



## **Leslie E. Lehmann, MD**

The Case for Support: Addressing the Needs of Cancer Patients Worldwide in the WHO Model Essential Medicines List

Union for International Cancer Control

[www.uicc.org](http://www.uicc.org)

# Cancer Community Proposals

- Proposal Trastuzumab
- Proposal Imatinib
- A section review
  - identify gaps (blood products)
  - identify changes which provide Member States with clarity (palliative care move)
  - create a mechanism which can provide regular recommendations to WHO select committee
    - drawing across UICCs expert membership: tumour types, professions, geographies and income settings
    - responding to need for tiered-approach
    - link to WHO guideline and policy brief activities
    - stimulate true international, tiered treatment guidelines and peer-reviewed publications



# Why? - Member States require WHO guidance to address cancer patient needs effectively



**8 million** people died from cancer in 2010 accounting for 15% of all deaths worldwide and 7.6% of DALYs (Global Burden of Disease 2010)

The estimated incidence of 12.7 million new cancer cases in 2008 will rise to **21.4 million by 2030**, with nearly **2/3 of all cancer diagnoses occurring in LMICs** (Globocan)

**The worlds poorest are hardest hit by the double disease** burden which still hasn't reached the full epidemiological and demographic transition. There is a need to integrate care for both communicable and noncommunicable diseases **using the tools that have been tried and tested in richer countries**

*"Beds that only ten years ago were filled with HIV-positive patients are now filled with women suffering from breast and cervical cancer, men suffering from liver and stomach cancer, and children diagnosed with Burkitt's lymphoma, acute lymphoblastic leukemia and CML. We are now tackling this growing burden of NCDs", Ministry of Health, Rwanda*

The burden of cancer is disproportionately faced by poor and vulnerable populations who have limited cancer care and cannot access even the cheapest cancer regimens. **Cancer now kills more people in developing countries each year than AIDS, tuberculosis and malaria combined.**

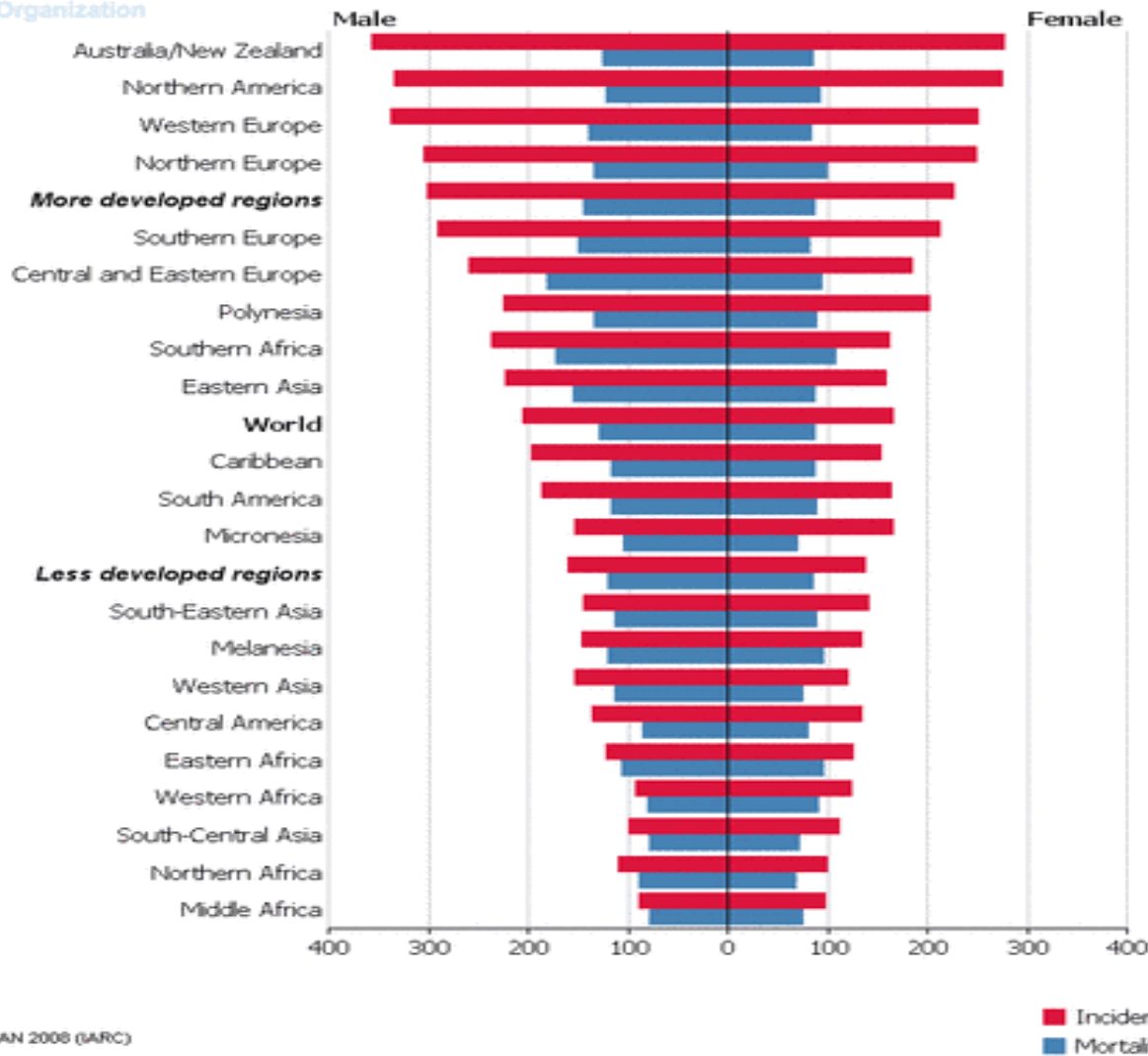
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# Disparities in both cancer incidence and mortality to be addressed by the political momentum for global action on NCDs

International Agency for Research on Cancer



✓ 25% reduction  
in NCD deaths by  
2025 May 2012

✓ Global  
Monitoring  
Framework (9  
targets/25  
indicators) Dec 2012

✓ Global Action  
Plan and Global  
Coordinating  
Mechanism May 2013

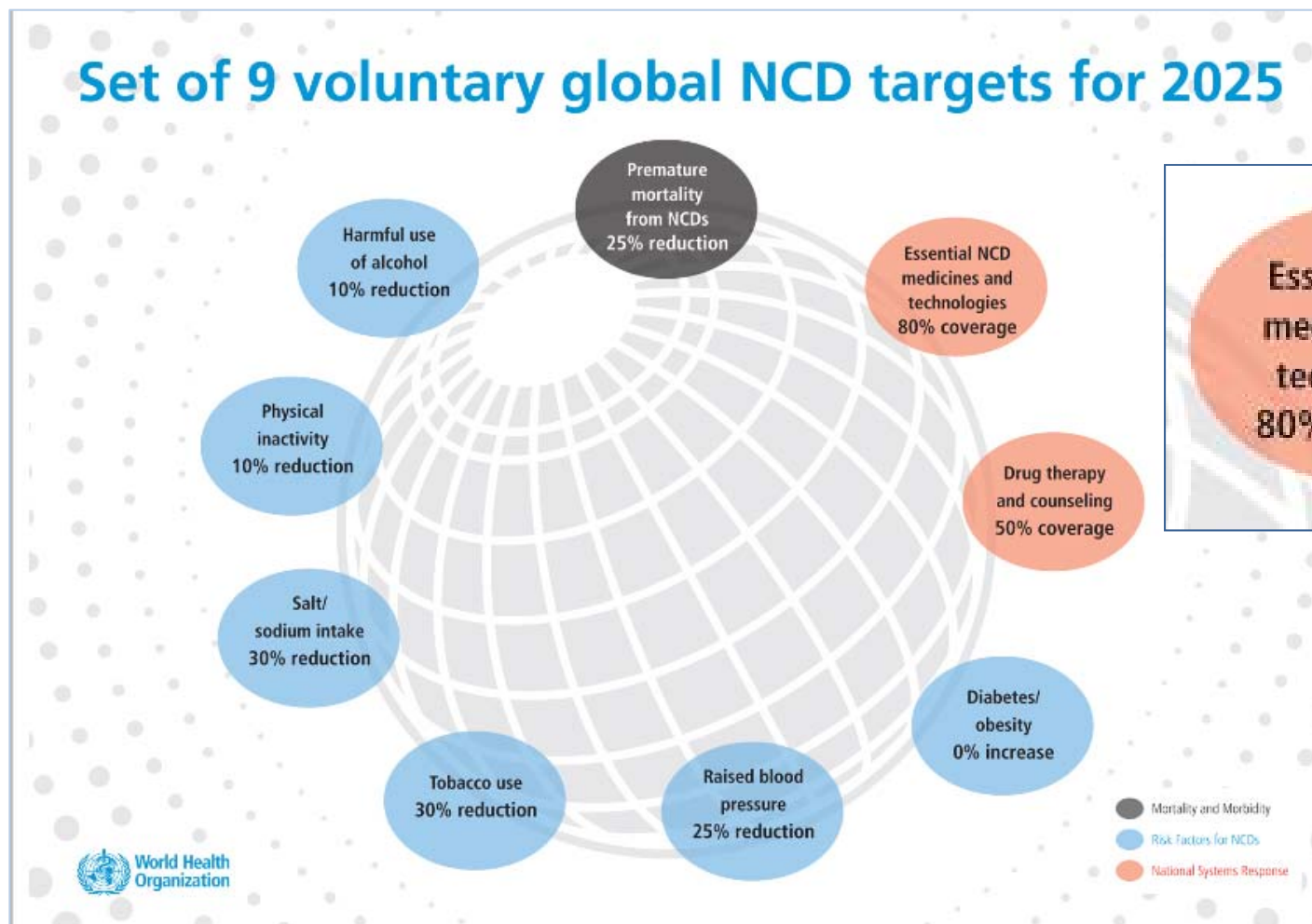
✓ National NCD  
plans Dec 2013

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# Approved global target on access



## Set of 9 voluntary global NCD targets for 2025



**Essential NCD medicines and technologies 80% coverage**

# Can WHO model EML be a tool to drive pricing strategies?



- Trastuzumab – first monoclonal antibody
- Imatinib – first Philadelphia-Chromosome target
  - Both have proven efficacy, safety and target population
  - Both still under patent, both expensive
  - Both require test and health system pre-requisites
  - Neither have cheaper alternatives with similar efficacy

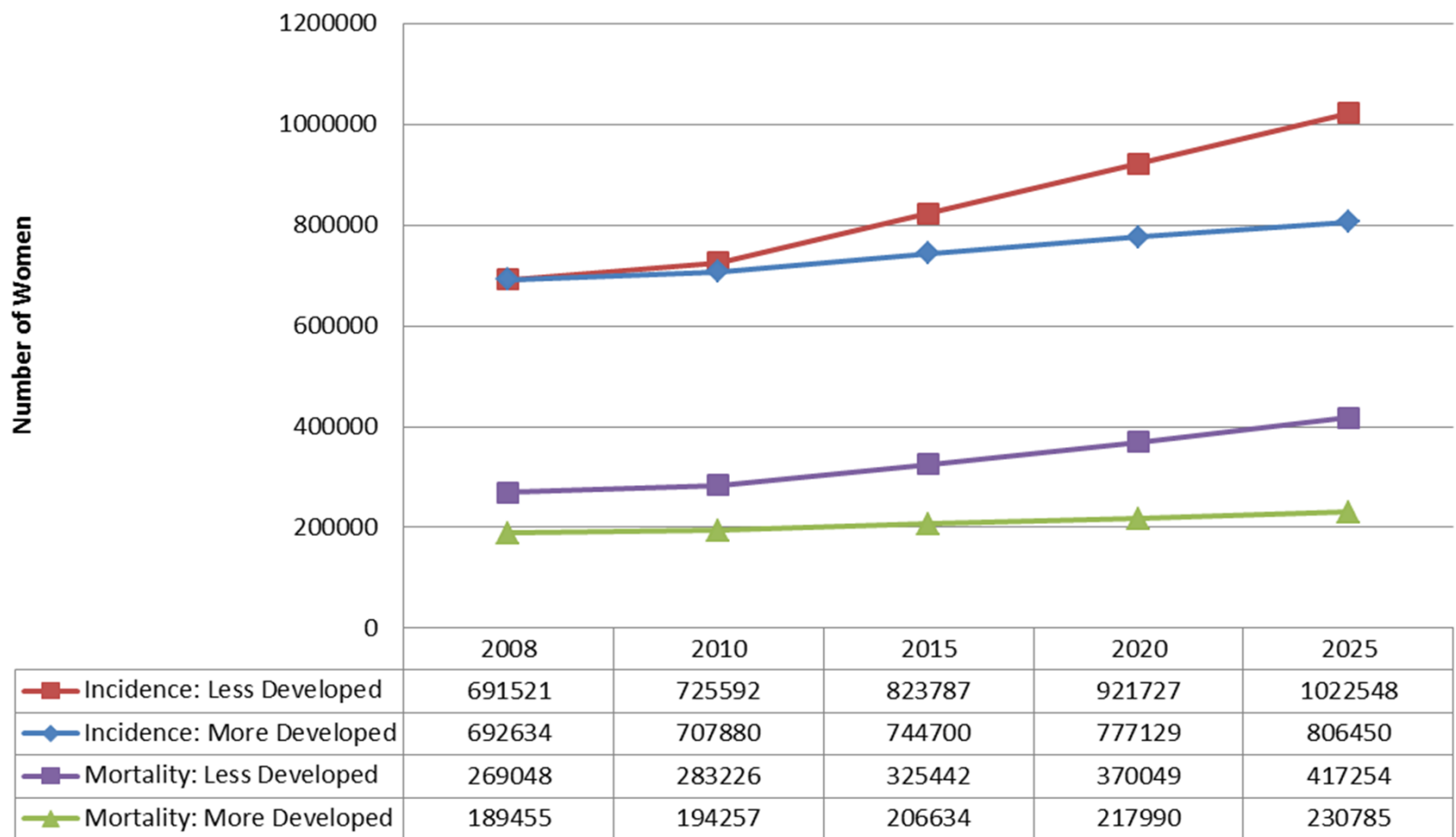
## What we would like to see happen?

- Originator-led, truly global tiered-pricing strategies
- Stimulation of the generics market
- Stimulation of innovative procurement strategies eg PAHO strategic fund (both drugs up for inclusion in next round)

*More must be done. We can achieve equitable access to proven, successful treatments ...we can save the lives of breast cancer patients , regardless of where they live. Confronting cancer is fundamental to the movement of global health equity.*

**Paul E. Farmer, Partners in Health**

## BREAST CANCER INCIDENCE AND MORTALITY More vs. Less Developed World Regions



## Testimony from a breast cancer patient in Malaysia, who is benefiting from Trastuzumab (Herceptin)



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# Trastuzumab for Her2neu positive BC

## Review consensus: inclusion + caveats



### 1. Testing capacities for Her2neu

“Rwanda is in the process of strengthening laboratory capacities in-country, anticipating in-country HER2 testing in the near future.” , MoH Rwanda

### 2. The need for a comprehensive approach

- importance of a health system that has the diagnostic, treatment and monitoring modalities required to manage use of Trastuzumab
- capable of multimodal cancer services including surgery, radiotherapy and chemotherapy as well as palliative care
- Settings that have all elements of comprehensive BC strategy

### 3. BHGI tiered approach based on resources & capacities

*(basic/limited/enhanced/maximal)*

“if it were not for the high market cost, Trastuzumab would be recommended at the basic or limited levels due to its high efficacy and favorable safety profile.”, Breast Health Global Initiative

## Supporting voices for Trastuzumab



*“The evidence is clear that future lack of availability of trastuzumab to women with HER-2 positive invasive cancers will lead to substantial loss of life, deaths that will be premature and otherwise would have been preventable”* BHGI Global

*“The addition of trastuzumab to the EML would greatly improve the lives of innumerable HER2-positive breast cancer patients, especially those in LMICs, by lowering the cost of and increasing access to this indispensable therapy”* Partners in Health

*“We fight for medical criteria to be respected regarding dosage and the length of usage. We believe this issue to be itself beyond health. It is an issue of human and citizen’s rights and we need a stronger voice united to end the inequity”* FEMAMA Brazil

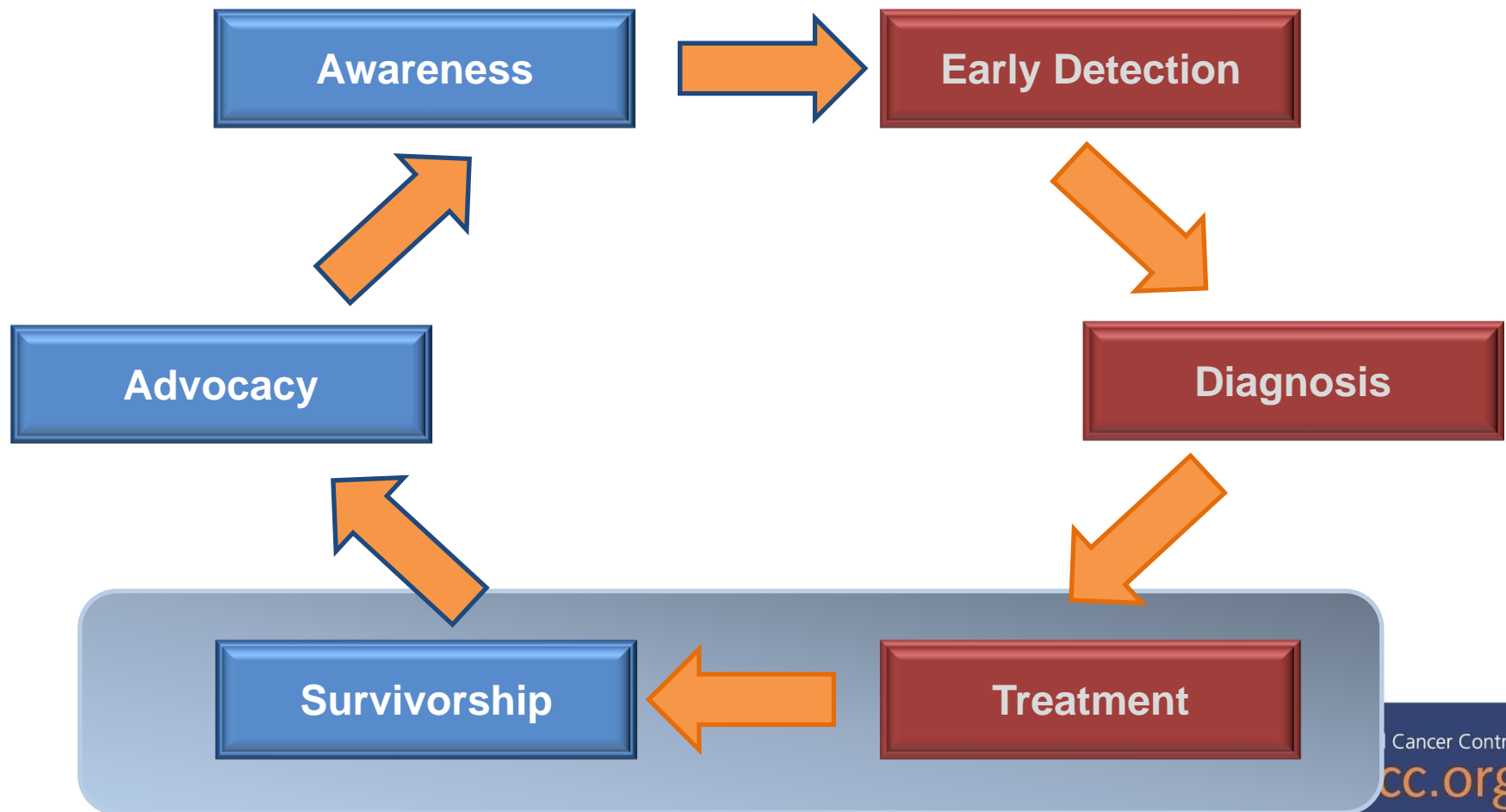
*“The use of trastuzumab may have broad public health impact and contribute to saving the lives of many patients in all countries across the globe”* ESMO Europe

*“Access not only is essential to patients survival but to social perceptions that can influence public health. In this way, society at-large accepts cancer not as a death sentence but as a condition for which there is help and hope”*

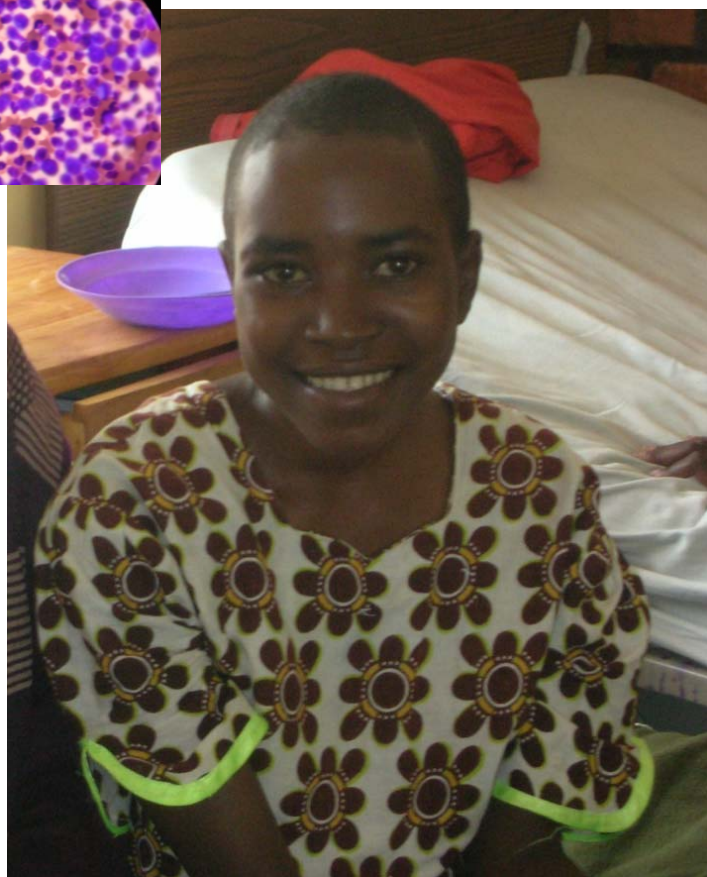
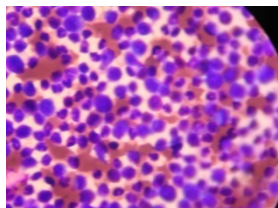
**LIVESTRONG**

## Public Participation

## Health Care Delivery



# 3-year CML survivor, on Imatinib



2007



2010

Relatively common disease with extrapolated incidence of  
> 100,000 patients annually and a much greater prevalence

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# Imatinib for CML, addressing concerns



## Positives

- 5 year survival increased by 35%
- Internationally recognised standard
- Promising price developments in generic market
- Potential for cost efficiencies on test - Cepheid GeneXpert also used for TB-MR (Unitaid)

## Concerns

- 35% Pts develop resistance = 65% have long term benefit
- Alternative treatments; Hydroxyurea and interferon provide only transient control of the disease an av. live expectancy of 4-5 years; stem cell transplants can be curative, but not applicable in most LMIC settings
- Compare with HIV treatments, survivors drive demand for cheaper 2nd/3rd generation drugs

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# Imatinib for CML

Propose: inclusion on EML + caveats



## 1. Testing capacities for Philadelphia Chromosome

## 2. The need for a comprehensive approach

Importance of a health system that has the diagnostic, treatment and monitoring modalities required to manage use of Imatinib

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## Supporting voices for Imatinib



*“Imatinib has demonstrated tremendous benefits in survival rate and quality of life for both pediatric and adult patients with CML”, ASCO*

*“The advent of imatinib has been transformative to our patients, who previously had no effective treatment options in settings like rural Rwanda or Haiti.”, Partners in Health*

*“Imatinib clearly fits the criteria as an essential medicine that has revolutionized the treatment of CML and continues to allow hundreds of thousands of patients to live productive lives with few side effects”, Max Foundation*

*“The therapeutic efficacy of imatinib results in long survival which means a higher prevalence [...], therefore further demanding global attention, especially given the simplicity of administration and the recent and continuing price concessions”, MoH Rwanda*

*“We have demonstrated what many have considered impossible in these settings; successful outcomes with high patient compliance and sound medical management. However, our patients cannot rely on charity forever”, Partners in Health*

# Thank you from UICC, DFCI and those that sent supporting letters



American Society of Clinical Oncology



GOOD SCIENCE  
BETTER MEDICINE  
BEST PRACTICE

European Society for Medical Oncology



Federação Brasileira de Instituições Filantrópicas  
de Apoio à Saúde da Mama



INTERNATIONAL CONFEDERATION OF  
CHILDHOOD CANCER PARENT ORGANIZATIONS



The Max Foundation

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