

Implementation of Country-Wide Pharmacoeconomic Principles in Cancer Care in Developing Countries: Expert-Based Recommendations

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Abstract

Introduction: Cancer care is a major challenge to health care and for optimal outcomes, health systems need to align policy across many areas of public life. The recognition that even the wealthiest nations can fail optimum outcomes indicates a need for increased efficiency in cancer control programs. Fundamental to this is the efficient direction of resources—a process that can be optimized through economic measures. This article contains expert recommendations on how decision makers can implement pharmacoeconomic principles at national level in developing countries. **Methods:** A multidisciplinary panel of 10 experts was formed of oncologists, clinical pharmacists, health economists, and chronic disease control and public health experts from different countries and health-care sectors. The panel developed consensus recommendations for different stakeholders using a framework analysis method. **Results:** Recommendations were categorized as national level, hospital level, industry level, and public-community level to support decision makers in implementing pharmacoeconomic principles in a systematic way. The recommendations included having proper well-structured, data-driven processes with a specific role for each stakeholder. We proposed required structures and processes in such a way that they can be customized based on individual country plans. **Conclusion:** The expert panel recommendations will serve as a guide to relevant stakeholders at a national level. Adaptation of these recommendations to each setting is important to accommodate the situation and needs of each country.

Keywords: Cancer care, cost of cancer care, health economics, pharmacoeconomics

INTRODUCTION

Cancer care is a major challenge to health care in the twenty-first century. With successful prevention and treatment of once fatal nutritional and communicable diseases, populations are living longer. This aging, coupled with the adoption of lifestyles that promote cancer, such as smoking, alcohol consumption, and physical inactivity, are driving increased global cancer incidence. The impacts of such changes are predicted to be greatest in developing

countries, especially in the Middle East Region, with incidence set to double in just 10 years, giving little time to affect health system changes to address the cancer epidemic.^[1]

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Submission: 03-May-2019, **Revision:** 07-Jul-2019, **Acceptance:** 22-Jul-2019, **Web Publication:** 10-Oct-2019

Access this article online

Quick Response Code:



Website:
www.jqsh.org

DOI:
10.4103/JQSH.JQSH_11_19

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How to cite this article: Jazieh AR, Pizzo E, Gulacsi L, Eldahiyat F, Abu-Helalah M, Ibrahim N, et al. Implementation of country-wide pharmacoeconomic principles in cancer care in developing countries: Expert-based recommendations. *Glob J Qual Saf Healthc* 2019;2:109-14.

Faced with such pressures, there is often a desire to implement simple, rapid, sweeping, and potentially disruptive policy changes. For optimal cancer outcomes, health systems need to align policy across many areas of public and private life, investing financial and skilled human resources in a balance of prevention, screening, early detection, and treatment services. The aim is to reduce cancer risk, incidence, morbidity, and mortality while improving quality of life for patients.^[2]

The recognition that even the wealthiest nations can fail to attain optimal outcomes indicates a need for increased efficiency in directing cancer control programs.^[3] Fundamental to this is the efficient direction of resources—a process that can be optimized through economic measures. To be successful, National Cancer Control Programmes need to be multifaceted, multilevel, and involve multiple stakeholders. The recognition that the link between health-care quality and cost is weak, indicating the need for health systems to spend wisely, not just spend more, to improve outcomes.^[4] This involves often difficult choices for which health economics offers a methodology for decision-making at every level.^[5]

Health economics is a new discipline, and its resources are distributed unevenly; often those nations with the greatest burden of disease and speed of change are those with the lowest capacity for economic decision-making.^[6] Although policies from international agencies such as the World Health Organization (WHO) may represent sensible general principles, the introduction of uniform global policies can fail in individual nations because of a lack of skills to adapt such policies to the individual demographics, diseases, management resources, and political and social strengths of each nation. Economics, and particularly health economics, is frequently misunderstood.^[7] Economics relies on a specific technical vocabulary, which, although precise, can act as a barrier to comprehension outside the specialty. The public and health-care professionals (HCPs) can be reluctant to accept that health resources are finite and misunderstand “economics” as solely the delivery of budget cuts. Mistrust can be heightened, because within economics there can be a diversity of opinion, and in many areas, evidence is variable or of low quality. Recognizing this requires a depth of economic resources across government and health systems.^[8] This problem is likely to be greatest in under-resourced nations or in health systems undergoing rapid transitions, especially where policies adopted directly from stable health systems in developing countries may be inappropriate.

For many countries, the pressing requirement for health economics is in addressing the dramatic inflation in the medicines budget for cancer, for rising prices of cancer drugs constitutes a pressing concern to health systems across the world.^[9,10] For this purpose, the application of

pharmacoeconomics can be used to make better decisions on treatment policy. The impact of pharmacoeconomics in this setting is likely to be significant; less than half of European-approved cancer medicines launched between 2009 and 2013 had evidence of a positive survival or quality-of-life benefit.^[11] Furthermore, the lack of proven benefits comes with a financial cost; every new cancer drug approved in 2017 cost US\$100,000 or more for a standard course of treatment.^[12] With such financial pressure, rationing of access to medicines will be inevitable. In a comprehensive or insurance-based system, this will be determined by willingness to pay and in a private system, by wealth and ability to pay. According to the WHO figures, the estimated total annual economic cost of cancer in 2010 was approximately US\$1.16 trillion.^[13] In addition to high cost and limited budget for cancer care, only one in five low- and middle-income countries have the necessary data to drive cancer policy.^[14]

There is always an inherent tension that needs to be recognized between the priorities of health economists and HCPs in deciding which treatments should be reimbursed. Clinicians necessarily focus on gaining the best outcomes for each individual patient, whereas economists typically think in terms of gaining the greatest health for the population within the resources available. Furthermore, since less than 5% of patients with cancer enter high-quality randomized trials, the applicability of evidence-based medicine to the general population may be lacking—even more so in developing regions.^[15]

This article summarizes expert panel recommendations that developing countries, and many developed countries, can use to guide their efforts to adopt pharmacoeconomic principles in oncology care.

METHODS

A panel of 10 experts of various background and expertise convened in person at Alfaisal University, Riyadh, Saudi Arabia, on November 16–17, 2018. The panel included oncologists, oncology clinical pharmacists, health economists, pharmacoeconomists, and public health and chronic disease experts, from different health sectors and countries, including Saudi Arabia, Jordan, United Arab Emirates, United Kingdom, Hungary, and the United States. Experts were notified in advance about the purpose of the meeting. The meeting was recorded for future reference.

The main question to be addressed by the expert panelists was as follows: “What are the recommendations to implement pharmacoeconomics practice in oncology care at a country level involving all stakeholders?” The responses were compiled, reconciled, and structured into specific categories of recommendations. The categories were identified by the stakeholders. Relevant evidence

from real-life experiences was drawn to support the specific recommendations.

The typed report was shared with the panelists for review and feedback, including expanding on some points or adding references before adopting the final version. There were no issues related to confidentiality, proprietary information, or any other ethical concerns.

RESULTS

The panelists reached a consensus agreement on recommendations based on specific categories at different levels, including national, hospital, industry, and community levels. Figure 1 depicts the relevant entities and how they may interact among each other.

The national level

This represents the national entity that is officially responsible for the decisions about funding and regulating cancer care in a particular country. This may represent the Ministry of Health (MOH) or subsidiary of it, or a dedicated health technology assessment (HTA) agency, or more than one entity with different scope of function. Regulation should include medications, medical devices, and diagnostics including the proper selection of a platform for precision medicine.

This national entity should be responsible for the following tasks.

Creating a national policy

The government should develop a national policy regarding coverage and reimbursement of cancer care,

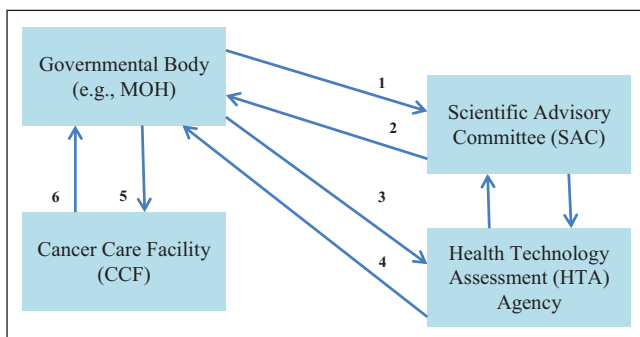


Figure 1: Proposed structure and processes to enhance pharmacoeconomic practice at a national level. 1—Governmental body (e.g., Ministry of Health [MOH]): Invites a multidisciplinary team of experts to create the SAC with clear tasks and expectations. 2—SAC provides the government body with recommendations about HTA, guidelines, and core data requirements. 3—Governing body develops HTA Agency with clear tasks, process, and shared budget. 4—HTA Agency supports governmental bodies in taking decisions regarding treatments and devices to be approved and how these should be used. 5—Governing body selects or accredits cancer facilities/centers to provide cancer care, request reports about the indications and treatments given, and assure payment. 6—CCF provides periodic reports with core data set to get reimbursed.

including how much and what to cover. This will depend on the economic condition of the country and the competing priorities for cancer care in that country, and these issues should be addressed based on the volume and complexity of cases managed. A national entity will be needed to conduct HTA studies of health-care technologies, including pharmaceuticals, in a transparent and scientifically robust manner.

The interpretation of data on the cost-effectiveness of treatment requires uniform agreement on the metrics used to make reimbursement decisions within each health-care system. Cancer medicine works on the twin aims of prolonging overall survival or length of life (metric: added life years) while preserving or increasing quality of life that is valued by patients (metric: utility). In contrast, public health programs look to measure the impact on how many years of disability or premature loss of life have been avoided by an intervention (metric: disability-adjusted life years). Furthermore, since societal perspectives differ on the value of different quality-of-life states (health states) between nations, national values that translate changes in quality of life into utility need to be understood.

Due to the public sensitivity over access to health, the National Medicines Policy will require patient and public participation in commissioning decisions. Stakeholder engagement across many domains of national life will be needed to create reimbursement policies that have the greatest breadth of support and understanding in society. Furthermore, collecting useful public domain data to assess the impact of these decisions involves negotiating a balance between access to informative health data and assuring patient privacy.^[16]

Generating and using accurate data

For cancer control to be optimized requires significant data on the type and incidence of cancer from cancer registries and the variation in both its treatment and its outcomes from health-care providers. Such data need to be representative, timely, and available to researchers and decision makers. Obtaining such data is challenging; for busy and often under-resourced HCPs, the link between time-consuming accurate data collection and better treatments can seem weak. Instead, the HCP's interest is often focused on the treatment process as a surrogate for treatment outcomes. There also needs to be recognition that a “perverse economic incentive” can occur when the focus is on treatment process in a fee-for-service health system.^[17]

Cancer is diverse, with more than 200 different cancers recognized by cancer registry systems from the Union for International Cancer Control. Within each cancer subtype, there is individual variability such that cancer treatment outcomes are typically measured and expressed as length and quality of life over a five-year period.^[18] Economists and HCPs have to work with this disease diversity and time

lag as an ever-present problem in interpreting changes in treatment process to shifts in patient outcomes, all of which makes creating high-quality treatment guidelines a challenge.^[19]

This diversity of cancer extends between global regions and nations. However, in any one country, cancer incidence tends to be dominated by a limited range of cancers, such that only 10–12 cancer treatment guidelines are likely to be needed to direct the care of 90% of a nation's patients with cancer.^[20] Inherent in the interpretation of outcomes for rare cancers is the potential for statistical imprecision in low-incidence orphan diseases.

To encourage everyone to collect and submit high-quality data, data submission can be tied to a financial incentive. This can be performed by setting and assigning a budget to institutions that are approved to manage cancer and are reimbursed on the basis of the services provided. However, this should depend on the following factors:

1. There should be a reliable information system for recording data on the cancer cases that allows better planning and distribution of resources. This could start from the most common types of cancer and include all others at a later stage. Providing accurate data on the number of patients and type of cancer treated is critical. The data requirement should be limited to a few core sets of data to avoid overwhelming everyone.
2. Treatments should ideally be delivered according to evidence-based guidelines and pathways. This not only directs patients to the most clinically effective and cost-effective treatments but also reduces variation in treatment, making treatment audits more useful in directing effective change.

Developing and implementing national guidelines

If there is national policy of coverage or coverage provided by a third party, national value-based guidelines for the most common forms of cancer should be developed and disseminated as a requirement for reimbursement. The guidelines must be clear with specific measures and indicators for compliance and adherence to them. These guidelines should be developed by or adapted and approved by a central national scientific committee acting without conflicting interests and with transparency of decision-making. The resulting guidelines should be freely available.

Creating a National Scientific Advisory Committee

The National Scientific Advisory Committee should provide scientific advice/recommendations to the government (MOH, HTA, or others) regarding the clinical guidelines to be applied at a national level. It should provide consultation on various aspects of pharmacoeconomic issues while maintaining high quality of patient care. This committee should be independent,

multidisciplinary, and composed of senior clinicians, health economists, and evidence-based experts.

Establishing a national cancer registry

It is critical to have a centralized population-based registry to collect available data on all cancers diagnosed in the country to facilitate development of strategic plans including prevention, screening, and treatment and to estimate work load and economic burden. Although registering rare cancers would help in addressing them better, having detailed information about the most common cancers is needed more. In addition, national registries will be an excellent source for real-world evidence, which is required for localized economic evaluations and HTA studies.

Establishing a national database for the cost of services

Unit cost of services data is fundamental for conducting economic evaluations to inform decision-making. Considering that health care in many countries is mostly provided by different governmental sectors, the real cost for each utility, such as bed cost, X-ray, and laboratory tests, remains unknown. Therefore, a practical approach to assessment needs to be adopted to estimate and publish the cost of these utilities in each country annually. A recommendation is to average the cost incurred at three to five major tertiary hospitals from different categories of health-care sectors (i.e., private, governmental, and military health care).

Assuring proper education

Educating decision makers, HCPs, and the public about the delivery of a value-based medicine policy is important. This may include introducing simple concepts about pharmacoeconomics such as cost-effectiveness to demystify critical issues. Increasing awareness about certain issues such as use of generic or biosimilar versions of cancer medicines would address many misconceptions about these topics. .

Utilizing advanced information technology

It is critical to implement a reliable and accessible information technology (IT) system to facilitate communication among all parties and collection of accurate data in a timely way. If electronic health records can be implemented and data collected automatically, it will make the process more efficient and reliable.

Investing in cancer prevention

Investing in cancer prevention and screening may yield better long-term outcomes (in terms of lives saved and better quality of life) and avoid future treatments of more advanced stages of cancer. Therefore, the efforts of primary and secondary cancer prevention initiatives should receive adequate attention and support.

Supporting health economics research

Supporting health economics research involves the following recommendations:

1. To work with main research funding bodies and including health economics research in their calls for grants. It is important to start with projects tackling major health problems in the specific country where policy is lacking.
2. To encourage investigators to include pharmacoeconomics outcomes in their research, particularly in randomized clinical trials.
3. To enhance data collection on population norms data, which will be needed to run pharmacoeconomics models for different diseases and interventions.
4. To support a clinical research environment that will attract global clinical trials. This would support decision on approval of new medications and provide patients to access to free medications before they are available in the market contributing to reduction of cost burden of cancer care.
5. To establish health economic centers, which can be used as a resource for performing the reviews for the government.
6. To encourage education in health economics is important to develop a cadre of experts who will be able to help in different related activities.

Hospital level

Hospitals and health-care facilities should develop their systems in concert with the national plans and should set up the infrastructure based on their expected roles and responsibilities. This is more applicable if the country has different payers without an assigned official reimbursement body. The following are some of the recommendations:

1. To structure a pharmaceutical and therapeutics committee to make evidence-based decisions about the hospital formulary and conduct economic evaluations of new pharmaceuticals considered for formulary addition to inform the committee's decision-making process. This entity will monitor addition or deletion of medications and monitor the use to help ensure efficient use of resources.^[21]
2. To create a working group to incorporate national guidelines into local practice evidence- and value-based protocols. If there are no guidelines, the group can develop or adapt international guidelines to the local setting and monitor adherence to guidelines.
3. To create a registry that can provide accurate cancer data to the national registry.
4. To provide core data to relevant national body.
5. To educate staff on pharmacoeconomic principles and develop communication skills to explain these to patients and families.
6. To monitor adherence to these principles in practice.
7. To enhance cancer prevention practices among HCPs and patients to minimize the impact of cancer diagnosis.

Industry level

The pharmaceutical industry should play a major role in implementing cost-effective care. The industry includes the following recommendations:

1. To collaborate with stakeholders at the national level and local hospital level to provide the best treatment options that satisfy the requirements.
2. To integrate economic evaluations into its clinical trials and share patient-specific information, such as quality-of-life data for particular indications and patient groups, out-of-pocket costs, and medical resource use data.
3. To support research and education initiatives and projects in pharmacoeconomics.
4. To share data related to drug usages, pharmacovigilance, and other relevant experiences and findings.
5. To offer various opportunities to share the cost burden, such as a risk-sharing scheme, patient assistance program, early access program, and others.
6. To help create a neutral platform to share ideas with governmental agencies or practitioners, such as European Federation of Pharmaceutical Industries and Associations in Europe.^[22]

These recommendations are not expected to be sole responsibilities of the industry, as many fall under governmental or hospital level, but the industry should contribute as much as possible to these issues.

Community level

The community has a major role to play, as health-care burden will impact all society. The following are some of the areas that can be addressed at community level:

1. To advocacy group/entities to represent patients' views at all levels. Patient representatives should attend and actively participate in Guidelines Committees, HTA, and other activities.
2. To educate the community the basic principles of pharmacoeconomics, so that they can understand why a particular drug or treatment is not adopted in the country.
3. To create groups to support patients with cancer financially, socially, and emotionally, if needed.
4. To encourage community groups/entities to enhance cancer prevention and screening efforts such as smoking cessation, tobacco control, or participate in cancer screening processes.
5. To create an environment to help all stakeholders work together through forums, workshops, meetings, or other structured entities.

DISCUSSION

Applying pharmacoeconomic principles is very complex endeavor that has many challenges and varies from one country to another. Our panel developed recommendations relevant to different stakeholders to

simplify the challenge of applying pharmacoeconomic principles in real life. Although it is impossible to have a one-size-fits-all approach, our recommendations are flexible and adaptable to various settings based on the available resources and expertise in the interested country.

Although it is ideal to have a comprehensive national plan that covers all involved aspects and stakeholders, the approach cannot be all or none. Some recommendations for specific stakeholders can be applied, when possible. Therefore, we recommend responsible stakeholders get the “low-hanging fruits” and do what they can to gain experience.

Furthermore, although it is better to have an overall plan for the whole program, we recommend proceeding in a step-by-step approach and escalating based on the successes attained to assure better yield of the plan.

As an inherent limitation of our project, it is impossible to have a representative of all developing countries to cover all possible scenarios and needs. However, the expert panels do represent different countries with exposure to the experiences of many other countries, provided an adaptable recommendation structure that covers many situations and settings.

CONCLUSION

The expert's recommendations offer various ideas and guidance from stakeholders to incorporate pharmacoeconomic and health economic concepts into practice. These recommendations should be put into a proper perspective, taking into account the local setting, the socioeconomic characteristics of each state, the culture, and the national priorities. Therefore, they should be adapted based on the epidemiological needs, the competing national priorities, and the available resources.

Acknowledgements

Elena Pizzo was (in part) supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North Thames at Bart's Health NHS Trust. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care.

Financial support and sponsorship

The authors disclosed no funding related to this article.

Conflicts of interest

The authors disclosed no conflicts of interest related to this article.

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