# Policy and governance solutions for ensuring equitable access to cancer medicines in low- and middle-income countries

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*Comment on:* Cherny NI, Sullivan R, Torode J, *et al.* ESMO International Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in countries outside of Europe. Ann Oncol 2017;28:2633-47.

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The special article published in the *Annals of Oncology* by Cherny and colleagues (1) coordinated by the European Society for Medical Oncology (EMSO) International Consortium conducts a comprehensive review and survey-based assessment on accessibility and affordability of cancer drugs globally (1). The study is particularly important given that the International Agency for Research on Cancer (IARC) expects the number of cancer cases to increase from 14 to 24 million cases between 2012 and 2030, with low- and middle-income countries (LMICs) disproportionately burdened (2). These predictions underscore the urgent need for international action to ensure affordable access to cancer medications in LMICs. This challenge is highlighted in Cherny *et al.*'s study which found LMICs have substantial problems accessing antineoplastic medicines and that generic anticancer drugs can be unaffordable (1).

Cherny and colleagues showed that, in low-income countries, over half of Essential Medicines List (EML) medications [a list of 'essential' medications selected and published by the World Health Organization (WHO) that are deemed to satisfy priority healthcare needs of populations and should be available in functioning health systems] were often only available at full cost, and about one-tenth were not available at all (1). This corresponds to similar analyses published in the *Bulletin of the World Health Organization* in 2016, which found a statistically significant association between per capita gross national income (GNI) and formulary coverage of essential cancer medications (3). It also tracks with research conducted by our own group examining cancer drug accessibility and pricing, where we found that the median "concordance" (i.e., the proportion of essential cancer medications listed on national formularies) was less than half for LMICs (4).

Cherny and colleagues also found an especially high discrepancy in out-of-pocket costs for essential cancer medications purchased in LMICs. Similarly, our team assessed the costs paid by 16 LMIC health systems to purchase cancer medications on the EML, and we also found a noticeable disparity in prices paid for these medications (5). While health systems purchased the median package of allopurinol (the least expensive cancer medication) for only $1.56, health systems were charged $1,800 for the median price of a package of trastuzumab (the most expensive cancer medication) (5). According to the World Bank, the GNI per capita for low income countries is $1,005 or less. This means that the price for a single package of trastuzumab exceeds an entire year's economic output for the median person living in a low-income country.

Hence, previous studies, our own published work, and the new report by Cherny *et al.*, form a collective body of evidence indicating that the way we govern access to cancer treatments is not working for the vast majority of the global population. Impacting access and affordability

to potentially life-saving and essential cancer medications are multiple factors including: formulary inclusion, health system budgeting and financing, healthcare insurance coverage and risk protection, patent and exclusivity status of drugs, supply chain and procurement issues, and trade and export challenges (6,7). This in turn can directly impact the quality of care and clinical outcomes for cancer patients, with negative effects (including increased morbidity and mortality) disproportionately borne by the poor, regardless of the income category of the country they live in (1). This includes high-income countries like the United States of America, where cancer drug pricing is a contentious public health and political issue (8).

## Global cancer governance solutions: a greater role for the IARC

Given the growing veracity of evidence pointing to a failure in cancer treatment access and affordability, what can be done from an international public policy perspective? Here, Cherny *et al.* highlight work being done by the United Nations and WHO on non-communicable diseases and cancer, the need to exercise flexibilities under the World Trade Organization trade-related aspects of intellectual property rights (TRIPS) agreement (including use of compulsory licenses by LMICs), global efforts to advocate for universal health coverage (UHC), and ESMO's own efforts to guide cancer drug inclusion on the WHO EML and conduct further research (9).

While these multi-stakeholder efforts are important, equally critical is exploring better ways to generate data that can characterize the specific challenges faced with access to cancer drugs that are driven by social determinants, geography, health policy, and commercial factors. For example, prior studies have relied on secondary data analysis and macro national-level economic indicators (3,4). Others, such as our study in *BMC Cancer*, utilized pricing data from a database managed by Management Sciences for Health, but has certain sampling limitations (5). The study by Cherny *et al.*, is a snap shot bounded by survey responses by practicing expert respondents in the field, but does not actually utilize published drug pricing data (1). Hence, a critical first step to better addressing this problem is advocating for policy mechanisms that increase the transparency and visibility of cancer drug pricing at the local, national, and regional level, while also identifying other indicators that impact procurement and accessibility.

Given this need, we first propose the expansion of the IARC's research mandate to encompass issues that more directly generate data and address the need for evidence-based policy making to improve treatment access for cancer patients. The IARC (an intergovernmental organization part of the WHO) has a history of compelling advances in cancer research (10). Additional research is urgently needed to better characterize cancer mediation pricing and to identify and propose solutions to overcome specific barriers to access. Furthermore, analyses are needed that use predictive modeling and other econometric techniques to aid the politico-economic community in understanding the relationship between money spent on cancer treatment programs and consequent impacts on the global burden of cancer. The IARC should be fully empowered to fulfill the aims of an expanded research portfolio that includes these much-needed analyses.

Second, armed with more robust pricing data, the IARC should spearhead evidence-based policy mechanisms that it can operationalize to reduce the cost and improve access to cancer drugs. This can include governance mechanisms like pooled procurement of cancer medications led by IARC. Pooled procurement has been used by other UN organs such as the UN Children's Fund (UNICEF), a UN specialized agency within the UN Development Group (UNDG), to acquire vaccinations for LMICs; the global health initiative UNITAID (that uses airline ticket levies to finance programs addressing HIV/AIDS, tuberculosis, and malaria) for developing countries; and the Global Fund to Fight AIDS, Tuberculosis and Malaria via a pooled procurement mechanism. This type of arrangement would allow the IARC to purchase EML cancer drugs from manufacturers on behalf of LMIC groups, thereby leveraging economies of scale in order to acquire a bulk order of medication at a lower price per unit. In fact, pooled procurement has been shown to lead to lower pricing and increased access when compared to other policy mechanisms, such as issuing compulsory licenses (11).

Third, under this expanded procurement role, the IARC would require additional financing. Hence, we propose that the IARC should be moved higher up the UN governance hierarchy, and also transforming its legal status into a UN specialized agency within the UNDG. If the IARC became part of this group as a specialized agency, it could benefit from being able to engage in greater financing, including fundraising activities. This expanded governance function might include negotiation with national governments, partnerships with philanthropic groups, and sponsorships

 

with private organizations. Initial designation as a UN specialized agency (versus as a department of the WHO) has proven beneficial for the Joint UN Programme on HIV/AIDS (UNAIDS), which conducts a large scope of fundraising operations for its wide-ranging strategies to combat HIV/AIDS (12). These operations include bilateral commitments, private philanthropy, and partnership with non-governmental organizations.

## Conclusions

If a woman in a rural region of a low-income country were to be diagnosed with breast cancer, current policies appear to do little to ensure this woman will receive appropriate care, meaning a cancer diagnosis is often a death sentence with little hope for adequate treatment. Though addressing the fundamental challenges in access to medicines seems complex, progress in ensuring affordable and available treatment for antiretroviral therapy during the HIV/AIDS epidemic is often touted as a successful political and advocacy case study in global health. For HIV/AIDS, UNAIDS was established in part to fill the gap in securing global financing, mobilizing advocacy, and improving access to treatment and has led to significant progress against HIV/AIDS in LMICs. Similarly, the policy proposals outlined here are meant to empower IARC to fill the gap in global treatment for cancer. Broadened versions of the policy proposals here may be warranted in order to adequately address insufficiencies in LMIC chemotherapy access. For example, the IARC could also be empowered to intervene in the supply chain management of chemotherapy, perhaps extending to the logistics of warehousing and distribution.

In summary, we believe that the IARC is well positioned to serve an enhanced role in global governance to better enable access to minimum standards of cancer treatment. In order to accomplish this mission effectively, the IARC should be expanded in three key ways: (I) broadening of its research portfolio to include analysis of medication pricing and access; (II) enabling the IARC to engage in pooled procurement for LMICs; and (III) expanding the IARC's mission, operational design, and financing by transforming it into a UN-specialized agency under UNDG membership. Though admittedly challenging, broad collaboration at a global level is a powerful tool that can resolve issues in cancer drug access desperately needed in order to ensure cancer does not further devastate populations in economically marginalized countries.

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## Footnote

*Conflicts of Interest:* The authors have no conflicts of interest to declare.

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