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The Drug Reimbursement Decision-Making System in Iran

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A B S T R A C T

Background: Previous studies of health policies in Iran have not focused exclusively on the drug reimbursement process. **Objective:** The aim of this study was to describe the entire drug reimbursement process and the stakeholders, and discuss issues faced by policymakers. **Methods:** Review of documents describing the administrative rules and directives of stakeholders, supplemented by published statistics and interviews with experts and policymakers. **Results:** Iran has a systematic process for the assessment, appraisal, and judgment of drug reimbursements. The two most important organizations in this process are the Food and Drug Organization, which considers clinical effectiveness, safety, and economic issues, and the Supreme Council of Health Insurance, which considers various criteria, including budget impact and cost-effectiveness. Ultimately, the Iranian Cabinet approves a drug and recommends its use to all health insurance organizations. Reimbursed drugs account for about 53.5% of all available drugs and 77.3% of drug expenditures. Despite its strengths, the system faces various issues, including conflicting stakeholder aims, lengthy decision-making duration, limited access to decision-making details, and rigidity in the assessment process. **Conclusions:** The Iranian drug reimbursement system uses decision-making criteria and a structured approach similar to those in other countries. Important shortcomings in the system include out-of-pocket contributions due to lengthy decision making, lack of transparency, and conflicting interests among stakeholders. Iranian policymakers should consider a number of ways to remedy these problems, such as case studies of individual drugs and closer examination of experiences in other countries.

Keywords: drug registry, drug reimbursement, health insurance, Iran, policymaking.

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Introduction

Expenditures in Iran on pharmaceuticals (inpatient and outpatient) accounted for more than 23% of all health care costs incurred by the Social Security Organization (SSO) in 2011 (SSO, internal annual reports). Previous studies have shown that the Iranian pharmaceutical sector is complex and that the process of decision making about drug reimbursement is complicated [1]. Beyhaghi and Basmenji [2] concluded that the current system suffers from a lack of integration and clarity, and emphasized the need to implement a more transparent and consistent system. Delgoshaei et al. [3] attempted to describe major problems in the drug reimbursement process in Iran and pointed to undefined and unreliable mechanisms, a reliance on traditional price setting methods, and a disregard for insurer capacity to actively negotiate prices with suppliers. Other weaknesses mentioned by them included insufficient support for the vulnerable classes (e.g., the retired) and indigent groups and inadequate measures to promote rational prescribing and dispensing of low-price alternatives at the pharmacy level [3].

A study of the drug reimbursement process in Iran is an important step to ensuring that the budget is used optimally. Studies to date, however, have not performed a detailed examination of the drug reimbursement process. The aim of this study was to describe the decision-making process regarding drug reimbursement in Iran. This article covers the current reimbursement process relating to drugs in Iran up to the end of July 2012, and we describe the role of the two main stakeholders (the Ministry of Health and Medical Education and the Ministry of Welfare and Social Security) and other important actors and stakeholders in this process.

Methods

Three different methods were used in this study. To investigate and describe the administrative rules and the directives of stakeholders involved in the drug reimbursement process, we examined formal government documents, including the latest laws enacted by the Iranian parliament, legislative documents, and published internal regulations of various stakeholders [4,5]. Interviews were conducted with three policymakers, and experts in the Ministry of Welfare and Social Security, the Food and Drug

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Organization (FDO), and the Medical Services Insurance Organization (MSIO) enabled us to add some details about the reimbursement process. Finally, we used periodically released and publicly available statistics, especially drug sale statistics published by the FDO. The numbers and costs of drugs sold by drug distribution companies to pharmacies are available in these publications [4], which enabled us to generate an overview of the current situation in Iran.

Results

Health Insurance Systems

Major changes in the Iranian national health insurance system began in 1994 with the introduction of universal health insurance [6]. This policy contained a description of the role of each stakeholder in the health care sector, the financing of health insurance organizations (HIOs), the health services tariff policy, and the minimum health service package to be adopted by all HIOs. Since the introduction of this policy, Iran has had four major health insurers: the SSO, the MSIO, the Armed Forces Health Insurance Organization (AFHIO), and the Imam Khomeini Relief Foundation (IKRF) [6].

The SSO, established in 1953, is a nongovernmental organization that covers about 43% of the population. The insurees comprise wage earners and salaried workers, many self-employed personnel in different businesses, and many civil servants [7]. SSO provides two kinds of health care schemes: direct and indirect health care. Direct health care is provided to SSO beneficiaries through 69 hospitals (8550 hospital beds) and 275 clinics [8]. Beneficiaries can also receive indirect health care from other providers, including health centers (privately, government-owned, army) and charity organizations. SSO beneficiaries who are referred to direct health care do not have to make any payments or co-payments (unless they receive indirect health care) [8]. Besides health care services, the SSO provides other social services relating to pension payments, disability compensation, and unemployment insurance services. These long-term services account for two-thirds of annual SSO expenditures.

The MSIO is a governmental organization established in 1994 that insures about 41% of the population, comprising mainly civil servants, the self-employed, and rural populations. The MSIO provides only health insurance services and has variable financing. The activities of the MSIO are similar to the indirect health care provided through the SSO.

The two other HIOs, the AFHIO and the IKRF, respectively, cover almost 6% and 2.5% of the population. AFHIO beneficiaries include armed forces personnel and their families, while IKRF beneficiaries include people with physical disabilities and people with economic or social crises that are so severe that they are not self-sufficient [9]. In addition, there are 30 or so smaller health financing schemes for privileged members of society or large organizations (e.g., government ministries, municipalities, banks, and cooperatives), which provide coverage to their employees and their families [10].

Key points about the Iranian HIOs are as follows:

1. Governmental organizations involved in the health care system are supervised by different ministries in the government. The SSO and the MSIO are supervised by the minister of welfare and social security, the AFHIO is supervised by the minister of defense, while the IKRF falls under the direct supervision of the Iranian president.
2. The occupation held by the head of household is the most important factor that determines HIO enrollment, insurance premiums, and level of commitment of the HIO to reimburse health care services. In fact, most people cannot select their health insurer and insurance premiums are paid monthly by their employers. Only self-employed people can choose between the SSO and the MSIO.
3. According to some experts, some people may benefit through coverage by multiple health insurers while others may have no health insurance coverage at all. The number of people without any coverage is estimated to be up to 10% of the population. Although the socioeconomic proportions of non-insured people have not been investigated, the experts argue they are mostly young and poor people who are not eligible to register by the SSO, the MSIO, and the AFHIO and do not need health care services (because of being young). Moreover, some rich people would not be insured because they can easily afford to pay for health care services in the private sector.
4. The contents of the minimum benefit package of the four main health insurers are determined by the Supreme Council of Health Insurance (SCoHI), and all insurers are obliged to provide whatever is included in the package. By law, patients must make co-payments of 10% and 30% of the costs of inpatient and outpatient services, respectively. Insurers make direct payments to pharmacies on a monthly basis, and patients have to pay both co-payments and a dispensing fee. The dispensing fee (about €0.70 in 2011) is a fixed-rate fee for labeling and repackaging that is generally paid out of pocket for every prescription received. In addition to the minimum benefit package and co-payment rules, organizations can provide excess services to prevent catastrophic household health expenditures. They may cover some nonreimbursed drugs or decrease the patient's share of financial contribution. The ratios of cost sharing in drug services provided by HIOs for diseases are given in Table 1. Cancer patients treated with nonreimbursed drugs receive financial support from HIOs using different approaches. For example, the SSO pays a limited yearly grant directly to patients. The MSIO compensates patients for the costs of the drug, the maximum amount being equal to the costs of pharmacologically similar drugs that are reimbursed. The AFHIO covers all drug costs through obligatory supplementary insurance. Last, the IKRF covers 50% of the costs of all nonreimbursed drugs.

The Drug Registration Process in Iran

All new drugs (except orphan drugs, with a disease prevalence of 1 or less in 200,000 people) [11] must be registered by the Council to Consider and Compile Drugs (CCCD) before they can become available in Iran. This council is part of the FDO, which is responsible for drug policy, which, in turn, is supervised by the minister of health and medical education. All CCCD members are Ministry of Health and Medical Education employees, and most of them are clinicians or pharmacists. The first step in the registration of any new drug that is produced or imported is the completion of three to four drug registry forms (Fig. 1). The applicant (e.g., drug company, group of physicians, and specialist society) must prepare documents that address the following items: efficacy, safety and adverse events, comparative efficacy with similar drugs, approval history, contraindications, warnings, precautions, monitoring parameters, pharmacokinetics, patient compliance, and pharmacoeconomic studies [12]. The CCCD, however, may exclude one or more of these items on the basis of the kind of drug and the availability of data.

Applications fall into three categories: 1) new molecules, 2) new dosage forms, and 3) new salts or new doses of any drug if the base has already been approved by the CCCD. Suppose the drug erythromycin, with stearate as a salt in its formulation, is available on the market and approved by the CCCD. If a new

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