

## Personalised Cancer Care – A Global Perspective

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### Abstract

Much debate surrounds the matter of personalised medicine. The problem of new treatments at high costs is usually mentioned in relation with inequalities and problems of access to care. But there is also an urgent need to discuss the impossibility for many healthcare systems in the world to provide myriad new diagnostic procedures and treatments to all populations. In this editorial, the current situation from a global perspective will be analysed and the position of some of the leading cancer organisations will be presented. We also discuss some possible actions to be developed to overcome this urgent and contradictory situation.

### Keywords

Personalised medicine, global, cancer care, limited resources, cancer drugs, developing countries, precision medicine, access to care

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There has been much discussion in the cancer community around so-called 'personalised medicine'. Controversy exists over its definition and about the likely impact personalised medicines will have on patients of different settings, genetic backgrounds and resources. There are also different names proposed: personalised medicine, precision medicine, molecular medicine and targeted therapies are some of them, and the imprecise definition adds some confusion to the subject.

We need to take into account different views according to the position of each player in the cancer care continuum: from the patient-doctor relationship to the criteria of medical societies and, moreover, public health perspectives. Each one has diverse considerations and deserves a separate evaluation.

Likewise, it is also relevant to reflect on different levels of analysis: from a global scale to regional or national guidelines and recommendations; from scientific societies' perspectives to a clinical level. In this editorial, the topic from a global public health perspective will be considered.

We are not considering this subject as a controversy between science and economy, or an argument against the urgent need for more and better knowledge on the mechanisms and processes in the development of cancer. We consider that this is a discussion about the best possible and more rational use of existing resources for cancer care and control and an analysis for better strategies. We also present some reflections on how to strategise and implement the existing available knowledge (that today only applies to around 10 % of the world's population) to be applicable to a broader portion of the globe.

Today, an individual's odds of surviving cancer is strongly correlated with where that person lives. Whereas in the US the 5-year survival rate for

patients with breast cancer is 84 %, in the Gambia, breast cancer survival is just 12.5 %.<sup>1</sup> Interestingly, gains in survival have not always been due to very expensive treatments. Frequently, increased survival has been achieved by cancer treatments that are relatively low cost. On the other hand, the curability rate obtained with the new targeted therapies is low or non-existent.

The European Society of Medical Oncology (ESMO) produced an editorial on the matter, defining personalised cancer medicine and making general considerations and recommendations on professionals' and patients' education.<sup>2</sup>

Similarly, the American Society of Clinical Oncology (ASCO) President, Dr Peter Yu, stated:

*"Although we have generated more effective therapies in the treatment of cancer through the knowledge we have gained in clinical trials, we have not always focused as much attention on how to apply that knowledge to individual patients to realize the goal of personalized medicine. I believe the best clinical results are achieved for each patient when the patient's personal values and goals are met. That is really what quality of care is all about: achieving outcomes that matter to patients."<sup>3</sup>*

The European parliament recently debated the matter of life-saving medicines and the excessively high pricing in certain member states. Speaking in the context of the debate, health spokesperson Michele Rivasi, who initiated the discussions, said:

*"The astronomical prices of some life-saving medicines is meaning those suffering from these illnesses are unable to afford their treatment. This is a scandal in itself but it is an even greater*

*scandal that the European Commission is refusing to address the issue, notably by tackling the issue of monopolies and abuse of market position.*<sup>4</sup>

## Cancer Drugs – Some Facts

The 20 leading oncology brands generated global sales just shy of US\$50 billion in 2012 with an overall expansion of US\$63 billion by 2018.<sup>5</sup> The cost of cancer drugs has more than doubled in the past decade. Of the 12 cancer drugs approved in 2012 by the US Food and Drug Administration (FDA) for cancer, 11 were priced at more than US\$100,000 per patient per year.<sup>6</sup>

Innovative cancer drugs are developed with public and private investment in cancer research. The pharmaceutical industry spends US\$6.5–8 billion per year on cancer research, but public investment in cancer research (i.e. governmental and charitable) is at much lower levels and, frequently, research and development of cancer drugs is mainly driven by commercial considerations rather than by public health priorities.

America's biopharma research companies are testing 771 medicines and vaccines to fight the many types of cancer affecting millions of patients worldwide. Approximately half of the investigational products in late-stage development are targeted therapies.<sup>7</sup>

The price of targeted therapies has been set very high, and as more targeted therapies enter the market and are used as long-term maintenance therapy, the overall cost of cancer care will increase significantly. Under the current circumstances, targeted therapies will become unaffordable for many countries, even for the most developed.

## World Health Organization Position

The World Health Organization (WHO) estimates that nearly one-third of the world's population does not have access to full and effective treatment with the medicines they need – this rises to over 50 % in the most underprivileged parts of the world. Even in highly developed countries, access to some drugs and the best available therapy is not guaranteed for everyone.<sup>8</sup>

Cancer therapies represent one of the great 'missing links' in cancer control efforts in low- and middle-income countries (LMIC). Access barriers to cancer drugs are especially striking in light of the many research advances of recent years, which have significantly elevated the role of systemic therapy in the management of many priority cancers. There is little or no international funding for cancer treatment compared to the billions of dollars that are used for other health-related purposes.

WHO has previously produced recommendations on the essential drugs required for cancer therapy, and over the last 5 years several new anti-cancer drugs have been aggressively marketed. Most of these are costly and produce only limited benefits.<sup>9</sup>

WHO divided currently available anti-cancer drugs into three priority groups (curable, increased curability-adjuvant and prolong survival). Curable cancers and those cancers where the cost-benefit ratio clearly favours drug treatment can be managed appropriately with regimens based on only 17 drugs. All of these are available, at relatively low cost, as generic preparations and the wide availability of these drugs should be the first priority, especially for LMIC.<sup>9</sup>

## Union for International Cancer Control Position

Worldwide access to the best possible cancer treatment, care and support is a top UICC priority. To deliver on its vision of a world

where cancer is eliminated as a major life-threatening disease for future generations, UICC is committed to participating in building collaboration and cooperation to address barriers in access to cancer drugs worldwide.<sup>10</sup>

## Barriers to Access

*Drug costs:* The high price of patent-protected cancer drugs makes them unaffordable for many countries. Patent enforcement by pharmaceutical companies in underprivileged countries can also inhibit access.

*Insufficient public funding of health:* Governments in some countries do not provide reimbursement for essential cancer drugs. This means that patients have to pay for drugs themselves.

*Poor infrastructure:* Many countries lack the facilities necessary to enable complex cancer drug regimens to be administered safely and effectively.

*Irrational use of cancer drugs:* There is a dearth of adequately trained health professionals who are competent to prescribe and administer cancer drugs. In addition, many countries lack national evidence-based treatment guidelines for the rational selection of cancer drugs.

*Bureaucratic policies:* In many countries national opiate policies are too restrictive, which limits the availability of morphine and other pain-relieving drugs. It is estimated that 80 % of cancer patients who suffer severe pain have no access to opiates.

*Counterfeit medicines:* In developed countries sales of counterfeit drugs represent less than 1 % of the pharmaceutical market. This rises to 10–30 % in parts of Asia and Latin America and up to 70 % in some African countries.

## Overcoming Barriers

- Some pharmaceutical companies have established drug donation programmes to address access problems in underprivileged countries. Although useful in the short term, these programmes are not a long-term solution to cancer drug access.
- WHO has developed a list of essential cancer medicines, which is updated and revised biennially. This list is used to guide procurement of cancer drugs in many underprivileged and developing countries. Currently it is under full review. This review was requested by UICC and Dana Farber, before WHO decided to update all the medications included in the list. ESMO, ASCO, National Comprehensive Cancer Network (NCCN) International and others are collaborating in this important task.
- Recycling existing drugs for cancer therapy; delivering low-cost cancer care. Drug repurposing is a strategy with fascinating potential for cutting the cost of cancer care as well as significantly affecting patient outcomes. The Repurposing Drugs in Oncology (ReDO) project, an international collaboration between researchers working for not-for-profit, patient-centred organisations in Europe and the US, aims to accelerate the repurposing of non-cancer drugs for new indications in oncology.<sup>11</sup>
- More cost-effective options. Several ways might be considered, such as modifying modes of administration, using shorter but still effective courses or doses, finding new combinations or

indications of less-expensive drugs or the use of generics after testing bioequivalence.<sup>12,13</sup>

- In March 2010, the US Congress passed the much awaited legislation which would give the FDA the authority to approve generic versions of an innovator biologic drug. Recently, regulators at the European Medicines Agency (EMA) worked to finalise draft recommendations for biosimilar versions of monoclonal antibodies.<sup>14</sup>
- A possible action proposed for global cancer leaders is to develop a global cancer fund to provide funding for public, academic and independent research as well as to promote low-cost cancer care interventions (*Franco Cavalli, personal communication*).

## Conclusion

It is critical to recognise cancer as a health priority that requires adequate public funding within the context of a national cancer control plan. It is

also urgent to provide rigorous and timely evaluation and licensing of all cancer drugs and to adopt a range of mechanisms to secure affordable prices for cancer drugs.

Worldwide access to the best possible cancer treatment, care and support is a major global priority and we all must be committed to participating in building collaboration and cooperation to address barriers in access to cancer drugs worldwide.

It is our obligation to promote the rational use of cancer drugs by preparing national guidelines for the treatment of common cancers and ensuring that the cancer drugs that are included in national guidelines are listed in the national formulary of essential medicines. As it was said by Dr John Seffrin, Chief Executive Officer (CEO) of the American Cancer Society (ACS) in 2008: "Every patient – regardless of where he or she is born – deserves an equal chance at a long life and good health." ■

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