Libyan International Medical University

Faculty of Pharmacy

RATIONAL ANTIMICROBIAL THERAPY IN THE EASTERN REGION OF LIBYA

Submitted by:

Afia. A. Khalifa

Under supervision of

Prof. Mustafa Elfakhri

Dr. Salma Bukhatwa

Supervisor's Approval: ----------

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Declaration

This is to certify that research work embodied in this thesis entitled "Rational antimicrobial therapy in the Eastern region of Libya" has been carried out by me under supervision and guidance of Prof. Mustafa Elfakhri and Dr. Salma Bukhatwa.

Afia. A. Khalifa

Abstract

Drug utilization studies conducted in Libya during the period 1991-2013, have pointed out the irrational use of antibiotics as a common practice that costs the health system more than 7.7 million Libyan Dinars / year. The aim of this study is to assess the trend of antimicrobial consumption in the Eastern region of Libya during 2012 – 2013.

Antimicrobial consumption data from the years 2012 and 2013 were obtained mainly from Benghazi office, Medical Supply Organization (MSO; the only official drug-importing body in Libya). This study concerned with antibiotics imported only to the Eastern region of Libya, population of which represents approximately 35% of total Libyan population. The WHO Anatomical-Therapeutic-Chemical (ATC) classification and the Defined Daily Dose (DDD) methodology were used to calculate antibiotic consumption. The total antimicrobial consumption data were calculated as DDD/1000 inhabitants/day.

Total utilization of antibiotics decreased dramatically from 15.466 DDD/1000 inhabitants/day in 2012 to 4.332 DDD/1000 inhabitants/day in 2013 which also shows a significant decline compared to 41.715 DDD/1000 inhabitants/day during the period 1991-1993. Consumption of penicillins decreased from 19.902 DDD/1000 inhabitants/day during 1991-1993 to 1.896 DDD/1000 inhabitants/day during 2012-2013 with pattern of amoxicillin/clavulanic acid consumption equals approximately 3 times ampicillin consumption and is the highest compared to all penicillins during that period. This was accompanied by a prominent increase in consumption of amphenicols and fusidic acid during 2012-2013 noting that fusidic acid consumption was the highest among all antibiotics.

MSO since 2011 (post 17th February 2011 revolution) lost its control on importing medicines due to receiving many drugs as donations from different international sources without acceptable level of coordination. This has been reflected on drug purchasing policy of MSO during 2013, which failed to regain the previously accepted level of DDD/1000 inhabitants/day antibiotics consumption.

In addition the decreased consumption of penicillins together with increased consumption of amphenicols and fusidic acid complies with the pattern of antibiotic resistance reported previously in Libya by Gengesh et al. 2013. Similar studies should be conducted to evaluate national drug consumption under normal conditions to be compared with regional and international data.

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List of Abbreviations

AT	Anatomical Therapeutic
ATC	Anatomical-Therapeutic-Chemical
CCDSM	Collaborating Center for Drug Statistics Methodology
DDD	Defined Daily Dose
DDDs	Define Daily Doses
DUR	Drug Utilization Research
DURG	Drug Utilization Research Group
DUS's	Drug Utilization Studies
EPHMRA	European Pharmaceutical Market Research Association
I.U.	International Unit
IMS	International Marketing Surveys
IPMRG	International Pharmaceutical Marketing Research Group
MU	Million Units
MSO	Medical Supply Office
NCPI	National Company of Pharmaceutical Industry
NMD	Norwegian Medical Depo
PDD	Prescribed Daily Dose
WHO	World Health organization

List of Publications

- **Afia A**. Khalifa, Salma A. Bukhatwa, Mustafa M. Elfakhri. Antibiotics consumption trend in Libya 2012-2013. *17th International Conference of the Union of Colleges of Pharmacy in the Arab world* 14-16 October **2014**, Ain Shams University, Cairo, Egypt.

- Salma Bukhatwa, Sara Trabelsi, **Afia Abduelmula** and Mustafa Elfakhri. Antibiotics misuse in Libya: Observational study. *FIP's World Congress of Pharmacy and Pharmaceutical Sciences Conference*, 30 August - 4 September **2014**, Bangkok, Thailand.

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Chapter I

Introduction

1.1. General Introduction

Medicines or drugs are substances or preparations which are intended for administration to human beings or animals in order to prevent, diagnose, alleviate or cure diseases and pathological symptoms, or to act on body functions.[1]

The terms Drug Utilization Research (DUR), Drug Consumption Study, Drug Utilization Study (DUS), Drug Utilization Review, Drug Usage Review, and Drug Use Evaluation are one more or less synonymous. The World Health Organization (WHO) has continued to use the term Drug Utilization Research (DUR) that is defined as follow:

"The marketing, distribution, prescription and use of drug in society, with special emphasis on the resulting medical, social and economic consequences".[2]

WHO recommended and inspired DUR studies; that was in 1964 when WHO first organized a symposium on drug toxicology in Moscow and one of recommendations was that serious consideration has to be first given to major public studies of drug utilization. Like many other developments at the time, the thalidomide had sparked this one. The Moscow Meeting led directly to a joint study undertaken by two directions –general of public health – Dr. P. Siderius in the Netherlands and Dr. A. Engel in Sweden – who collected data not only from their own countries, but also from a range of others. Both scientists visited six European countries in1966-1967 on behalf of the WHO, who arranged a meeting in Oslo in 1969 of people who were interested in drug usage problem which lead to formation of Drug utilization Research Group (DURG).[3]

1.2. Scope of DUR

The pharmaceutical industry always uses DUR to identify areas of need for new drug development, to determined pattern of use and potential increase in usage of both new and existing medicines and in the performance of scale division.

DUR is an important area of post marketing surveillance for new product and thus can provide national drug regulation agencies with information on adverse drug reactions. Health care purchaser aims to achieve both the optimal care (efficacy with minimum toxicity) for their client group as well as an accurate prediction of the associated economic implications. Furthermore, health care provider seeks to match the most effective provision, which are officially stipulated. Indeed, health care professionals and scientists tend to employ DUR to investigate methods of improving the quality of drug usage.[4]

1.3. Types of Drug Utilization Studies (DUS's) and Their Use

1.3.1. Quantitative studies

The objective of such study is to quantify present state, development trend, and time course of drug usage at various levels of the health care system, whether national, regional, local, or institutional.

Routinely compiled drug statistics on drug utilization data that are the result of such studies can be used to estimate drug utilization in population by age, sex, social class, morbidity and other characteristics, and therefore can identify areas of possible over – or under – utilization.

They also can be used as denominator data for calculating rates of reported adverse drug reactions, to monitor the utilization of specific therapeutic categories where particular problem can be anticipated, to monitor the effects of informational and regulatory activities as markers for very crude estimate of disease prevalence, to plan for drug importation, production and distribution, and to estimate drug expenditure.

1.3.2. Qualitative studies

The qualitative studies assess the appropriateness of drug utilization, usually by linking prescription data to the reasons for drug prescribing. The crucial difference between these studies and quantitative DUS's is that qualitative studies include the concept of appropriateness and thus the appropriateness of drug prescribing may be compared. Drug use criteria are based upon such parameters as indication for use, daily dose, or length of therapy. Other possible criteria for poor drug prescribing include the failure to select a more effective or less hazardous drug if available, justification of the use of fixed components, or the use of a costly drug when a less costly equivalent drug is available.[5,6]

1.4. Defined Daily Dose (DDD)

1.4.1. Definition of DDD

The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults. [7]

1.4.2. DDDs as a unit of measurement

The DDD methodology was developed in Scandinavian countries in the late 1970s and is now internationally adopted and supported by WHO. It should be emphasized that the DDD is a

unit of measurement and does not necessarily correspond to the recommended or prescribed daily dose (PDD). The DDD is often a compromise based on a review of the available information about doses used in various countries. Drug utilization figures should ideally be presented as numbers of DDDs per 1000 inhabitants per day or, when drug use by inpatients is considered, as DDDs per 100 bed-days. For anti-infectives (or other drugs normally used for short periods), it is often considered to be most appropriate to present the figures as numbers of DDDs per 1000 inhabitants per day.

1.5. Drug classification system

During the past century, large number of potent and effective drugs has been introduced, as a result of progressive development in pharmaceutical industry. Such industrial developments have not only improved drug therapy but have also increased the drug consumption and medical care cost. This has been attracting increasing interest in collection and analysis of drug utilization data.

A drug classification system represents a common language for describing the drug assortment in a country or region and is a prerequisite for national and international comparisons of drug utilization data, which have to be collected and aggregated in a uniform way.[7]

Drug classification is important tool for DUS's and for performing comparative studies of both supply and consumption of medicines. Drugs can be classified in different ways depending on their chemical structure, mechanisms of action, therapeutic indications or site of action. Any of the different classification ways can lead to certain classification system depending on the aims of the proposed study. The DUR in the European Pharmaceutical Market Research Association (EPHMRA) and the Norwegian Medical Depot (NMD) are always developing the methods and units of measurement for reaching a standard international classification system and attaining good experimental methods in this field to support the DUS's reliability. From the various drug classification systems obtained previously two of them have survived (1) the Anatomical-Therapeutic (AT) classification and (2) the Anatomical- Therapeutic–Chemical (ATC) classification that was in principle derived from it.

1.5.1. Anatomical-Therapeutic -Chemical (ATC) Classification

The main purpose of the ATC classification is as a tool for presenting drug utilization statistics and it is recommended by WHO for use in international comparisons.

1.5.1.1. History

The ATC classification system is used by the EPHMRA and by the International Pharmaceutical Market Research Group (IPMRG). ATC classification has also been adopted by various European and American countries, and it is also used by International Marketing Surveys (IMS); which conducts surveys for the pharmaceutical industry.[6,8]

The ATC classification system is derived from the AT concept when the pioneering work, done by two consultants (Engel and Siderius) at the WHO-Euro, and one of the important results was the NMD that developed a classification system known as the ATC classification. At the end of 1970s the DURG members recommended the ATC/DDD methodology for international DUS's, illustrating that in order to achieve comparative data for drug consumption between different countries, it is necessary to have a common basis regarding drug classification for all drugs or medicines available.

In 1981 WHO recommended the ATC/DDD for international DUS's, in connection with this, and to make the methodology more widely used, a central body responsible for coordinating the use of methodology; the WHO Collaborating Center for Drug Statistics Methodology, (CCDSM) that was established in Oslo in 1982. According to the agreement between WHO-Euro, and NMD, the main tasks of the center were to classify drugs according to the ATC system, to establish DDDs for drugs which have received an ATC Code, and to review and revise as necessary the ATC classification system and DDDs.

Priority is given to the classification of single substances, while combination products available international are dealt with as far as possible.[7]

1.5.1.2. Structure of the ATC system

The ATC classification system divides the drugs into different groups according to the organ or system on which they act and according to their chemical, pharmacological and therapeutic properties. Drugs are classified in groups at five different levels. The drugs are divided into 14 main groups (first level), with two therapeutic/pharmacological subgroups (second and third levels). The fourth level is a therapeutic/pharmacological/chemical subgroup and the fifth level is the chemical substance. The second, third and fourth levels are often used to

identify pharmacological subgroups when these are considered to be more appropriate than therapeutic or chemical subgroups.[7]

Since 1976, the ATC system has been further developed by the Nordic Council on Medicines in collaboration with WHO CCDSM.

It is important to note that the ATC classification is not intended to be used for marketing purposes and does not necessarily reflects the recommended therapeutic use in all respect.

1.5.1.3. Main principles for ATC classification System

1. Drugs are classified according to their main therapeutic use, on the basic principle of only one ATC Code for each pharmaceutical preparation.

2. A drug may be used for two or more equally important indications and the main therapeutic use of drug may differ from one country to another. This will often give different classification alternatives. Such drugs are usually only given one code, and the main indication being decided on the basis of the available literature.

3. A drug can be given more than one ATC Code if it is available in two or more strengths or formulations with clearly different therapeutic uses.

4. Drugs which do not clearly belong to any group should be placed in an X group.[6,11]

1.6. Import, Storage and Distribution of Drugs in Eastern Region of Libya

All the drugs consumed in Libya are imported except few items, which are manufactured locally. The headquarters of the National Company of Pharmaceutical Industry (NCPI) was in Tripoli and until 2004 was responsible for all drug manufacture and imports in Libya. its branches are the channels of drugs distribution for governmental hospitals & private pharmacies and clinics.

on 2004 till date the Libyan Secretariat of Health by executing a public tender through Medical Supply Organization (MSO) has become responsible for purchasing and distribution of drugs to public hospitals and clinics. Worth noting that on sporadic intervals a budget has been allocated to major public hospitals to locally purchase their own general drug demands. However, during the last seven years the MSO Benghazi's branch has been hold responsible of serving the whole public sector of the Eastern region of Libya. The population of this

region is about 1,807,336 million - according to the last population census 2006 - mostly concentrated at the coast (Figure 1).

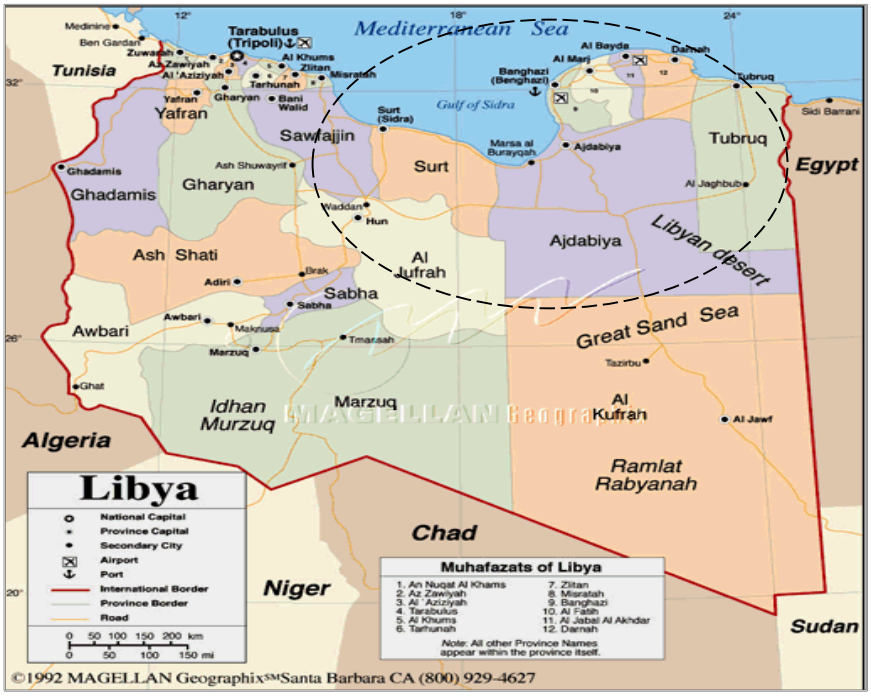

Figure 1 : Areas of the Eastern region in Libya

Adopted from www.pinstopin.com

1.7. Previous local drug utilization studies

Since 1970s WHO strongly urged the international health authorities to adopt DUS's in order to determine and evaluate the trend and pattern of drug consumption. WHO delegates attended symposium on the subject in Libya, which was held in 1977, to emphasize the importance of DUS's. Prof. Lund, a pioneer in the field, visited Libya in 1977 and provided the first detailed report on the situation to the health authorities in the country. In response to urgent need for such studies a team of University staff members of the Department of Pharmacology / Faculty of Medicine / University of Benghazi, who developed interest in DUS's, gathered and decided to start serious studies on the use of drugs. Studies conducted by that group of investigators covered the period 1980-1982 and dealt with utilization of many groups of drugs including antibiotics.[12] Thereafter individual activities and studies have been carried out by several workers both in Benghazi and Tripoli. Different methods and approaches were followed where prescription analysis methodology was a frequently adopted methodology.[13-19] The results of most of these studies were communicated to health personal

attending local conferences (Table 1).[14,15,20-25] A point that was rather astonishing is the similarity of results of most of these studies with regard to drug use in various regions of Libya irrespective of the region or the year covered by the study (Table 1).[14,15,20-25] This clearly indicates that results of such studies and recommendations of the various local meetings on the problem of drug misuse or over use had no influence on prescribers nor on health authorities in the country.[13-25] Such an attitude may deter interested and active workers in the field from continuing their investigations.

There has been a local MSc. thesis in the field of drug utilization and it was designed by Burkan ZE, in 1999 on the basis of results of the previous studies conducted in the seventies.[26] Antibiotics was one of the drug groups included in that study. The study covered the period 1991-1993 and discussed import and consumption of many drug groups in the Eastern region of Libya, based on ATC/DDD methodology.[26] Burkan demonstrated that ampicillin was the first choice treatment among all penicillins used at that time.[26] Same study showed that anti-infectives' consumption in the Eastern region of Libya was higher than that in Nordic countries and Australia during the study period.[26] The study ended by recommending more DUS's within the country for the purpose of further reviewing national drug policies.

Table1 : Data from prescription analysis[14,15,20-25]

Indicator	1991	1994	1996	1997	2002	2009	2010	2013
Average no of drugs / prescription	3	4	2.70	2.60	2.20	1.53	2	2
% Of antibiotics prescribed	42	57	47	55.6	45.6	33.3	58.9	57
% Missing name of patient	11	0	1.3	2.5	5.6	6	4.72	6.7
% Missing age of patient	8	3.5	17	23.6	27.9	35.8	26.44	49
% Missing sex of patient	100	28	100	89.4	99.4	99.6	89.43	51
% Missing signature of doctor	7	-		14.8	7.5	55.6	10.52	21
% Missing of dose	5	0	1	7.7	3.50	47.1	3.33	5
% Missing of diagnosis			-	98.9	98.7	99.8	100	100
% Missing of date	-	-	-	51.0	32.9	64	58.8	48
% Missing period of treatment	96	100	73	80.1	48.1	52.5	6..6	28

1.8. Antibiotics

Antibiotics and similar drugs, together called antimicrobial agents, have been used for the last 70 years to treat patients who have infectious diseases. Since the 1940s, these drugs have greatly reduced illness and death from infectious diseases. However, these drugs have been used so widely and for so long that the infectious organisms developed resistance toward such antibiotics making the drugs less effective.

1.8.1. Definition of antibiotic

Substance that destroy or inhibit the growth of other pathogenic microorganisms and is used in treatment of external or internal infections. Some antibiotics are produced by microorganisms, and most of them are now manufactured synthetically.

1.8.2. Classification of Antibiotics

Antibiotics are classified in to more than 16 classes by several ways; on basis of:

- Mechanism of action
- Spectrum of activity
- Mode of action

1.8.3. Problems with antibiotics use

1.8.3.1. Allergy

An antibiotic allergy or hypersensitivity reaction can happen with any drug, and allergies are one of the most common antibiotics side effects leading to emergency room admission. Health care providers should always be informed of any previous allergic reaction to any medication, including antibiotics. Mild allergic reactions may only result in a skin rash. More severe allergic reactions, called anaphylaxis, can lead to shortness of breath, wheezing, hives, and swelling of the face, lips or tongue. Anaphylaxis is a medical emergency that requires immediate medical attention.[27]

1.8.3.2. Resistance

Antibiotic resistance is the ability of bacteria to resist the effects of an antibiotic – that is, the bacteria are not killed, and their growth is not stopped. Resistant bacteria survive exposure to the antibiotic and continue to multiply in the body, potentially causing more harm and spreading to other animals or people (Figure 2).

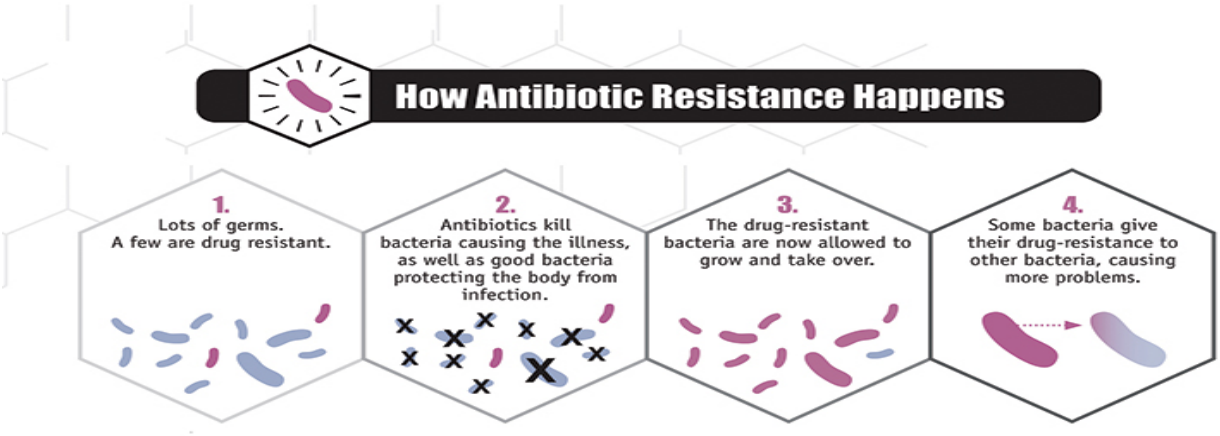

Figure 2 : Antibiotic resistance

Adopted from www.cdc.gov

1.8.4. Costs of antibiotics consumption in Libya

Actually, DUS's conducted during the period 1991–2013 in Libya, have pointed out the irrational use of antibiotics as a common practice that costs the health system more than 7.7 million Libyan Dinars/year (unpublished data obtained from MSO).

1.9. Objectives of the work

This study discusses policy of rational use of antibiotics in the Eastern region of Libya via quantitative determination of antibiotics utilization.

1.10. Aims of the work

Current study was carried out at the Eastern region of the Libya to:

1. Assess antibiotic consumption during the period 2012 -2013.
2. Determine the Annual Total import into the annual total consumption using (DDD/1000 inhabitants/day) as a technical unit of measurement.
3. Compare the results with previous local studies carried out during the period 1980-1993 and consequences of changes.
4. Compare the so obtained results with corresponding international data.

Chapter II

Materials and Methods

2.1. Sources of information

2.1.1. Main store of the General Secretariat of Health in Benghazi

This store supplies all public health institutions in the Eastern region of Libya with their needs of drugs and medical supplies. Information obtained from this store was reliable as their records were well maintained.

Data obtained from the store included tenders requirements, imported quantities, consumed, expired, stock and drug inventory for the following years; 2012 & 2013, this of course in addition to quantities of drug issued periodically to each health facility.

2.1.2. Medical Supply Organization (MSO)

MSO is the only body responsible for the drug supply to public health institutions in the Eastern province. Some of the obtained information was made available by MSO Technical Department while others had been collected from existing drug stores within the public health centers which are enrolled in this study.

2.1.3. Main web site of population census

Information concern the Libyan population census that was conducted on 2006 are available at the following website www.gia.gov.ly.[28]

Distribution of population among different areas of Eastern region of Libya is shown in (Table 2 & Figure1). Areas included in the Eastern region of Libya, are the cities of Ajdabia, Benghazi, Al-Kufra, Al-Marj, Al-Beida, Derna, and Tobruk and the surrounding smaller townships. Total number of inhabitants in the Eastern region of Libya in the years 1991, 1992, 1993 & 2006 is shown in (Table 3).

Table 2: Number of inhabitants in different parts of the Eastern region of Libya according to the population census in 2006[28]

City	Grand total		
	Population density	%	Population
AL Batnan	1.86	2.79	157 747
Derna	5.17	2.88	162 857
AL-Gebel EL-Akhdar	18.04	3.64	206 180
AL-Marj	13.65	3.26	184 531
Benghazi	59.35	11.93	674 951
Ajdabia	1.65	3.17	179 155
AL-Kufra	0.11	0.85	48 328
AL-Wahat	1.64	2.50	141 495
AL-Joufra	0.37	0.92	52 092
Misurata	18.62	9.60	543 129
AL-Margheb	62.96	7.56	427 886
Tripoli	1273.74	18.80	1 063 571
Jafara	169.23	7.97	451 175
Zawia	105.57	5.14	290 637
Nikhat Al Kham	47.19	5.08	287 359
Al-Gabal Al-Gharbi	3.95	5.35	302 705
Nalut	1.40	1.66	93 896
Sebha	7.81	2.35	133 206
Wadi A- Shati	0.87	1.39	78 563
Murzuk	0.22	1.39	78 772
Wadi AL-Haya	2.42	1.35	76 258
Ghat	0.34	0.41	23 199
Total	3.38	100.00	5 657 692

Table 3: Total number of inhabitants in the Eastern region of Libya

Year	Total number of population in Eastern region of Libya
1991	1123968
1992	1155552
1993	1189081
2006	1807336

2.2. Data collections and calculations

2.2.1. Drug Import to the Eastern region of Libya

Total amounts of drugs imported annually from each of the eight drug groups consumed during the two years of the study were obtained by adding up the figures from stores of the NCPI and stores of MSO as both stores complement one another in supplying drugs to the Eastern region of Libya, for both private and public sectors respectively. Imported drugs in the present study included drugs that were actually received and delivered to the stores.

2.2.2. Drug consumption in the Eastern region of Libya

The amounts of drugs consumed in all Eastern region of Libya were obtained from the records of the Secretariat of Health stores and from the stores of the NCPI.

Figures for regional annual sales were calculated by adding inventory figures of drugs remaining in stores from previous year to the amounts of drugs imported during the studied year minus drugs remaining at end of that particular year including expired drugs. These sales figures plus the distribution figures obtained from stores of the Secretariat of Health constituted total annual drug consumption for the Eastern region of Libya, as shown in the following equation:

Annual drugs sales= (drug remaining from previous year+ drug imported the study year)-(drug remaining from the study year+ drug expired the study year)

Equation 1: Annual drug sales

2.2.3. Conversion of data to DDDs

1. Since most drugs are available in different strengths and different dosage forms, then a suitable form was designed to accommodate all these different strengths and forms of drug (Appendix I). Collecting information in this form also facilitated counting the annual total amounts of drugs in grams (g), milligrams (mg) or International Units (I.U.).
2. The annual total quantity of the active ingredient for each drug is converted into DDDs by dividing the annual quantity of a drug by its standard DDD (Appendix II).
3. The annual DDDs of a drug were further divided by 365 days to obtain the number of DDDs imported or consumed per day, (DDD/day).
4. Finally the resultant (DDD/day) were further divided by the annual number of inhabitants of the Eastern region of Libya and multiplied by one thousand to report import or consumption data as DDD/1000 inhabitants/day, as shown in the following equation:

$$\frac{\textbf{Amount of drug imported or consumed in a year (in mg)}}{DDD(mg)x365daysx\ number\ of\ inhabitants} x100 = \frac{DDD}{1000inh}/day$$

Equation 2: Calculation of consumption of antibiotics as DDD/1000 inhabitant /day[10]

Chapter III

Results

3.1. Utilizations of antibiotics in Eastern region of Libya during the years 2012 & 2013

Antibiotics included in the study were classified according to ATC classification system (Table 4). The utilization of these antibiotics during the years 2012 & 2013 was presented as DDD/1000 inhabitants/day (Table 4). Utilization of tetracyclines in 2012 was 0.42 DDD/1000 inhabitants/day and increased to 1.88 DDD/1000 inhabitants/day in 2013 (Table 4). Utilization of amphenicols in 2012 was 4.47 DDD/1000 inhabitants/day but no amphenicols were in the market in 2013 (Table 4). Utilization of penicillins in 2012 was 2.050 DDD/1000 inhabitants/day and decreased to 1.742 DDD/1000 inhabitants/day in 2013 (Table 4). Utilization of quinolones in 2012 was 0.009 DDD/1000 inhabitants/day and increased to 0.012 DDD/1000 inhabitants/day in 2013 (Table 4). Utilization of macrolides in 2012 was 0.42 DDD/1000 inhabitants/day and decreased to 0.140 DDD/1000 inhabitants/day in 2013 (Table 4). Utilization of cephalosporins in 2012 was 0.320 DDD/1000 inhabitants/day and decreased to 0.209 DDD/1000 inhabitants/day in 2013 (Table 4). Utilization of aminoglycosides in 2012 was 0.203 DDD/1000 inhabitants/day and decreased to 0.156 DDD/1000 inhabitants/day in 2013 (Table 4). Utilization of other antibiotics in 2012 was 7.574 DDD/1000 inhabitants/day and decreased to 0.193 DDD/1000 inhabitants/day in 2013 (Table 4). Total utilization of antibiotics decreased dramatically from 15.466 DDD/1000 inhabitants/day in 2012 to 4.332 DDD/1000 inhabitants/day in 2013 (Table 4).

3.2. Antibiotics consumption in Eastern region of Libya during (2012-2013) compared to consumption during (1991-1993)

Consumption of tetracyclines decreased in 2012-2013 by 3.9 DDD/1000 inhabitants/day compared to 1991-1993 (Table 5). Consumption of amphenicols increased in 2012-2013 by 2.1 DDD/1000 inhabitants/day compared to 1991-1993 (Table 5). Consumption of penicillins decreased in 2012-2013 by 18.0 DDD/1000 inhabitants/day compared to 1991-1993 (Table 5). Consumption of quinolones increased in 2012-2013 by 0.01 DDD/1000 inhabitants/day compared to 1991-1993 (Table 5). Consumption of macrolides decreased in 2012-2013 by 1.6 DDD/1000 inhabitants/day compared to 1991-1993 (Table 5). Consumption of cephalosporins decreased in 2012-2013 by 0.9 DDD/1000 inhabitants/day compared to 1991-1993 (Table 5). Consumption of aminoglycosides decreased in 2012-2013 by 0.2 DDD/1000 inhabitants/day compared to 1991-1993 (Table 5). Consumption of other of antibacterials increased in 2012-2013 by 2.5 DDD/1000 inhabitants/day compared to 1991-1993 (Table 5).

Total consumption of antibiotics was dramatically decreased in 2012-2013 by 31.816 DDD/1000 inhabitants/day compared to 1991-1993 (Table 5).

3.3. Percentage (%) antibiotics consumption in Eastern region of Libya during the periods (1991-1993) and (2012-2013)

Penicillins, sulfonamides and tetracyclines represented 50.34, 13.64 & 12.16% respectively of total antibiotics consumed during 1991-1993 in Eastern region of Libya (Table 6). Meanwhile penicillins, tetracyclines and amphenicols represented 26.71, 23.06 & 14.45% respectively of total antibiotics consumed during 2012-2013 in the Eastern region of Libya (Table 6).

3.4. Penicillins and fusidic acid consumption in Eastern region of Libya during the period 1991-1993 and 2012-2013

Ampicillin represented 97.4% of all penicillins consumed during 1991-1991, but its use was reduced to 11.88% among all penicillins consumed during 2012-2013 (Table 7). Amoxicillin and amoxicillin/clavulanic acid combination represented 1.35 & 1.22% respectively of all penicillins consumed during 1991-1993, but their use was increased to 26.37 & 37.97% respectively of all penicillins consumed during 2012-2013 (Table 7).

In addition, ampicillin represented 37.23% of all antibiotics consumed during 1991-1993, but its use was reduced to 02.58% among all antibiotics consumed during 2012-2013 (Table 7). Amoxicillin and amoxicillin/clavulanic acid combination represented 0.52 & 0.47% respectively, of all antibiotics consumed during 1991-1993, but their use was increased to 05.15 & 07.27% respectively, among all antibiotics consumed during 2012-2013 (Table 7).

Noting that fusidic acid represented 38.25% of all antibiotics used during 2012-2013 and hence its consumption was the highest among all antibiotics used in 2012-2013 (Table 7).

Table 4: Utilization of antibiotics in the Eastern region of Libya during the years 2012 & 2013

Drug group according to ATC system	DDD/1000 inhabitants/Day	
	2012	2013
JO1A-Tetracyclines		
Doxycycline	-	1.83
Tetracycline	0.42	0.05
Total (%)	0.42 (2.71)	1.88 (43.4)
JO1B- Amphenicols		
Chloramphenicol	4.47	-
Total (%)	4.47 (28.9)	
JO1C-Penicillins		
Amoxicillin	0.39	0.63
Ampicillin	0.30	0.21
Amoxicillin + Clavulanic acid	0.72	0.72
Benzathine Penicillin	0.01	0.10
Penicillin G	0.18	0.06
Flucloxacillin	0.40	0.002
Cloxacillin	0.05	0.02
Total (%)	2.05 (13.2)	1.742(40.21)
PO1D- Quinolones		
Levofloxacin	0.002	0.002
Ciprofloxacin as lactate	0.007	0.01
Total (%)	0.009 (0.05)	0.012 (0.27)
JO1E- Macrolides		
Erythromycin	0.41	0.14
Clarithromycin	0.01	0.0001
Total (%)	0.42 (2.71)	0.14 (3.23)
JO1F-Cephalosporins		
Ceftriaxone sodium	0.27	0.0007
Cephalexin	0.03	0.15
Cefotaxiem sodium	0.02	0.058
Total (%)	0.32 (2.06)	0.209 (4.82)
JO1G- Aminoglycosides		
Gentamycin Sulphate	0.19	0.13
Amikacin	0.013	0.026
Total (%)	0.203 (1.31)	0.156 (3.60)
JO1X- Other Antibacterial drugs		
Vancomycin	0.003	0.18
Fucidic acid	7.57	0.001
Clindamycin	0.0005	0.01
Total (%)	7.574 (48.9)	0.193 (4.45)
End Total	**15.466**	**4.332**

Table 5: Antibiotics consumption in the Eastern region of Libya during the periods (1990-1993) & (2012-2013)

Drug group according to ATC classification	Average DDD/1000 inhabitants/day		
	1991-1993	**2012-2013**	**Difference in DDD**
Tetracyclines	5.016	1.150	- 03.9
Amphenicols	0.091	2.235	+ 02.1
Penicillins	19.902	1.896	- 18.0
Quinolones	-	0.011	+ 0.01
Macrolides	1.887	0.280	- 01.6
Cephalosporins	1.234	0.265	- 00.9
Aminoglycosides	0.416	0.180	- 00.2
Other antibacterials	1.341	3.884	+ 02.5
End total	**41.715**	**9.899**	**- 31.816**

Table 6: Percentage (%) antibiotics consumption in the Eastern region of Libya during the periods (1991-1993) & (2012-2013)

Drug group according to ATC classification	Average % drug consumed during 1991-1993	Average % drug consumed during 2012-2013
Tetracyclines	12.16	23.06
Amphenicols	00.23	14.45
Penicillins	50.34	26.71
Quinolones	-	00.16
Macrolides	04.49	02.97
Cephalosporins	03.05	03.44
Aminoglycosides	01.01	02.46
Sulfonamides	13.64	-
Other antibacterials	14.94	26.68

Table 7: Penicillins and fusidic acid consumption in Eastern region of Libya during the period 1991-1993 and 2012-2013

Drug name	1991-1993 %From Penicillins	1991-1993 %From total Antibiotics	2012-2013 % from Penicillins	2012-2013 % from Total Antibiotics
Amoxicillin	01.35	0.52	26.37	5.15
Ampicillin	97.40	37.23	11.88	2.58
Amoxicillin + Clavulanic acid	01.22	0.47	37.97	7.27
Benzathine Penicillin	-	0.73	02.64	0.56
Penicillin G	-	-	06.33	1.21
Flucloxacillin	-	0.39	10.6	2.03
Cloxacillin	-	5.21	01.85	0.35
Other antibacterials (Fusidic acid)	-	0.20	-	38.25

Chapter IV

Discussion and conclusion

4.1. Discussion

Among all dugs available for medical use, the list of anti-infective drugs is progressively increasing. Such increase is not a consequence of development or advances made in science and technology as such but it is primarily the result of the over growing need for new anti-infective drugs to surpass the problems of continuing misuse of this group of drugs and the development of resistant bacterial strains.[27] Surveillance of antimicrobial consumption is important in improving the quality of antimicrobial use. It is a key role in establishing the rationale for the use of antimicrobials. Countries with the highest per capita antibiotic consumption have the highest resistance.[29] This problem is a global one and DUS's have always been useful in emphasizing the problem and the pitfalls of daily prescribing of such group. Many organizations have recommended that antibacterial drug use at national levels should be monitored to better understand the relationship between the use of antibacterial drugs and emerging bacterial resistance. All previous local studies from different areas of Eastern region of Libya from 1980 up to 2013 showed no changes in the prescribing and consumption pattern of antibiotics in spite of the obvious changes in number of populations in these areas during that period.

Present study determines the consumption of anti-infective drugs in Eastern region of Libya during 2012-2013 and compares results with previous local study conducted 1991-1993. The total amount of antibiotics imported and consumed in the Eastern region of Libya during the years 2012-2013, were obtained from Benghazi office, MSO. All data were converted into DDD/1000 inhabitants/day. Taking in consideration that DDDs applications may have some problems and limitations; firstly, in drug consumption data it is clear that not all drugs reaching the patient are consumed. Secondly, in case of general consumption studies all age groups are used as denomination while some drugs are for specific group only.[8] Thirdly, data on drug use in different countries may not be directly comparable due to difference in definition of drug and its therapeutic use. Fourthly, parts of medicines may be bought outside the target area or the people buy their medicines from outside the target area. Fifthly, for a drug used for several indications DDD/1000 inhabitants/day does not indicate how many patients can be treated over a certain period of time (Ex. one year), and finally, DDD cannot be used for the purpose of comparing costs of various treatment schemes, unless the DDDs are clinically equivalent in the actual cost.[6,9,10] But still ATC/DDD methodology is recommended by WHO experts to achieve comparative data for drug consumption between different countries.

Regarding the Eastern region of Libya, in general total consumption of antibiotics during the years 2012 & 2013 was far lower compared to that during the period 1991-1993 (Table 5). Decreased antibiotics consumption is a tricky figure as it may represents an improvement in antibiotics prescribing and consumption policy (a rational use) which consequently may reduce problems of allergy, resistance … etc. but if such decreased antibiotic consumption do reflect diminished supply and availability which is below actual needs then this could indicate that national drug policy needs a peer review, as antibiotics are life-saving drugs.

Current study showed decreased ampicillin consumption together with increased augmentin consumption. This is in agreement with the fact that microbial resistance towards ampicillin was significantly shown previously in Libya.[30] This may also be supported by the observation that fusidic acid was used in large amounts after 17th February revolution compared to previous years.

The decreased consumption of penicillins together with increased consumption of amphenicols and fusidic acid complies with the pattern of antibiotic resistance reported previously in Libya.[30]

Our study is subject to potential limitations. First, our study is an ecological study – where data are collected on a population rather on an individual level. Therefore the relationship between the observed levels of consumption and resistance should be interpreted with some caution. Secondly, data did not differentiate consumption in private and public sectors. Thirdly, in 2011, many drugs entered the Eastern region of Libya as donations and distribution process of these drugs were not clear, as a result, the total antimicrobial utilization in the Eastern region of Libya may be higher than that reported here.

The most effective approach for improving antimicrobial use is probably a combination of many interventions, which should be supported by government and regulatory authorities. Also, more restrictive policy and rational antibiotic guides are required.

4.2. Conclusion

MSO since 2011 (post 17th February 2011 revolution) lost its control on importing medicines due to receiving many drugs as donations from different international sources without acceptable level of coordination. This has been reflected on drug purchasing policy of MSO during 2013, which failed to regain the previously accepted level of DDD/1000 inhabitants/day of antibiotics consumption. MSO must regain its control on importing

medicines depending on clear policies that should be built on professional accurate local studies, which comply with international reference standards.

4.3. Recommendations

We believe that additional work should be done before definitive recommendations can be made, even though, following recommendations may be taken in consideration:

1. There is a need to peruse DUS's at local, regional and national levels.
2. Similar studies should be conducted to evaluate national drug consumption under normal conditions to be compared with international data.
3. Raising the awareness of public and the health authorities about the need to review national drug policy to encompass sound planning for manufacture, import, stores, distribution, rational prescribing, dispensing and consumption of drugs.

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Appendix I

Libyan International Medical University

Department of Pharmacology &Toxicology

Drug Utilization Data
Drug General Supplier
The population of Eastern region =1807336

Year 2012

Name of Drug	Total of Drug Consumed in a year	Total of Drug DDDs /1000*DDD	Total of DDDs/day	DDDs/day/population/1000 inhabitants
Tetracycline	283189000	283189	775.860274	0.001
Amoxicillin	257609440	25760944	705.779288	0.001
Doxycycline HCl	26965400	2696540	7387.78082	0.010
Cephalexin	49088750	24544.375	67.244863	0.0009
Chloramphenicol	2172000	724	1.98356164	0.0011
Chloramphenicol Palmate	88625	29.5416667	0.0809	4.4762
Cloxacillin	68330500	3415.25	9.35684932	0.00000518
Amoxacillin Trihydrate + Clavulanic acid	359718809	299765.674	82127582	0.00045441
Amoxacillin + Clavulanic acid	359718809	299765.674	821.27582	0.00045441
Ampicillin	405751750	202875.875	555.824315	0.00030754
Erythromycin	708000	708	1.93972603	0.00000107
Ceftriaxone sodium	270341000	180227.333	493.773516	0.00027321
Clindamycin	466800	389	1.06575342	0.00000059
Penicillin G	240182400	120091.2	329.016986	0.00018205

Appendix I cont'd

Drug Utilization Data
Drug General Supplier
The population of Eastern region =1807336

Year 2013

Name of Drug	Total of Drug Consumed in a year	Total of Drug DDDs/ DDD	Total of DDDs/day	DDDs/day/population/1000 inhabitants
Tetracycline	37064000	37064	101.545205	0.00005619
Amoxicillin	418297312	418297.312	1146.02003	0.00063409
Doxycycline HCl	120841800	12084180	33107.3425	0.018311831
Flucloxacillin	3888000	7776	21.3041096	0.00001179
Cephalexin	201475000	100737.5	275.993151	0.00015271
Cloxacillin	35824500	17912.25	49.0746575	0.00002715
Amoxacillin trihydrate + Clavulanic acid	103210275	86008.5625	235.639897	0.00013038
Amoxacillin + Clavulanic acid	476094920	396745.767	1086.9747	0.00060142
Ampicillin	278921750	139460.875	382.084589	0.00021141
Erythromycin	300000	300	0.82191781	0.00000045
Ceftriaxone sodium	569561000	379707.333	1040.29406	0.0005756
Clindamycin	2230800	1859	5.09315068	0.00000282
Penicillin G	84543600	42271.8	115.813151	0.00006408
Clarythromycin	127500	127.5	0.349	0.00000019
Erythromycin Stearate	95884000	95884	262.69	0.00014535
Fusidic acid	1650000	1100	3.01369	0.00000167
Amikacin	17645500	17645.5	48.3438	0.00002675
Benzathine Penicillin	41728400	130.092	356.416	0.00019721
Cefotaxime Sodium	231203000	38533.83	105.5721	0.00005841
Ciprofloxacin as lactate	28189600	7047.4	19.3079	0.00001068
Gentamycin Sulphate	17192000	85.96	0.235	0.00000013
Piperacillin Sodium + Tazobactam	19930500	1423.60714	3.90029	0.00000216
Vancomycin HCl	238081000	119040.5	326.138	0.00018045

Appendix II

Defined Daily Dose (DDD) for Antibiotics used in this study

and used in the comparative study in 1991-1993

Name of Drug	DEFINED DAILY DOSE
Amikacin	1g
Amoxacilin	1g
Ampicillin	2g
Amoxicillin + Clavulanic acid	1.2g
Benzathine Penicillin	0.6g
Cefotaxime	6g
Ceftriaxone sodium	6g
Cephalexin	1.5g
Cefotaxiem sodium	6g
Chloromphenicol	3g
Ciprofloxacin	4g
Claritromycin	1g
Clindamycin	1.2g
Doxycycline	100mg
Erythromycin	1g
Fusidic acid	1.5g
Gentamycin Sulphate	200mg
Penicillin G	2MU
Penicillin V	3MU
Tetracycline	1g
Vancomycin HCl	2g
Floxacillin	2g
Levofloxacillin	o.5g
Piperacillin Tazobactam	14g

Poster presented in the FIP congress, August 2014, Bangkok, Thailand.

Antibiotics misuse in Libya: Observational study

[1]Salma Bukhatwa, [2]Sara Trabelsi, [2]Afia Abduelmula and [3]Mustafa Elfakhri
[1]Department of Pharmacology & Toxicology, Faculty of Pharmacy, University of Benghazi
[2]Department of Toxicology, Faculty of Pharmacy, Libyan International Medical University
[3]Department of Biochemistry, Faculty of Medicine, University of Benghazi

Topic: Community Pharmacy: access to medicines / FIP 2014

Introduction

Drug utilization studies conducted during the period 1991–2013 in Libya, have pointed out the irrational use of antibiotics as a common practice that costs the healthcare system more than 7.7 million Libyan Dinars/year. Aim of this study is to report both quantitatively and qualitatively the antibiotics prescribing trends in Libya.

Methods

Proportion of both prescribed and non-prescribed antibiotics to total drug sales was assessed in 51 private pharmacies in Benghazi city. Drug sellers were interviewed by a structured questionnaire and antibiotics sales were recorded.

Total of 1040 prescriptions from public sector in Benghazi city were collected and analyzed for both prescribing and patient-care indicators.

Conclusion

Antibiotics purchasing without prescriptions remains a major problem in Libya. Well defined policies and regulations regarding drug dispensing should be set. Educational programs that enhance knowledge of drug sellers and community awareness of antibiotics' misuses should be implemented.

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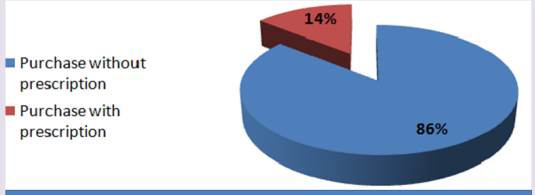
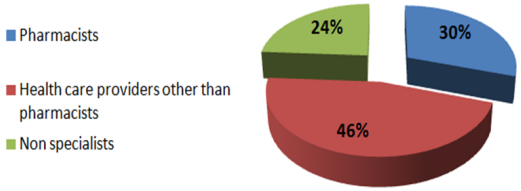
Results

Antibiotics sales in private pharmacies



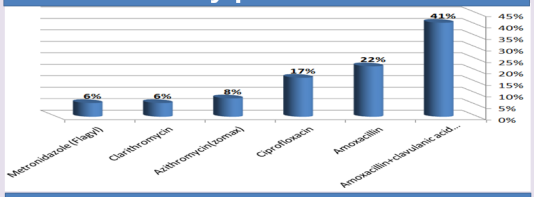
Specialty of healthcare providers in private pharmacies



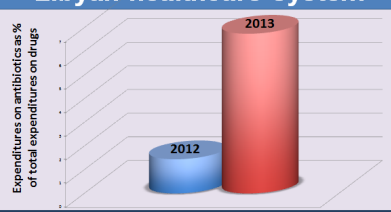
Missing information on prescription

Indicators	1991	1994	1996	1997	2002	2009	2010	2013
Average number of drugs/ Prescription	3	4	2.70	2.60	2.20	1.53	2	2
% of prescription with antibiotics	42	57	47	55.6	45.6	33.3	58.9	57
% Missing name of patients	11	0	1.3	2.5	5.6	6	4.72	6.7
% Missing age of patients	8	3.5	17	23.6	27.9	35.8	26.44	49
% Missing signature of doctors	7	-	-	14.8	7.5	55.6	10.52	21
% Missing date	-	-	-	51.0	32.9	64	58.8	48

Most commonly prescribed antibiotics



Expenditures on antibiotics within the Libyan healthcare system



Poster presented in the 17th International Conference of the Union of Colleges of Pharmacy in the Arab World, October 2014, Cairo, Egypt.

Antibiotics consumption trend in Libya 2012-2013

*Afia A. Khalifa[1], Salma A. Bukhatwa[2], Mustafa M. Elfakhri[3]

[1]Faculty of Pharmacy, Libyan International Medical University, Benghazi, Libya

[2]Faculty of Pharmacy, University of Benghazi, Benghazi, Libya

[3]Faculty of Medicine, University of Benghazi, Benghazi, Libya

INTRODUCTION

This study concerned with drugs imported only to the Eastern region of Libya, population of which represents approximately 35% of total Libyan population.

The aim of this study is to assess the trend of antimicrobial consumption in Libya during 2012 – 2013.

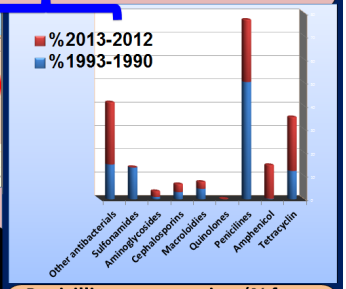
METHOD

The total amount of antibiotics that were imported and consumed in the Eastern region of Libya during the years 2012-2013, were obtained from Benghazi office, Medical Supply Organization (MSO). All data was converted to DDD/1000 inhabitants/da

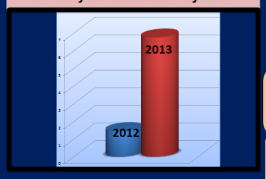
RESULTS

Class	1991-1993	2012-2013	Difference in DDD
Tetracyclines	5.016	1.150	-03.9
Amphenicols	0.091	2.235	+02.1
Penicillins	19.902	1.896	-18.0
Quinolones	-	0.011	+00.01
Macrolides	1.887	0.280	-01.6
Cephalosporins	1.234	0.265	-00.9
Aminoglycosides	0.416	0.180	-00.2
Other antibacterial	1.341	3.884	+02.5
End total	41.715	9.899	-31.816

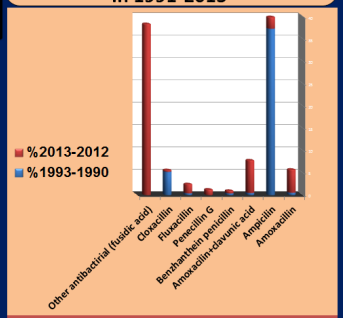
Antibiotics consumption in Eastern region of Libya in (1991-2013)% from the total



Expenditures on antibiotics within the Libyan healthcare system



Penicillins consumption (% from the total) in Eastern region of Libya in 1991-2013



CONCLUSION

17th February 2011 revolution

MSO LOST ITS CONTROL ON IMPORTING MEDICINES DUE TO RECEIVING MANY DRUGS AS DONATIONS FROM DIFFERENT INTERNATIONAL SOURCES WITHOUT ACCEPTABLE LEVEL OF COORDINATION

DURING 2013, MSO STILL FAILED TO REGAIN THE PREVIOUSLY (1991-1993) ESTIMATED LEVEL OF DDD/1000 INHABITANTS/DAY ANTIBIOTICS CONSUMPTION WHICH WAS IN AGREEMENT WITH SIMILAR ACCEPTED INTERNATIONAL DATA.

THE DECREASED CONSUMPTION OF PENICILLINS TOGETHER WITH INCREASED CONSUMPTION OF AMPHENICOLS AND FUSIDIC ACID COMPLIES WITH THE PATTERN OF ANTIBIOTIC RESISTANCE REPORTED PREVIOUSLY IN LIBYA

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