
Lawrence N. Shulman1, Claire M. Wagner2,3, Ronald Barr4, Gilberto Lopes5,6, Giuseppe Longo7, Jane Robertson8, Gilles Forte8, Julie Torode2, and Nicola Magrini8

1 Abramson Cancer Center, University of Pennsylvania, Philadelphia, PA, USA
2 Union for International Cancer Control, Geneva, Switzerland
3 Harvard Medical School, Boston, MA
4 McMaster University, Hamilton, Ontario, Canada
5 Centro Paulista de Oncologia e Hcor Onco, São Paulo, Brazil
6 Johns Hopkins University, Baltimore, MD
7 Azienda Ospedaliero-Universitaria Policlinico di Modena, Modena, Italy
8 World Health Organization, Geneva, Switzerland

Funding Support from the National Cancer Institute Center for Global Health and the LIVESTRONG Foundation

BACKGROUND: In 2013, there were more than 8 million deaths attributed to cancer, and nearly 15 million new cancer cases worldwide. The majority of this burden falls on countries that are often already triply burdened by infectious diseases, under-resourced systems, and inadequate numbers of health professionals. Access to medicines is a critical component of addressing gaps in cancer care outcomes, and has been prioritized by the United Nations in the post-2015 development agenda. Since 1977, the World Health Organization (WHO) has published a Model List of Essential Medicines bi-annually as a tool for policy-makers and procurement agencies.

APPROACH: In January 2014, the WHO invited the Union for International Cancer Control (UICC) to convene a task team to review the cancer therapies on the WHO’s Model List. UICC, and leadership from Dana-Farber Cancer Institute led a process that identified 27 diseases for review. This process was driven by the guiding principle of the magnitude of benefit of systemic therapies – for which the focus was on first-line options – and prevalence of disease, as in the case of lung cancer, for example. Documents were disease-based and included an Executive Summary, Public Health Relevance, requirements for diagnosis, treatment and monitoring, overview of regimens, review of benefits and harms, and recommendations for medicines to be added to the EML. Approximately 100 oncology experts from around the world participated. Disease-based documents were produced by at least 3 experts each, resulting in recommended treatment regimens which defined the medicines proposed for addition to the EML. Further, the UICC task team recommended the establishment of a regular evaluation of cancers to be included for review, and anti-neoplastic agents indicated for treatment.

RESULTS: The new approach led to 16 new cancer medicines being approved by the WHO Executive Secretariat and added to the List, from a total of 22 proposed, including all of those recommended for children, and a method for periodic review and evaluation.

IMPLICATIONS: Establishment of a disease-based approach to defining where cancer medicines can have the largest impact has been critical, as has the establishment of a scheduled re-evaluation of the list based on new data. The UICC and partners are beginning efforts to utilize the new list of cancer medicines with policy-makers in low- income settings with the goal of narrowing the gap to essential therapies for cancer patients in low and middle income countries.

HIGHLIGHTS

- On the first WHO EML in 1977, there were 7 antineoplastic medicines included. The next major reviews of the cancer medicines on the EML last occurred in 1984, 1994, and 1999.
- 16 medicines were approved by the WHO Executive Secretariat for addition to the Adult EML in 2015, and 10 medicines were approved for the Children’s EML.
- 6 medicines were not approved: arsenic trioxide, dasatinib, DES, erlotinib, gefitinib, and nilotinib.
- This was the first time a disease-based approach was integrated into the cancer medicines on the Adult EML.
- Prior to the UICC Review, only 18 cancers could be adequately treated with the medicines listed on the Adult EML, and only 3 on the Children’s EML.
- Since the 2015 WHO EML changes, an additional 11 adult cancers and 7 pediatric cancers can be treated, bringing the total addressable cancers to 29 and 10, respectively.

NEXT STEPS

- The UICC and its partners are working to engage with constituents from around the world to expand access to the medicines listed on the EML.
- A meeting on June 5, 2016 at ASCO in Chicago will aim to explore the broad implications of these EML additions.
- Please email advocacy@uicc.org for more information.