertise within a network of experts by establishing independent expert advisory groups. These groups regularly advise the secretariat in several key areas, including priority medicines, diagnostics, and regulatory affairs. Members of these advisory expert groups are appointed by the Executive Committee.

The model employed by the ATOM Coalition is aimed at creating a robust governance and organisational structure that drives the Coalition's efforts through strategic collaboration, shared expertise, and effective communication.

Target Group of Countries

In the first phase of operations, the ATOM Coalition focuses its efforts on increasing access to essential oncology medicines in 46 LLMICs. These countries are potential participants of the Coalition-supported global access programmes via the medicine access pathways outlined above, and include: Angola, Bangladesh, Belize, Benin, Bhutan, Bolivia, Cambodia, Côte d'Ivoire, Burundi, Cameroon, Egypt, El Salvador, Ethiopia, Republic of the Congo, Georgia, Ghana, Guatemala, Guinea, Haiti, Honduras, India, Indonesia, Kenya, Kosovo, Kyrgyzstan, Lao, Madagascar, Malawi, Mongolia, Morocco, Mozambique, Nepal, Nicaragua, Papua New Guinea, Pakistan, Philippines, Rwanda, Senegal, Sri Lanka, Tajikistan, Togo, Tunisia, United Republic of Tanzania, Uzbekistan, Uganda and Zambia.

Concurrently, in the first stage, a targeted country support programme is rolled out in a subset of 10 countries in a phased manner. These are: Côte d'Ivoire, El Salvador, Honduras, India, Mongolia, Nepal, Pakistan, Senegal, Uganda and Zambia. These countries were identified based on an analysis conducted by the ATOM Coalition Secretariat on a range of readiness criteria, including the presence of ATOM Coalition partners, local civil society organisations, and UICC members invested in access to cancer care, in addition to basic cancer care infrastructure, existence and composition of national essential medicine lists, ongoing access programmes in the country, and the willingness of manufacturers to make their medicines available in those markets. This was followed by a more in-depth study of the 10 countries and health care systems based on a survey conducted with ATOM Coalition partners, combined with findings from UICC's in-house knowledge base, and desk research on publicly available global databases.[20] Table 1 shows the key indicators that were studied and weighted to support the assessment of the potential feasibility and impact of ATOM Coalition country support for each of the 10 countries. Based on this analysis, three countries were identified as pilot countries for the Coalition's country-support programme of work: El Salvador, Mongolia, and Zambia. Learning from this group of countries about the enabling factors and barriers to increasing access to cancer medicines will inform the expansion of the initiative to other geographies.

Co-Design of Country Support Activities

The primary objective of the ATOM Coalition's country-support efforts is to address the critical challenges and barriers affecting access to essential oncology medicines at national level. While there are common access challenges affecting LLMICs,[12] the Coalition adopts a needs-based approach. This entails working with governments and other key stakeholders to first assess the capacity to produce, acquire, distribute, and use cancer medicines and then agree on what the most pressing needs and barriers could be lifted or relaxed through joint actions.

Engagement with national stakeholders is formalised through a memorandum of understanding (MoU) between the UICC and Ministry of Health in each country. The MoU sets the basis for establishing 1) a coordination group composed

Table 1 Indicators Used to Prioritise the Roll-Out of the ATOM Coalition Country Support Programme

Pillar	Key indicators	Relative weight of the indicator
Demographics and burden of cancer	Total population	Critical
	Incidence rate	Critical
	Mortality rate	Critical
	Mortality to incidence ratio	Critical
	Estimated cancer incidence increase by 2030	Critical
	Estimated cancer mortality increase by 2030	Critical
Economics and financing landscape	Income level	Critical
	Health expenditure as % of gross domestic product (GDP)	Critical
	Health expenditure per capita	High
	Government health expenditure per capita	Critical
	Private health expenditure per capita	High
	External health expenditure per capita	High
	Out-of-pocket health expenditures per capita	High
	UHC service coverage index	Medium
Regulatory and policy infrastructure and preparedness	National cancer control plan or strategy	High
	National essential medicines list (NEML)	High
	Year of last NEML update	High
	Cancer medicines included in the NEML	Low
	NEML and WHO essential medicines lists similarity (%)	High
	National medicines regulatory authority	High
	WHO regulatory self-benchmarking	Low
	WHO regulatory formal benchmarking	Low
	WHO-listed authority	Medium
Health system capacity	Population-based cancer registry	Critical
	National breast cancer screening programme	High
	National cervical cancer screening programme	High
	Most widely used method for screening cervical cancer	High
	National clinical guidelines for cancer management	Medium
	Public cancer centres per population	Low
	Radiotherapy capacity	High
	Health care professionals per population (general physicians, specialist medical practitioners, medical and Pathology laboratory scientists, pharmacists)	High
Environment for collaborations and partnerships	Active UICC members	Medium
	Relevant ECHO programmes deployed	Medium
	ATOM Coalition partners implementing capacity building projects	Critical
	ATOM Coalition partners with on-site staff	Medium
	Access to global access initiatives (eg WHO's collaborative registration process, PAHO's strategic fund)	High
Ease of doing business	Trading across borders	Medium
	Enforcing contracts	Medium
	Infrascope public-private partnerships overall score[21]	Medium

Notes: For internal prioritisation purposes, the various indicators of feasibility and potential impact of the in-country support programme were ranked on scale from critical, high, medium, and low which were then plotted into a feasibility impact matrix. The different weights were attributed based on perceived correlation of each indicator to the overall feasibility and impact scores as well as the accuracy and precision of the data sources. More information can be found on Union for International Cancer Control (UICC). Available from: https://www.uicc.org/resources/analysis-access-related-capacity-building-gaps-and-opportunities-atom-coalition-countries.[20]

of health authorities, cancer centres, the ATOM Coalition Secretariat, local advocacy and civil society organisations, and government partners that are currently implementing related projects, and 2) a technical working group composed of only local experts appointed by relevant public institutions to guide a situational analysis around three critical areas of access: regulatory affairs, supply chain management, and health system capacity. ATOM Coalition private sector partners are called upon to contribute with expertise after the locally-led priority-setting exercise is finalised. The involvement of ATOM Coalition private sector partners is restricted to specific consultations as identified by the technical group. Figure 1 presents an overview of the engagement between the Secretariat, partners and country counterparts.

A comprehensive situational analysis requires an in-depth understanding of the main infrastructure available, operational capacity, and communication along the complex network of agents with a role in access to medicines, from regulatory affairs to clinical use. In the context of regulatory affairs, the assessment aims to understand the main processes and capabilities that national regulatory authorities have at their disposal to ensure an efficient regulatory system that is commensurate with the current capacity. This includes an analysis of the regulatory infrastructure that follow international guidelines[22] and any collaborative approval processes and ongoing practices, such as collaborations with stringent regulatory authorities and/or the adoption of WHO's collaborative registration process mechanism.[23] In the face of growing pharmaceutical expenditures that are challenging health systems,[24] it is important to understand and articulate the how resources are allocated for medicines expenditures as well as the mechanisms that determine which medicines are included in the national medicine formularies and their eligibility for reimbursement.

Simply having authorisation to enter a market and an agreement by payers on what they will be willing to pay for a medicine does not ensure that the medicine will reach patients in need. For this to occur, countries and the private sector must rely on and continuously invest in strengthening their supply chains. Countries will also need to strengthen their procurement practices. Weaker supply chains have been associated with prolonged stockouts and price increases for patients due to the cumulative effect of mark-ups.[25] The Coalition collaborates with local, regional and global experts in various countries to explore how various procurement agents, including wholesalers and healthcare institutions, undertake their demand forecasting, communicate with each other, apply contractual methods (eg group negotiation[26]), set up their quality assurance systems, and distribute cancer medicines within their health systems.

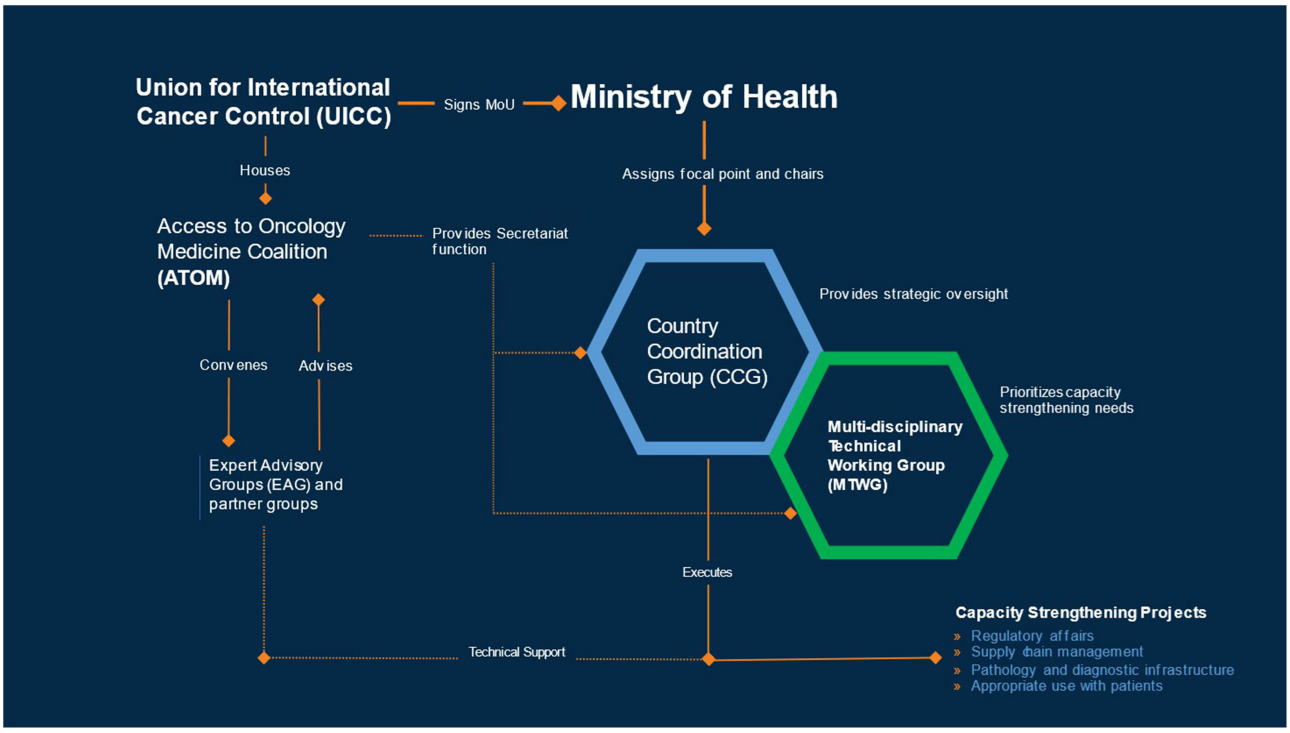

Figure 1 Overview of ATOM Coalition's model to operationalize capacity strengthening activities and how diverse actors are engaged.

As cancer medicines follow a complex journey to reach patients, the health system needs to ensure that patients are diagnosed early enough and properly referred and navigated within the system to receive quality care and achieve optimal outcomes. At this stage, the situational analysis explores the challenges related to diagnostic infrastructure and capabilities, and how the diagnostic-therapeutic process is coordinated among professionals. Additionally, understanding which mandatory diagnostic tests, particularly molecularly-based diagnostic procedures, are reimbursed by insurers is key, as patients in some LMICs must bear the financial costs of these tests, limiting their access to medicines.[27]

A complete picture of access to medicines can only be found by looking at what medicines form part of the therapeutic arsenal that physicians can effectively prescribe, and which patients can effectively access in each country. This last mile of the medicine journey is decisive in determining whether there are any discrepancies between what is listed on the national essential medicine lists and what is made available to those who need them the most. As systemic therapy is rarely performed in isolation, appropriate clinical use of the medicine also needs to consider an assessment of the application of evidence-based and resource-adapted clinical guidelines, how the various disciplines related to cancer care are engaged, and the role of cancer patients in the clinical decision-making process. The analysis of how cancer medicines, particularly chemotherapeutic agents, are stored, prepared, administered, and monitored, completes the assessment.

Though the intention of the situational analysis and associated in-country governance structures is to enable a country-led process, lack of data availability, time constraints and competing priorities from the multiple stakeholders and/or turnovers involved can create bottlenecks. In light of this, the Coalition's Secretariat is structured to allow for an agile response and to adapt to such situations with the goal of enabling national counterparts to guide and lead the process. This is an important aspect of the Coalition's work after priority actions have been identified by countries, which will also affect the subsequent phases of implementing programmes and measuring, reporting and learning.

The Coalition's capacity strengthening work is similarly intended to promote a sustainable engagement with country counterparts with an initial commitment envisioned for a period of three years, which will then be reviewed for continuity in line with country priorities and needs. It is expected that by the end of 2024, capacity strengthening activities will begin in the three pilot countries, following the formalization of agreements with Ministries of Health, the composition of in-country governance structures and the finalisation of respective situational analyses. Socialisation and reach-out efforts are envisioned to occur concurrently to expand to additional geographies in a phased approach. Beyond the country engagement milestones, the Coalition's capacity strengthening pillar will be assessed in relation to progress achieved vis-à-vis the initial benchmarking provided by the situational analysis. Such a framework assesses among other factors: progress achieved in the availability, affordability and accessibility of medicines for those in need. In concordance with its country-led mission, the Coalition's measurement process leverages local expertise to adapt tools and methods for context-sensitivity and relevance.

Moving Towards System Strengthening and Sustainable Access

A Coalition of partners with such a diverse set of expertise and interests can only be meaningfully operationalised at the country level if there is alignment towards common goals and actionable workplans. The ATOM Coalition is committed to evaluating opportunities to support actions that address gaps emerging from the situational analysis, as prioritised by national health authorities. Through a strong emphasis on creating platforms for local stakeholders to identify their own gaps and needs across the access to medicines pathway, the ATOM Coalition anticipates contributing more fit-for-purpose capacity strengthening support and improving coordination among international partners with potential gains in efficiency in both governments and their partners. Sustained commitments and actions by both governments and ATOM Coalition partners will be key to enabling the validation and refinement of this model for coordination towards increased access to cancer medicines.

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Disclosure

The authors report no conflicts of interest in this work.

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