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ONWARD Driving equitable access and system readiness in cancer care

ONWARD: Oncology Needs, Workforce, Access, Research & Disparities

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Introduction

Cancer represents a significant and growing global burden, making it a key political priority and underscoring the need for continued innovation and improved access to care

Cancer remains the second leading cause of death globally, accounting for ~10 million deaths annually[1]. Rising incidence driven by aging populations[2], as well as higher rates among younger people[3], is placing a growing burden on patients, caregivers, healthcare systems and society[4]. This context has contributed to cancer becoming firmly established as a global policy priority, reflected in major international and national initiatives [5–7].

Figure 1. Global cancer burden in numbers

Despite meaningful advancements in cancer care, substantial unmet patient needs persist, driven by the complexity of the disease and the diversity of affected populations

Diagnosis and treatment outcomes have steadily improved in many cancer types, reflecting advances in screening (e.g., breast and lung) and new treatments (e.g., some myelomas)[8,9].

At the same time, cancer is highly heterogeneous and adaptive, requiring personalized, multi-line treatment strategies rather than a one-size-fits-all approach[10,11]. This complexity has contributed to an increasingly crowded oncology landscape, which can create a perception that patient needs are largely met, and new therapies offer limited incremental value. However, this overlooks critical gaps in certain diagnostic and treatment settings where current options offer suboptimal response rates, tolerability, and/or quality of life (QoL). See Figure 2 for examples.

Figure 2. Oncology indications with important outstanding unmet needs [12-27]

Platinum-resistant ovarian cancer (PROC)	Associated with poor prognosis: **<1-year median overall survival** in many cohorts, limited treatment options, and declining QoL due to high symptom burden and side effects of existing treatments[12–14]
Metastatic colorectal cancer (mCRC)	Only **~50% of frontline patients achieve any response** to current therapies, with efficacy declining sharply with each line of therapy[15–18]
Chronic lymphocytic leukemia (CLL)	Continuous, indefinite treatment with current regimens is associated with **cumulative toxicities, and a considerable QoL and health-economic burden**[19]
Late line multiple myeloma (MM)	Novel therapies offer improved efficacy but with **important trade-offs related to safety and treatment burden** • **CAR T:** immune-mediated toxicities[20], administration limited to specialist centers[21], and long wait times for treatment (~10-15% MM patients die between waitlist and CAR T infusion[22–24]) • **Bispecifics:** infection risk[25] and burdensome dosing regimens (step up, treat to progression)[26,27]

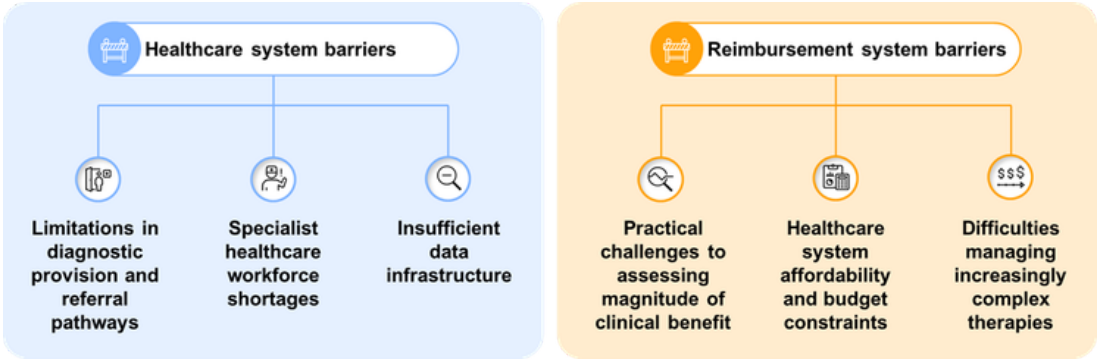
Access to innovation is essential to address persistent unmet needs, yet it remains constrained by systemic healthcare and reimbursement barriers and by an increasingly challenging global environment

Addressing access barriers is critical to ensuring that innovation translates into meaningful patient and societal benefit. This paper explores six key barriers to the timely uptake of innovation, which can make a significant difference for patients globally, from initial diagnosis to novel emerging treatments (see Figure 3). The intention of this paper is to highlight global access challenges and illustrate these with relevant country-level examples.

Importantly, these barriers exist in a rapidly changing global environment, marked by concern over the sustainability of increasing cancer costs[4], competing demands on public budgets[28], and shifting US pharmaceutical policy that risks launch delays and reprioritization in other markets[29]. Evolving implications of the Most Favored Nation (MFN) policy has the potential to apply additional pressure on existing barriers, especially in systems with relatively lower drug prices (e.g. Japan, South Korea, Australia[30]) and including those with historically strong access to innovation (e.g., Japan[31]).

The effects are cumulative: in Japan for instance, 70% of new medicines in late-stage clinical development in the United States (US) and European Union (EU) have not begun development there[32], reflecting the unpredictable drug pricing environment and potential shortcomings in the policy ecosystem in terms of incentivizing innovation. This context presents a critical opportunity for countries to strengthen their health systems and adapt policies to support better cancer care in the future.

Figure 3. System-level healthcare and reimbursement barriers limiting access to oncology innovation



Healthcare system-related barriers

1. Limitations in diagnostic provision and referral pathways

Diagnosis and referral to an appropriate specialist are critical pre-requisites for ensuring timely patient access to innovative oncology treatments. Recent advances in colorectal cancer (CRC) screenings, for example, are associated with earlier intervention and a reduction in morbidity and mortality globally[33].

While cancer screening has improved significantly in high-income settings, long wait times for specialists and referral bottlenecks remain commonplace[34]. Two-thirds of OECD countries report waiting times for cancer care (including diagnosis) as an issue, and over half have developed waiting time strategies, sometimes as part of national cancer control plans[34]. In China, despite significant progress with respect to cancer screening programs and guidelines, challenges remain[35] and diagnostic delays persist[36–38]. Study findings evaluating Europe's Beating Cancer Plan found that, despite progress in advancing cancer control at EU and national levels, gaps remain in implementation, screening, monitoring, and equitable access to molecular diagnostics and personalized cancer medicine[39].

Sub-national disparities in access to screening and diagnosis are a significant challenge. Twice as many people participate in CRC screening in northern Italian regions versus southern regions, attributed to better access and public awareness in the north[40,41]. In Australia and Canada, specialist services (e.g., imaging) are concentrated in urban areas resulting in rural access gaps that are frequently exacerbated by other socio-economic inequalities[42,43].

Beyond screening, access to biomarker testing required for precision oncology medicines is inadequate in most countries due to lack of reimbursement and limited capacity for testing and processing[44,45]. This is a challenge in many high unmet need indications, which require biomarker testing to guide personalized treatment approaches (e.g., supporting testing for FRα-targeted therapy in ovarian cancer and comprehensive molecular profiling to identify CRC patients eligible for targeted therapies or immunotherapies)[46,47].

2. Specialist healthcare workforce shortages

Cancer care is highly specialized and depends on a skilled workforce, such that shortages in appropriately trained staff can be a limiting factor for patient access. Meanwhile, oncology workforce shortages are a nearly universal healthcare system challenge due to rising cancer burden, a limited training pipeline, and reliance on a large number of different specialists for effective treatment[48,49].

For instance, China's rising cancer burden places increased demands on an already resource-constrained healthcare system, where limited availability of trained oncology clinical professionals can hinder capacity and access to care[50,51].

In Canada and Australia, regional variability in oncology workforce and specialist capacity are a focus area for policy[52,53]. In both countries this challenge is characterized by recruitment and retention issues, a demanding work environment contributing to provider burnout, and education and training systems that fail to keep pace with workforce needs[52–54]. Finally, lower availability of specialist oncology workforce in remote and rural areas has significant consequences, as seen in Australia, where it can contribute to poorer survival outcomes[55].

3. Insufficient data infrastructure

Data infrastructure is a core health system capability that enables effective patient identification, timely diagnosis, and longitudinal outcomes tracking to support reimbursement and access. It is crucial in cancer care due to the need for highly coordinated care delivery, and particularly for advanced therapies (e.g., CAR T) where long-term evidence generation may be needed to support clinical and reimbursement decision making[56,57].

However, establishing and maintaining effective national data infrastructure requires significant investment and interoperability across sub-national jurisdictions. In decentralized systems this can be very challenging, since local control over data systems often results in data silos, fragmentation and limited interoperability (e.g., between Canadian provinces, Italian regions, and Australian states)[58–60].

Collection of real-world data (RWD) with the support of registries can provide important insights into treatment effectiveness, safety and patient outcomes in routine clinical practice. This is particularly valuable in oncology where populations are often more heterogenous than those included in controlled trials[61]. However, RWD is not routinely collected, and the resulting data can vary substantially in quality, completeness, and interoperability, particularly compared to data collected in controlled trial environments. This can hinder its perceived validity and credibility for use to support risk-sharing access solutions (e.g., managed-entry agreements)[62].

Reimbursement-related barriers

4. Practical challenges to assessing magnitude of clinical benefit

Value offered by novel therapies, particularly the magnitude of clinical benefit, is important for both ensuring payer value-for-money and rewarding innovation. In oncology, however, distinct evidence challenges and high unmet need make assessments using conventional evidence standards and value frameworks difficult.

Acceptance of alternative (i.e., non-overall survival) endpoints and trial designs varies across countries, but these are often associated with lower value rating compared with ‘typical’ evidence packages[63,64]. Although they can complicate interpretation of comparative outcomes, oncology often necessitates single-arm trials, cross-over designs, and surrogate endpoints (e.g. minimal residual disease in MM[65]) to meet ethical imperatives and accelerate evidence generation in fast-progressing, high-unmet-need indications[66–68]. Differing standards of care across countries further complicates development of evidence packages that reflect all relevant context (e.g., a recent cohort study in CLL found substantial differences between the US and China in terms of therapy patterns and specifically the frequency of BTK inhibitors and agents used in first line[69]).

Furthermore, patient perspectives on what constitutes a meaningful survival or QoL benefit are crucial in oncology, particularly where prognosis is very poor[70]. One example of this is PROC where symptoms control and maintaining QOL are key therapy goals[71]. Another is enabling treatment-free periods in CLL (versus intensive, indefinite program of infusions), helping patients to reengage in social and economic activities and have a more positive outlook on life[72,73]. Despite this, consideration of patient-reported outcomes and preferences in health technology assessment remains inconsistent and sub-optimal in many systems, often due to validity concerns and issues integrating these data alongside clinical and economic evidence.

5. Healthcare system affordability and budget constraints

While healthcare system budget constraints are inevitable and fiscal responsibility is critical, challenges arise when pricing and reimbursement policies prioritize short-term cost containment over value recognition and access to innovative oncology treatments. This tension is evident across markets (including China[74], Australia[75], Canada[76], and in Europe[77–79]). It is often associated with lengthy delays between regulatory approval and reimbursement, as well as differences in access between countries (e.g., between 2021 and 2024, the median time to availability of oncology products was 420 days in Italy, 761 days in France[80]).

Disproportionate focus on cost-containment may also lead payers to benchmark novel therapies against low-cost supportive care or generics. This approach is unlikely to adequately reflect the significant investment in research and development and additional therapeutic value of new treatments, potentially weakening incentives for continued innovation in oncology[81].

Furthermore, annual healthcare budgets and standard economic evaluation frameworks may not reflect downstream savings realized beyond the first year (e.g., reductions in time on treatment after one year, treatments with one-time administration)[82]. Accordingly, reimbursement decision-making should consider the broader long-term clinical and economic value of treatment (including delayed disease progression, QoL improvement, reduction in mortality and downstream complications) as well as potential healthcare cost savings over time.

6. $$$ Difficulties managing increasingly complex therapies

Oncology is the focus of many innovative treatments which offer significant value, but also inherent additional complexities with value recognition and reimbursement. CAR T, for instance, is an advanced therapy involving single or short-course administration that can deliver long-term and potentially curative benefit, but is also associated with complex manufacturing, high upfront cost and inherent uncertainty about long-term durability[83,84]. Certain contracting agreements can help manage clinical uncertainty and mitigate budget impact (e.g., outcomes-based agreements, coverage with evidence development). However, these are complex and resource-intensive, relying on robust data collection and financing infrastructures and hence may not be scalable or applicable in all contexts[85].

Combination regimens are a cornerstone in oncology treatment for their ability to target multiple pathways, improve response rates and delay resistance[50]. Yet, they present unique access challenges across global markets[86,87]. In Europe, for instance, combinations have lower rate of availability compared to other oncology products (12% lower in Spain and 18% in Italy) and longer time to availability (average +147 days in Spain, +178 days in Italy)[88]. An issue facing combination therapies is that standard value assessment approaches are not designed to isolate the incremental contribution of each component where clinical outcomes reflect their combined effect[89]. Another issue is demonstrating cost-effectiveness (CE) because even if the additional component is priced at zero, the first may already be reimbursed at the willingness to pay threshold[90,91] (important for CE-focused markets, such as Canada[92]). Finally, contracting agreements are often complicated when components are owned by different manufacturers[86], particularly where this goes against local trade rules and there is a lack of institutional frameworks to support cross-company coordination for this purpose (e.g., in South Korea[93]).

Exploring how to address key barriers: Illustrative approaches

Efforts have been made to address these barriers, offering inspiration for potential ways forward. Figure 4 outlines some examples of directional solutions to these issues across different markets.

Figure 4. System-level healthcare and reimbursement oncology access barriers and potential solutions [53,94 - 103]

Call to action: Coordinated stakeholder action grounded in recognition of unmet need in oncology

Timely access to novel oncology treatments relies on system readiness as much as scientific progress. Access barriers in oncology today are interconnected, systemic, and shaped by a complex global environment where policy pressures risk exacerbating these barriers and amplify the urgency for solutions.

This is not a call to reinvent healthcare and reimbursement systems, but rather to foster coordinated discussion and alignment across stakeholders on how to optimize current systems and frameworks to improve access to novel oncology therapies. Most importantly, it requires shared recognition of the persistent unmet needs in oncology and the urgency of advancing innovation and access for the benefit of patients, families, and society. There is a real opportunity to close access gaps and ensure that continued progress translates into meaningful benefits for patients, families, and society.

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