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# Survey investigating the knowledge and awareness of payers and patient advocacy groups about the health technology assessment process in Lebanon

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**Abstract**

The survey aims to assess the knowledge and awareness of Reimbursement Bodies (RBs) and Patient Advocacy Groups (PAGs) in Lebanon and the possible involvement of patients in the health technology assessment (HTA) process in the absence of a well-established HTA structure and to identify the actions to be taken at this level. Structured questionnaires were administered to eleven key participants from both RBs and PAGs. The survey utilized two different questionnaires, each composed of two open-ended questions and ten close-ended questions. RBs recognized the need for clinical and technical guidelines to optimize the HTA process, whereas PAGs stated that they are familiar with the current assessment and reimbursement process. A lack of interaction between the payers and the PAGs was reported mainly due to the absence of laws that involve patients in the assessment process. All the payers and three out of five of PAGs encouraged the involvement of PAGs in the assessment process. They reported that patients require support, education, and training to be efficiently involved. A short-term plan for involving patients in the assessment process can be implemented in light of RBs' and PAGs' openness for such involvement. In the long run, the collaboration between both parties needs to be more formalized and structured. Education and training programs are to be suggested for other PAGs. The institutionalization of an HTA body that unifies all the fragmented RBs, including a patient's representation to optimize the reimbursement process and to engage patients, is recommended.

## Introduction

The move toward universal health care has led to a constraining rise in global costs. It has also stimulated interest in more appropriate use of health interventions to maintain access. Governments implemented several mechanisms to provide universal coverage and promote innovations while encouraging efficient and effective use of health technology (1;2).

Health technology assessment (HTA) is a form of policy research that examines the short- and long-term consequences of using a health technology (3).

A recent paper published in April 2020 proposed a new definition of HTA: "HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system" (4).

In fact, HTA is a complicated deliberative process that balances evidence provided from a range of sources with the views and opinions of stakeholders, using value judgments to determine the policy decisions. Effective patient participation in HTA is necessary to create a fair process requiring a two-way flow of information, not just information-giving or limited consultation on selected components (5).

In fact, researchers who can simplify and clearly explain treatment pathways can, on the other hand, gain valuable knowledge from patients. Patient organizations can also work with their members to determine preferences using standard methodological techniques leading to utilities. Additionally, the members can serve as channels to undertake surveys on costs of care (6;7).

The extent of patient involvement in HTA varies considerably between countries. HTA bodies and patient organizations have reported a positive impact of patient involvement on the processes and/or outcomes of HTA (8). The HTA International Interest Sub-Group for Patient and Citizen Involvement has developed values and quality standards for patient involvement in HTA via an 18-month research process (9).

## Commentary

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These values recognized in the European Patients Academy on Therapeutic Innovation (EUPATI) Guidance on Patient involvement with HTA include: (i) relevance when patients have unique knowledge, perspectives, and experiences that contribute to essential evidence for HTA; (ii) fairness as all patients have the right to contribute to the HTA process; (iii) equity by seeking to understand the diverse needs of patients with particular health issues; (iv) legitimacy as patient engagement increases by contributing to the decision-making process's openness, accountability, and credibility; (v) capacity building as patient involvement processes break the barriers of preventing patient involvement in HTA and build capacity for patients and HTA organizations to work together (10).

Worldwide, patients play a critical role in the assessment process performed by different HTA bodies (10). Since 2010, the Canadian Agency for Drugs and Technologies in Health (CADTH) created opportunities for patient groups to contribute to HTAs in the Common Drug Review (CDR) process. In each new drug assessment, the CADTH invites patient groups to share their perspectives via a written template (11).

Patient groups respond to questions to provide their perspectives regarding the impact of a disease on patients and their families, experiences with current therapies, and hopes regarding the drug under assessment. Patient group input is sought early in the process, so patient insights can be included within the assessment protocol and the assessment reports. These reports go to the CADTH Canadian Drug Expert Committee (CDEC) for an independent review and are used as the basis for deliberations when making reimbursement recommendations (12).

In 2016, a new collaboration called "Shared Decision-Making Collaborative" came into being and it comprised of leading healthcare organizations and individuals in the United Kingdom (UK). Its members include the National Health Service (NHS) England, the General Medical Council, professional bodies, patient organizations, and universities such as the National Institute for Clinical Excellence (NICE). This group has set out plans that will increase patients' involvement in decisions about their care (6).

### *Reimbursement Bodies and Patient Advocacy Groups*

Lebanon is an upper middle-income country. Its surface area is 10,452 $km^2$ with an estimated population of 4,421,000 inhabitants and a current health expenditure of 936 USD per capita in 2017 (13). Lebanon is characterized by a highly fragmented healthcare system and the Lebanese population is covered by many RBs. The Ministry of Public Health (MoPH) covers almost 46 percent of the population, whereas the others are covered by the National Social Security Fund (NSSF; 28%), military schemes (9%), Civil Servants Cooperative (5%), and private insurance and Out of Pocket (12%). This fragmentation is further characterized by a diversity of supervising authorities, making regulation and coordination very complicated (14).

The NSSF has establishe a mandatory insurance, enrolling all workers in the private sector. It covers 90 percent of hospital bills (through direct payment), whereas it reimburses 80 percent of fees paid by patients for ambulatory care (including medications), and 95 percent of fees for selective diseases like cancer. The NSSF often provides speedy reimbursement for drugs to treat certain diseases such as cancer, multiple sclerosis, chronic hepatitis, and postorgan transplantation (15).

Civil Servants Cooperative (CSC) is a public institution with administrative and financial autonomy. It covers around 3 percent of the Lebanese population. The civil servants insured are the public sector employees who abide by the laws of civil service. CSC covers 90 percent of hospitalization costs and 75 percent of outpatient services including dental care. For dependent family members, CSC covers 75 percent of hospitalization and 50 percent of ambulatory care (16).

The MoPH covers the remaining uninsured population. Expensive drugs are dispensed free of charge from the MoPH drug store directly to citizens suffering from cancer, mental illnesses, multiple sclerosis, and other morbid diseases (16). It covers 85 percent and 95 percent of hospital bills for private and public hospitals, respectively.

The financing of the healthcare system in Lebanon includes a blend of different approaches, whether it is financed by taxpayers' contributions like the MoPH (Beveridge model) or the social health insurance model (Bismarck model) or a blend of both like the NSSF, or even an out-of-pocket approach that also exists in Lebanon. The tutelage, entitlement, coverage, and sources of financing of the main RBs are presented in Table 1.

Patient Advocacy Organizations or Patient Advocacy Groups (PAGs) provide patient- and caregiver-oriented education, advocacy, and support services. In Lebanon, PAGs are formally organized, nonprofit groups that concern themselves with medical conditions or potentially life-threatening medical conditions. Their mission is to support people affected by those medical conditions or to support their families. These organizations advocate for and provide services to people with physical and mental conditions such as cancer, mental illnesses, diabetes, and cardiovascular disease via different platforms, including outreach programs, meetings, counseling sessions, Web sites, and published materials (17). A PAG usually seeks to raise public awareness of a disease's symptoms, risk factors, and treatment options and promotes research to cure or to prevent that disease (18).

According to a recent study assessing the current and future status of HTA implementation in countries of the Middle East and North Africa (MENA) region, HTA is still in an early stage of implementation with some heterogeneity among countries. The institutionalization of HTA has already been initiated in selected MENA countries (19). However, the healthcare sector in Lebanon lacks an independent HTA to perform the assessment of interventions and only committees appointed in each RB are held responsible for including HTA input into policy decisions. Each RB has its own regulations to assess technologies and finance the healthcare sector. This usually occurs with a clear absence of patients' involvement in any of the laws and regulations implemented by these bodies. The idea of involving patients in the reimbursement process is new to the country, and there is a need to examine and understand the point of view of the payers, RBs, and PAGs around this topic to suggest a certain framework of action. The results of an international survey conducted in eleven developed countries in 2017 addressing patient advocates and members of patient organizations about their experiences and perceptions showed that considerable progress has been made in terms of engaging patients and patient groups in HTA over time. However, gaps remain in how involvement is supported, including facilitating involvement, clarity on roles, two-way flow of information, and methods for enhancing communication between patient organizations and HTA agencies (20).

To our knowledge, none of the developing countries in the MENA region has focused specifically on this issue, to date.

**Table 1.** Main reimbursement bodies: tutelage, entitlement, coverage, and sources of financing

| Funding body | Tutelage | Entitlement | Population coverage (%) | Description of coverage | Financing |
|---|---|---|---|---|---|
| NSSF Maternity and Sickness Fund | Ministry of Labor | - Employees of the formal sector<br>- Contractual and wage earners of the public sector<br>- Employees of autonomous public establishments<br>- Teachers in public schools, taxi drivers, newspaper sellers, university students, physicians starting February 2001 | 28 | Pays directly 90% of hospital bills, reimburses 80% of fees paid by the patients for ambulatory care, and 95% of fees for some type of diseases like cancer | Employer: 12% of salary (7% starting April 2001)<br>Employee: 3% of salary (2% starting April 2001)<br>- Government: 25% of total expenditures + the employer share for government contractual and wage-earners + Contributions for taxi drivers, students, and newspaper sellers |
| CSC Health Fund | Presidency of the Council of Ministers | Regular staff of the public sector and dependents | 5 | Covers 90% of hospitalization costs and 75% for outpatient services including dental care | Government budget (of which 1% deduction of the payroll) |
| Military Schemes | Ministry of Defense/ Ministry of Interior | Uniformed staff members and their dependents | 9 | Ambulatory and hospital care (100% for the member, 75% for the spouse and children, 50% for dependent parents)<br>Government budget | Government budget |
| MoPH | Ministry of Public Health | Uncovered Lebanese | 46 | Covers 85% and 95% of hospital bills for private and public hospitals, respectively<br>Dispensing expensive drugs free of charge for cancer and rare diseases<br>Providing vaccines and essential drugs to the public through a network of Primary Healthcare Centers | Government budget |
| Private Insurance and Out of Pocket | Ministry of Economy and Trade | Voluntary enrollment | 12 | Variable | Households (risk-based premiums) – Employers and employees for complementary insurance |

MoPH, Ministry of Public Health; NSSF, National Social Security Funds; CSC, Civil Servants Cooperative.

The objective of this survey is to assess the knowledge and awareness of RBs in Lebanon and the possible involvement of patients in the HTA process performed by these bodies. This also provides a situational analysis of selected PAGs and their level of information about the assessment process of technologies established in the country and their point of view when it comes to their capabilities and active involvement in the policy decisions. Finally, the potential implementation of a patient-centered healthcare assessment and recommendations about actions to be taken at this level will be suggested.

## Methods

Data collection was conducted between May 2018 and July 2018 via two structured questionnaires. The questionnaires were developed based on both the existing literature in this research area and the professional experience of the authors. These questionnaires ranged in length from 25 to 35 min and were administered face-to-face by a trained person who was a postgraduate researcher enrolled in Pharmacoeconomics and Market Access of Health Products Master's degree. Participants were assured of their anonymity and confidentiality of their responses. Written informed consent was obtained from each participant. This research protocol was approved by the Institutional Review Board of the Lebanese University. A permission to conduct the study was requested from the Lebanese University.

The survey utilized two written well-structured different questionnaires. Each questionnaire was composed of two open-ended questions and ten close-ended questions. The first questionnaire was administrated to the RBs, whereas the second one addressed the PAGs. The open-ended questions prompted participants to answer with sentences giving deeper and new insights into the subject.

The close-ended questions were divided into two categories: Category 1 for "Definition" to assess the knowledge about the process each group of participants is performing and Category 2 for "Awareness and Action" to assess the awareness of the participants in the study and evaluate the efforts made by the participants to create a framework of action.

Then, the open-ended questions were used to determine the level of knowledge of some basic definitions like reimbursement decision-making process for the payer's participants, definition, and name of an international well-known PAG for the PAG's participants. Questions about the role of PAGs in their involvement at the early stages of HTA and in providing real-world data and participants' needs for training and education to increase influence and advocacy capabilities were also addressed to both parties.

The selection of the options proposed for developing questions was provided during informal interviews with key people from the surveyed institutions, input from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Lebanon Chapter board members, some patients involved in patient support programs or patient access groups, and input from some academicians working in the field of health economics.

The structured questionnaires were administered to the RBs, providing health coverage for approximately 75 percent of the Lebanese population and for selected active PAGs, advocating and providing services for patients affected by different medical conditions. A PAG representative was mandated to express the collective views of the group on a specific issue or disease area. Eleven key participants from both RBs and PAGs were contacted. Key payers included four members of the tender committee at the MoPH, one member of the Department of Drug Control at the NSSF, and one member of the tender committee at CSC. These participants are considered as policy and decision makers at the level of their institution as they play an important role in the drug technical evaluation, reimbursement process, and pharmaceutical procurement policies and regulations. The sample of PAGs focused on those likely to have the highest influence on the public based on outreach, advocacy, and operating at the national level. These groups included the Lebanese Breast Cancer Foundation (LBCF) (21), Faire Face (22), the Barbara Nassar Foundation (23), Association Libanaise contre la Sclérose en Plaques (ALISEP) covering multiple sclerosis (24), and the Chronic Myeloid Lymphoma Group (CML group) (25). The person designated by the Advocacy Group as its interlocutor was chosen based on his/her seniority and his/her perfect knowledge of the healthcare system and its stakeholders. All of the approached groups were willing to participate in order to give their opinion on the decision-making process.

## Results

Participants from three RBs responded to Category 1 and Category 2 questions. All answers are aggregated in Table 2.

### *Responses from the Reimbursement Bodies*

The MoPH and CSC participants answered open-ended questions defining the reimbursement decision-making process by using mainly two keywords, "cost" and "access", without any additional information. However, the NSSF participant elaborated on the outcomes of the reimbursement decision-making process that has direct implications for sales prices through payment and rebates, and sales volume through drug approval or rejection. In addition, the NSSF participant declared that approaches used in making reimbursement decisions also impact patients and care providers through the availability of particular products, as well as payment and cost-sharing for drugs and devices, potentially leading to indirect effects on sales volume.

#### *Category 1 Questions: "Definition"*

All participants included "price" within the criteria used to make the reimbursement decisions. For respondents of the tender committee at the MoPH (two of total participants), "price" was the only criterion considered. Three of the participants used both "price" and "clinical effectiveness" for decision making, whereas only the NSSF participant considered "price," "clinical effectiveness," and "patient preference" all together. One participant

**Table 2.** Aggregated results from the reimbursement bodies' questionnaire

| Questions | Participants *N* (%) |
|---|---|
| *Category 1: Definition* | |
| The criteria you use in order to reimburse a new technology? | |
| Price only | 2 (33) |
| Clinical effectiveness only | 0 |
| Patient preferences only | 0 |
| Price and clinical effectiveness | 3 (50) |
| Price, clinical effectiveness, and patient preferences | 1 (17) |
| How can the assessment and the reimbursement process be optimized? | |
| Updating and implementing clear clinical and technical appraisal guidelines by the MoPH | 4 (66) |
| Adopting pharmacoeconomics methods by assessing value versus money | 1 (17) |
| Making the reimbursement process more organized in time | 1 (17) |
| Do you amend the reimbursement assessment process if needed? | |
| Yes | 5 (83) |
| No | 1 (17) |
| *Category 2: Awareness and Action* | |
| Do you know what a Patient Advocacy Group is? | |
| Yes | 6 (100) |
| If YES; the role of the Patient Advocacy Groups is to provide: | |
| Financial support to the patients only | 0 |
| Psychological support to the patients only | 0 |
| Financial and psychological support to the patients | 3 (50) |
| Financial and psychological support to the patients and can support the decision-making bodies about a certain a drug or technology | 3 (50) |
| Have you ever been contacted by any of the Patient Advocacy Groups? | |
| Yes | 2 (33) |
| No | 4 (67) |
| Do you communicate with any of the Patient Advocacy Groups during the assessment of a new intervention? | |
| Yes | 1 (17) |
| No | 5 (83) |
| Are Patient Advocacy Groups in Lebanon now capable of becoming active participants with the reimbursement bodies? | |
| Yes | 2 (33) |
| No | 4 (67) |
| Based on your experience, do you want Patient Advocacy Groups to be involved in the assessment and reimbursement process? | |
| Yes | 6 (100) |
| If Yes; the participation of Patient Advocacy Groups can be through: | |
| An independent committee of different patient groups | 4 (67) |
| Direct participation in the Reimbursement Bodies' committees | 2 (33) |

from CSC suggested using the pharmacoeconomics (PE) methods by assessing value versus money as optimization mechanisms. Five of the participants favored the reimbursement process amendment for an optimal resource allocation and improved medication access for patients.

In the participants' opinion, the reimbursement process is implemented to ensure the appropriate access of healthcare by reimbursing treatments and hospitalization costs. MoPH participants argued that the only way to optimize the reimbursement process is by updating and implementing clear clinical and technology appraisal guidelines by the MoPH. The Department of Drug Control at the NSSF had a different opinion and suggested optimizing the timelines of the assessment process.

### *Category 2 Questions: "Awareness and Action"*

All RBs' participants are aware of the existence of PAGs in Lebanon, understand the role they play worldwide, and acknowledge their influence on the decision-making process. Three of these participants stated that the role of these groups is to provide financial and psychological support to the patients. The other three added that PAGs could also support the decision-making bodies by providing them with data and information about a certain drug or medication. Only two of the participants reported that PAGs had contacted them and five of the participants reported that they never contacted PAGs during the assessment of any new medication that is not required by the law. In contrast, only one participant reported contact with PAGs. Only two participants sounded positive about the capability of PAGs in Lebanon of becoming active participants with RBs, however noting that they would need more education, training, awareness, and financial support. All six participants were positive about the involvement of PAGs, rather than individual patients in the assessment process of new medication. Moreover, four out of the six respondents suggested that the participation of PAGs could be through the formation of an independent committee of different PAGs that can issue official scientific feedback and data to be used as a compelling document upon the assessment of any new medication. Two participants suggested a direct participation of PAGs in the RBs' committees.

The involvement of patients through PAGs in the assessment process can bring an added value according to all participants.

For the PAGs' contact, the communication was in the early stages of hemophilia medication purchase to the MoPH, where the payer was trying to get more information about the described hemophilia cases, the medications needed to be provided for each category of hemophilia patients, and the number of patients in each category. PAGs also need to be unified to create a more powerful voice.

The cumulative responses gathered from open-ended questions suggested that patient input can provide data about adverse events, toxicities, and safety. PAGs provide real-world data, a clear clinical view of the Lebanese population that is usually not provided in many clinical studies and that can help in defining and setting protocols and guidelines more precisely. A lack of economic and medical knowledge is the common challenge that all RBs might face with PAGs, in addition to the subjectivity of patients in certain areas and the lack of understanding of budget constraints and regulations. Hence, an education and training plan for PAGs with respect to the aspects of HTA turned out to be crucial.

In total, participants from five PAGs responded to Category 1 and Category 2 questions. All answers are aggregated in Table 3.

**Table 3.** Aggregated results from the patient advocacy group's questionnaire

| Question | Participants (%) |
|---|---|
| *Category 1: Definition* | |
| What is the exact role of a Patient Advocacy Group? | |
| Financial support to the patients only | |
| Psychological support to the patients only | |
| Financial and psychological support to the patients | 3 (60) |
| Financial and psychological support to the patients/Support the decision-making bodies about a certain a drug or technology | 2 (40) |
| Do you provide any educational programs to the patients? | |
| Yes | 4 (80) |
| No | 1 (20) |
| *Category 2: Awareness and Action* | |
| Do you know the reimbursement schemes in Lebanon? | |
| Yes | 5 (100) |
| No | 0 |
| Are you aware of the process that Reimbursement Bodies follow to assess and reimburse a certain drug? | |
| Yes | 4 (80) |
| No | 1 (20) |
| Do you contact any of the Reimbursement Bodies for a change in a decision they already took? | |
| Yes | 1 (20) |
| No | 4 (80) |
| Are the patients aware of the role that Patient Advocacy Groups play worldwide? | |
| Yes | 2 (40) |
| No | 3 (60) |
| Do you want to be involved in the Reimbursement Bodies' assessment and reimbursement process | |
| Yes | 4 (80) |
| No | 1 (20) |
| Are Patient Advocacy Groups in Lebanon now capable of becoming active participants with Reimbursement Bodies? | |
| Yes | 2 (40) |
| No | 3 (60) |
| If Yes, the participation can be through: | |
| An independent committee or scientific board | 2 (40) |
| Direct participation with tender and reimbursement committees | 3 (60) |
| What added value the participation of Patient Advocacy Groups can bring to reimbursement bodies | |
| Real-world data | 3 (60) |
| Increase credibility and transparency of Reimbursement Bodies | 1 (20) |
| Method to improve the reimbursement process | 1 (20) |

### Responses from Patient Advocacy Groups

Four out of five participants answered open-ended questions by defining PAGs as a formally organized nonprofit group of people dealing with patients suffering from the same disease and having common needs. The remaining participants extracted a sentence from the literature defining PAGs as "groups who educate, advocate for, and provide support services to patients and their caregivers." The European Cancer Patient Coalition (ECPC) was cited by only one participant as an example of a well-known PAG in Europe. The participant acknowledged that the role of this group ensures that the voice of cancer patients in Europe is represented in all relevant policymaking decisions in the European Union. In addition, the participant commended the ECPC work on raising awareness among policy makers about cancer issues affecting European citizens.

#### Category 1 Questions: "Definition"

Three of the participants agreed that PAGs' role is to provide financial and psychological support to patients and two of the participants added that PAGs play a key role in providing data to decision-making bodies to support them in the decision-making process. Education is provided to patients by most of the PAGs participating in this study (four participants) mainly about treatment modalities, medications, adverse events, and diet. Patients reach out to PAGs who never initiate contact with any patient. Patient Advocacy Groups promote themselves through social media, awareness activities, Web sites, and flyers.

#### Category 2 Questions: "Awareness and Action"

All PAG participants are aware of the reimbursement schemes in Lebanon. The majority of the participants (four participants) are familiar with the process each RB follows, based on their own experience with these bodies. Moreover, two of the participants stated that patients in Lebanon are aware of the role that PAGs play worldwide. Four out of five participants never contacted any RB. Only one patient group (CML group) contacted the MoPH regarding a reimbursement decision after it was taken and successfully reversed the decision: the MoPH made a drug used for the treatment of CML available after the PAG supported them with additional information and data.

In addition, four out of five participants were positive about being involved in the assessment process of technologies with the RBs. As for their capability of becoming active participants, one of the four participants suggested that an independent committee or scientific board should be formed to submit to the governmental bodies' useful data and information to be used in the assessment process. Another participant suggested a direct participation with tender and assessment committees established within different Reimbursement Bodies rather than being independent of these committees.

All groups argued that their participation could bring an added value to the RBs assessing the process. Three groups suggested providing the governmental bodies with information about the new medications available worldwide and real-world experience from patients and problems they face, if any. One group suggested methods to improve the reimbursement process and discuss the pricing of drugs with the MoPH, whereas the last group commented that its involvement could increase the credibility and transparency of these RBs.

According to all PAG participants, reimbursement is a process that financially supports patients to ensure access to advanced health technologies. The participants who never contacted an RB linked this lack of interaction to the absence of laws that mandates the involvement and the participation of patients in the process and to the lack of both human and financial resources in PAGs.

Finally, PAG participants were asked about their opinion in regard to involving them in the early stages of an HTA, such as identifying technologies for the assessment and prioritization process. PAG participants recognized their lack of knowledge and skills required to contribute effectively to HTA decision making. They sought urgent training and education on the mechanisms of their involvement in the HTA process, as well as the provision of good medical and economic education to increase their influence and advocacy capabilities.

A summary of key findings based on the survey results is presented in Table 4.

## Discussion

The study aimed to investigate the knowledge and awareness of the key payers and PAGs about the HTA process implemented in Lebanon.

Upon asking the RBs in Lebanon about the reimbursement criteria they use, a single common criterion was reported, although using a single criterion will underutilize important other factors, leading to choices based on an ad-hoc priority-setting process (26). The use of multi-criteria decision analysis (MCDA) as a decision-making tool takes into account multidimensional factors and enables a comparison of medical technologies by combining individual criteria into one overall appraisal (21). Only one participant, representing the NSSF, reported the possible use of QALY and patient preference, whereas half of the payers' respondents claimed that they use both price and clinical effectiveness in the evaluation process. These results are compatible with the WHO report that suggests the use of cost-effectiveness approaches to access essential new medicines in Europe and evaluates new medications based on different aspects and not only price (13;22). MoPH decisions in Lebanon are price-driven due to the limited budget allocated by the government (13). This is supported by the regulation upon which purchase decisions are made in price-based tenders. However, MoPH participants argued that the clinical effectiveness of medications or technologies are not disregarded, being a prerequisite for registration of any new drug or technology prior to getting the marketing approval through the technical file, clinical trials, and analytical tests. Unfortunately, the efficacy of an intervention demonstrated under ideal study conditions (explanatory trial) will not necessarily predict the effectiveness of the same intervention described under real-world conditions (pragmatic trial) (23). According to the NSSF key respondent, the use of cost-effectiveness methods is part of their strategy to provide adequate medications to all patients, while making efforts to work on better resource allocation, with no laws or regulations requiring reimbursement of the lowest priced drug.

In our study, the majority of RBs advocated a possible amendment of the current reimbursement process to better allocate resources. Both the MoPH and the NSSF agreed with the suggestion of modifying the reimbursement assessment process and adding some requirements; among those, the input of PAGs.

**Table 4.** Summary of key findings based on the survey results including both types of questions

| | |
|---|---|
| Knowledge of reimbursement bodies about assessment and reimbursement criteria and PAGs about the HTA process | Reimbursement bodies are aware that the appraisal of HTA considered a wide range of factors (MCDA) in addition to cost, effectiveness, setting evidence-based, and clinical practices guidelines. PAGs are familiar with the current assessment and reimbursement process. They are aware of the role that patients play worldwide in providing a clear input of evidence in the HTA process. |
| Responsibilities of PAGs as patient representatives and their role in the assessment and reimbursement process | Both reimbursement bodies and PAGs stated that PAGs' main responsibility is to provide financial and psychological support to patients.<br>PAGs raise awareness among its members on the HTA process. Reimbursement bodies are aware of the influencing role of PAGs worldwide in supporting the decision-making bodies with data and information about technologies. PAGs recognized their engagement as active partners with different HTA bodies in the world. |
| Communication between reimbursement bodies and PAGs during the assessment and reimbursement process | Both reimbursement bodies and PAGs mentioned a lack of interaction between them due to the absence of laws mandating the involvement of PAGs in the HTA process.<br>PAGs and reimbursement bodies are aware that public engagement is highly important for ensuring more accountability, credibility, and transparency. |
| Capabilities of PAGs to be involved in the reimbursement bodies' decision making | Reimbursement bodies and PAGs agreed that PAGs are currently not capable of becoming active in the assessment process.<br>Reimbursement bodies and PAGs identified a need for education (medical and economic) training and financial support to increase PAGs' influence and advocacy capabilities. |
| Active involvement of PAGs with reimbursement bodies in policy decisions | Reimbursement bodies are willing to incorporate PAGs in the decision-making process because they can bring an added value.<br>PAGs would like an involvement in the form of joining independent committees to collaborate for, and contribute to, the development and implementation of health-related policies. |

HTA, Health Technology Assessment; MCDA, Multi-Criteria Decision Analysis; PAGs, Patients Advocacy Groups.

This clearly indicates that payers are willing to incorporate PAGs into the reimbursement process.

More than half of the participants from both the MoPH and the CSC report that setting health economic guidelines is the first step toward optimizing the reimbursement process in Lebanon, making health care more consistent and efficient. This will close the gap between what clinicians do and what the scientific evidence supports. Implementing PE methods is also among the optimization techniques suggested, indicating that the RBs are open to the new advancements used worldwide to perform evaluations. These results are compatible with the WHO report that suggests the use of PE methods to evaluate new medications (24). On the other hand, the Department of Drug Control in the NSSF emphasized on setting timelines needed to reimburse a certain drug among other optimization strategies that the NSSF may adopt. This wide spectrum of suggestions, apparently tailored for each RB, is the result of a fragmentation in the reimbursement schemes in Lebanon and the different processes each body follows.

Participants from both groups provided similar definitions for PAGs. However, mixed answers were reported about their exact role. This heterogeneous image indicates that two types of PAGs exist in the country: the first provides only financial and psychological support to patients, whereas the second believes that, besides this supportive role, PAGs advocate and support the decision-making bodies. These results also indicate that payers have different perceptions about PAGs, because half of the RBs suggest that PAGs' role is to provide only financial and psychological support to patients.

A lack of interaction is reported between RBs and PAGs at the level of decision making. This is mainly due to the absence of laws and regulations that obligate and control patients' involvement. In one instance, the reported contact between the hemophilia group and the MoPH, at the early stages of the drug purchase, indicates that a possible collaboration can potentially aid payers to better allocate resources. Another example is the CML group, which was capable of successfully changing a decision concerning the marketing authorization of a nonqualified drug and replacing it with a more effective one. These two reported incidents show the supportive role that PAGs can provide to decision-making bodies. Laws and regulations should exist to encourage interaction in a structured manner. According to Wortley, the role of public engagement assumes high importance if the existing system lacks transparency and does not provide a voice for patients (25).

Although feedback from HTA agencies to patient groups about their submissions is often not provided, HTA bodies in many countries encourage patients and PAGs to become active partners and provide capacity building and training for all participating patients (20). This aligns with our study results that demonstrated the importance of providing education to patients. Most of the participants from both PAGs and RBs argued that currently, patient groups cannot actively participate with payers. They need further education, training, and financial support to become more influential and increase their advocacy capabilities (27). The European Patient Forum (EPF) mentioned in its report that capacity building for patient involvement in HTA should not just entail educational and training activities; it should also include organizational and workforce development, leadership, and resource allocation. Participants in the EPF survey also stated that PAGs need to join forces and engage more patients to increase their influence (28).

Participants from both RBs and PAGs encouraged patients' involvement in the assessment and reimbursement process. PAGs are representatives of the Lebanese population and can provide payers with data about adverse events and toxicities, data that potentially cannot be provided by clinical trials. On the other hand, PAGs want to be involved with the payers, as their involvement can enhance the decision-making process. In addition, more

than half of the participants, from both parties, reported that the most efficient way by which of such involvement can be ensured is in the form of the constitution of an independent committee composed of different representatives from different PAGs. This committee will submit an official report, along with available data and information concerning any topic under discussion. This mechanism of involvement is similar to the one used in the CADTH by which patients provide an official submission document that is incorporated subsequently in the CDR process (25). As all countries or collaborations that undertake HTA, and based on Facey et al. (29), we should consider how Lebanon can elicit the needs, preferences, and experiences of patients to support the creation of patient-centered healthcare policies.

One of the limitations in our study is the inclusion of a small number of participants. There is also a risk of selection bias, given the nature of the sample based on which the study was conducted. An under- or overestimation of a question could be experienced by a participant, leading to an information bias. Besides, the methodology used in this study was complex using different questionnaires and different types of questions. For this purpose, further studies using the same questionnaire for both groups are needed in order to obtain clearer and more definitive answers.

## Conclusion

The present study reveals that RBs show openness toward patient involvement in the HTA and reimbursement process, despite the lack of mutual learning, capacity, and interaction between PAGs and RBs in Lebanon. PAGs also seek this kind of engagement, yet, several limitations remain: the absence of financial support, poor training, low awareness, and the lack of proper laws and regulations. The study also shows that it is not so much a matter of the lack of knowledge as much as the lack of training.

The collaboration between both parties needs to be formalized and structured. HTA bodies would invest in the collection of robust evidence from patient organizations about the burden of disease, experiences of living with the disease, unmet needs, and the technology, in a similar way that investment is made in clinical and cost-effectiveness assessments. PAGs are encouraged to be proactive in approaching RBs to begin discussions about involvement, but the burden also lies on RBs to be creative and reach out to new patient populations to ensure that willing participants are not excluded. Education and training programs are to be suggested for other PAGs in the near future. It is also recommended to institutionalize HTA and unify all the fragmented Lebanese RBs while including patient representatives to optimize the process.

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