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# Health Policy Issues and Priority Research Topics Related to Access and Use of Medicines in Iran: A Qualitative and Consensus Development Study

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## ABSTRACT

**Background:** Access to medicines needs to be fully integrated with health financing, human resource planning, service delivery, information and governance systems. We aimed to explore key themes for the identification of priority policy research questions in the area of access to and use of medicines.

**Methods:** We interviewed a purposeful sample of twenty participants in Iran. The interviewees were selected from diverse stakeholders and the listing comprised of the Ministry of Heath, Departments of Health, Industry, Researchers, Development Partners, Advocates, Clinicians, Pharmacists and Private Providers. Qualitative data was analyzed using the framework approach. We then conducted a nominal group technique meeting to reach consensus on research priorities.

**Results:** Seven themes explain important access to medicine policy and practice issues: health sector organization, health sector pharmaceutical policies, health system financing/ insurance system, drug distribution system in the country, individual, household and community level, health care providers, and policies beyond the health sector. As a result of the consensus development process, 17 research priorities related to access to and use of medicines were identified.

**Conclusion:** The key informant interviews clearly demonstrate that the majority of policy concerns were not addressed. There was a mismatch between the concerns and research, and hence the outcomes of this study can contribute to developing a research agenda for improving access to and appropriate use of medicines.

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## 1. Introduction

The provision of reliable access to affordable, appropriate and high-quality medicines is a key component of a functioning health system [1]. Access to medicines needs to be fully integrated with health financing, human resource planning, service delivery, information and governance systems [2].

Prescribing costs have been growing 6%-8% per year in the global context [3]. In Australia in one year prescribing costs rose more than 23% [4], and in the USA the prescribing expenditure increased thirteen-fold in only thirty years from 1960-1990 [5]. General Practitioner (GP) prescribing amounts to over 10% of total Britain's National Health System (NHS) spending and it is estimated that about 75% of visits to office-based doctors end up in prescribing. Therefore, focusing on quality and cost of prescribing is important and vital.

Access to and appropriate use of medicines is often poor in Low and Middle Income Countries (LMICs). WHO estimates that the average availability of essential drugs in LMICs is 35% in public sector facilities and 66% in the private sector [6]. Medicines account for a high proportion of health spending in LMICs, between 20%-60% (developed country spending is around 18%) [7]. Moreover, between 50%-90% of expenditure on medicines in LMICs is out-of-pocket [8]. This inequitable mode of financing creates significant access barriers for the poor and / or may lead to catastrophic household expenditures. The poor as well as other population groups often rely on the private informal sector for medicines, particularly in rural areas. Over and inappropriate prescription and dispensing of medicines are prevalent [9].

Despite progress in some areas - such as price and availability - data on access to and use of medicines is often weak [7]. Even where data are available, there is limited contextual evidence and analysis to assist in interpretation or in the development of policy options to improve access to medicines in different health systems and country settings, especially for LMICs. Health Systems Research (HSR) is essential to understanding, planning, monitoring and evaluating the interaction of health system components in delivering health outcomes efficiently. The importance of health systems research was confirmed by the High Level Forum task team report at the Global Ministerial Forum on Research for Health in Bamako in 2008 [10]. The application of HSR tools and methods in the field of Access to Medicines will help understand the weaknesses of this building block and generate and use adequate evidence to formulate policies.

Another reason for limited attention to ATM research may be due to the perceived level of availability of medicines. For example in Iran it is generally considered that medicines availability is high, and with a well spread health systems in the country, they are also widely distributed to the remote areas of the country. The exception to this may be highly specialized or expensive cancer treatments which are offered via limited outlets in the country, and the most of these outlets are located in Tehran or other metropolitan areas. Hence the issues of ATM may not be considered as major research issues. There are valid reasons for this: the success of the generic production of medicines in Iran, relative low price of medicines in the country, and the wide spread coverage of health care insurance in the country. It is safe to assume that certain aspects of access to medicine are still an 'orphan' research topic in the region.

The World Health Organization (WHO) Framework for Access to Medicine (WHO 2002) was used as the basis for data collection and synthesis. Under this framework accessibility has been defined as having four parameters: that the available medicines are effective and of consistently good quality, that there is no financial obstacle to a patient receiving it, and that required knowledge and guidance are available for proper use of these medicines any isolated effort to improve one part may be effective for that part but it would not improve the overall situation. The qualitative study reported in here was conducted as part of a multi-part project. We aimed to explore key themes for the identification of priority policy research questions in the area of access to and use of medicines.

## 2. Methods

### Participants

We interviewed a purposeful sample of twenty participants. A list of stakeholders was developed in a two-step consultative process. A matrix was developed to categorize the organizational background and settings from which the stakeholders would be selected. These included WHO regional office, the ministries of health and their entities, civil society organizations (as patient representatives), medical associations (as clinician representatives), pharmacists associations (as pharmacist representatives), research institutions, development partners' etc. The interviewees are selected from diverse stakeholders and the listing comprised of

**Table 1.** Key informants' matrix, the interviewees were selected from the following categories

| Interviewees | KI1 | KI2 | KI3 | KI4 | KI5 | KI6 | KI7 | KI8 | KI9 | KI10 | KI11 | KI12 | KI13 | KI14 | KI15 | KI16 | KI17 | KI18 | KI19 | KI20 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Patient representatives | - | - | - | - | * | - | * | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Pharmacies and distribution | - | - | - | - | - | * | - | - | - | * | - | - | - | - | - | - | * | - | - | - |
| Clinicians / medical institutions | - | - | - | - | - | - | - | - | - | - | * | * | - | - | - | * | - | - | - | - |
| Academics in relevant disciplines | - | - | - | - | - | - | - | - | * | - | - | - | * | - | - | - | * | - | - | * |
| Ministry of Health | - | * | * | - | - | - | - | * | * | - | - | - | * | - | * | - | - | - | * | - |
| PHC networks / public provision of health services | - | * | - | - | - | - | - | - | - | - | - | - | - | * | - | - | - | - | - | - |
| Insurance organizations | * | - | - | * | - | - | - | - | - | * | - | - | - | - | - | - | - | - | - | - |
| Pharmaceutical companies | - | - | - | - | - | - | - | - | * | - | - | - | - | - | * | - | - | - | - | - |
| WHO and other sectors | - | - | - | * | - | - | - | - | - | - | - | - | - | - | - | - | - | * | - | - |

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the Ministry of Heath, Departments of Health, Industry, Researchers, Development Partners, Advocates, Clinicians, Pharmacists and Private Providers. Key informants' matrix is provided in Table 1.

The participants were invited by telephone calls or emails, explaining the objectives of the study and introducing the investigators. The time, location and mode of the interviews (telephone or face-to-face) were mutually agreed. The interviewees were paid no honorarium.

## Interview guide

A semi structured interview guide was developed using the general ATM structure developed by the WHO and the Alliance for Health Policy and Systems Research. We updated this structure to form broad questions. Then the structure was discussed in a meeting of investigators. We then presented the interview structure to a meeting with regional investigators and study advisers. In the end a three part interview guide was developed.

The first part was the introductory and intended to capture the general aspects of the interviewees' background as educational level, affiliations and experiences. The second was an open question about issues regarding access to medicines. This part was meant to investigate the interviewees' personal opinions about the access and use of medicines concepts. In the third part of the guide – which was the main part – the interviewees were asked about different level of access according to each component of the WHO / ATM framework (individual, household and community level, health service delivery level- both public and private services delivery channels, health sector policy, beyond the health sector). Interview analysis was done manually and the WHO 2002 Access to Medicine Framework was taken as the conceptual framework for analysis.

## Interviews

Thirty individuals were invited to interviews and twenty three agreed to participate. In the end twenty face-to-face and telephone interviews were conducted in late 2010 and early 2011 (three other interviews did not in the end result in mutually convenient time set ups for the interviews). Interviews, except one, were tape recorded and transcribed, each interview lasting 30-45 min. Six participants were female and 14 were male.

## Qualitative data analysis

We used thematic content analysis approaches to analyze the data. For analysis of the data resulting from this study, framework analysis of the qualitative data was used, which included 5 steps of familiarization, identifying a thematic framework, indexing, charting and finally mapping and interpretation. This framework has been specifically designed for the analysis of qualitative data resulting from policy making [11]. For this purpose, after familiarization with the domain and diversity of the themes, the key concepts and themes were identified and based on these and the guideline questions from the interview, a thematic framework was set. Afterwards, all data from the individual interviews and Focus Group Discussions (FGD) were reread and reassessed based on the obtained framework and familiarization step.

**Table 2.** An example of the consensus development tool

| Please Express Your Opinion About the Priority of Each Issue as a Research Topic by Ticking a Number From 1 (No Priority) to 9 (Maximum Priority) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Code | Priority of Research on the Topic | | | | | | | | |
| | No Priority | | | | | | | | Maximum Priority |
| 1 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 2 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 3 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |

The thematic framework resulting from the data was put to discussion and reassessment in several meetings within the research team and finalized. Subsequently, based on the created thematic resource, the primary indexing of interviews was carried out. The research team reassessed and modified the indexes several times. Finally, the obtained indexes and analytical table were finalized. The next step was the interpretation of the themes, in which the concepts, conflicts, theories and experiences were compared against each other and the trends and interactions were identified and analysed. We obtained verbal consents from the participants and offered no honorarium.

### Consensus development process

All the interviewees were invited to attend the consensus development meeting. The meeting was conducted following a nominal group technique approach. First a brief overview of the study and the step that had been followed was presented in the meeting. Then the participants were invited to offer their views on the main ATM concerns and issues. Under each main theme a set of topics were offered to the participants. After a brief discussion of the topics, they were invited to vote on the importance of the topic as an ATM research topic relevant to that category. The voting was in private and on previously prepared table that allowed the participants to select from 1 (no priority) to 9 (maximum priority) for each potential research topic. Voting for each category was conducted separate from the other categories.

For the analysis of the findings, we calculated the mean (standard error) of the scores for each topic to observe the distribution of the responses. We then grouped the score into three groups: 1-3 (“low importance”), 4-6 (“medium importance”) and 7-9 (“high importance”). We identified the topics as “high importance” if 70 per cent of the respondents scored the topic as high importance (Table 2).

## 3. Results

As a result of analyzing the interviews, we identified 7 themes and 90 sub-themes or important ATM policy and practice issues (Table 3). Examples of concerns relevant to each main category of the themes are provided.

### Health Sector Organization

The interviewees insisted that decision making about all aspects of access to medicines should (must) be integrated and also we have lack of evidence for decision making about pharmaceutical policies. “Ministry of Health and health system decision makers should consult the experts before making decisions … [such as] Thalassemia Society, physician societies, Cancer Society, scientific societies or senior and established physicians … many decisions are without using expert opinions” (KI5).

In terms of policy making, the main responsible organization has to be the Ministry of Health and the Food and Drug Organization, and all other inter-sectoral organizations should act on that basis but the health system decision-makers are very different. The Ministry of Health provides health related goods priorities, while priorities of under coverage services provision including medicines determined by the Ministry of Welfare. As a result, in some cases, there is no rational relation between determined priorities.

One of the sub-themes in this filed is the public-private health system mix. One longstanding and polarized debate in global health concerns the appropriate role and balance of the public and private sector in providing healthcare services to populations in low- and middle-income countries [10].

### Health sector pharmaceutical policies

The interviewee insisted that although there is an essential need for developing and updating a national drug policy in the country, but there are many regula-

**Table 3.** Conceptual thematic framework– qualitative analyses and policy concerns

| Themes | Sub Themes | Participants' Quotes |
|---|---|---|
| Health sector organization | Public-private health system mix<br>Pharmaceutical policy formulation/ evaluation & promotion<br>Pharmaceutical regulatory function and enforcement<br>Health facilities (hospitals, clinics) | (KI3) "We cannot ignore educational problems. Our education system is not perfect".<br>(KI4) "I believe we do not have a serious and strong policy to support research and development in drug production and the margin of benefit for importing drug is higher, and this is why we she drug imports are increasing".<br>(KI4) "The biggest problem is questioning the generic strategy in the country".<br>(KI15) "Some people say we need to give monetary issues to the Ministry of Commerce, and the Ministry of Health focuses on quality control. Even before the revolution that we think the structure was different, at that time for medicines pricing, the ministries of commerce and health representatives were present". |
| Health sector pharmaceutical policies | National drug policy/ National drug formulary<br>Pricing<br>Generic versus brands<br>Quality assurance (GMP)<br>Quality control/ Drug quality<br>Post marketing surveillance / Adverse drug reactions<br>Public and private health system interactions | (KI2) "Each company that intends to import a medicine, they need to get the Article 20 Commission's approval. … this takes time, they need to have full documentation … then there are monetary issues, nowadays opening an LC with a bank is difficult". |
| Health system financing / insurance system | Health system financing, national health budgets, social health protection<br>Universal coverage<br>Social welfare and social protection policies<br>List of medicines under coverage<br>Cost coverage - financial protection<br>National subsidy and benefit distribution | (KI1) "Financial [limitations] has resulted in insurance organizations, including both basic and complementary insurance; do not make contracts with all existing pharmacies. This has important access implications".<br>(KI4) "Should we include expensive and unaffordable-for-all medicines in the national formulary or no? If we say it should be included, then many people cannot afford it, and naturally some people will be deprived of it. If we say it they should not be included, then some people say that we could afford it, why shouldn't we get it?"<br>(KI7) "At least we need to have a database of all diabetic patients. … If the insurance organization and the Ministry of Health who is responsible for it have the data, a lot or repetitions will disappear and many costs will reduce and can be used to cover other expenditures …"<br>(KI17) "We need to look at the large picture, and see if there is a disease that each year 50 people suffer from it and die, is it ok to spend 10, 20 million dollars on it, or should we keep that to vaccinate 1-2 million children. Which one is our priority?"<br>(KI14) "As for insurance coverage, I think we need to compare ourselves with other countries. Our insurance coverage is not bad". |
| Drug Distribution system in the country | Private –sector drug distribution systems<br>Governmental /public distribution systems<br>Drug availability in the market (pharmacies)<br>Informal distribution network<br>Geographical distribution (pharmacy, health facility, hospitals)<br>Drug distribution in the hospital<br>Prescriptions' drug distribution without prescription<br>Counterfeits | (KI3) "Subsidized medicines are the same story, because we have not used proper technology … patient has to go to a certain pharmacy once or twice a month, because we say that medicine is in short supply, is expensive, is subsidized [by the government] …using IT and modern distribution systems we could have get it to the patient where she lives…"<br>(KI3) "The laws are [part of the problem]. E.g. for opioids … and end stage cancer patient has to travel to the center [to get it] …"<br>(KI13) "We, in the pharmaceutical sector, gave permission of accessing medicines via emergency center [single item importers], it affected quality, and the medicines were bought from distributer before the quality was assessed in a laboratory". |
| Individual, household and community level | Demand for medicines and health care services<br>Public knowledge and awareness<br>Self-medication<br>Affordability ,Out-of-pocket, price of medicines<br>Socio-cultural constrains | (KI4) "Whoever prescribes the medicines, also sets public preferences [that is] … the medical society influences [people], people alone are not that influential".<br>(KI6) "For certain internally produced drugs, the users do not have enough trust in local products, sometimes because they cannot see the quality".<br>(KI7) "Physician has to send him [patients] to other physicians to give him consultation. The patient might say I would not get insulin, and the physician will back down and we will be away from our aim of treating the patient".<br>(KI14) "There are other diseases not considered by the Ministry of Health as 'special disease', while the disease are really special and their medicines are expensive (includes thalassemia, hemophilia, and kidney replacement therapies)". |

| Themes | Sub Themes | Participants' Quotes |
|---|---|---|
| Health care providers | Induced Demand for medicines and health care services<br>Rational drug use/ Evidence based medicine<br>Payment methods<br>Fee splitting<br>Consultant pharmacist, clinical pharmacy | (KI2) "If a pharmacist just thinks of money, she would not care what the patients get, will give them whatever they want, even without prescription, if they pay".<br>(KI11) "The set so many laws for OTCs but the pharmacies dispense whatever they want to people".<br>(KI12) "A very important role that pharmacies can play is to correct costumer drug utilization culture. Many people when they visit a pharmacy may be looking for more expensive and trendier medicines. … the pharmacists … can guide people …". |
| Policies beyond the health sector | Ministry of commerce<br>Ministry of finance<br>Standard organization<br>Ministry of industries<br>The medical council | (KI1) "For example, does the Ministry of Commerce have enough expertise for market control? … Or does is look at it [pharmacy] like a general shop or outlet? This is a specialized issues and should be outside the Ministry of Commerce".<br>(KI2) "Each company that intends to import a medicine … there are monetary issues, nowadays opening an LC with a bank is difficult"<br>(KI3) "If a drug needs to be imported in an emergency, its import should register with us, and another time with [Ministry of] Commerce, and once with the Customs". |

tions and commissions such as drug selection, pricing, planning for procurement committees who are involved in the drug supply chain, but their decisions in some cases contradict each other. Sometimes also these committees have complicated guidelines that act as a main obstacle to easy access to needed medicines. "National formulary is the first hurdle. If the medicine is not listed, it cannot be imported" (KI2).

Such barriers forced us to think of other ways for providing availability of medicines like 'Single item importer. 'Single item importers' are an issue in Iran. They bring medicines that are not listed on Iran's national formulary. Physicians decide they need a drug for their patients and 'single item importers' deliver" (KI2).

The drug pricing, is another important issue in this theme. "At the moment we at the Ministry of Health set the [medicines'] price, while insurance organizations are best suited to do that. I mean it is the insurance organization that can bargain with the producer, importer to reduce the prices..."(KI3).

Furthermore the price of majority of medicines in Iran is low. It makes some defects. In terms of medicines' quality, there is a significant difference in the efficiency and side effect of the active ingredient with 96 percent of purity, which is the minimum standard requirement, and the one with 99% purity. Pharmaceutical companies have to pay a huge price for this 3% difference, for the one with 99%, the price may triple. Although in the pricing, raw materials are only one of the factors, and other factors, particularly the cost of research and education must be considered. "… because of weakness in our insurance system, they keep down the medicines' prices at the company, and [the company] in turn will buy cheap ingredients. Medicines price in Iran, part of it is from outside via 'single item' importing which are very expensive, the ones that have to be of good quality are very cheap and lack quality …" (KI11). Poor quality of some of medicines has consequently cost impact on health system as well. "Our first statement is this: if the quality of a medicine is bad, and the price is low, that's no use to us because we need to pay the price later" (KI16). Besides that, medicines due to their lower prices being smuggled to the neighboring countries.

## Health System Financing / Insurance System

Iran's way of financing health services can be categorized as 'mixed-financing'; i.e. different types of health care financing are observed alongside each other. Major types of financing healthcare in Iran include general revenue financing, social health care insurance, and household out-of-pocket payments. There are other methods, especially private actuarial health care insurance, mainly involving secondary coverage for those already insured by social insurance. Private insurance market in Iran, though, is still small. The mixed nature of health care financing in the country means the health system faces several challenges that differ considerably with each other [12]. Certain private insurances or insurances provided by the banks offer full coverage for the insured … even plastic surgery … others don't. Even the coinsurance level differs, some at 10%, others 20% or 30%. Hence we do not see the equity we expect to see between insurance packages. While most probably the premium they [users] pay is not that different" (KI6).

It is now several years that different parties call for insurance funds' pooling into a smaller number of funds, ideally one major national fund for social insurance.

Structural and organizational differences have proved very resistant to drives for structural changes. Hence it is advisable to move towards integration of 'policies' rather than structural integration of the funds. Recently there have been important improvements in this direction, notably changing Iran Health Insurance Organization's (IHIO) premium rate from a fixed rate for every insured individual towards a proportion of payroll similar to (but not exactly the same as) the Social Security Organization's premium collection approach. "60% of our patients [thalassemia] are covered by the IHIO, they have lots of problem. Their coverage is less than Social Security Insurance Organization" (KI5).

Another issue in this field is the difference between the under coverage list of medications as well as other health services. This may be considered as a sort of inequity on access to medicines. "All medicines are now [covered by insurance] … some are covered 90% of cost, other insurance [organizations] may pay all of it, or are covered via separate subsidies. 300 million US$ is just the subsidy paid for special diseases of hemophilia, thalassemia, MS" (KI9).

### Drug Distribution System in the country

There are different and sometimes contradictory opinions about drug distribution system in Iran by policymakers. Some of them believe that developing several drug distribution centers by preventing monopoly, will increase the level of access nationwide, while some others insisted that increasing the number of distribution systems resulted in decreasing the quality of their services. "Another problem of distribution companies is that we have lots of distribution companies and some of the do not have the minimum standards for keeping medicines" (KI10).

Concerning drug availability, many of them are available in all retail pharmacies, however some certain medicines such as anticancer and chemotherapy medicines are just distributed to special mainly governmental pharmacies in some main cities. "Right now not all medicines can be distributed everywhere. Some medicines are just for certain pharmacies. E.g. some people may have to travel to Tehran for certain medicines, as they are not available in provincial cities" (KI2).

From the pharmacy point of view, we have problem at the distribution system. The pharmacy cannot be sure whether a medicine gets more expensive or cheaper. It does not how much they can stock and for how long the drug is easily available, sometimes pharmacies have to stock medicine instead of the distributors.

Unfortunately there always is a list of medicines in short supply. Although the number of drug shortages in different periods vary depending on the policies, but the problem is permanent. There was a time that we had a critical situation, if you remember we were suffering, and our people were suffering because of medicines scarcity; I mean there always was a long list of medicines in short supply" (KI9).

### Individual, household and community level

There was a genuine belief that general practice was under increasing pressure of patients. "In our country inappropriate use of medicines, is more deep-rooted than many other countries. If you ask doctors why they prescribe such medicines, they respond that because of patients' request" (KI3).

One of the main issues in this field related to our public knowledge and awareness about medicines. For majority of medicines, affordability is not an important issue, so people insist to get medicines even though they do not need it. On the other hand, patients demand for imported brands are more than those locally produced due to get higher quality. "For certain internally produced drugs, the users do not have enough trust in local products, sometimes because they cannot see the quality" (KI6).

"I think [household] out-of-pocket [expenditure] is important, but the cultural issues are more important. If the demand reduces and becomes more rational, access will improve" (KI14). Although, it must not be ignored in some medicine categories that imported, the prices are not affordable for, almost, all patients, and they may lead to catastrophic cost. "Access can be viewed from different angles. In terms of availability, we have no access problem … but whether people can afford it is another matter" (KI10).

### Health care providers

The interviewee pointed that the knowledge and attitude of health care providers have an important role in access to medicines. Nowadays with high access to large amount of information through mass media or internet, the appropriate consultation process may lead to control induced demand for health care services. However economic issues for health care providers should be considered. "Pharmaceutical companies should not

**Table 4.** ATM research priorities. The results of the consensus development meeting

| Access to Medicines Priority Topics by the Level of Barriers to ATM | | Agreement on the Topic as High Priority for Research |
|---|---|---|
| | **Topic** | |
| A: Health sector policy | Assessing the procedures and regulations for adding medicines to the national drug list (formulary) and identifying improvement models | 11 |
| | Evaluation of the impact of laws and regulations on controlling drug use | 9 |
| | Evaluation of the effect of the 'single item importing' policy on final cost of medicines, quality and access, and health system expenditure | 9 |
| | Assessing strategies to eliminate financial links between providers and patients, and its impact on provision of pharmaceutical services | 9 |
| | Evaluation of the impact of different payment methods on quality of health care services | 9 |
| | Evaluation of drug pricing policies and its impact drug utilization and access to medicines and health outcomes | 9 |
| | Evaluation of pharmaceutical policies,regulatory function and enforcement for traditional and herbal medicines | 8 |
| | Evaluation of pharmaceutical policies and procedures, and the applications of post marketing surveillance reports | 8 |
| B: Health system financing/insurance system | Evaluation of the process of adding medicines to the insurance organizations' list of medicines covered | 11 |
| | Evaluation of the impact of different payment methods on quality of health care services | 9 |
| | Evaluation of drug pricing policies and its impact drug utilization and access to medicines and health outcomes | 9 |
| | Evaluation of the effect of free medicine provision in Social Security Insurance Organization (SSIO) (and charity) owned facilities on drug usage patterns and access to medicines | 9 |
| | Evaluation the relationship between pharmaceutical pricing policies and costs and benefits of pharmaceutical companies | 8 |
| | Assessing strategies to eliminate financial links between providers and patients, and its impact on provision of pharmaceutical services | 8 |
| C: Drug production and distribution system in the country | Evaluation of the extent and effects of drug promotions activities of the industry and its impact on prescribing behavior of providers | 9 |
| | Evaluation of the effect of the 'single item importing' policy on final cost of medicines, quality and access, and health system expenditure | 9 |
| | Evaluation of the impact of regulatory function providing financial incentives for pharmacists' that provide appropriate pharmacy services on increasing quality and improving rational drug use indicators | 8 |
| | Evaluation the role of pharmaceutical companies on prescribing and drug use patterns | 8 |
| D: Beyond the health sector | No agreement was made for this domain | |
| E: Individual, household and community level | Identifying effective methods on improving public knowledge and awareness about drug use | 8 |
| F: Health care providers | Identifying effective continuous education methods for physicians to improve drug use patterns and access to medicines | 8 |

be allowed to serve doctors … to keep medical society away from the low of financial links with pharmaceutical producers and importers" (KI4).

Moreover the number of needed health care providers as what indicate by standards is a problem specifically in small towns and rural areas. "We do not have standards for the required number of [pharmacist] providers, have copied other countries, or have lowered standards based on the number of pharmacists. We need to define evidence base geographical access standards …." (KI1).

### Policies beyond the health sector

"If the Ministry of Commerce comes and opens an office in Foods and Drugs [Organization] and do the works from there … is better than we send people in the [Ministry of] Commerce's loop … when we move around people between different ministries, different organizations … this puts an expense on the person or company … the company will not pay out of pocket … public have to pay more in the end from their pocket as insurance budget is limited" (KI17).

"Scientific societies are influential in adding a medicine to the national list, and with the relations they have with companies and can heavily promote a drug. For example if a company collaborates with the neurology society and introduce its drug, and the medicine becomes the best seller in Iran, you know how much it will sell. The can increase or decrease drug sale, bankrupt a company …" (KI2).

"… We have problems in making regulations within the sector, not much problem with The Ministry of Commerce but within the Ministry of Health …" (KI10).

### Consensus development on research priorities

A total of 125 potential research topics – generated from the qualitative research and a review of literature - were presented to the consensus development meeting. The participants further added 15 new potential topics during the discussions that took place in the meeting. As explained in the methods, the topics were categorized under the seven main themes. In the end twenty priority topics were selected by the participants. Three topics appeared twice in the results (i.e. under two different main themes). Hence seventeen unique research topics were identified in this process (Table 4).

Under one theme (beyond the health sector), no agreement on a topic as a research priority issue was observed. This is despite the fact that this area was considered a major policy concern in qualitative interviews. This may reflect the nature of the health system in Iran, in which the majority of decisions are taken within the sector, and hence the impact of issues from outside is not seen as important. It may also be the result of a lack of useful input from the interviews and literature and hence resulting in a situation in which the proposed topics did not deemed priorities.

## 4. Discussion

The provision of reliable access to affordable, appropriate and high-quality medicines is a key component of a functioning health system [1]. Access to medicines needs to be fully integrated with health financing, human resource planning, service delivery, information and governance systems [2]. This is the first study conducted in this region that has collated published literature and summarized the main policy concerns to identify ATM research priorities. In this study we used an extensive search of local and regional literature, interviews with key informants, analysis of previous priority setting exercises and consensus development approaches to identify the main research priorities for ATM research. We developed detailed maps of research on the issue, conceptual frameworks of policy concerns and issues, and identified lists of ATM research priorities for the countries of focus and the region as a whole.

The main concerns of the key informants were around the affordability and financing aspects of access to medicines, followed by issues of availability and rational use of medicines. The key informants paid attention to all levels of barriers to access: The household level, providers (public or private sector), health system, other sectors and cross border issues. The identified previous research on the issue, however, did not reflect that.

The results of the study indicate that ATM research in the region is heavily biased towards RUD [13, 14]. RUD research has been mainly in the shape of prescription audits, the majority of it showing there are important problems in prescriptions. In recent years there is shift towards interventional studies assessing the impact of interventions on improving prescribing outcomes [15]. There are two important patterns to note in here. First, the RUD research, although forming the majority of ATM research is yet to show a substantial effect in improving drug utilization patterns.

The prescribing problems of focus in ten years ago remain unresolved today, if not joined by new challenges (e.g. non-generic prescribing). Second, it seems a change in research strategies is required and future studies should focus on interventional issues. Fortunately there is a move in that direction. Also further demand side (why public still sees fascinated with antibiotics) and health systems angle (what are the financial and organizational barriers to improving prescribing patterns) research will be required.

This study clearly indicates that there is dire need for further research on financing and affordability aspects of ATM in the region. This should be given paramount attention in future research funding and calls for proposals. Also cross-border issues and other sectors roles on access to medicines in the region has not explored widely. It seems that many household (demand side) studies in the region remain of poor quality and limited methods. Together, these main areas should provide the main aspects of access to medicines research in the region.

This is in no way indicating that further RUD or studies of health systems and availability access are not needed. Or that the barriers at the levels of providers and health systems are exhaustively identified. Rather it seems that individual researchers and available funding route are giving attention to these issues at the moment, which should continue while further resources should be mobilized for studies related to the relatively ignored aspects of ATM research in the region.

Almost 80% of AT research in the region is originating from the region. However, there is a wide variation in the number of publications originating from different countries. Certain countries (e.g. Somalia), or certain areas of other countries, do not appear in the literature [14].

## 5. Conclusions

The picture of research on the ATM in the region is better than what had been reported in recent publications that had not followed extensive methodologies. There is a growing trend, over the years, of more and better quality studies from the region appearing in international journals. Still, a concurrent trend will be required to ensure the local audience of such research (i.e. practitioners, policy makers and media) remains informed of the new development as a result of ATM research in countries in the region. An active knowledge translation approach will be essential.

The key informant interviews clearly demonstrate that the majority of policy concerns were not addressed by published research. There was a mismatch between the concerns and research, and hence the outcomes of this study can contribute to developing a research agenda for improving access to and appropriate use of medicines in the region and the three countries of focus.

## Ethical Considerations

### Compliance with ethical guidelines

The Ethics Committee of Tehran University of Medical Sciences approved the study.

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### Authors contributions

Study design: Arash Rashidian; Interview and data collection, Writing the original draft: Fatemeh Soleymani, Nader Jahanmehr; Revising the manuscript: Arash Rashidian; Analysis, approving the final manuscript: All authors.

### Conflict of interest

The authors declare no conflict of interest.

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