

**Original Research Article****Current Pharmaceutical Situation (Services) in Yemen and Future Challenges**

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ABSTRACT

This article deals with Yemen's current pharmaceutical scenario and possible future challenges that it may face. The manuscript provides an overview of health services particularly pharmaceutical services and the critical health challenges facing the people of the country. Details included are statistical data with regard to the health of the Yemeni population and their demographic backgrounds following administrative issues, policy for the medicinal trade and production, the regulation and financing. The manuscript also deals with the government's action about medicines, their procurement, and distribution in the public sector, and the public perception of medicines. Rational use of medicines is determined by the knowledge and attitude of the consumers. Future challenges are also anticipated. World health systems have been facing an incredible transformation to address new challenges with regard to the demographics, disease trends, the emergence and the re-emergence of diseases along with higher costs of health care delivery. This has led to a comprehensive review of health systems and how they function to serve the masses. Some health systems do not seem to adequately provide services that really matter to the people and some deteriorate, following governments' lack of efficiency in supporting and extending the services. Other issues can also affect the ability of the health systems to deliver including health administration, healthcare financing, the lack of balance of the human resources, inaccessible and poor quality services and the impact of modifications and reform prevalent in other economic areas.

Introduction

Yemen has not been able to escape the many chronic diseases that have also plagued other Arab countries and the developing world in other regions. It has been known to have high incidence of both communicable diseases (malaria, tuberculosis, schistosomiasis, sexually transmitted diseases

and vaccine-preventable diseases) and non-communicable diseases (such as cardiovascular diseases, renal problems, cancer, and eye diseases). As if this is not enough, Yemen also displays certain factors of lifestyle that can pose risks or are hazardous to the people (the factors include tobacco use, 'qat' chewing, malnutrition, injuries and accidents) and inadequate

necessary sanitation (especially water sanitation). Unfortunately these are steadily increasing.

The health situation in Yemen is acknowledged as the least favourable in the world. Low birth weight has been known as one of the leading contributors to Yemen's very high infant and under-five mortality rates. The causes for this are three-fold- poverty, closely-spaced pregnancies and low health

awareness. High fertility rate is also another issue among Yemeni women. Higher fertility would add more pressure on a woman's body and thus, they run the risk of being subject to potential death, or mortality. Of course, this is exacerbated by the fact that Yemen is poor in resources and being over-populated this would definitely be a big issue to address.

Table 1: The basic indicators of healthcare in Yemen

Under-5 mortality rank	43
Under-5 mortality rate (U5MR), 1990	125
Under-5 mortality rate (U5MR), 2012	60
U5MR by sex 2012, male	64
U5MR by sex 2012, female	56
Infant mortality rate (under 1), 1990	88
Infant mortality rate (under 1), 2012	46
Neonatal mortality rate 2012	27
Total population (thousands) 2012	23852,4
Annual no. of births (thousands) 2012	752,2
Annual no. of under-5 deaths (thousands) 2012	43
GNI per capita (US\$) 2012	1110
Life expectancy at birth (years) 2012	62,9
Total adult literacy rate (%) 2008-2012	65,3
Primary school net enrolment ratio (%) 2008-2011	76,4

Source:
 [1] http://www.unicef.org/infobycountry/yemen_statistics.html#121

Other factors including not being able to access healthcare, and not being able to afford healthcare expenses, parents not being too educated and poor access to the basic necessities, like water and sanitation are also responsible.

The most common and serious health conditions Yemen faces are diarrhoea, malnutrition, complications of pregnancy, acute respiratory infections, and malaria. AIDS is becoming increasingly prevalent, and non-communicable conditions such as cancer, heart disease and trauma are also on the rise[2].

Health Care System

As a proper introduction to the issue at hand, Yemen is an Arab country located in the southern Arabian Peninsula with a population of 24 million, 70% of whom live in rural areas. Yemen divided administratively into 24 governorates and

Sana'a Capital Trust. Each governorate subdivided into a number of districts. The health care services (either public or private) are mainly centralized in major cities; though primary health units/centers, polyclinics and hospitals are scattered throughout the country.

The health care system consists of a public and a private sector. There are three levels of health care. The first level is primary health care that focuses on primary health programs and provides the first level of care. Primary health care facilities consists of health units, health centers and polyclinics. Primary health units commonly have one medical assistant or nurse and/or midwife. Primary health care centers normally have one or two physicians, nurses, a laboratory and some diagnostic facilities. The second health care level is secondary health facilities which consist of regional hospitals, specialising in curative services. The third one is the tertiary

health facilities which include the national hospitals offering specialised care, and they are university-based hospitals.

The entire healthcare system in Yemen is monitored by the Ministry of Public Health and Population (MOPHP) which is directly responsible for the health sector and this sector takes up the largest percentage of Yemen's public employees. As it is in most other countries, Yemen does not escape the issues of not having adequate number of staff, having to deal with poor construction and organisation, poor quality healthcare services, not having enough medicines that are deemed essential for patients and insufficient issues of budget and Government funding.

It can be safely summarised that the health services in Yemen have been outgrown by the exponential population growth. With prominent morbidity and mortality from various diseases and with high levels of malnutrition prevailing, and the higher rates of fertility reported. Therefore, Yemen health care system has still a long way to go[3].

National Policy Issues

A National Health Policy (NHP) does exist in Yemen, and it was updated in 2010. Unfortunately the corresponding implementation plan does not exist. Similarly, the National Medicines Policy (NMP) document also exists in Yemen which was updated in 1998[4]. In brief these two policies are exist but neither structurally implemented nor regularly monitored and evaluated. In general there is no formal implementation plan and there are no clear responsibilities.

In terms of drug distribution for health care purposes, Yemen should consider the drawing up of a concrete and updated statement of NMP such has been adopted in many other WHO member states. Next, a policy relating to clinical laboratories does not exist as well. Access to essential medicines/health technologies as part of the fulfilment of the right to health, is recognized in the constitution or national legislation but they are not fulfilled. It is unfortunate that there are no official written guidelines on medicine donations. It is important to establish a well designed, well managed and cost-effective supply system with aim of: increasing access to essential medicines; maintaining constant supply and minimizing medicine losses.

In sum, there is no national good governance policy in Yemen and this is probably why Yemen's MOPHP have to take measures to ensure clear-cut guidelines and policy are reformulated and re-outlined. They have to be thorough, covering all aspects of healthcare and the guidelines have to be delivered efficiently and effectively to the authorities of the three levels of the healthcare system in Yemen before they can be implemented in different health care facilities, in both the public and the private sectors.

It is worth to mention that the National Health Strategy (NHS) 2010-2015[5] has stated that: "The Ministry of Public Health and Population has exerted some great effort towards improving the health conditions for the people through its

constant attempts to reform the health sector and modernize it. The policies and strategies that have been adopted by the Ministry since the end of the 1990s were an obvious extension of the issues adopted in the First National Conference for Health Development in 1994. This strategy hasn't ignored or cancelled the accomplishments of the previous strategies but rather it was built on their success and is having its priorities updated in line with the national, regional and international developments bearing in mind the national and local characteristics and in consistency with the various economic, social, political and geographic conditions".

Medicines Trade and Production

The World Trade Organization (WTO) does issue legal provisions and grant patents to medicine manufacturers, but since Yemen is new member of this organization (2014), the provision and patent do not exist in the country. As is the case with any agency which should be responsible in managing and enforcing Intellectual Property (IP) Rights. Yemen Pharmaceutical Country Profile (2006) states that due to this, there has been no clear vision about IP Rights since the negotiation with international agencies is still in progress. The profile further adds that there are some legal provisions for the connection between patent status and marketing authorization, there has yet to be a similar provision for data exclusivity for pharmaceuticals and patent term extension. Yemen is also lagging behind, in terms of initiatives to manage and apply for the IP Rights towards promoting public health. Although the tested locally manufactured products have been proven to be of good quality, the Yemeni pharmaceutical industry still necessitates a great deal of serious attention and improvement from various angles, such a production, manufacturing, knowledge, attitude and behaviour, policy-making- all together to elevate people's awareness of the nature of medicines, the use of medicines, and for the betterment of the public's health status. Thus, on the surface, we can say that the medicine trade and production in this country has to be better monitored and guided, in order improve the quality, safety and efficacy, also to reduce the cost and to curb the adverse effects of pharmaceutical products[5].

Medicine Regulation

In general medicine regulations and legislations aims to ensure the quality, safety, efficacy of medicines and accuracy of medicine information. It is developed, implemented, monitored and re-enforced by Medicine Regulatory Authority (MRA). The government of Yemen granted the power of responsibility to the MRA. MRA is responsible for registration of medicines; importation, distribution and sales of medicines; medicine promotion; licensing of pharmaceutical establishments, their staff and performance; pharmaceutical quality assurance; commitment to Good Manufacturing Practice (GMP) and regulation enforcement. The SBDMA is the main MRA in the country. It is a semi-autonomous agency concerned mainly with authorizing

marketing, importing and manufacturing control; providing licenses for medicines, medicine producers and wholesalers; controlling the medicine market and controlling the quality and pharmacovigilance of the imported medicines and medical appliances.

In the last five years, the medicines regulatory system has been placed under proper assessment. The SBDMA receives funding from the government budget but it also retains its revenues from regulatory activities.

In Yemen, marketing authorization for all pharmaceutical products is required. Since mutual recognition mechanisms do not seem to be available, publicly available criteria have been adopted to assess applications for marketing authorization of the products. Yemen Pharmaceutical Profile, 2006 states that there were 9,500 pharmaceutical products registered in Yemen in 2007. However, one weakness that is apparent is that the MRA fails to distribute a list of the registered products, updating the names of the products on a regular basis, in order to know about the authorized products that are officially available in the country. The Profile further reveals that there is a guide for the registered pharmaceuticals but it has not been updated for more than a decade. Registration and authorization should have made the public feel 'safe' about using the medicines that are suitable to their health complications and needs, but the seemingly lackadaisical attitude of the authority regarding updating the medicines and pharmaceuticals marketed have created loopholes in the healthcare system in Yemen. Similarly, even though legal provisions exist to allow the appointment of government pharmaceutical inspectors and to allow them to check premises in which pharmaceutical activities are performed, local manufacturers, private wholesalers and retail distributors have claimed that inspections have been infrequent and there has been suggestions of contradiction between the responsibilities of the MRA and those accountable for the pharmaceutical affairs in the MOPHP.

Medicine Financing

As has been seen earlier, Yemen is a country challenged with limited economic and social development. Its health indicators are some of the lowest globally, and improving them is very difficult battle. In 1995, the Government launched an economic reform program with support from the World Bank and the International Monetary Fund (IMF). The Government revenues are 37.7 per cent of Gross Domestic Product (GDP), over 68 per cent from oil, 24 percent from taxes, and the remainder from other sources[5]. The external debt to GDP ratio is 74.9 per cent (before rescheduling) and gross official reserves account for about 4 months of imports Another challenge to the Government's efforts to strengthen its economy came in 1998 following a dramatic drop in oil prices. The resulting 15 per cent across-the-board cut in the public sector budget, further tightened scarce resources for the health sector. As a result, public spending on health is currently about 2 per cent of GDP and 4.8 per cent of total government

expenditure - the lowest per capita health spending in the region.[5] Limited public resources and poor health indicators are catalysts for rethinking of the health strategy by the MOPH in partnership with the World Bank and other key donors.

Potential sources of funds for public pharmaceutical procurement include government financing, user fees, health insurance, community co-financing for health facility visit, diagnosis and treatment, and donor financing. These options vary in terms of their efficiency, equity and sustainability. The most important considerations for public procurement are total funds available, adequate access to foreign exchange and the regularity with which funds are available. It is the responsibility of government, policy makers and senior managers to establish appropriate and reliable funding for public drug procurement as a high priority, and to implement mechanisms which provide adequate funding on time to support public sector procurement.

Looking specifically into Yemen, there are six major sources of funds for government health spending:

1. The central MOPHP budget;
2. Foreign assistance;
3. Governorate health budgets; (there is a small budget allocated to each governorate to cover some of their health expenses)
4. The Social Fund for Development (provided by the Prime Minister's Office);
5. The Public Works Project (under the Ministry of Planning & Development); and
6. The Ministry of Finance, which directly funds the central MOPHP budget, the governorate budgets, as well as Al-Kuwait and Al-Thawra Hospitals in Sana'a and the SBDMA (institutional budget).

It is important to increase government funding for priority diseases, poor people and disadvantages to improve the availability and accessibility of safe and effective essential medicines.

Pharmaceutical procurement and distribution in the public sector

The local pharmaceutical industry covers approximately 10–20 per cent of the total market[6]. Yemen is a member of the Arab Union of the Manufacturers of Pharmaceuticals and Medical Appliances, and ranks 11th among Arabic countries in medicine production. Yemen spends about US\$263 million a year on pharmaceutical products, according to the SBDMA[6]. Most of this expenditure is spent on importing medicines from 50 countries through 400 licensed importers, as local pharmaceutical plants produce only 10–20 per cent of Yemen's requirements. There are about 500 foreign pharmaceutical companies and more than 13,000 brand and generic medicines registered in Yemen. In 2012, the MOPHP and the SBDMA started a new policy to ensure the quality of medicines in Yemen[5].

In 1964, the Yemeni government initiated a joint venture with private investors in establishing the Yemen Drug Company (YEDCO). This company started in marketing pharmaceutical

products. The company imported drugs from foreign companies and marketed and distributed them in local pharmacies and drug stores. A few decades down the line, YEDCO took a step forward by starting its first pharmaceutical factory in Sana'a for producing pharmaceutical products. The second pharmaceutical company, Shibapharma was established in Sana'a 29 years after the Yemen Drug Company. ShibaPharma products are sold in Yemen and even exported to Middle Eastern and African countries.

We had mentioned earlier in this paper that the dispensers in pharmacies are mostly not pharmacists, and a journal has revealed that a few pharmacies even use the old versions of the British National Formulary (BNF) or the East Medical Index[7]. This implies, that poor quality and out-of-date drug information resources in pharmacies can affect the quality of the information provided to patients and prescribers, and the consumers will not be updated regarding new information on pharmaceutical drugs they are purchasing.

In a manual of the World Health Organization (1999) entitled "Operational Principles for Good Pharmaceutical Procurement", it has been mentioned pharmaceutical procurement is a complex process involving many steps, agencies, ministries and manufacturers[8]. Existing government policies, rules and regulations for procurement as well as institutional structures are frequently inadequate and sometimes hinder overall efficiency in responding to the modern pharmaceutical market. There are many steps in the procurement process. No matter what model is used to manage the procurement and distribution system, efficient procedures should be in place: to select the most cost-effective essential drugs to treat commonly encountered diseases; to quantify the needs; to pre-select potential suppliers; to manage procurement and delivery; to ensure good product quality; and to monitor the performance of suppliers and the procurement system. Failure in any of these areas leads to lack of access to appropriate drugs and to waste of resources. In many public supply systems, breakdowns regularly occur at multiple points in this process.

In Yemen, drugs supplied to the public sector are procured through international tender and rarely by limited competitive tender or local purchase from local agents. Procurement is based on the prequalification of suppliers. Public sector procurement in Yemen is both centralized and decentralized. The government supply system department in Yemen has a Central Medical Stores at the national level in Sana'a Capital Trust which, also known as Sana'a central medical stores. There are another 4 regional public warehouses responsible for storage and distribution of medicines, medical appliances and medical supplies. Each regional store stores and distributes medicines, medical supplies and medical appliances to the public (MOPHP) stores in a number of governorates which are located near to it. The governorate main stores distributes medicines, medical appliances and medical supplies to the MOPHP health

facilities in the governorate. There are 95 national guidelines on Good Distribution Practices. In Yemen a licensing authority that issues Good Distribution Practices licenses does not exist, notwithstanding.

It is important to ensure that selected and procured medicines are necessary for health care of the nation, available to communities and individuals and can be safely and effectively used.

Selection and rational use of medicines

In Yemen many papers and documentation, regarding to pharmaceutical regulation and procurement are commonly exist and yet when it comes to the implementation, updating the policies and information the scenario is poor. The National Essential Medicines List (NEML), for instance was last updated in 2009 [4] and we are sure that a lot of the medicines would have been reexamined and revised since then.

However, the last alignment between the List and the Standard Treatment Guidelines (STG) was reported in 2010. There is no public or independently funded national medicines information center functioning to provide medicinal information or findings to prescribers, dispensers or consumers. Public education campaigns are also lacking. For the past two years, there have been no campaigns aiming to educate the public on using medicines rationally. Not only that, surveys which might be another medium of information to the public at large have also not been conducted. No national program, or committee, seeking to monitor and promote rational use of medicines seems to be under consideration by the MOPHP.

It is equally disappointing that Yemen has no regulations which necessitate hospitals to organize/develop committees concerned with Drug and Therapeutics, and subsequently adherence to STG is also does not exist, or in some cases, have become obsolete.

For physicians, nurses, medical assistants and other health staff, pharmaceutical issues are not detailed and explained to them as a part of continuing education. Even if continuing education is mandatory, pharmaceutical concerns have sadly been underestimated and are not included.

This brings us to the next issue- pharmacovigilance. Pharmacovigilance is defined by the World Health Organization (WHO) as the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any possible drug-related issues. Drug regulatory mechanisms were strengthened following the 1961 tragedy involving thalidomide [9]. One thing that had seemingly escaped the awareness of the people at the time was how prescribing drugs for off-label purposes or in simple words, for purposes other than those intended and prescribed for, was (and still is) a common practice in a lot of countries today. Little did they know then that some drugs can cause

adverse reactions which are sometimes severe and even detrimental and fatal. In 1961, it occurred to the physician who had first introduced thalidomide to his pregnant patients that it was the same product that might have caused severe birth defects in the babies he himself had delivered. In fact, the drug interfered with the babies' normal development, causing them to be born with phocomelia, resulting in shortened, absent or disfigured limbs. Through confirmation of the effects it had on the babies, the drug was banned in most countries.

In Yemen, the monitoring of adverse drug reactions was started by the establishment of a pharmacovigilance centre in 2011 by the SBDMA[2]. So far there is no published information about its work, number of reports and how they are processed. In addition problems related to drug smuggling, counterfeit drugs, improper and irrational use of drugs, importation of unnecessary drugs and medical errors are widely existed.

Academics from the Faculty of Pharmacy at Aden University decided recently, with responsible officers from SBDMA in Aden, to initiate a pharmacovigilance programme in Yemen, to expand the pharmacovigilance centre of SBDMA to cover the whole country and implement the basic steps for establishing pharmacovigilance nationwide.

Considering the fact that the public is not fully aware of the risks of medicines and the possibility of their misuse and abuse, the government of Yemen has decided to dispense drugs only by prescriptions except some medicines which can be dispensed without prescriptions namely over-the counter (OTC) medicines. However, The MOPHP and the Supreme Board of Drugs and Medical Appliances (SPDMA) fail to regulate, control, and monitor the prescriptions. In general, people in Yemen may not have been very well informed about the potential effects of drugs and dispensing medication without a valid prescription is common in this country. All medicines including prescribing-only medicines (POM) such as antibiotics, antipsychotic, cardiovascular drugs can be obtained without a prescription from pharmacies. Pharmacies are mostly run by pharmacy technicians and untrained dispensers, in addition to few qualified pharmacists. Thus we cannot expect that the pharmacy staff would know the detailed impact of a drug they sell to customers. It is common place in Yemen, that these dispensers are regarded as 'physicians' so in many times they do diagnosis, prescribing and dispensing medicines for various health complications and diseases, despite their non-existent knowledge and authority.

Rational use of medicines aims to improve the use of medicines by health providers, individuals and community through rational prescribing, dispensing and appropriate use of individuals and community.

Future Challenges

Having looked into the demographic and the current pharmaceutical states of Yemen, its health system and services, pharmaceutical policies, trade and production, regulations, financing, pharmaceutical product procurement and distribution, and finally down to the laymen, their knowledge, attitude, and practice, also the poor handling of information and updates, we can predict a number of future challenges.

First of all, the authorities need to be educated about the importance of updating the policy and information resources on pharmaceutical products that will be sold, or are already sold at the counter. This is the greatest challenge to overcome. The second challenge is to reform the pharmacy curriculum taught in the public and private universities and institutes and to educate the community pharmacies and drug stores owners and employers. This is because the importance of formal and continuing education and to increase the awareness as it is common to dispense any medicine without prescription in Yemen. Also they have to know that their role is not just dispensing but also to educate the patients and consumers about the drugs they are dispensing.

Another challenge is that the numbers of physicians have outnumbered the clinical pharmacies in the country. Thus, there is a need for the MOPHP to build more pharmacies, especially in Yemeni hospitals. As the top people are informed and educated about the importance of pharmacovigilance through a number of campaigns, workshops, talks, or through reading materials, the public also needs to be informed and made aware of the importance of being treated and diagnosed by qualified physicians, rather than depending on the 'diagnosis' of staff working at the pharmacies.

There is also a challenge in identifying and confiscating counterfeit drugs in Yemen. Therefore, drug policing needs to be made stricter and the MOPHP must prepare a guideline on the types of drugs that are sold in the market. The healthcare professionals and the public must be informed of the existence of these counterfeit drugs and to be able to distinguish between drugs that are 'valid' and drugs counterfeited.

Next, Yemen has to think of ways to address the problem of curbing the number of pharmacies and drug stores operated by unqualified persons. This non-qualification issue has contributed to the fact that pharmacy practice has been undermined in Yemen, both in terms of recognition from the Ministry of Higher Education and in terms of the general perception of the state of the profession in Yemen.

Conclusion

Despite the progress Yemen has made with regard to expanding and improving its health care system over the past decade, the system remains severely underdeveloped. To improve pharmacy practice in Yemen, many changes are crucial, including updating the pharmacy curriculum taught, implementing standards for pharmacy practice, implementing and/or reinforcing pharmacy legislations and regulations, as

well as integrating pharmacists more comprehensively in the healthcare system as a member of the health care team. Additionally, the quality of the pharmacy workforce needs improvement, and awareness needs to be increased among the public, physicians, other healthcare professionals, and policy makers about the value of pharmacists as health professionals. Everyone, from the MOPHP, the policy makers, to healthcare professionals and the community have to be educated about pharmacovigilance, the adverse effect of drugs and the danger of being exposed to them. This is not an easy task, but can help the Government address the different pharmaceutical-related challenges and transform Yemen's healthcare system.

Conflict of interest statement

We declare that we have no conflict of interest.

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