The Role of Humanitarian Donations in Decreasing Preventable Mortality From Cancer in Low-Income Countries: Models to Improve Access to Life-Saving Medicines

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Although there are many challenges to providing high-quality cancer care in low-resource settings, such as trained personnel at all levels, health care infrastructure, and reliable supply chains for essential supplies, the lack of affordable access to high-cost potentially life-saving medications remains a significant one, leading to countless preventable deaths worldwide. Although we are grateful for interventions such as one supported by Pfizer, the American Cancer Society, and the Clinton Health Access Initiative designed to improve affordability of some generic cancer drugs, given the potential availability of more costly but highly effective therapies, we see the value in a range of solutions.[1] Some, though, have strongly voiced a repudiation of humanitarian donations in the context of global access to cancer treatment, claiming that it poses a dangerous precedent that may prevent us from saving the lives of hundreds of thousands of patients with cancer.[2] Although long-term sustainable access to high-quality cancer care will only be achieved with a complex, comprehensive, multipronged approach that includes innovative social business models and affordable drugs and other services, the reality is that there are patients today being successfully treated for whom the only path to access is through humanitarian donations of medicines. Unless we define parameters for the role of humanitarian donations and accept them as an important and timely solution, albeit a partial one, thousands of lives will be needlessly lost.

New innovative therapies are not developed for use in low-income countries (LICs), nor are they priced accordingly. Although patients in high-income countries benefit, unless we take drastic measures, many millions of people will suffer premature, preventable death from cancer because of the unavailability and unaffordability of these treatments.

Cancer care infrastructure is weak in many LICs, sometimes lacking the capability to perform critical molecular studies that link targeted therapies with appropriate patients and to safely and effectively administer and monitor these therapies. But there are an ever-increasing number of cancer programs in LICs, often supported by partnerships with cancer centers in the developed world, that can perform the necessary molecular testing and safely and effectively treat and follow these patients.[3]

The feasibility of a humanitarian program linked with molecular targeting is demonstrated by the Glivec International Patient Assistance Program (GIPAP), which was the largest and most successful international drug donation program in the history of global oncology.[4] Starting in 2001, the program provided continued access to imatinib to patients with chronic myeloid leukemia (CML) and GI stromal tumor in 80 low- and middle-income countries. More than 75,000 patients benefited from this program managed by The Max Foundation, receiving donated imatinib from Novartis on a continuous basis for as long as their physicians prescribed it. Published patient outcomes have supported the success of this program, which is now being carried forward under the partnership of CMLPath to Care, a joint initiative of Novartis and The Max Foundation.[5] In 2015, the World Health Organization added imatinib and other targeted therapies to their Essential Medicines List for cancer, supporting the potential impact of these drugs.[6]

Lessons learned from GIPAP should be considered in today's discussions on humanitarian efforts that can prevent avoidable cancer deaths in LICs.

1. It is possible to provide sustainable humanitarian access to a novel drug in a large number of countries and to a large number of patients on a continuous basis. The donation program has provided access to imatinib for patients beyond the patent expiration 15 years later, thanks to the evolved structure of CMLPath to Care. The longest treatment provided for an individual patient is 16 years, and > 5,000 patients have received access to imatinib for ≥ 10 years. If this program had not been put in place and successfully run for 16 years, many would likely conclude that the long-term nature and cost of the treatment would make such a program infeasible.
2. Giving a drug free of charge to a patient does not mean that treatment is completely free or that it does not require investment by local stakeholders. Access to treatment, even when the drug is donated, requires substantial investment from both patients and health care providers. Ministries of Health, through their public institutions and their health care providers, invest a great deal of resources and effort managing the treatment of their patients. Patients and their families bear the costs related to transportation, loss of wages, housing, monitoring and diagnostic tests, hospital visits, and more.
3. It is often argued that giving free drugs will be ineffective, and even dangerous, if put in the hands of health care providers who lack knowledge, skills, and the needed infrastructure to provide safe and effective care. An essential component of GIPAP and now CMLPath to Care is an assessment of the cancer care delivery infrastructure that must be deemed adequate before a drug is provided.
4. Providing free-of-charge product rather than providing tiered pricing can make business sense for manufacturers, especially when focusing on sophisticated, innovative, and new oncology drugs. On the basis of the economic status of a country and their population, to make a drug affordable, reduction in price for many cancer products would be so high (in many cases > 90%), that it makes more business sense to provide it for free.[7] Furthermore, GIPAP demonstrated that it is possible for a manufacturer to transition to local commercial business after providing humanitarian access for the population of a country. In the case of GIPAP, from the original 80 countries receiving free-of-charge drugs, 40% of the countries currently have commercial programs for imatinib.
5. Humanitarian access programs are as important to physicians as they are for patients. Working in greatly challenging environments, being able to treat their patients with these treatments shows that commitment from international bodies translates into more successful and rewarding outcomes and encourages physicians to remain abreast of the latest treatment options.
6. Stigma is a known pervasive factor in leading to premature cancer deaths, but no anti-stigma campaign can succeed in the absence of survivors of cancer. The Max Foundation's model, Max Access Solutions, has resulted in thousands of survivors of cancer in LICs, and survivors are more likely to speak out about their disease, leading to increased awareness and the potential to decrease stigma.
7. Last but not least is the humanitarian side; in this era of globalization, we are leaving our friends behind and they know it. There is only one thing worse than hearing your loved one is diagnosed with cancer: it is to be told that there is a treatment that could help, but because of the place where you live, your loved one cannot access it and will therefore die a premature and avoidable death.

Humanitarian donations of costly life-saving medications are clearly not the answer to all problems arising from the current cancer epidemic, but they can contribute greatly to reducing inequities of care. Widely denouncing the need for donations only gives cover to those who have a responsibility to make their drugs available to these patients in need yet are reluctant to do it. The goal of The Max Foundation's Max

Access Solutions is to create a robust patient program, a network of partner leading cancer treating institutions, and a validated end-to-end supply chain into cancer treatment centers to enable safe humanitarian access, for as long as this is the only way to provide access to those patients who need it but cannot afford it.

Access to life-saving treatment is a human right. Those of us dedicated to preventing premature cancer deaths must ensure that all patients who can be helped are helped.

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