ECONOMIST IMPACT

Evaluating clinical practice guidelines for Multiple Myeloma in Latin America

Supported by Johnson&Johnson

About this report

Evaluating clinical practice guidelines for Multiple Myeloma in Latin America is an Economist impact white paper, supported by **Johnson & Johnson**. The report provides an independent analysis of Multiple Myeloma (MM) clinical practice guidelines (CPGs) within the region. It evaluates the role of CPGs, their development, implementation challenges, care across institutions, accessing innovation, and more, and focuses on five countries in the region (Argentina, Brazil, Colombia, Dominican Republic, and Mexico). The insights in this report are based on an extensive literature review and desk research, expert panel discussions, and in-depth interviews with relevant clinical experts, scientific leaders, and patient advocates. The editorial team at Economist Impact would like to thank the following individuals for generously contributing their time and insights that have been critical to this research:

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- **Alejandro Irastorza**, Medical Professor and Medical Audit Manager, Medicus, Argentina
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- **Humberto Martinez-Cordero**, Haematologist; Spokesperson, Grupo de Estudio Latino Americano de Mieloma Múltiple (GELAMM): Instituto Nacional de Cancerologia
- **Alma Ortiz**, Deputy Director, Mexican Association for the Fight Against Cancer
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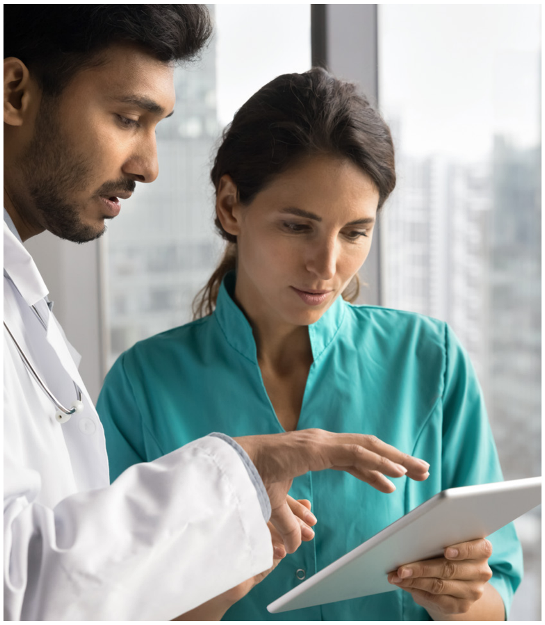


Multiple myeloma (MM), a haematological malignancy characterised by the abnormal expansion of plasma cells in the bone marrow, leads to complications such as renal failure, anaemia, bone lesions, and hypercalcaemia. MM accounts for 1% of all cancers and 10% of haematologic malignancies globally. The burden of MM is rising globally, including in Latin America (LATAM).[1]

Clinical guidelines vary in the region

The existence and nature of clinical practice guidelines (CPGs) vary across the region. Some countries have active and up-to-date guidelines, while others have outdated guidelines. Some countries do not have their own guidelines, relying instead on international guidelines such as the European Society of Medical Oncology (ESMO) guidelines and the National Comprehensive Cancer Network (NCCN) guidelines from the United States.

The public-private divide in implementing guidelines and accessing treatment

Disparities in the implementation of CPGs and treatment are most present between public and private institutions. Patients treated in the public sector face more difficulty than patients seeking care in private systems leading to fragmentation and gaps in care.[2,3] Private institutions generally have greater access to resources relative to public institutions, creating disparities in the quality of care between public and private institutions. Though private institutions have less barriers for patients within private systems, the quality of care in private institutions is beginning to worsen.[4] For example, Brazil's private health system is experiencing shifts as costs increase and a reliance on the public health system (SUS) increases concurrently.[5]

LATAM's regulatory and cost environment related to MM care and management are significant barriers to alignment on novel treatments in the public system. The approval process for reimbursements of novel agents results in significant wait times for patients reliant on public health services, which ultimately exacerbates disparities in treatment access between patients treated in public versus private settings.[6] Though costs can be barriers, viewing healthcare costs as investments in patient access is integral for improving health outcomes.[7]

There is room to improve the care landscape

The current bottlenecks can be alleviated by integrating CPGs across healthcare settings, allowing for such guidelines to be frequently updated with the best existing data, and thereby ensuring that guidelines are considered in decision-making when it comes to regulatory affairs, access, and reimbursement.

Introduction

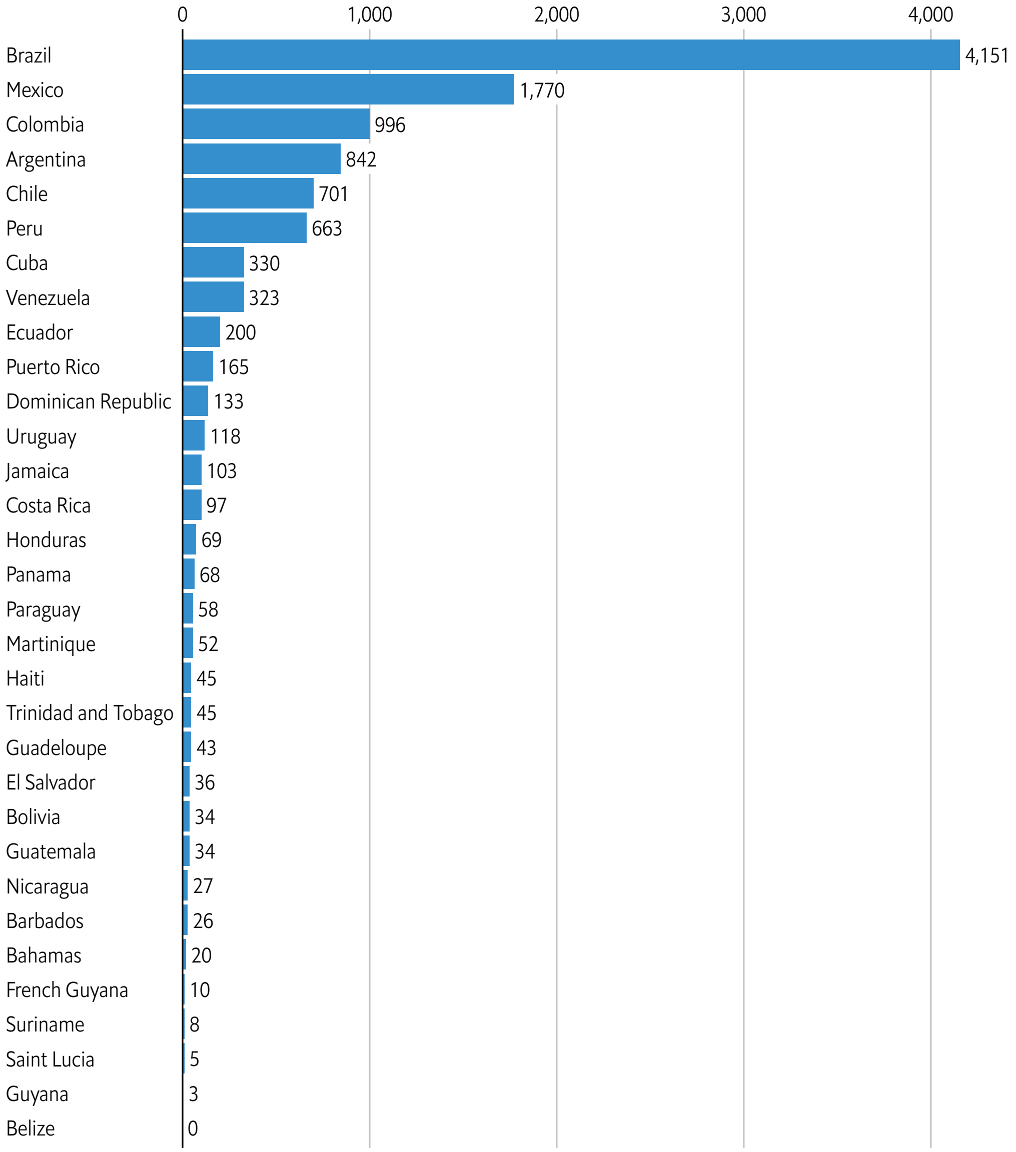
Multiple myeloma (MM) is the 24th most common cancer in the world. It is a blood cancer that originates in plasma cells within the bone marrow, accounts for 10% of all blood cancers, and ranks second among blood cancers in terms of new cases per year globally.[6,8,9] There has been a surge in the incidence of MM globally, which is attributable to an ageing population and increased life expectancy.[1] MM represents around 1% of all cancers globally and incidence of the disease is higher in individuals over 60 years of age and with those who have a family history of the disease.[10] In Latin America (LATAM), there is a significant burden of MM, specifically in Brazil, Argentina, Colombia, Chile, Mexico, Peru, and Uruguay.[1] Guatemala had the highest increase in mortality for men (15.1%) and women (10.2%) in 2018.

> **“There has been a surge in the incidence of multiple myeloma globally, which is attributable to an ageing population and increased life expectancy.[1] ”**

As detailed in figure 1, LATAM, Brazil, Mexico, Colombia, Argentina, and the Dominican Republic have the highest incidence rates of MM. Brazil reported the highest number of cases in the region, exceeding 4,000 in 2022. Figure 2 shows the Age Standardised Incidence Rate (ASIR) across different regions. The wide distribution highlights disparities in healthcare reporting, disease prevalence, or diagnostic capacity between countries within the region. These disparities influence understanding of disease burden which are critical for improving early detection, treatment, and survival.

Figure 1: Estimated number of prevalent cases of multiple myeloma in 2022

Latin America and Caribbean

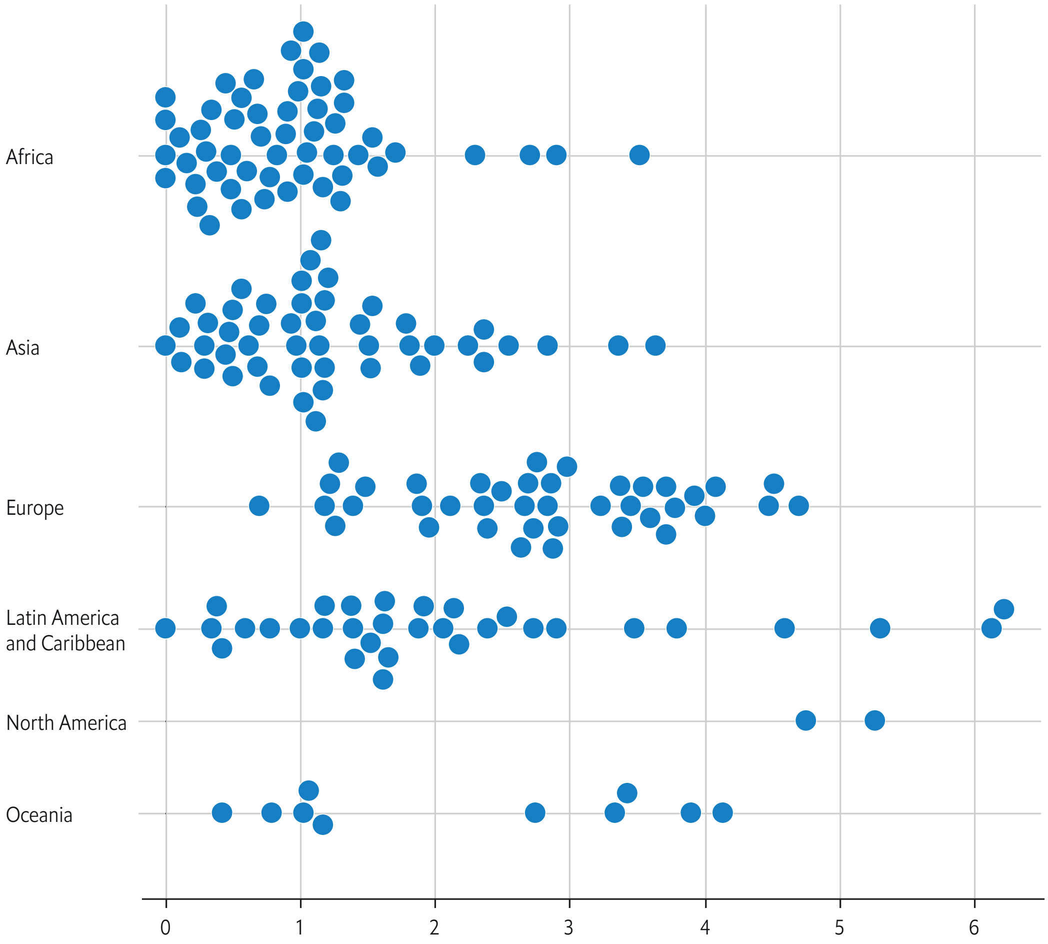


Source: Globocan
Graphic insight: Economist Impact

Figure 2: Age-standardised incidence rates of multiple myeloma across global regions in 2022

Incidence rate per 100,000 people, standardized to a global age distribution

Individual countries, grouped by region



Source: Globocan
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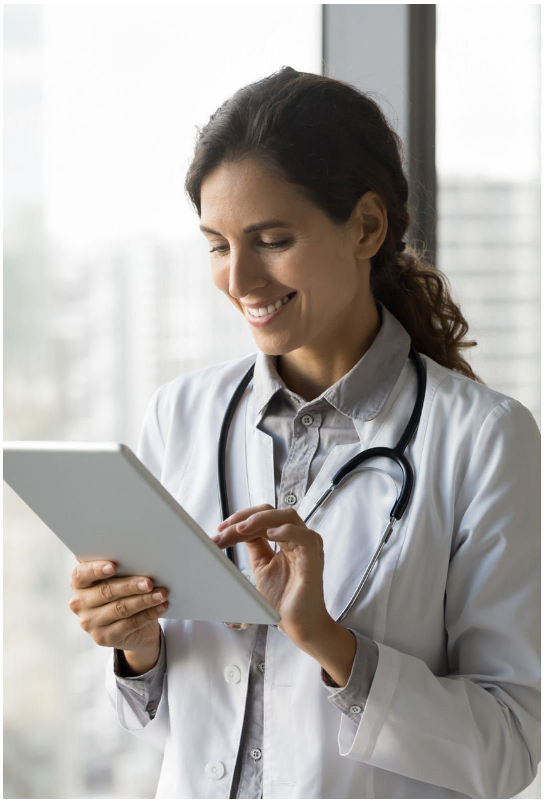
Clinical practice guidelines

CPGs play a significant role in shaping treatment patterns and patient outcomes.[11] Relying on the most up-to-date scientific evidence, CPGs provide specific recommendations on treatments, disease management, accessibility, and more.[12] CPGs are important in healthcare for several reasons, including but not limited to: standardised patient care, best practices, improved patient outcomes and decision support for clinicians. CPGs function to ultimately ensure the best treatment for patients.[13-15]

CPGs are instrumental in establishing disease management standards to mitigate the health and economic burden. These guidelines also play a critical role in ensuring patients receive adequate care and treatment. Natalia Paola Schutz, Doctor in the Department of Internal Medicine at the Hospital Italiano de Buenos Aires, reflecting on her experience in Argentina's Hospital Italiano de Buenos Aires, explained, "We usually adapt these kinds of guidelines [European Society of Medical Oncology (ESMO)] to determine what we do have access to in Argentina. We use guidelines to also ensure access to treatment because if it's not in the guidelines, health insurance companies are reluctant to reimburse treatments. Being in the guidelines is also a way of saying okay this is my standard of treatment, so I want access to it." Though not legally binding, deviations from CPGs must have a clinical justification.[12]

A data-driven approach is helpful in the development of CPGs, as it can provide the foundation for evidence-based recommendations. In LATAM, there is an opportunity to employ this approach more broadly.[16] Researchers explain that in convening a group of experts to develop CPGs



or consensus statements, it is recommended to involve a diverse group of stakeholders such as clinicians, scientists, methodologists, and patient representatives. Once convened, the process should ideally begin with defining the scope, specifying the clinical problem, affected population, interventions, expected outcomes, and priorities. Below is a chart illustrating the typical process of drafting CPGs.[16]

While some of the steps detailed above are common to how countries in the region develop their CPGs, there are also differences in their specific approaches to the process. In the case of our countries of focus, Argentina and the Dominican Republic do not have their own national guidelines specifically for multiple myeloma. They instead rely on international guidelines to manage MM. Brazil, Colombia, and Mexico, on the other hand, rely on a combination of international and national guidelines to manage MM care. Argentina's approach to treatment protocols "relies on a consensus of experts, adapting ESMO guidelines to fit local access and reimbursement conditions," according to Dr Schutz. Though some countries rely on other international CPGs, Humberto Martinez-Cordero, Haematologist and Spokesperson for the Grupo de Estudio Latino Americano de Mieloma Múltiple (GELAMM) Instituto Nacional de Cancerologia, explains that there needs to be a push to develop LATAM-specific guidelines.

Beyond the availability of CPGs within the region, some countries have made an effort to evaluate CPGs. Mexico is one such example,

Figure 3: Process of drafting clinical practice guidelines

1. Convene a group of experts. Diverse stakeholders including clinicians, scientists, statisticians, methodologists, and patient representatives are convened to begin the drafting process.

2. Defining the scope. Specifying the clinical problem, impacted population, interventions, expected outcomes, and priorities.

3. Systematic review of evidence. Utilising tools like GRADE* to assess the quality of the evidence. *The grading of recommendations, assessment, development, and evaluation (GRADE) criteria is used to provide a structured framework for assessing the quality of evidence and strength of recommendations in healthcare.

4. Drafting recommendations. Drafted based on available evidence, balancing benefits and risk, and clinical applicability.

5. External review, ethical considerations, dissemination. Independent experts come together to assess clinical applicability while ensuring fairness and rigour of guidelines. Finalised for publication and dissemination.

Source: Economist Impact
Graphic insight: Economist Impact

which has undertaken assessments such as the AGREE-II tool in addition to GRADE to evaluate CPGs within the country.† In addition to this systematic approach, experts make mentions of specific nuances that should be considered in the development stages of CPGs.

Though the importance of CPGs is clear through several impact-focused studies, there are limitations associated with them too. Implementation of CPGs is varied as are its application of recommendations across settings, such as private clinics, and rural and urban clinics.[17] Barriers to adoption also remain a challenge. Resource limitations and delayed approval of newer treatments in public clinics highlight other challenges hindering implementation.[17] Alejandro Irastorza, Medical Professor and Medical Audit Manager at Medicus, explains that Argentina "does not yet have a Health Technology Assessment (HTA) agency. Proposals have been pending for almost a decade, leaving a critical gap in evaluating coverage and costs." This can prevent new and innovative therapies from entering the system, which can adversely impact coverage for patients, costs for the system, and reimbursements for providers.

CPGs involve more than the patient and provider. Generally, payers use CPGs to understand and aid in designing clinical pathways that both optimise patient outcomes and control costs.[18] Ideally, payers and their relation to CPGs would work seamlessly to balance efficient resource management and optimal patient outcomes. However, in practice, there are instances of misalignment between payer policies and CPGs' recommendations, which may impact care quality.[19] There is an example outside of the LATAM region in which payers have been encouraged by advocacy groups to update policies to improve alignment with guidelines to ultimately improve health outcomes.[19]

Given the variability of CPGs across the region, fragmented care across institutions within the region is a concern. CPGs provide justification for reimbursable treatments in many instances, reinforcing what healthcare insurance companies

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† AGREE-II stands for Appraisal of Guidelines for Research and Evaluation. It was developed to reduce variability in guideline quality and to assess the methodological rigour and transparency of developed guidelines. It is regularly updated to refine its framework for assessment.

are willing to cover. According to Dr Schutz, “Health insurance companies reimburse treatments that are covered within clinical guidelines. Clinical practice guidelines do not necessarily influence policy, but they do influence the coverage of certain treatments through insurance.” Guidelines that are currently used for reimbursement within the region have not been updated with the latest data on MM. For example, Colombia and Brazil’s own guidelines are from 2020 and 2022, respectively, whereas Mexico’s are from 2009. Despite relying on international guidelines concurrently with national guidelines, national guidelines are the ones that inform reimbursement. Because of lapsed updating, they do not take into account the most recent data on the disease. Dr Martinez-Cordero echoes that guidelines in his country ensure that “Every patient in Colombia can receive the whole treatment. In our guidelines, we’ve defined the first- and second-line treatments very well. It does not matter if the patient had private or subsidised care. Every patient can receive every single drug that we have available, but the issue is that our guidelines are not updated.”

Within the region, there are inconsistencies in terms of the timeliness of CPGs. Some countries consistently update the guidelines, whereas others use outdated guidelines to set the standards and frameworks for MM management. “Clinical guidelines for the public health system are outdated and don’t consider innovative drugs…making it difficult to address relapsed or refractory cases,” expresses Angelo Maiolino, Professor of Haematology at the Federal University of Rio de Janeiro’s Department of Medical Clinic.

Having updated CPGs also allows for patients to have the most optimal care since these guidelines contribute to the rigorous assessments of available treatment options.[20] As therapies advance, having updated CPGs ensures that clinicians are able to take into account these innovations when selecting the best care pathways for their patients. Updating CPGs also aids in standardising care to ensure that variability in treatment approaches is limited.

Key challenges in the utilisation of CPGs for MM management

Disparities are immense between the public and private sectors as private insurance companies are more likely to be able to reimburse innovative treatments that are often described in CPGs, whereas within the public sector, ability to cover innovative drugs is limited.[21] To highlight one relevant example, many international CPGs reference autologous stem cell transplantation (ASCT) and different novel therapies as the most effective way to treat MM, but access to these treatments in LATAM is limited, especially in public settings. Access to treatments in the public sector is characterised by limited funding of treatments, inadequate inventory management, and long administrative procedures before prescription that lead to limited access.[6]

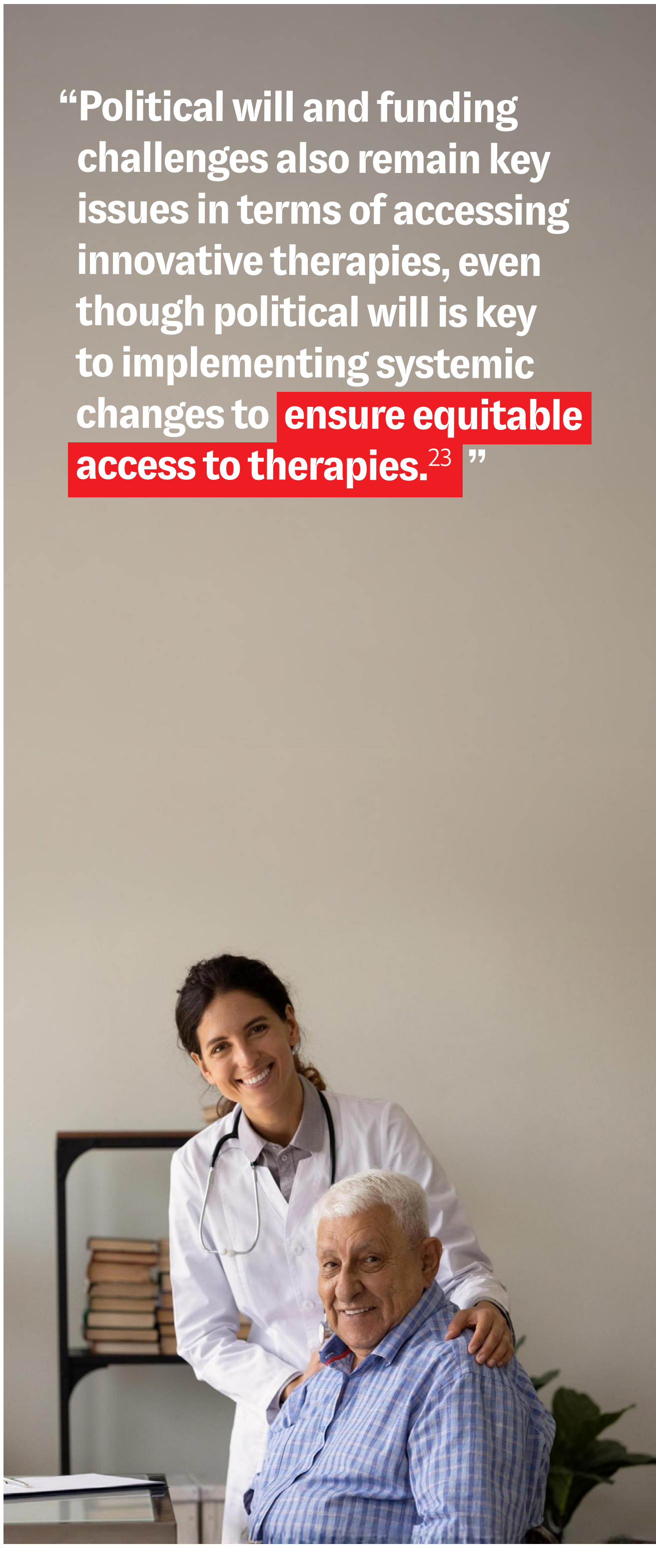
Financial and systemic barriers are also more likely given the fact that there are different levels of access and reimbursement processes for government-subsidised care in the public system. Though financial and systemic barriers are present, they should be viewed as opportunities for investments to better patient outcomes. Specific to LATAM, a lack of investment in MM care has led to delayed or not-performed transplant procedures.[22] According to the Pan American Health Organization (PAHO), there is a push to encourage governments to prioritise investments in order to ultimately move towards universal, comprehensive, sustainable, and resilient health systems that will help overcome inequities.[7]

As treatment guidelines and standards of care evolve, public clinics lag in adoption, relative to private clinics.[17] The variability in adopting treatment protocols in practice is seen in the differences between experiences of MM patients in public and private settings. Within LATAM, private systems offer better access to more innovative, effective agents, while public systems often rely on older, less effective therapies.[23] In a 2019 study that assessed treatment patterns and clinical outcomes of MM in LATAM, it was found that 54.3% of patients treated in private clinics received advanced therapies compared to 15.2% in public clinics.[17] A 2023 study highlighted that within the region, 88% of patients seek care through public healthcare systems where access to diagnostic tests and novel therapies is limited, contributing to disparities in patient outcomes, especially relative to their private-setting counterparts.[24] This is reinforced in Brazil's disparities between its private and public health systems. Dr Maiolino expressed that "Within the public health system, patients only have access to standard therapies, while private patients can access more innovative drugs like bispecifics and CAR-T therapies."

Disparities between the public and private sectors are not limited to therapy access. In Mexico, a disparity they are experiencing is diagnosis. According to Alma Ortiz, Deputy Director of the Mexican Association for the Fight Against Cancer, "Access to multiple myeloma (MM) treatment in Mexico presents significant challenges due to variations across public institutions. Patients' access to care is heavily influenced by the public institution they are affiliated with."

Argentina also has similar divides between its public and private system, where "less than 5% of patients, mainly those seeking care in private, high-quality centres have access to innovative treatments like CAR-T and bispecifics," according to Dr Schutz. She further explained that "The main inequity in Argentina lies between private and public systems, where wealthier individuals are able to access innovation through private insurance and mobility to larger cities." The public-private disparity underscores systemic barriers to access, while also highlighting that socioeconomic status continues to determine access to life-saving innovations.

Political will and funding challenges also remain key issues in terms of accessing innovative therapies, even though political will is key to



> **"Political will and funding challenges also remain key issues in terms of accessing innovative therapies, even though political will is key to implementing systemic changes to ensure equitable access to therapies.[23] "**

implementing systemic changes to ensure equitable access to therapies.[23] Underfunded and fragmented health systems, as well as economic instability, are all a result of limited political will to enact change in these areas, which ultimately limits access to innovative therapies. Limited political will also drives up out-of-pocket costs in the absence of adequate public funding, leaving significant cost burdens to fall on patients.[23] The urgency of having the political will to care for multiple myeloma is underlined by Martha Alvarado Ibarra, a specialist physician and Hematology Coordinator who belongs to the National System of Researchers of Mexico, explaining that: “It is urgent that our political system becomes sensitive to a malignant disease that affects our population, on average 56 years old, while in other countries it is over 65 years old, and that they can approve a national access system to complete laboratory studies for diagnosis and also the medications to guarantee the treatment of patients with multiple myeloma. The disparity in hospital resources is critical.”

Innovations in treatment and therapies are not absent, but avenues to access these innovations are somewhat barren. Deniss Diaz Tavares, Doctor in the Rosa Emilia Sánchez Pérez de Tavares National Cancer Institute’s (INCART) Haematology Department and President of the Dominican Society of Hematology, brings light to the gravity of the situation in the Dominican Republic, explaining, “Innovation is already sufficient; the real challenge lies in regulatory approvals and public sector access, ensuring these advancements reach those who need them most.”

Many health policies at times lack long-term perspectives for sustainable resource allocation based on disease burden; proactive planning to improve resource management does not take place.[23] Innovative drugs have received regulatory approval since the early 2000s but their integration into public healthcare systems faces significant delays.[23] One such example is Mexico, where between 2004 and 2018, some patients in the public sector were receiving general chemotherapy instead of innovative treatments.[25] In Colombia, the situation is similar, where patients seeking care in the private sector had improved baseline prognostic features because they had access to advanced therapies earlier than patients in the public sector did.[26] Argentina’s inequity in accessing MM care is economic, according to Dr Irastorza.

There is room to improve the care landscape

As the landscape of MM continues to evolve, progress has undeniably been made in diagnosis and treatment pathways. However, there are still gaps within MM management that need to be addressed. These gaps range from advocacy to interdisciplinary approaches, to expanding coverage and more. Below are some gaps that have been identified:

Ensuring guidelines are integrated across healthcare settings: Integrating CPGs across healthcare settings is essential to enhance care quality and ensure evidence-based practice. According to Dr Irastorza, "Clinical guidelines are often developed by independent societies like the Argentine Society of Haematology. However, they are not binding and lack the enforcement needed to guide consistent policies." Experts are looking for a shift here. As Dr Maiolino explains, "To improve, we need better integration between national health system guidelines and medical society guidelines, fostering communication between agencies."

Leveraging advocacy as a tool to implement guidelines: Active implementation methods such as education, training, and stakeholder engagement are necessary to promote the adoption of CPGs. Developing high-quality guidelines is not enough, there needs to be active efforts to ensure guidelines are applied in clinical practice.[27] Working to engage legislators is on clinicians' radars. Dr Schutz expressed that "Clinical trials provide access to innovation and improve the quality of care, but we need government involvement to expand these opportunities beyond top university centres." Advocacy is a tool that can enact this change and the work of the International Myeloma Foundation (IMF) is one to follow. It engages with policymakers at local, state, and national levels to advocate for laws and policies that will benefit MM patients. One such example is the IMF's work on the Cancer Drug Parity Act in the United States which was passed in 43 American states to increase access to oral oncology drugs.[28] The IMF's legislative advocacy is centred around passing laws that improve access to treatments, ensure fair insurance coverage, and ultimately fund research to understand the disease better.[29]

Expanded laboratory coverage is necessary for early detection: CPGs often discuss diagnosis and staging as expanded laboratory coverage results in improved diagnostic accuracy, reduction in late-stage diagnosis, standardisation of care, equity in healthcare, and support for policy advocacy.[30,31] Most patients within the region confront delayed diagnoses as budgets directly impact the timeliness of diagnosis. In the public system, access to a variety of treatments can be an issue. "While private healthcare in Mexico offers a wider range of treatment options, this disparity is not reflected in the public health system. The government needs to prioritize the real healthcare needs of the population and allocate budgets accordingly," emphasizes Mrs Ortiz. "Furthermore, diagnostic limitations pose a significant barrier. Mexico lacks sufficient diagnostic laboratories with national coverage, leading to a reliance on a single laboratory operating within the public-private sector. This restricted access impacts the affordability and accessibility of diagnostic tests for MM confirmation." The Dominican Republic also has an issue with diagnosis. According to Dr Diaz Tavares, "All bone marrow biopsies are performed in the country because we have pathologists. We do not have access to reliable immunohistochemistry and cytogenetics in the country at the moment so we have to go to the United States for laboratories."

Expand the availability of innovative treatments: There are significant delays in diagnosis in rural areas because access to diagnostic tools and specialised care is limited.[6] These delays are coupled with the slow adoption of new therapies into national guidelines, which ultimately exacerbates the disparities in treatment access between patients treated in public versus private settings.[32] Specifically within the public sector, financial and regulatory constraints limit the availability of treatments and thereby worsen patient outcomes. Without reforms in access, the public-private divide in MM treatments and outcomes will persist.[6] Mrs Ortiz strongly advocates for increased involvement of decision-makers in expanding access to innovative treatments. "Inequities in access to cutting-edge guidelines and therapies should be a major consideration for policymakers," she explains. "We are talking about thousands of patients in Mexico who lack access to these crucial advancements."

Ensuring most updated data is leveraged for CPGs: Data-driven CPGs ultimately allow for a greater understanding of healthcare processes and provide a foundation for evidence-based recommendations.[33,34] With significant data gaps in the region, it is likely that the data within studies coming out of the region is not a true representation of the actual burden of MM.[6] Having updated, relevant data informing CPGs can ensure the incorporation of treatment efficacy and real world effectiveness into CPGs.[35]

Forming national alliances for a unified approach to MM management and developing regional CPGs: An example of a national alliance for a unified approach is Canada's Alliance for Clinical Trials in Oncology. The Alliance works to discover, validate, and disseminate effective strategies to prevent and treat cancer.[36] Members of the alliance include scientists and clinicians from diverse disciplines. Developing regional CPGs for LATAM is also on the radar of experts. "Developing a Latin American guideline could serve as a catalyst for highlighting the disparities in access to innovation and treatment across the region. This initiative would present an opportunity to advocate for improved medical care for myeloma patients throughout Latin America," concludes Mrs Ortiz.

Investing in concerted efforts that leverage a multidisciplinary approach to drafting CPGs can make managing MM more equitable. These CPGs should be homologated and developed with strong, up-to-date data. Once published, there needs to be a drive to ensure these guidelines are frequently updated, encapsulating new research and the evolving landscape of MM. We can thereby develop standardised care for MM that relies on the most up-to-date knowledge of the disease, while also working to ensure that gaps between public and private care are as limited as possible.

Summary of CPGs within focus countries

Country	CPGs / Adopted treatment protocols
Argentina[37]	Argentina does not have its own CPG that is specific to MM. Instead, the country relies on international guidelines such as the NCCN and ESMO guidelines to inform its treatment protocols. What Argentina does have as a CPG is titled, "The 2023 Guidelines for Diagnosis and Treatment of Monoclonal Gammopathies", published by the Argentine Society of Hematology (Sociedad Argentina de Hematologia). The guidelines serve as a comprehensive resource for healthcare professionals managing plasma cell disorders. These guidelines provide structured diagnostic criteria, classification schemes, and evidence-based treatment recommendations for conditions such as MM, Monoclonal Gammopathy of Undetermined Significance (MGUS), Amyloidosis, Waldenström Macroglobulinemia, and POEMS Syndrome. Generally, the document highlights advancements in understanding plasma cell disorders, clinical relevance, and multidisciplinary insights from various doctors. In regard to the specificities of MM, the document provides an overview of the disease, establishes diagnostic criteria, risk stratification, treatment, and maintenance therapy.
Brazil[38]	In Brazil, the management of MM is guided by both national and international CPGs. The Brazilian Medical Association (Associação Médica Brasileira) and the Brazilian Society of Hematology, Hemotherapy, and Cellular Therapy (Associação Brasileira de Hematologia, Hemoterapia e Terapia Celular) have developed comprehensive guidelines for the diagnosis and treatment of MM. These guidelines provide evidence-based recommendations tailored to the Brazilian healthcare context. These guidelines, updated in 2022, focus on providing standardised recommendations based on systematic reviews and expert analysis for various aspects of MM treatment.
Colombia[39]	Colombia relies on both international and national guidelines to manage MM. Healthcare professionals refer to the ESMO and NCCN guidelines to guide diagnosis and treatment protocols for MM, though they are not formally mandated to do so. According to the Colombian Association of Hematology and Oncology (Asociación Colombiana de Hematología y Oncología-ACHO), Colombia's standard to manage MM aligns with ESMO and NCCN in several key areas.
Dominican Republic	The Dominican Republic relies on international CPGs to guide its management of MM. The country does not have national protocols for MM. According to Economist Impact's 2024 expert panel on MM, relevant stakeholders met to improve or add to national protocols but there have not been updates to this endeavour since the meeting.
Mexico[40]	Mexico relies on international and national CPGs alike to guide the management of MM. Mexico's guidelines were drafted in 2009 by a group of haematologists. Their approach was to review various international guidelines, compare them, and complement their own. The central approach in drafting the Mexican guidelines was to review guidelines from the United States and Europe and adapt them to Mexican medical practice.

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