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ORIGINAL ARTICLE

Improving fund allocation in Iran Health Insurance Organization by applying internal reference pricing: a policy brief

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Abstract

Background Improving healthcare quality services is one of the governments' major commitments, which often faces budget constraints. Addressing this challenge requires that health insurance companies set great store by productivity and performance. However, not only are health insurance companies plagued by productivity negligence but, also, many low- and middle-income countries often place a low priority on performance.

Methods Among many strategies which could influence optimal resource use in health insurance companies, this paper picks up on internal reference pricing (IRP). In this study, we first reviewed the literature on the advantages and disadvantages of IRP policy implementation. Then, we calculated the financial impact of each decision and held an expert panel to explore the best method of implementation and some recommendations for mitigating unwanted results.

Results This policy implementation can potentially bring about a 1.5 million US dollar annual saving for Iran Health Insurance Organization (IHIO).

Conclusions In the wake of the recent budget deduction of the IHIO, a package of cost-containment methods was proposed, which, among others, included IRP. To streamline a policy, policymakers need to be fully aware of its advantages and disadvantages and keep its implementation barriers in proper perspective. All aspects of IRP have been fully elaborated in this paper to help health managers with evidence-based policymaking.

Keywords Pharmaceutical policy · Reference pricing · Insurance, health · Cost control · Review

Introduction

Improving healthcare quality services is one of the governments' major commitments (Acosta et al. 2014; Tang et al. 2004). Budget constraints is the most important hurdle for many health systems all over the world in providing high-quality services. Growing life expectancy, aging populations, and increasing costs of medical treatments contribute to a steady rise in healthcare expenditures. Accordingly, Iran's health share of its gross domestic product (GDP) almost doubled from 3.7 to 6.9 over two decades, i.e., from 1995 to 2014 (Health expenditure, total (% of GDP).

Based on Pourmohammadi et al., Iran ranked 8th in health system finance among the Eastern Mediterranean Region (EMR) countries in 2014 (Pourmohammadi et al. 2018).

There are several insurance companies in Iran, the most important of which is Iran Health Insurance Organization (IHIO). This insurance organization provides health services for almost 50% of the whole Iranian population, amounting to about 40 million. In addition to a quick rise in the number of the covered population between 2014 to 2016, thanks to the government's new healthcare plan which intends to increase the population coverage of basic health insurance and reduce out-of-pocket (OOP) payments for inpatient services, Iran's

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increasing population, increasing demand, and increasing cost of health services have convinced policymakers to introduce a range of cost-containment policies to curb health expenditure, specifically pharmaceutical costs (Moradi-Lakeh and Vosoogh-Moghaddam 2015).

Pharmaceutical pricing and purchasing policies are determining factors in drug expenditures. Some examples of these cost-containment policies are price cap, price negotiation, reference pricing, index pricing, and volume-based pricing policies (Acosta et al. 2014).

In this article, the implementation of internal reference pricing (IRP) is reviewed as a method for mitigating the pharmaceutical expenditure burden on public health insurances.

This policy, which is alternatively referenced in the literature as reference pricing, reference-based pricing, maximum allowable costs, best available prices, and minimum pricing, was first introduced in Germany in 1989 (Barros 2010). Reference pricing is divided into two subsets. (I) External reference pricing, which has been used in Iran for a long time, is a method to set medicine prices using a benchmark of price in reference countries. In addition, it can be used as a negotiation leverage between governments and pharmaceutical companies. (II) IRP is based on a comparison between new medicine prices with prices of reference medicines at three different levels: (a) medicines with identical active ingredients, (b) medicines that are related pharmacologically but may have different indications, and (c) all medicines in all classes used for a particular indication. Iran's health insurance has recently planned to implement these methods.

In IRP, the price of the reference medicine is reimbursed and patients have the option of purchasing drugs that are more expensive than the reference ones (cost share drugs) and pay for the extra costs. In this case, policymakers just set the reimbursement price. However, manufacturers, distributors, or retailers are free to set their own drug prices (Grootendorst et al. 2001). Iran implements different pricing policies in different circumstances, such as cost plus for non-innovative, locally produced medicines, external reference pricing for imported medicines, and generic reference pricing for reimbursement. In the wake of the recent budget deduction of IHIO by 107 million US dollars (at an exchange rate of 37,000 Iranian rial for each US dollar) in 2017, a package of cost-containment methods was proposed, which, among others, included IRP.

Materials and methods

For evidence-based policymaking, policymakers need to be fully aware of the advantages and disadvantages of each policy before implementation. Each new strategy in pricing and reimbursement may lead to positive and negative results in both health outcome and health system cost. Therefore, policymakers should be informed about the pros and cons of targeted policy to use its positive effects and reduce its negative ones. As the IRP policy is proposed to be implemented in IHIO, in this study, as a policy brief, we tried to provide relevant evidences to policymakers in a scientific manner.

Two main strategies were employed in this study for addressing the aim of the study. First, analysis of the associated documents, reports, and published literature to collect appropriate data. The literature review was done by three researchers in different databases, including PubMed, Google Scholar, and Scopus. After extracting published policies, their impacts on access, costs, and health outcomes were assessed.

In the second step, we calculated the financial saving of this policy for non-steroidal anti-inflammatory drugs (NSAIDs) based on their defined daily dose (DDD), their dosage form, and their official price in Iran. NSAIDs are frequently chosen for applying IRP because their efficacy and safety profiles are similar.

Finally, the expert panel discussion took place in Iran Food and Drug Administration (IFDA) in 2017 with regulatory experts and directors, as well as academic experts in pharmacoeconomics, to improve our evidence with their opinions. They had at least 3 years of experience in the health insurance system and had direct involvement in decision-making. The total number of focus group participants was 15 (6 females and 9 males). All the discussions were transcribed for thematic analysis. In this focus group, we evaluated different aspects of IRP policy and tried to explore the best way to implementation, which can mitigate unwanted results.

Results

Many countries, such as Canada, USA, Australia, New Zealand, the Netherlands, Denmark, Sweden, Spain, Belgium, Italy, Poland, Slovenia, and Germany, use the IRP method. Although most countries just apply generic reference pricing, some countries such as the Netherlands, Canada, Germany, and Australia also apply reference pricing to identical chemical and therapeutic classes (Drummond et al. 2011; Grootendorst et al. 2001; Kaló et al. 2007).

By changing its policy from external to internal reference pricing in 2005, Denmark succeeded in decreasing drugs prices, patient copayments, producers' revenue, and healthcare expenditures (Kaiser et al. 2014).

Different countries have different experiences with IRP and the selected therapeutic category. Mardekto and Kos' study showed that therapeutic reference pricing (TRP) is an effective cost-reduction policy for proton pump inhibitors (PPIs), angiotensin-converting enzyme inhibitors, and lipid-lowering agents in the Slovenian healthcare system, which affects medicine market dynamics on all therapeutic classes and medicine prices (Marđetko and Kos 2018).

The Ministry of Health in Canada started a reference drug pricing program in 1995 with histamine2 receptor antagonists, non-steroidal anti-inflammatory agents, and nitrates; afterwards, angiotensin-converting enzyme inhibitors and calcium-channel blockers were added to this program (Hazlet and Blough 2002).

Marshall et al. evaluated the implementation of reference pricing in Canada for common gastrointestinal drugs, including all histamine-2 receptor antagonists and PPIs. Although evidence shows the success of IRP in altering prescribing habits and reducing expenditures, there is also evidence of an increase in the senior citizen beneficiaries' financial burden (Marshall et al. 2002). In addition, the one-year implementation of the reference pricing of angiotensin-converting enzyme inhibitors in Canada failed to change the overall use of antihypertensive therapy and, conversely, caused a sustained reduction in drug expenditures (Schneeweiss et al. 2002). Similarly, Kaye et al. estimated the impact of the implementation of reference pricing for HMG-CoA reductase inhibitors (statins) in the US Municipal Health Benefit Fund prescription drug program through a retrospective data analysis. The results revealed that the implementation of this policy led to utilization rise and saving money, without an increase in members' copayments (Kaye et al. 2013).

By comparing prescription patterns, physician visits, and associated transactions (i.e., laboratory tests), emergency room visits, hospitalization, hospital length of stay, and vital statistics as a measure of health status before and after the implementation of histamine2 receptor antagonists reference pricing policy, Hazlet Blough noticed that it failed to change patients' health status (Hazlet and Blough 2002).

However, some evidence shows that the effects of the reference pricing method is limited and produce a small and short-lived reduction in pharmaceutical expenditure. It may be attributed to the fact that the IRP usually does not cover patented drugs. On the other hand, in the case of IRP, companies may increase the prices of their other non-covered products in other countries; therefore, reference pricing cannot influence the quantities and structure of consumption because, by lowering prices for the relevant drugs, an increase in the extent of demand elasticity would be expected (Barros 2010; Puig-Junoy 2005). In addition, in some cases, it might be associated with more frequent visits to the physician to switch to (an)other drug(s), and the replacement of relatively more expensive drugs, with the same indication but without being directly targeted by the reference pricing policy, is likely. Therefore, based on the premises of economic theory, setting a reimbursement rate based on reference drugs might prompt an increase in the prices of reference medicines. Although the literature points to the neutrality of this policy on health outcomes, some scientists believe that it may enhance some patients' health status and, as a result of the policy, they might need more acute therapy and more frequent hospital admissions, which could incur additional charges. Moreover, the impact of reference pricing is substantial only when there are large differences in the prices of drugs in a given group or cluster. It is also almost impossible to find therapeutically equivalent medications, which may decrease low-income or elderly patients' access to specific medications. Finally, medicine substitution might cause confusion and uncertainty for patients, consequently raising patients' or their private insurer's expenditures (Grootendorst et al. 2001; Marđetko and Kos 2016; World Health Organization, WHO 2015).

Above all, there is an argument against reference pricing that this policy may hinder pharmaceutical innovation, decrease patients' compliance, or, in some circumstances, even make patients quit the course of treatment because of the prohibitively expensive drugs (Ioannides-Demos et al. 2002). The points mentioned above are summarized in Table 1.

Lastly, one of the most critical questions that we are faced with is: how should we select reference products when there is some degree of efficacy differences among products, especially when there are different doses of the same substance which are not linearly priced? This question can be answered in two different ways, as follows:

1. Selecting the cheapest units of products. This approach leads patients to choose the lowest dose of the cheapest products. This approach also puts a burden on patients who require higher doses because of their worse medical condition (Kaló et al. 2007).
2. Selecting the cheapest products according to their price per defined daily dose (DDD). Since the price of different doses of products is not linear, this approach may lead to the prescription of the highest available doses, which are relatively or much cheaper thanks to the implementation of this method (Kaló et al. 2007).

Although this method is explicitly stated as a misuse of the DDD system by the WHO, it is common practice worldwide and we have also used this method for our calculations. Certainly, determining the relative value of different doses of different products of targeted groups based on economic evaluation studies and establishing the reference price based on its data is the most reliable method; however, it is not practical in all cases. Finally, there are several approaches to setting reference prices on minimum or average prices (Kaló et al. 2007).

In the next step, the information obtained from the literature review was reviewed and discussed by the expert panel. New issues were addressed, including evaluation of political and legal support and necessary information technology infrastructure for implementation of this policy. The necessity of specific strategies development to inform physicians and patients and prevent or limit social dissatisfaction by its step-by-step implementation was tackled, and then tracking and evaluating its consequences was undertaken.

Table 1 Analyzing internal reference pricing (IRP) policy

Effects	Favorable effects	1. Decrease drugs prices
		2. Decrease patients' copayments
		3. Decrease healthcare expenditures
		4. Improve prescribing habits
		5. Improve logical utilization
		6. Convince patients to choose cheaper medicines
	Unintended effects	1. Decrease producers' revenue
		2. Cause confusion and dissatisfaction due to lack of knowledge
		3. Increase patients' or their private insurers' payments
		4. Shift the total use of drugs in the reference drug groups to other groups, which may be more expensive
		5. Might increase the prices of the companies' other non-covered products
		6. Extend demand elasticity
		7. Increase frequency of physician visit to switch to another drug
		8. Might lead to irrational prescription
		9. Hinder pharmaceutical innovation
		10. Might make patients quit the course of treatment midway
	Equity	Although it may enhance low-income or elderly patients' access to specific medications in the targeted medical category, equity may improve due to better funds distribution in other categories.
Limitations		1. The effects of reference pricing beyond 2 years are not clear
		2. It is almost impossible to find therapeutically equivalent medicines
		3. It is effective when there are large differences in the prices of drugs in a given group
		4. Market response depends on the variability of therapeutic alternatives in market

Suggestions

Following the need to reduce the expenditures of IHIO, a three-step IRP policy has been suggested according to the related literature and expert opinions.

To begin with, the insurance coverage of a few brand medicines whose generic alternatives are now available on the domestic market should cease. Although, in Iran, the cheapest generic alternative has been the reference of reimbursement for a long time, there are still some cases of brand medicines on the insurance list. By applying the first level of IRP to 13 reimbursed branded drugs, including five medicines in transplantation, four in thalassemia, and four in multiple sclerosis, 6.7 million US dollars would be saved in IHIO annually.

Next, the second level of IRP should be applied. According to other countries' experience, NSAIDs are suggested for reference pricing, which could be followed by PPIs, H2 blockers, and antihistamines.

For working out the amount of cost saving in this policy, the financial results of therapeutic reference pricing are considered for NSAIDs, due to whose high consumption and similar safety and efficacy profiles are considered for IRP level II in many countries. Nine oral NSAIDs, tolmetin, naproxen, meloxicam, diclofenac, indomethacin, mefenamic acid, ibuprofen, celecoxib, and piroxicam are available on Iran's pharmaceutical market. Except for meloxicam and celecoxib, which are not reimbursed, and naproxen, which is reimbursed only for specialists' prescriptions, 70% of the price of the other NSAIDs in Iran are reimbursed by insurance companies.

Table 2 summarizes their consumption based on DDD, as defined by the WHO, for their most common indication. The cost of daily intake is sorted from low to high. Then, the extra copayment for each medicine is calculated based on the minimum price method.

The minimum daily treatment cost belongs to oral diclofenac (50 mg), which is about 3.6 US dollars per day.

In Table 3, the sales volume of each item was extracted from the official statistics sheets for the Iran pharmaceutical market in 2016 (statistics sheets). In cases where the drug has more than one dose, the sales volume of all doses was converted to the specific dosage, which is indicated in Table 2.

The total cost reduction for IHIO would be around 1.5 million US dollars annually if we proceed with the following three assumptions: (1) 50% of NSAIDs are sold without

Table 2 Available non-steroidal anti-inflammatory drugs (NSAIDs) on Iran's insurance list

No.	Generic name	Unit Price (US cents)	DDD (mg)	Pills per day	Cost of treatment per day (US cents)	Price reduction in daily expenditure (US cents)	Price reduction in unit price (US cents)
1	Diclofenac* (50 mg)	1.8	100	2	3.6	0	0
2	Piroxicam (10 mg)	2.4	20	2	4.8	1.2	0.6
3	Ibuprofen (400 mg)	1.7	1200	3	5.1	1.5	0.5
4	Celecoxib (100 mg)	3.2	200	2	6.4	2.8	1.4
5	Mefenamic acid (250 mg)	2	1000	4	8	4.4	1.1
6	Tolmetin (200 mg)	8	700	3.5	28	24.4	6.97

*Reference medicine

DDD, defined daily dose

prescription and paid for completely by patients; (2) 50% of prescriptions are paid for by other insurance companies, such as Social Security Insurance Organization (SCIO); and (3) only 70% of drug costs is reimbursed.

Discussion

Although such a significant amount of yearly cost saving is attractive for IHIO, the public's poor understanding and lack of knowledge regarding IRP may lead to the confusion and dissatisfaction of patients and physicians. In addition, it may cause a change in prescription patterns. For instance, patients and physicians may assume that lower-cost medicine is of an inferior quality and prefer to switch to other more expensive ones. So, it is recommended that this issue be taken into account via public education before policy implementation. To this end, pharmacists and physicians' expert opinions as primary sources of information about the IRP system should be enlisted. In addition, the experience of other countries such as Slovenia, which tried to address these concerns by handing out information leaflets to the public, should be considered (Marđetko and Kos 2016).

Although the IRP results may not be sustainable in the long term and ultimately lead patients to choose cheaper drugs, making producers reduce their prices for preserving their market share, and reducing the total use of drugs in the reference drug groups (Acosta et al. 2014; WHO 2015), we recommend taking advantage of this policy, even for a short period.

Conclusions

As mounting evidence suggests that the first and second categories of internal reference pricing (IRP) can reduce third-party drug expenditures in the short term, and the effects of reference pricing beyond two years are not clear, the next steps, that is, the improvement of cost-containment policies based on pharmacoeconomics studies, should be followed to maintain the achievements from the first step.

It is also worth noting that the third level of IRP, referencing the most cost-effective alternative in the same therapeutic group, is currently applied in Iran Health

Table 3 Predicted cost saving by implementing internal reference pricing (IRP)

No.	Generic name	Sales volume	Price reduction in unit price (US cents)	Total reduction (US dollars)
1	Indomethacin (50 mg)	1,028,076,581	0	0
2	Diclofenac (50 mg)	33,502,970	0.6	201,018
3	Piroxicam(10 mg)	871,484,811	0.5	4,357,424
4	Ibuprofen (400 mg)	410,480,720	1.4	5,746,730
5	Mefenamic acid (250 mg)	270,752,313	1.1	2,978,275
6	Tolmetin (200 mg)	11,501,300	6.97	801,805
Total				10,277,377

Insurance Organization (IHIO) in the case of some monoclonal antibodies seen in Crohn's disease and rheumatoid arteritis, reducing the cost to 3.2 million US dollars. Therefore, in future, the great cost reduction by cost-effectiveness studies will be expected.

Not only are health insurance companies plagued by productivity negligence, but, also, many low- and middle-income countries often place a low priority on performance. Among many strategies which could influence optimal resource use in health insurance companies, this paper picked up on IRP and its advantages and disadvantages as a policy brief.

Compliance with ethical standards The authors declare that ethical standards have been implemented.

Conflict of interest The authors declare that they have no conflict of interest.

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