Original Article

Expert-Based Strategies to Improve Access to Cancer Therapeutics at the Hospital Level

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Abstract

Background: Challenges related to access to cancer medications is an increasing global problem that has far-reaching impact on patients and healthcare systems. In this article, we are enlisting suggested solutions at the hospital or practice level to maximize the access to these important treatment modalities. **Methods:** An expert panel of practicing oncologists, clinical pharmacists, and health economists convened using a framework approach. The panelists identified individuals and entities that impact the use of cancer therapeutics and how they can improve the utilization and access to them. They enlisted the potential actions that hospital management and staff can take to enhance access to cancer therapeutics, then they grouped them into specific categories. **Results:** List of potential strategies and related action items were compiled into different categories including hospital leadership, drug evaluation entities, pharmacy, physicians, patients and families, and other parties. Recommendations included various actions to be considered by each group to achieve set goals. **Conclusion:** Our expert panel recommend multiple strategies and approaches to reduce the cost of cancer medications and improve patients' access to them. These recommendations can be adapted by the decision-makers and staff of the hospitals to their own settings and the current circumstances.

Keywords: Access to cancer therapeutics, cancer, cancer medications, cost of cancer care

Introduction

The cost of cancer care is rising significantly, similar to other healthcare sectors. There are many reasons for increasing the economic burden of cancer including hospital admissions, hospital visits, loss of productivity, cost of medications, and cost of cancer care.[1,2] Cancer medications are very expensive and continue to increase exponentially.[3,4] The cost of these medications became so prohibitive that many countries cannot afford the incoming large number of new and expensive cancer medications.[5,6] The high cost of cancer care has been discussed and explored by many experts in the past. Reasons could be summarized within high cost of drug development, lack of true generic price check, the seriousness of the disease, the high cost of generic cancer drugs compared to those used in nonmalignant diseases, the incentive for more chemotherapy, lack of thresholds for clinical benefit, and more.[7,8] The impact of high cost for medication is not only limited to the financial/economical impact on individuals or societies but also it may be detrimental to patient care in different ways, mainly due to the lack of access of this medications. The financial toxicity to the patients may prevent them from getting the prescribed treatment.

There are many plans and proposals to reduce the cost of medications with variable distribution of responsibilities from the pharmaceutical industry, regulatory agencies, health technology agencies, professional societies, patients' advocacy group, and healthcare professionals. Improving access to quality cancer therapy cannot be attributed to only one

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stakeholder. It is the responsibility of all stakeholders in the oncology ecosystem including drug manufacturers, providers, policymakers, and patient organizations. We have to call on each one to incorporate so that together we can provide high-quality cancer care.[7,8] Regulations, strategies with clear policies, procedures, and guidelines at the national and institutional level are essential.

In this article, we enlisted various stakeholders involved in access to cancer therapeutics to determine how to can improve the access while controlling the cost at the hospital level.

Methods

A team of oncology experts was assembled including senior oncologists (Abdul Rahman Jazieh, Khalid AlSaleh, and Marc Thill), pharmacists (Nagwa Ibrahim and Fatma Maraiki), and health economists (Hana Abdulkareem and Fatma Maraiki). The team members have extensive clinical, administrative, and health economics experience.

A framework analysis method was used to address the issue of access to cancer therapeutics at a hospital level.[9]

The expert panel responded to two open-ended questions:

Who is involved in acquiring, prescribing, dispensing, and using cancer medications? The second question was, what are the potential actions that these entities can take to strike a balance between improving patient's access to best evidence-based therapeutics and the significant financial impacts of these medications.

Data were collected from the panelists, and the involved entities were divided into specific categories. Potential action steps of each group were listed also and grouped into categories. Then, the panelists received the final recommendations. Although data were collected from the experts based on their own institution experience, obtaining supporting evidence from the literature was sought subsequently.

Results

The panelists identified six categories of individuals/entities who can impact the use of cancer medications including hospital leadership, pharmaceutical and therapeutic committee, pharmacy, physicians, patients and families, and others. All potential actions of each group are listed and explained in Table 1.

Hospital leadership

Hospital leadership plays an important role in improving access to medications wherein the aim is to provide the best care to the patient while saving money. The strategy, vision, and mission of the organization should dictate the priority of the optimal allocation of resources and budget management.

The hospital leadership should allocate the budget and resources for medications in a very structured way. The first step is to instruct end-users (department level) to request medication and justify their medication needs. Budget allocation should be based on the mission of the hospital and type of facility services, secondary or tertiary care. Evaluation of new medication should include other medications, new technology, and new therapy for comparison.

The hospital leadership has critical roles in controlling access to quality cancer medication for many reasons. We will discuss various components that leadership can work on to achieve these goals.

Strategy

- Make strategic decisions and plans to be a value-driven organization. This will assure providing the best care while considering the cost-benefit balance. This will require setting priorities and assessing the whole process of cancer care, not only the cost of medications.
- Evaluate all types of care provided to patients, such as diagnostic and therapeutic procedures and interventions, in addition to reviewing the work process and the attained outcome.
- Make sure that all staff understands and buy into these concepts, so they can participate and contribute to the success of this strategy.
- The leadership has to understand the special requirements and needs for cancer patients and put these needs into proper perspective.[10]

Budget allocations for cancer patients

There is no system, organization, or even a country that has infinite resources for the many competing needs for different patient populations. Therefore, a systematic approach is needed to tackle the budgeting issues and save scarce resources. Suggested guiding principles for budget allocations are as follows:

- Emphasize the personalized medicine approach, where the right patient gets the right treatment. Precision medicine will pay off if utilized properly. It can improve patient outcomes and reduce the cost by limiting the unnecessary cost of treating nonresponders.[11]
- Invest in prevention and screening programs with the coordination with the national and community entities based on hospital setting and eligible patients and other variables.[12]
- Use the input of subspecialty physicians and consider the alternative treatment modalities for the disease
- Establish a disease registry as plans built on actual data, not on assumptions, are more likely to be considered for budget allocation. Physicians can use a scoring system or benchmarking system for the registry.
- Consider various methods of allocations including leaving access open for competition among various disciplines or allocate budget per disease group and let the discipline teamwork within their allocated budget.
- Consider devices/tools and procedures in managing cancer patients, such as regional therapies and others.
- Consider new emerging technologies/innovation in assessing new therapeutics, such as next gene sequencing,

Table 1: Access to quality cancer therapeutic at a hospital level

Category	Step	Specific actions
Hospital leadership	*Strategy*	• Make strategic decisions and plans to be a value-driven organization • Create proper culture
	Budget allocations for cancer patients	• Prioritize: Personalized medicine • Prevention/screening program • Sub-specialty/specialized • Assigned resources based on group of patients not individual • Consider devices/tools • Consider new technologies/innovation
	Enforcing evidence-based medicine	• Create a system to adapt, implement and monitor international guidelines best practices
	Building infrastructure for proper drug evaluation	• Establish pharmacy and therapeutics committee and oncology subcommittee • Have health and pharmaco-economic experts • Set elements for drug evaluation
	Establish disease registry/data	• Plan based on actual data not assumption • Use benchmarking: examples are ASCO-QOPI • Electronic records
	Education	• Train and educate staff about the concepts of the cost effectiveness and quality improvement
Drug evaluation entities such as pharmaceutical and Therapeutic committee, cost effective experts evidence based medicine	*Establish clear policies and procedures on the function of the committee*	• Advisory committee to medical staff, administration, and pharmacy • Development of drug policies • Evaluating and selecting medicines for the formulary list • Developing standard treatment guidelines • Conducting effective interventions to improve medicine use • Managing adverse drug reactions • Managing medication errors • Information dissemination and transparency • Drug management cycle
	Medication selection and approval	• Use of pharmaco-economics and health technology assessment • Use scoring system • Review allocation of leadership • Use a particular framework: ASCO, ESMO, NCCN, NICE • Simulation and risk-sharing approaches, biosimilars, generics • Consider therapeutic interchange
	Price negotiation	• Risk-sharing approach • Outcome-based approach • Therapeutic interchange • Portfolio deals with the pharmaceutical companies
	Monitoring	• Assure adherence to guidelines • Periodic report: Drug use evaluation • Develop off-label use policy • High quality clinical pathways
	Referral process	• Scan horizon for new approved drugs or innovative drugs • Individual practitioner request • Leadership decision
	Establish an oncology specific subcommittee	• Drug evaluation • Economic evaluation: new medication impact • Encourage delisting: scan all formulary use • Physician prescription: guidelines and monitors • Periodic updates for the guidelines • Request approval of the newly approved indications for the available drugs to avoid shortage • Identify clinically meaningful outcomes in cancer
	Enforce patient education and staff awareness	• Develop patient education program • Educational materials
	Delisting	• Systematic review of the formulary and delist unused medications

Contd...

Table 1: Contd...

Category	Step	Specific actions
Pharmacy	*Monitoring utilization/medication control*	• Use clinical guidelines and algorithm • Report deviations from guidelines • Prescribing restrictions • Electronic prescribing • Medication management policy
	Managing inventory/supply chain	• Selecting the right vendors
	Minimize waste	• Policy on dispensing medication and avoid waste • Monitor waste systematically • Apply dose rounding policy • Exchange program
	Avoid overstock	• Order the right quantity • Avoid expiration
	Exchange program	• Establish agreement with other hospitals to share expensive or rarely used medication or medication needed on short supply
	Control refills	• Give one month supply only • Have left over medication reviewed • Implement express mail services
	Ensure education	• Counseling patients and their families
Physicians	*Adapt international guidelines and assure adherence to them*	• Adapt guidelines/pathways • Enforce compliance with guidelines in the system • Monitor certain indication
	Encourage delisting	• When requesting new addition of medication • When the drug is not included in the recent protocols any more
	Avoid marketing studies	• Proper ethical committee review • Apply investigational drug studies
	Utilize clinical trials	• Encourage trials that give access to innovative therapy • Clear policy to post-trial access to medication
Patients and families	*Use medication properly*	• Establish counseling program
	Return left over medication	• Policy on how to manage left over medication
	Make your voice heard (advocacy)	• Assure their process to hear patients and family concerns about medication
	How to look for information	• Educate patients about reliable source of information • Develop patient information resources
Others:	*Establish pharmacovigilance*	• Use hotline or create mobile applications for patient and provider use
Pharmacovigilance,		• Monitor all new medication
Purchasing and contracts	*Value-based pricing*	• Develop value-based pricing strategy

ASCO: American Society of Clinical Oncology, QOPI: Quality Oncology Practice Initiative, ESMO: European Society of Medical Oncology, NCCN: National Comprehensive Cancer Network, NICE: National Institute for Health and Care Excellence

liquid biopsy, or any tests that help select the patients who are likely to benefit or local therapies such as stereotactic radiosurgery and others.

Enforcing evidence-based medicine

- Create a system to adapt, implement, and monitor international guidelines and best practices.[13-16]
- Build capacity in evidence-based medicine (EBM). Learning guidelines adaptation is an essential skill that should be acquired by professionals in an organization that treats cancer patients. No matter how well done the national and international guidelines are, the local setting will vary, mandating the need for adapting these guidelines to the local setting. This will help in streamlining the treatment choices based on availabilities and priorities set by the organization. An example of how to adapt guidelines is published and can be used as a template for adapting other guidelines.[17]
- Adapting guidelines is not enough unless it is accompanied by a rigorous plan of implementation and monitoring with timely feedback and corrective actions.

Building infrastructure for proper drug evaluation

- Evaluating medications is a complex process that requires expertise and commitment of staff and resources. Historically, this task is performed by the institutional pharmacy and therapeutic committees.
- These committees should undergo major transformation in their structure and process. They should include health and pharmaco-economics experts who will be able to do proper cost-effectiveness analysis. Involvement of the specialty experts in the discussion is paramount to bring a perspective from the frontline and end user.
- Establishing an oncology pharmaceutical and therapeutics (PandT) sub-committee may be required in

large tertiary cancer centers. This sub-committee will do more specialized drug evaluations and bring final recommendations to the general PandT committee.
- The process for doing evaluations should be clear on how to request, review, evaluate, approve, and follow-up.
- The evaluation process should be delivered clearly, and a well-defined framework of approving drugs should be defined including what would be acceptable or would not.

Establish disease registry/data

- The plan should be based on actual data not assumption, and therefore, it is critical to have accurate data about the number and types of cancer cases managed at the facility and type of treatment required.
- Patient management and outcomes should be benchmarked against international data such as the American Society of Clinical Oncology Quality Oncology Practice Initiative (ASCO QOPI) or Surveillance, Epidemiology and End Results data.[16,18-20]

Education

- Ownership of the idea of conserving resources is important for staff compliance and cooperation with the principles of cost-effectively. Understanding, how the decisions are made will increase the awareness of the staff and enhance their participation in various initiatives.

Pharmaceutical and therapeutics committee

Evaluation of drugs is very challenging, especially for the purpose of assessing their benefit to the patients and the economic impact on the hospital. Depending on the size of oncology service, there should be a dedicated entity, like a PandT subcommittee for oncology, to help in evaluating the cost-effectiveness and EBM of medications.[10,21] The committee's role is to evaluate new medications, selection of medications, and approval of medications that are needed and monitor their use.

Establish an oncology-specific subcommittee

Establishing an oncology-specific subcommittee will enable the clinicians to weigh in the decision, as they are the front-line staff who are dealing with the patients and have a better grasp and feeling of the impact of the treatment on patient outcomes. They understand the whole disease impact and the available alternatives. This subcommittee will address all issues related to oncology medications, such as full clinical and economic evaluation, and guidelines for prescription and monitoring and delisting.

Establish policies and procedures

Establish clear policies and procedures for the function of the committee including the composition of the committee, which should include practicing oncologists, clinical pharmacists, and experts in health and pharmaco-economics and EBM. The process for selecting, evaluating, and approving medications should be clear. Monitoring the utilization also should be addressed.

Referral process of medications

There are multiple ways a medication is referred for review to be added to the formulary, these include:
- Scan horizon by looking for newly approved drugs or innovative treatments and request adding them.
- Request by individual practitioner based on emerging data in the most common scenario.
- In rare occasions, leaders may request medications or treatment modality based on news or patients request or strategic decision.

Medication selection and approval

- There should be the clear adoption of a particular framework, such as ASCO, European Society of Medical Oncology, National Comprehensive Cancer Network, or others to evaluate medication.[17,22-24]
- Consider alternatives such as biosimilar or generics.[25]

Price negotiation

There are multiple approaches to get a discounted price on medications dependent on the indication, the benefits, and the availabilities of other options (competitors). One of the basic requirements is to have a system of interacting with suppliers in open and transparent way and be able to interact directly with them to negotiate the best deals. A risk-sharing approach is usually welcome by many major pharmaceutical companies, and it may take different approaches.

Direct discount is the first step, especially if the evaluation revealed the lack of cost-effectiveness of a particular medication. The hospital may get further discounts or risk sharing for other products that are already on the formulary, which will result in cost savings that can be utilized to get more products.

Enforce patient education and public awareness

Education of patients and public awareness may help in many ways to address issues related to access, such as understanding that not all medications available in the market will be suitable for them and alternatives should be discussed with them to make a choice. Patient advocacy groups may help facilitate access to medication through policymakers.[26]

Monitoring

The addition of medication to the formulary, even for use as a nonformulary, should be monitored by the organization to make sure that the medication is used per indications and for the right patients.

Delisting

There should be a regular systematic review of the formulary to delist the unused medications and unneeded medications that were replaced by better medications. This may require a class review to determine the best choices for the institution, such as tyrosine kinase inhibitors in lung cancer.

Pharmacy

Pharmacy staff play a major role in providing quality access to cancer medication and contributing to cost savings, including the following.

Monitoring utilization/medication control

- Adhere to clinical guidelines and algorithm and capture any new deviation from the guidelines.
- Report deviations to the leadership of the department and devise plans to address them.

Managing inventory/supply chain

This ranges from selecting the right vendors and requesting the right amount of drug to monitoring inventory and shelf life of medications.

Minimize waste

- There should be access to a policy on dispensing medication and avoid waste.
- Monitor waste systematically and implement quality projects to reduce waste.

Exchange program

- Establish agreement with other hospitals to share expensive or rarely used medication or medication needed with short supply.

Control refills

- The pharmacy should dispense a supply for one cycle only and request patients to bring back leftover or empty boxes to be reviewed and assure adherence to treatment.

Ensure education

- Counsel patients and their families about the proper use of medications, the importance of proper storage, and the importance of returning all remaining medicines.

Physicians

Physicians are the main gatekeepers in the utilization of cancer medications, as they are the ones who will have the clinical expertise and the responsibility to discuss with patients their treatment options and then prescribe them. Physicians should be supportive of cost-effectiveness data use.[27]

Adhering to guidelines

- Internationally accepted guidelines should be adapted to the hospital setting in a multidisciplinary fashion to assure selection of the best choice for their settings. The guidelines and pathways should be implemented and monitored to assure adherence to these guidelines.

Encourage delisting

- When requesting the new addition of a medication, a decision about existing medication should be made and encouraged to eliminate redundancy.

Do proper clinical trials

- Clinical trials are one ways to have access to new agents and should participation be encouraged. However, marketing studies with no added value should be avoided.
- Clear policy and agreement regarding post-trial access to medications should be addressed.

Patients and families

Having educational training, information sharing, and counseling of the patient and families will be very helpful in the access to medications.

Proper use of medication

- Ensuring the education of the patients and families about the goals of care and the proper use of medication can lead reduce waste. Encouraging patients to bring the leftovers will help evaluate compliance and can also help other patients in need based on the specific medications and existing policies.

Make your voice heard (advocacy)

- The patient representative should have a say in the process of obtaining certain medication and also contribute to the societal debate about the distribution of healthcare resources and services/medication made available to patients.
- Patients and families should be advised to raise their concerns about medications through the proper channels.

Pharmacovigilance

Establishing pharmacovigilance in the institution by creating a hotline or mobile application for the patient and healthcare provider to use is a good way of accessing the information related to management, indication, and medication prescription.

Conclusion

Access to quality cancer therapeutics requires a multilevel, multidiscipline approach to optimize the results. This article will serve as a guide for these individuals and entities. The roles of each stakeholder are listed, and having a comprehensive approach will assure better utilization of these recommendations.

Recommendations

The expert panel recommends that facilities that offer cancer treatment should assemble a team from stakeholders and decision-makers listed in this article to review all suggested interventions and adapt what is appropriate to their own setting and circumstances.

Monitoring certain indications and key performance indicators for each major activity are important to assure continuous improvement and containment of the expenditure.

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Conflicts of interest

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