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HERBAL MEDICINES

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Dear fellows and readers

Welcome to the 11th issue of SJRUM.

It is nice to meet with you again on a new issue of SJRUM, this issue is unique, it revolves around herbs and medicinal plants; man’s companions for ages and for years to come in sickness and in health.

Preparing this issue; the editorial board went through lengthy discussion filled with enthusiasm for medicinal plants and fears about safety. I could not escape the eternal controversy surrounding use of medicinal plants.

We present here balanced, comprehensive views about various aspects of herbs and medicinal plants. The readers will be updated about the current situation in Sudan, the legislation and policies beside the position of the WHO on this subject. Educational materials hammering on practical issues regarding medicinal plants are provided along with advice for healthcare professionals when confronted herbal use.

We hope that the readers will benefit from this issue of SJRUM and indeed we hope to influence their practice in this regard.

Dr. Nuha M. Agabna
**Where are we from:** Herbal Medicine Regulatory Situation

**Regulations and Regulatory Authorities**

**Practice:**

All traditional and complementary medicine practices are considered health practices, and are therefore subjects to control by the Ministries of Health (Federal and States MoH).

The herbal/traditional medicine National Policy represent the primary reference on which all laws and regulations depend, controlling all the aspects of the practice.

### Products

**Regulatory bodies:**

**National level:**
- National Medicines and Poisons Board
  - Pharmaceutically formulated Herbal products
  - Equipment and consumables used in complementary medicine practices
- Dietary supplements registration department – MOH
  - Herbal products used as dietary supplements

**State level:**
- Department of Medicinal and Aromatic Plants at Khartoum MoH
  - Raw herbs and herbal products and formulations

**Laws and Legislations:**
- The medicines and poisons act of 2009
- Medicinal and aromatic plant strading regulation List of 2013

### Practitioner

**Regulatory bodies:**

**National level:**
- Sudan Medical Council
  - Registration and granting permissions to practice (for physicians, pharmacists, dentists) specializing in the fields of traditional medicine
  - Sudan National Council for Medical and Health Professions
  - Registration and granting permission to practice (for herbalists and traditional healers)

**State level:**
- Department of Medicinal and Aromatic Plants at Khartoum MoH
- Department of private health institutions regulation at Khartoum MoH
- Departments of health and environmental affairs within the seven localities

**Laws and Legislations:**
- Sudan Medical Council Act of 1993, modified in 2004
- Medical and Health Professions Council Act of 2010

### Place

**Regulatory bodies:**

**National level:**
- National Public Health Coordination Council

**State level:**
- Department of Medicinal and Aromatic Plants at Khartoum MoH
- Department of private health institutions regulation at Khartoum MoH
- Departments of health and environmental affairs within the seven localities

**Laws and Legislations:**
- National Public Health Act of 2008
- Khartoum State Pharmacy Act of 2012
- Private Institutions regulation executive list of 2015

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1. Researcher at the Medicinal and Aromatic plants and Traditional Medicine Research Institute.
Inferior Quality of Herbal Medicines and its Deleterious Impact on their Safety and Efficacy

Sami A. Khalid

Herbal medicines remain to be a popular healthcare choice with the general public not only for the treatment of minor ailments (e.g. coughs and colds), serious chronic diseases (e.g. asthma, depression, diabetes) and the well-being but also for other uses such memory enhancers (Ginkgo biloba) and adaptogens (Panax ginseng). Recent trends indicate that in 2012, 17.9% of all US adults used botanical supplements whiles in Germany, 90% of the public use natural medicines at some time during their life and over 50% of the population has done so in other European countries. The global market for herbal dietary supplements or phytomedicines was approximately US$ 60 billion in 2000 and is estimated to increase dramatically, reaching US$107 billion by the year 2017.

A substantial number of the general public receives information on herbal medicines through various sources, including newspaper articles, television, internet and some other sources of advertising media but much of this information is presented uncritically and lacking any clinical evidence. As a result, there have been ongoing concerns about the quality, safety and efficacy of most currently available herbal medicinal products. This led to a heightened awareness for the need to protect the public against unsafe, inefficacious and poor-quality herbal products.

Nevertheless, it is obvious to appreciate the importance of the quality control of herbal medicines hence their pharmacological effects are brought about by their myriad chemical compositions hence a single herbal medicine contains a complex mixture of hundreds or even more chemical compounds. The availability of detailed information of the qualitative and quantitative aspects of the chemical composition of these herbs is undoubtedly of prime importance hence this information is a prerequisite to our understanding of their pharmacological and toxicological effects.

Pharmacists, doctors, nurses, herbal-medicine practitioners supposed to be knowledgeable about these issues in order to be able to advise patients and the public at large on the safe, effective and appropriate use of herbal preparations. This article aims to provide pharmacists and other healthcare professionals with a short yet important message about the deleterious impact of the comprised quality of herbal medicines on the safety and efficacy of their final product. Unfortunately, a large number of the currently marketed herbal products are lacking scientific evidence to assure the public about their quality, safety and efficacy.

Cases of adulteration and contamination have led to severe illness and even death in some cases. Identifying the plant material in botanicals and phytomedicines using organoleptic tests, macro- and microscopic identification of plant parts are often leading to misidentification. To overcome this problem DNA barcoding methods, which are used to identify species diversity, have been applied to botanicals and plant-derived dietary supplements, in recent years.

1. Dean Faculty of Pharmacy, University of Sciences and Technology.
A recent review on the chemical adulterants revealed that among the 81 herbal products claimed to enhance the sexual performance 28 contained sildenafil. Examination of 14 herbal products claimed to treat arthritis revealed that 3 samples contained ibuprofen while the analytical examination of 19 herbal products claimed to treat hypertension 8 samples contained captopril.

We have witnessed during the last two decades several important developments with respect to the regulatory aspects for traditional medicine in almost all developed countries. The most significant of these has been the introduction of the EU Directive http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm Therefore, with respect to quality, healthcare professionals and consumers should be aware that the labels of unlicensed (unregulated) herbal medicines may not reflect their actual contents, and that the precise constituents of herbal medicines containing the same herbal ingredient(s) but produced by different manufacturers are likely to differ substantially.

As far as the safety of herbal medicines is concerned we are confronted with the intrinsic toxicity of the herb involved itself as well as problems due to adulteration (e.g. with other herbs or conventional medicines) and contamination (e.g. dust, insects, rodents, parasites, microbes, fungi, mould, toxins, pesticides, and toxic heavy metals), commonly associated with them in the recent years. The concurrent use of herbal and other medicines remains a major concern for healthcare professionals because of the potential for important drug interactions. Evidence of pharmacokinetic and pharmacodynamic interactions between herbal medicines and conventional medicines is emerging but has been little formal clinical research directed into these interactions.


References:

Clove oil and Dental Pain

Mariam Mohamed is a 40 years old housewife. She is a mother of five children who live in Umbada locality. She had a throbbing pain that causes her insomnia for the last 3 nights. The pain is related to the right lower first molar. She went to the nearest pharmacy where a pharmacist gave her clove oil (Eugenol® oil) to be applied in her affected tooth. Mariam applied the oil in her tooth 2 times and the pain was relieved and she started to feel better. On the next day she developed ulcer in the surrounding soft tissue, but she decided to ignore it especially because her tooth pain was relieved. After few weeks Mariam developed a swelling under her tooth and the pain and insomnia were back again and this time it was all over the right side of the mouth. It also caused difficulty in mastication, and swallowing. She tried to use the Eugenol again several times but it did not relieve her pain, and her gum ulcer had become more severe. She went to Khartoum Dental Hospital and she was diagnosed with per-apical abscess and burning ulcers (chemically induced).

Problems

• Dental pain is an indicator of severe infection in the related tooth therefore temporal relieve of the pain without removal of the infection can lead to serious consequence.
• The patient developed a burning ulcer which is an adverse effect of clove oil.

Solutions

• Clove oil is been usually dispensed as over the counter for tooth’s socket in almost all the countries but the most important is to apply directly to the tooth with a cotton bud and to avoid skin or gum contact. It is very important for the pharmacist to causation the patients to stop its use if irritation occurs and seek help from the dentist as soon as possible.
• Similarly to all medications, it is very important to keep clove oil tightly closed and out of reach of children and don’t be used by pregnant women. It is not advised to be dispensed for less than 16 years of age.

Lesson learnt

• Although clove oil is herbal medicine it has adverse effect if it is used by non-dental professionals. It should only be used in dental clinic in tiny amounts and under precautions.
• Dental infection is serious if not treated in a proper way it may progress to cellulitis that can lead to death.

1. Head Department of Community Dentistry, Collage of Oral and Dental Medicine, Karary University.
Hajja Amna a 78 years old obese widow with a sedentary lifestyle, living in Omdurman had a Deep Vein Thrombosis (DVT) event 6 months ago that progressed into Pulmonary Embolism (PE). She was managed properly and discharged on warfarin, targeting an international normalized ratio (INR) at 2.5, to control her coagulopathy. She was doing well for two and half months, when she developed problems in digestion and gases. A friend advised her to use anise (اليانسون) tea daily to improve her digestion. Shortly after the concurrent use of warfarin with anise, Hajja Amna noticed some bruises on her skin coupled with minor bleeding during teeth brushing but did not seek medical advice. Lately she was brought to the emergency department of the nearest hospital, unconscious, deteriorating and falling into coma. She was diagnosed with cerebral hemorrhage. Her INR was found shooting very high at 10. Upon taking history, the clinical pharmacist detected the possible drug herb interaction between warfarin and anise (Pimpinella anisum), which contains natural coumarins that acted synergistically with her warfarin dose.

Problems

- Warfarin induced cerebral hemorrhage is a well recognized preventable complication, if medications, herbs and foods that contain coumarins are avoided.
- The patient failed to regularly checking her INR. She did not seek medical care when adverse effects appeared.

Solutions

- History taking should include medicinal herbs/home remedies to be able to detect medication related problems including interactions. They should actively advice patients on chronic medications to watch their symptoms and report any problems.
- Many herbs, food and medicines may influence warfarin action. Commonly recognized herbs and foods that are susceptible for interaction with warfarin are anise (اليانسون), fenugreek (الحلبة), chamomile (البابونج) and parsley (البقدونس) and other green leafy vegetables.
- Warfarin and anticoagulant medications require educating patients about signs of the adverse events with emphasis on the importance of seeking medical care immediately when they occur.

1. Lecturer of pharmacy practice, Faculty of Pharmacy, University of Sciences and Technology.
Karkadi Serious Interaction

Sarra I. Rashid

Mohammed Ahmed is 70 years old male with long history of hypertension, using lisinopril 10 mg once daily. He went to the clinic complaining of fatigue, light headedness, nausea. The doctor referred his symptoms to the hypotensive effect of Angiotensin Converting Enzyme Inhibitor ACEI (Lisinopril) and decreased the dose to 5 mg. Mohammed went to the nearest pharmacy and dispense his medication. The community pharmacist advised him to take his medication regularly. After a week Mohammed collapsed and rushed to the nearest emergency hospital, where he was found to be severely hypotensive (BP =80/60 mmHg). After counseling the patient, it was found that he was regularly taking excess amount of Hibiscus sabdariffa flower juice. His condition was managed with normal saline intravenous solution and was released home after being educated about the hypotensive effect of Karkadi.

Problems

- Healthcare providers are not well informed about the pros and cons of herbal preparations.
- Karkadi has hypotensive action as it contains some anthocyanins which are acting as competitive inhibitors of ACE, hence anthocyanins are acting by a mechanism similar to Lisinopril and other related ACE inhibitors such as Benazepril, Captopril, Enalapril, Fosinopril, Moexipril, Perindopril, Quinapril, Ramipril, and Trandolapril.

Solution

- Healthcare providers should be educated about herbal remedies and there potential interactions with other medications.

Adulteration of Herbal Preparations with Sildenafil and Tadalafil

J Pharm Bioment Anal - July 2010

Adulteration of herbal products with sildenafil, tadalafil and/or vardenafil has been reported worldwide especially in countries where the use of herbal medicine is very common like India.

A study conducted by the Faculty of Pharmacy, University of Khartoum to screen the presence and concentration of sildenafil and tadalafil medicines in a number of Sudanese herbal preparations revealed alarming results. Thirty samples taken from products marketed as herbal preparations for impotence. The samples were purchased from open market and/or licensed companies. The analyses have shown that 40% of the samples were adulterated with sildenafil (>165 mg) and tadalafil (>60 mg) per dose. This could explain the side effects reported by patients using these herbal preparations. Knowing that the maximum daily dose is 100 mg for sildenafil and 20 mg for tadalafil, repeated use of these preparations could result in fatal side effects.

A Chinese Nobel Prize winner in Medicine for discovery of the most effective treatment for malaria of herbal origin.

The Guardian - Oct. 2015

TuYouyou was awarded a shared Noble prize in Medicine for discovering one of the most effective treatments for malaria. The 84-year-old pharmacologist was awarded half of the prestigious 8m Swedish kronor (£631,000) prize for her discovery of artemisinin from the Chinese plant Artemisia annua, a drug that proved to be an improvement on chloroquine, which had become far less effective as the malaria parasites developed resistance.

The unique chemical structure of the artemisinin was elucidated in 1975 by Youyou and her team, while working on a secret military project during China’s Cultural Revolution, using a 1,600 year old recipe. The first clinical trials were conducted in Vietnam on 21 individuals infected with plasmodium falciparum which resulted in complete eradication of the parasite. Tu worked with other scientists to develop the drug artemisinin and volunteered to be the first human subject to test the drug. Artemisinin based pro-drugs are recommended by the WHO clinical guidelines as part of the first line management of malaria.

European Medicines Agency to publish user friendly summaries on Herbal medicines for the public

European Medicines Agency - August 2015

In August 2015, the European Medicines Agency (EMA) has started to publish summaries of recommendations from its Committee on Herbal Medicinal Products (HMPC) on the effective use of herbal medicines in an easy to understand language for the public.

The summaries include information on the herbal substance, the HMPC conclusion and its recommended uses, the data supporting the recommendations and the potential side effects associated with the use of the herbal substance. These summaries are designed to help citizens to make an informed choice when using herbal substances for medicinal purposes and self medication.

1. Head of clinical pharmacy services, Radiation and Isotope Centre Khartoum.
To ensure safety and benefit, herbal medicines and their practice should be regulated. Despite the long history and widespread use of herbal medicines in Sudan, there are no regulations to govern them nor their practitioners or practices. Here we present the UK experience. The existing practice of herbal medicine in UK is governed by a number of UK and EU regulations. These relate mainly to the classification, use of, and access to herbal products; besides a few rules relate to practitioners.

**Herbals restrictions**

Products generally need to be licensed, except in limited cases, and the purpose of such regulation is first and foremost to protect public health. There are further rules governing the use of medicines in herbal practice.

**Determining whether a herbal product is a medicine**

A ‘medicinal product’ is defined in two ‘limbs’, one relating to presentation, the other to function. A product is medicinal if it falls within either of the limbs:

1. ‘Any substance or combination of substances presented as having properties for treating or preventing disease in human beings’; [the first limb]

2. ‘Any substance or combination of substances which may be used in, or administered to, human beings, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis’ [the second limb].

This applies to all medicines, herbals included. A product is medicinal if it falls within either of those definitions.

**Licensing a herbal medicine**

If a product is determined as a medicine, it requires either a marketing authorisation (product licence) or since 2004, it can be licensed using a simplified Traditional Herbal Registration (THR).

THR is produced for manufactured herbal medicines suitable for use without medical supervision. This THR is the responsibility of member states under the of directive 2004.

There by, herbal medicinal products can receive a certificate of registration instead of a marketing authorisation. The THR scheme is administered by UK Medicines and Health Products Regulatory Authority. To achieve THR for their products, manufacturers or suppliers must demonstrate: a history of traditional use for at least 30 years (of which generally 15 years must have been in the EU); evidence of safety; adherence to appropriate manufacturing standards; and provision of appropriate product information to users.

The THR scheme is for minor self-limiting conditions including infections such as viral, bacterial and fungal diseases, colds and respiratory problems, and skin conditions.

**Unlicensed manufactured medicines and ‘sell-through’**

Unlicensed remedies can to be made up and supplied by a practitioner to meet the needs of an individual patient following a one-to-one consultation, and these are not restricted. However, unlicensed manufactured medicines produced on a large scale are not permitted on the market under the Traditional Herbal Medicinal Products Directive.

The European Court of Justice issued a ruling...
on 29 March 2012, where the Court stressed that no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that State in accordance with the Directive or Regulation 726/2004. In other words, placement on the market is, as a rule, dependent on a marketing authorisation issued on the basis of the full records and data required by the law, allowing for the assessment of the safety, efficacy and quality of the product in question.

However, there are exceptions to this rule. Under Article 5(1) of the Directive, a Member State may exclude from the Directive's scope, in order to fulfil special needs, medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised healthcare professional and for use by a named individual patient under his direct personal responsibility (commonly known as the "named patient specials exception").

The Court emphasised that the concept of "specials" applies only to individual situations justified by medical considerations and presupposes that the medicinal product is necessary to meet the needs of the patient. Where the doctor providing treatment wishes to prescribe a medicinal product but another product with the same active substance, the same dosage and the same form is already authorised and available on the national market, it would not be permissible to use the named patient specials exception. It is no longer lawful to sell a manufactured herbal medicine in the UK without a marketing authorisation or a Traditional Herbal Registration.

Reference:
Preliminary Evaluation of the Microbial Quality of Medicinal Plant Marketed by Herbalists in Omdurman, Central Sudan

Hatil H. EL-Kamali¹, Hiba A. AL-Mustafa Ibrahim², Sami A. Khalid²,³

Introduction

The World Health Organization estimates that about 80% of the world’s population relies mainly on herbal medicine for primary health-care¹.

Sudanese traditional medicine is characterized by a unique combination of knowledge and practices of Arabic, Islamic and African communities. Sudanese traditional medicine is practiced by different local medicinal men. The treatments given by these local medicinal practitioners include various drugs. These drugs can be divided into three categories (a) drugs of vegetable origin; (b) drugs of animal origin; or (c) mineral or soil substances or chemical compounds or synthetic products².

Microbial contamination of medicinal herbal can be influenced by environmental factor such as temperature, humidity and extent of rainfall during pre-harvesting and post-harvesting periods, handling practices and the storage condition of cured and processed medicinal plant materials.

The present study was designed to throw light on microbial quality of some plant materials in the Omdurman city market, Khartoum State, Central Sudan.

Materials and Methods

Fungal isolation and identification:

Plant samples (Acacia nilotica sp. niloticafruits, Perpomia sp. fruits, Quercusinfectoria galls, Aloexylonagallochumwood) were surface sterilized with 70% alcohol and cut with sterile inoculating needles and were inoculated to a set of plates at room temperature. The plates were observed daily and the different growing organisms were transferred onto Potato Dextrose Agar (PDA) in separate Petri dishes. These plates were incubated at room temperature. Cultures were identified to genus/species levels and they were monitored macroscopically and microscopically. The various fungi were identified on the bases of their characteristic features following AL-Doory,1980³.

Results and Discussion

Plant materials sold in Herbal Shops in Omdurman Market are usually displayed openly and often become dust ridden over a long period of time until they are eventually sold. It seems that there has been no attention focused by researchers on the shelf lives of these plant parts. Sometimes they were stacked in shade insides sacs or containers, which likely promote microbial contamination.

Six fungal species, Penicillium sp., Rhizopus sp., Memnoniellaechinata, Aspergillusniger, Phoma sp. and Fusarium sp. were isolated from some plants materials stored in the market for 1-2 years. Some of those saprophytic organisms may also cause diseases in humans. The general features of the fungi isolated are presented in Table 1.

Because they are widespread in the atmosphere, moulds are common natural contaminants of medicinal herbs. It is known that, under favourable condition, some fungi can synthesize toxic metabolites such as mycotoxins. Aflatoxins are among the most commonly known mycotoxins, which are mainly represented in Sudan with Aspergillusflavus and A.parasiticus⁴.

¹. Faculty of Science and Technology, Omdurman Islamic University.
². Faculty of Pharmacy, University of Technology and Science.
³. Faculty of Pharmacy, University of Khartoum.
Moulds are responsible for bio-deterioration of raw materials of some medicinal plants. These moulds are responsible in a substantial reduction of crude herbal drug shelf life and market value. Medicinal plants contamination with fungi adversely affects the chemical composition of the raw crude plants materials; therapy decreases the medicinal potency of herbal drug\(^5\). Furthermore, the fungal metabolites increase the risk to serious toxicity episodes.

Table 1: Identification of fungal strains isolated from deteriorating plant materials

<table>
<thead>
<tr>
<th>Genus/Species</th>
<th>General Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Penicillium</em> spp.</td>
<td>The mycelium consists of a highly branched network of multinucleate, septate hyphae. Many – branched conidiophores sprout on the mycelia, bearing conidiospores.</td>
</tr>
<tr>
<td><em>Rhizopus</em> spp.</td>
<td>Grow as filamentous, branching hyphae that lack generally cross-walls.</td>
</tr>
<tr>
<td><em>Memnoniella echinata</em></td>
<td>Black mould. Conidia in chains.</td>
</tr>
<tr>
<td><em>Aspergillus niger</em></td>
<td>Conidial heads are large and become radial later. Conidia are dark-brown and round in shape and are rough walled and in chains.</td>
</tr>
<tr>
<td><em>Phoma</em> spp.</td>
<td>Spores are colorless and unicellular. The pycnidia are black and depressed in the tissues of the host.</td>
</tr>
<tr>
<td><em>Fusarium</em> spp.</td>
<td>Filamentous fungi. The taxonomy of the genus is complex.</td>
</tr>
</tbody>
</table>

**Conclusion**

The first step in quality control of botanical preparations is the correct identification of the plant intended for use and their microbial load should be established and the contaminates isolated and identified. Herbalists should be trained to apply safe handling and storage of medicinal plant materials and pharmacist should be appointed to take a role in their quality control and their rational use.

**References:**

Social pharmacy is concerned with human beings who form families, societies and organization of healthcare system. Natural sciences like chemistry, biochemistry with the other core pharmaceutical sciences and the basis of pharmacist's professional expertise, both of which form pharmacy practice, are not adequate for providing good pharmaceutical services. Since pharmaceutical services involve human subjects and are carried out by practicing pharmacists, this understanding brings up the concept of social pharmacy into the picture of changing pharmacy practice, since human subjects, need to be supplemented with knowledge about medicines and their use.

From social pharmacy prospective, scientific researchers, policy makers and practicing pharmacists need to use scientific approaches to identify local challenges in pharmacy practice through addressing certain research questions, the answers of which may facilitate the change in pharmaceutical practice e.g. reasons why a patient is taking or not taking a medication? Types of drug information needed to improve the patient's understanding about his/her prescribed medicine? How does a pharmacist can identify problems related to use of a medicine? And how can the innovative pharmaceutical sciences be introduced into our healthcare system?

The policy of pharmaceutical practice is part of the national healthcare policy and should cover all aspects of medicines, medicine development, manufacture, marketing, distribution, pricing and reimbursement, pharmacovigilance, patient eligibility, prescribing practice and professional services. Optimally, the pharmaceutical policy should be developed by practicing pharmacists through application of a balanced approach to identify the local challenges in pharmaceutical practice and develop policies that become informed by evidence based reference.

One of the important tools that can advance the practice of pharmacy profession in our local setting is the existence of professional pharmaceutical societies.

Pharmaceutical societies are specialized professional organizations started to be established as early as 1852 in USA and since then, the number is continuously increasing. Currently, there is a huge number of them in most of the countries over the world.

Pharmaceutical societies carry variety of activities which reflects the nature of diversity in pharmacy profession. Some of them are educational, others offer certificates or accreditation of pharmacists and others may provide training to pharmacists on specialized pharmaceutical area of practice.

Pharmaceutical societies have very important roles in shaping the pharmacy profession e.g. publishing position papers for pharmacists, lobbying governments and serve the interests of their members, dissemination of information through journals, newsletters and conduction of pertinent studies, maintenance of practitioners’ competency, codes of ethics and standards of...
practice, career planning assistance, posting jobs, sponsorship of workshops for career advancement, financial benefits, discount rates and credit cards and participation in pharmacy profession governance, help create, revise organizations’ policies specially at professional meetings.

Some of these pharmaceutical organizations are international e.g. the international pharmaceutical federation or Federation Internationale Pharmaceutique (FIP), which is an international federation of national organizations that represent pharmacists and pharmaceutical scientists worldwide, founded in 1912 and is based in Hague in the Netherlands. FIP is composed of two boards; the board of pharmaceutical practice, which is further subdivided into 8 specialized sections; the academic pharmacy, clinical biology, community pharmacy, health and medicines information, hospital pharmacy, industrial pharmacy, military and emergency pharmacy, social and administrative pharmacy. While, the second board of pharmaceutical sciences is a forum for the worlds' pharmacists who exchange experiences through communicating and networking at the pharmaceutical worlds congress which is regularly held every four years in a different location.

Other national pharmaceutical societies also exist in different countries like USA, United Kingdom, Korea, Denmark, Kuwait, Nigeria, China, India, Saudi Arabia and others.

In Sudan there is one professional pharmaceutical association, the Sudanese society of clinical pharmacy registered in 2012, and has carried some academic and training activities.

As a conclusion of the mentioned information, pharmaceutical societies are expected, in the long term, to fill the vacuum in pharmacy practice, improve competencies of practicing pharmacists and help bridge the gap in the pharmacy educational curricula as well as the regulations of pharmacy profession. These benefits may be reached through the activities of these pharmaceutical societies. Practicing pharmacists are also expected to gain important skills needed for the new role of pharmacists, like critical thinking and effective communication.

References:


Mouthwashes are liquid antiseptic preparations that are intended to be held in the mouth passively or swilled around the mouth to reduce the microbial load in the oral cavity. They are used at home as part of an oral hygiene routine and for gingivitis. Other mouthwashes might be given for other reasons such as for their analgesic, anti-inflammatory or anti-fungal action mainly prior to and after oral surgery procedures such as tooth extraction. They may also be gargled, where the head is tilted back and the liquid bubbled at the back of the mouth. It is therefore of high importance for professionals to explain the following information to their patients:

- Mouthwashes are for rinsing and spit out; they should not be swallowed.
- Different brands have different active ingredient/s.
- It is advisable not to rinse or drink water immediately after using the mouthwash.
- Chlorhexidine gluconate use as a mouthwash has been associated with an increase in staining of teeth and other oral surfaces.
- Oral irritation and allergic symptoms have been reported as side effects associated with use of Chlorhexidine gluconate mouthwash.
- Alcohol-containing mouthwashes may cause dry mouth (Not available in Sudan).
- Mouthwashes are contraindicated for children less than 6 years.

The table below presents some of the most common brands available in Sudan:

<table>
<thead>
<tr>
<th>Brand</th>
<th>Active ingredient/s</th>
<th>Frequency of administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yaxoral®</td>
<td>Chlorhexidine gluconate</td>
<td>2-3 times per day</td>
</tr>
<tr>
<td>Claradine®</td>
<td>Chlorhexidine digluconate</td>
<td>3-4 times per day</td>
</tr>
<tr>
<td>B-fresh®</td>
<td>Cetylpyridinium Chloride + Sodium fluoride</td>
<td>Twice daily</td>
</tr>
</tbody>
</table>

Reference:

1. Head of Oral and Maxillofacial Surgery Department, Faculty of Dentistry, University of Khartoum.
Q. Are herbs and medicinal plants safe?
A. This is difficult to answer simply; they are and they are not!

Many commonly used simple herbs are safe, even in large amounts and when used concurrently with many prescribed medication. The WHO identified 75 such plants/herbs. On the other hand there are toxic and poisonous plants and many of these are known.

Safe herbs can be adulterated with chemicals or medicines. People who promote medicinal plants and many traditional healers add chemicals and medicines to enhance the therapeutic effect of their herbs. This is very risky because the additives could be toxic, in high concentrations or have interactions.

Q. Should we discourage use of herbs and traditional medicines?
A. Herbs have been used for countless years, and proved effective in curing and managing many conditions. People in Sudan are used to herbs and strongly belief in their benefit; many also belief in traditional medicines and traditional healers. It is important; to identify this beliefs in your patient and you should not undervalue their health beliefs or challenge them. Explain to the patient about his disease and the role of prescribed medication; be clear about the expected outcomes and prognoses. This information can protect the patient from being deceived by traditional healer or putting false hope on traditional medicines.

Q. People use herbs and home remedies at the same time with prescribed medication, is this safe?
A. There are many interactions between herbal medicines and prescribed medications.

Many of these are not known, or reported yet. However, healthcare providers should always keep in mind that some medicinal plants have benefits and patients should not be denied such benefits.


The best thing to do is to identify the herbs the patient is using and watch for any adverse reactions. If such adverse reactions appear advice the patient to stop the herbs and report the incidence to the pharmacovigillance centre (http://www.who-umc.org/)

One important point to consider is the “magical herb” that is promoted by traditional healers to solve every health problem, such herbs are usually adulterated with chemicals and medicines that could interact or overdose prescribed medications.

Q. Can I recommend herbs for my patients?
A. Sure, many home remedies (herbal medicines) are effective in controlling various conditions, remedies for cough, common cold, diarrhoea, indigestion, premenstrual symptoms, apses, and wounds are just few examples. Many herbs have proved to have benefit in specific ailments and your patient should be assured about their benefit. The use of home remedies is recommended over pharmaceutical in some conditions like cough and common cold because they spare the use of antibiotics.

1. Lecturer of pharmacology, Faculty of Dentistry, University of Khartoum.
Mohammed Elfatih M. Saeed, a young Sudanese scientist

Randa A. Almahdi¹

Background

Chemotherapy has been the hallmark of cancer treatment for decades, but the non-specificity of these cytotoxic drugs targeted rapidly dividing cells without differentiation between cancerous and normal cells, resulted in severe side effects. This has led to development of recent strategies focusing on specific proteins involved in the tumor growth and progression to find novel cancer targeted therapeutics with activities against resistant cell lines.

Sudan is rich with flora of medicinal and aromatic plants. Unfortunately, most of which have not yet been fully exploited, and need to be subject to validation by scientific methods, standardization and randomized clinical trials to provide novel, improved or modified herbal remedies. Nevertheless, a voluminous information about the antitumor and chemopreventive effects of herbal medicines were generated with breakthroughs occurred in this field. The application of innovative modern technologies (e.g. pharmacogenomics) to study medicinal plants seem to be promising, as an attractive strategy to explore their cytotoxic effects.

A young Sudanese scientist, who has screened 65 plant extracts representing 35 Sudanese medicinal plants- for cytotoxicity against various multidrug resistance (MDR) cancer cell lines, has recently achieved one of the recent impressive developments involving research on Sudanese medicinal plants.

Mohammed’s success story started in 2011 when he participated in a symposium at the International Center for genetic engineering

¹. Lecturer of pharmacy practice, Faculty of Pharmacy, University of Sciences and Technology.
and biotechnology – Italy, by his project. His work was selected as one of the best three researches, and was reviewed by a number of scientists attending the symposium who encouraged him to carry on his work. Afterwards, he was encouraged by Professor Hassan Khalid Alsubki to apply for a PhD degree in a German University and so he did send his proposal which has been accepted and was offered full fees scholarship (without the living expenses) for the degree through professor Thomas Efferth from the Institute of Pharmacy and Biochemistry, Johannes Gutenburg University. Africa city for technology- Sudan has covered his living expenses, and Dr. Eisa Basharie Minister of science and technology fully adopted the research as a national project for Sudan. Later on, the current Sudanese ambassador in Berlin and the German University has inaugurated a Memorandum of Understanding (MoU) in 2014.

Summary of his work:

Mohammed has used resazurin assay to determine the cytotoxicity of the extracted plants. Through Microassay–based mRNA expression profiling, compare and hierarchical cluster analyses several genes responsible for sensitivity and resistance have been identified to selected phytochemicals; sesamin and apigenin in order to predict their mode of actions. Molecular docking on homology models of P-glycoprotein (ABCB 1) and ABCB5 was performed also for the selected phytochemicals to localize their binding sites to target proteins.

The resazurin assay showed that the extracts of *Trigonella foenum-graecum* (الحلبة) and *Ambrosia maritma* (الدمسيسة) had the most powerful cytotoxic effects among the screened medicinal plants, while the selected phytochemicals; sesamin and apigenin were identified as the most powerful cytotoxic agents among isolated compounds from the screened Sudanese plants. Microassay–based analyses showed that the genes from (transcriptional or translational regulation, signal transduction, cellular proliferation, intracellular trafficking, RNA metabolism, endoplasmic/ sarcoplasmic reticulum function…etc) were significantly correlating with the response of tumor cell lines to the selected compounds.

Sesamin is a lignan present in sesame oil and a number of other plants, has proved chemopreventive and anticancer activities both in vivo and in vitro, consisted of genes that do not belong to the classical resistance mechanisms, and was anticipated to be valuable to bypass chemo-resistance of refractory tumors. Apigenin is a common dietary flavonoid of considerable cytotoxic activity both in vitro and in vivo. It inhibits P-glycoprotein, BCRP through increasing cellular uptake of doxorubicin and acts synergistically with established anticancer drugs (doxurubucin or docetaxel) in MDR cells, so it may overcome MDR in otherwise refractory cells.

These findings were very promising in terms of finding novel therapeutic options for multidrug resistant cancer cells from our Sudanese medicinal plants, to be used with or without the conventional cancer treatment. The research needs to be substantiated by in vivo work to examine their effectiveness in real patients.

Reference:

Traditional and complementary medicine T&CM is an important and often underestimated part of health care. T&CM is found in almost every country in the world and the demand for its services is increasing. TM, of proven quality, safety, and efficacy, contributes to the goal of ensuring that all people have access to care.

Many countries now recognize the need to develop a cohesive and integrative approach to health care that allows governments, healthcare practitioners and, users of healthcare services, to access T&CM in a safe, respectful, cost-efficient and effective manner. Governments and consumers are interested in more than herbal medicines; they are considering T&CM practices and practitioners. And whether they should be integrated into health service delivery.

The WHO Traditional Medicine (TM) Strategy 2014–2023 was developed in response to the World Health Assembly resolution on traditional medicine, and reappraises and builds on the WHO Traditional Medicine Strategy 2002–2005, and sets out the course for T&CM in the next decade.

The strategy has two key goals:

1. to support Member States in harnessing the potential contribution of T&CM to health, wellness and people centred health care
2. and to promote the safe and effective use of T&CM through the regulation of products, practices and practitioners.

These goals will be reached by implementing three strategic objectives:

1. Building the knowledge base and formulating national policies
2. Strengthening safety, quality and effectiveness through regulation
3. Promoting universal health coverage by integrating T&CM services and self-healthcare into national health systems.

**WHO support for T&CM by:**

- Facilitating integration of T&CM into national health systems.
- producing guidelines for T&CM by developing and providing international standards, technical guidelines and methodologies for research into products, practices and practitioners.
- stimulating strategic research into T&CM by providing support for clinical research projects on its safety and effectiveness.
- advocating the rational use of T&CM through the promotion of its evidence based use.
- and mediating information on T&CM by acting as a clearing-house to facilitate information exchange.

**Progress in T&CM use:**

1. **Policy and regulations:** many countries have established national/regional policies and regulations to promote the safe and effective use of T&CM. For example Sudan.
2. **Practices:** acupuncture was originally traditional Chinese medicine now it is international and accepted by many countries.
3. **Education and research:** the number of Member States providing high-level T&CM Education programmes including Bachelor, Master and Doctoral degrees at university level have increased from only a few to 39. Furthermore, in some countries TM is included in university curricula for health profession students. For instance, various universities in the Economic Community of West African States, Democratic Republic of Congo, South Africa and Tanzania include

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Global review of T&CM:

Health systems around the world are experiencing increased levels of chronic illness and escalating healthcare costs. This lead people to turn to T&CM in both developed and developing countries. There is an increasing demand for TM practices and practitioners worldwide.

Experience: Mongolian TM Family Medicines Kit

In the challenging geography of Mongolia’s mountains and deserts, nomadic herds men often struggle to reach a district hospital. A family traditional medicine kit project was started in 2004 and covers more than 150,000 people. The survey reported that 74% of respondents said that the kits were convenient to use, and the medicines had been effective when used with user’s manual. The medicines used cost approximately US$8 per family per year.

Types and qualifications of T&CM practitioners

T&CM practitioners can be TM practitioners, CM practitioners, conventional doctors or other health professionals. Differing approaches to regulation make it difficult to determine the absolute numbers of practitioners. TM practitioners can be divided into a number of categories based on their training/education, registration status, etc.

Potential cost savings are an important reason for individuals to opt for T&CM services. For example, a randomized controlled trial included an economic evaluation of physiotherapy, manual therapy, and general practitioner care for neck pain: results showed that the manual therapy group improved faster than the physiotherapy and general practitioner care group, and that the total costs of manual therapy (€447) were about one third of the costs of physiotherapy (€1297) and general practitioner care (€1379).

Reference:
Sudanese patients normally don’t disclose herbal medicines use information to their healthcare providers (HPs). This was revealed by the results of a study conducted in some selected primary healthcare centres in Khartoum. One of the most common reasons patients have not discussed their use of medicinal plants is that their HPs has not asked them about it. Patients also fear their HPs’ negative attitude when informed. Part of the patients thought that medicinal plants use is not an important issue to rise; they are just herbal!

Therefore HPs are encouraged to ask their patients the following questions:

1. Are you taking any dietary supplements, including herbs?
2. Are you taking herbs for treatment of a short-term conditions or illness or for weight loss, weight gain, increased energy, increased immune function, or disease prevention?
3. If so, which ones, how often, in what dosage, and for how long?
4. Are they branded or heritage products?
5. Have you noted any reactions of effects (positive or adverse) related to taking the herbal preparations?
6. If reactions are adverse, do they occur when you use the herb in conjunction with other supplements or conventional medications or simply when they are used alone?
7. Do you have any conditions that might preclude your taking some particular herbs? (pregnancy, diabetes, hypertension)
8. Are you taking any conventional medications that might contraindicate the use of some herbs? (MAO inhibitors, Warfarin etc.)

In the Sudanese setting it is of high importance to discuss herbal medicines use with patients. This is due to the fact that Sudan is rich with medicinal plant, but the safety and efficacy of these herbs is not assured due to the absence of the laboratory tests. More over herbal medicines contributions in Sudan is not fully known nor documented, most of researches are scattered, and not representative to the national profile of the country.

The use of herbal remedies is deeply rooted in the Sudanese culture. Those remedies are highly used for self-medication, complementation of conventional therapies, and maintaining overall health and well-being. Patients' believes in herbal medicines efficacy, its easy accessibility and lower cost, the experience of others and frustration with conventional therapy has highly encouraged patients to seek their use. Unfortunately, the sources of information about herbal remedies are not accredited most of the

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times. Users get the information from their family and friends, but rarely from their healthcare provider.

It is of high importance that patients be informed that concomitant use of medicinal plants with prescription or over-the-counter (OTC) medications can put them at risk for a variety of serious drug interactions. For healthcare providers (HP) to provide safe and patient-centred healthcare, patients are required to disclose their use of medicinal plants to their healthcare providers.

HPs can get herbal medicines use information from their patients by developing an open rapport, through which patients are made to feel comfortable sharing information. Upon assessment, HPs should be non-judgmental and unbiased in attitude about a patient's choice to use herbal medicines. It is also important for HPs to be aware of current evidence-based interventions to answer patient questions and concerns honestly, knowledgeably, and safely.

According to the consultation results HPs should advise their patients on their use of herbal medicines. The most important advices are:

- To stop taking herbs at least 7 days before any surgery.
- Avoid taking them altogether if pregnant or nursing or infants or Child.
- Not to take herbs and medications together or at the same time.
- Be alert to possible adverse effects and interactions with lab tests.
- Advise those patients taking dietary supplements to read and follow the label instructions.
- Don't exceed recommended dosages or take the herb for longer than recommended.
- Advise patients to ask any questions, particularly about the best dosage to take.

References:

3. Talking with your patients about complementary medicine: a Resource for Clinicians, national health and medical research council, government of Australia, 2014.
The World Health Organization defines herbal medicines as those that include herbs, herbal materials, herbal preparations and finished herbal products that contain as active ingredients parts of plants, or other plant materials, or combinations.

Herbal drugs are not only used for general well-being and to prevent or treat common minor ailments; but they are also used by individuals with serious chronic diseases. Uses also include pregnant and breast feeding women; children and the elderly.

As with conventional medicine, it is reasonable to expect that interaction between herbal remedies and medicine, other herbs or foods can occur. Some consumer of herbal remedies may already be taking, or may begin to take, conventional Over-The-Counter (OTC) or prescribe medicines.

As the healthcare professional most likely to interact with patients that consumes herbal remedies, they do have role to play in advising on and monitoring the concurrent use of herbal and conventional medicines.

Concern about the concurrent use of herbal and conventional medicines are amplified when considered together with the general lack of professional involvement in individual decisions regarding the use of herbs and the lack of disclosure of their use to healthcare professional, even when problem arise.

Types of interactions

It is beyond the scope of this material to discuss in details the mechanism of herbal-drug interaction and healthcare providers are encouraged to consult standard references texts, such as Stockley's drug interactions for this information. Although some interaction are unique, as with conventional drug interaction, herbal interaction usually can be classified as pharmacokinetics (when the absorption, distribution metabolism or excretion of one substance is affected by another, i.e., a herbal remedy can affect the pharmacokinetics of a medicine and vice versa) and pharmacodynamics (when one substance change the effect of another at its site of action). Like conventional medicine, the pharmacokinetics of herbal medicine and, hence, their potential for pharmacokinetic interaction, are influenced by factor, such as age, genetics and cigarette smoking.

Herbal-drug interaction

The potential interaction between herbal and conventional medicine has been recognized for some time. Generally, information on herbal-drug interaction, particularly in the clinical setting, is still limited.

For example, there are isolated reports of bleeding episodes in patient taking warfarin or aspirin and who began taking ginkgo. Ginko is widely used to support memory functions, hypertension, respiratory problems and sexual dysfunction. An experimental increase in toxicity was also seen when amikacin is given with ginkgo. There is also isolated report of increased interaction normalized ratio (INR) in patients taking warfarin and garlic supplement. Garlic is widely use as lipid lowering agent and for hypertension. The users of St John's Wort (to manage mild symptoms of depression) parallel with cyclosporine realise reduction in later levels which led to transplant rejection in some cases (see table 1 for more examples).

Table 1: Shows selected examples of potential pharmacodynamics herbal-drug interaction for several popular herbal and conventional medicines.

<table>
<thead>
<tr>
<th>Medicines</th>
<th>Herbs</th>
<th>Reasons for potential interaction</th>
<th>Nature of potential effect</th>
</tr>
</thead>
</table>
| Anticoagulant      | garlic, ginger, ginkgo, willow, Anise | - Inhibit platelet aggregation  
- Antiplatelet activity  
- Ginkgolide constituent antagonize platelet-activating factor  
- Salicylic constituent  
- Contains natural coumarins | Potentiating                |
| Anticonvulsant     | willow, Hibiscus   | Salicylic constituent: displacement of phenytoin from binding sites     | Potentiation                |
|                    |                    | contain Angiotensin Converting Enzyme Inhibitor (ACEI) like chemicals   | Potentiation                |
| Antidiabetic       | ginseng, Rosemary  | Hypoglycaemia activity  
Hyperglycaemia activity  
- Potentiation  
- Antagonism     |                                      |
| Anti-diarrheal     | Aloes, senna       | Hydroxyanthracene constituent with laxative activity                     | Antagonism                  |
| Laxative           | As above           | As above                                                                 | Potentiation                |
| Cardiac glycoside  | ginger             | Cardioactive                                                             | Potentiation                |
| Hypnotics and anxiolytics | chamomile | Sedative activity                                                         | Potentiation                |

Pre-operative use of herbs

The need for patients to discontinue use of herbs before undergoing surgery has been proposed on the basis that there is a potential for interaction to occur with anaesthetics, anticoagulant and other substances use before, during or after surgery, as well as direct pharmacological effect of herbs which could interfere with, for example, control of blood pressure.

To conclude healthcare providers should work to educate themselves and thereafter their patients with regard to using both herbal and conventional medicines at the same time.

Adapted from:
The traditional use of plants to cure illness by healers in Africa and Sudan is no exception, is usually associated with various ritual, spiritual and magical elements. Although these aspects are of general interest to cultural anthropology, rational phytotherapy is considered as a part of modern life sciences hence it focuses on seeking scientific evidence to validate the pharmacological activity of medicinal plants. To this end, rational phytotherapy contributes to the demystification and “secularization” of traditional medicines. The definition of rational phytotherapy, however, must not be mixed up with alternative medicine, which frequently lacks scientific evidence for activity, but is nevertheless applied by alternative practitioners and herbalists. Therefore, a number of strict official and scientific benchmarks are set for the efficacy, tolerability and safety of the herbal medicines within the context of what currently known as rational phytotherapy. The present article intends to enumerate a number of essential elements that are collectively considered as prerequisites to consolidate the concept and the practice of rational phytotherapy (Figure 1).

Figure 1:
comparison of herbalism vs rational phytotherapy

1. Department of pharmaceutical Biology, Instituted of Pharmacy and Biotechnology, Johannes Gutenberg, Germany.
2. Faculty of Pharmacy, University of Science and Technology.
3. Faculty of Pharmacy, University of Khartoum, Sudan.
Among the aforementioned elements, ethnobotany which encapsulates the philosophy and essence of traditional knowledge on medicinal herbs standing very prominently. This knowledge is commonly handed over by verbal recipes from generation to generation and eventually been transformed into an ethnopharmacological context. Therefore, the systematic documentation of medicinal plants in their cultural settings, along with their current traditional use, local (vernacular) and binomial scientific names are urgently required. This in turn requires taxonomist who are confronted with a number of difficult tasks offinding the proper biosystematical classification.

The main goal of this endeavor is to pave the way for the utilization of these diverse genetic resources by the pharmaceutical industry to develop phytopharmaceutical products (i.e. bioprospecting). This approach may involve the elimination of considerable steps usually associated with R&D of a single chemical entity during the discovery and development process in terms of the time and cost invoved to what now defined as reverse pharmacology. Many supporters of herbal medicines argue that “products with a long history of popular use are generally safe when used properly at their common therapeutic doses”.

A crucial question underlying this statement is the extent to which the absence of records of toxicity could be taken as evidence of the absence of toxicity or safety of herbal medicines. Nevertheless, one of the most crucial stages in the whole chain of events is the quality control of herbal medicine which has a direct impact on both the safety and efficacy of the final products. Most of the techniques involved in the pharmacognostical aspects of quality control and the study of the isolation and structure elucidation of the bioactive secondary metabolites present in any medicinal plants are very intimately pertinent to pharmacognosy and phytochemistry, respectively. Although phytochemists are usually involved in screening the pharmacological activities of these plants they are most frequently collaborate with other scientists such as molecular biochemists, immunologists, pharmacologists and toxicologists.

To guarantee the marketing of safe and efficacious phytopharmaceuticals especial regulatory compendia have been developed by international or national authorities to regulate the approval of these medicines e.g. the Food and Drug Administration (FDA) in the United States and the EMEA in Europe, both of which enforce regulatory sets of specifications including the quality, purity standards, dosage, production, precautions, storage, and labeling of these medicines.

The monographs provide the specifications of each plant in a monographic format. These monographs are usually compiled into what is known as pharmacopoeias which are considered as official documents specifying the quality, purity standards, dosage, production, precautions, storage, and labeling of medicines. In contrast to European EMEA, the United States Food and Drug Administration (FDA) makes no distinction between herbal and conventional medicines regarding the requirements for pre-marketing demonstration of safety and efficacy. Based on this fact, herbal products with presumed beneficial effects generally do not meet the criteria for approval as medicines, and are commercialised in the USA as food or dietary supplements. This has been introuced from 1994 as what is currently known as the Dietary Supplement Health and Education Act (DSHEA). This act intends to regulate how herbs and herbal products can be sold in the USA. This regulation is supported by the Current Good Manufacturing Practices (cGMPs) for Dietary Supplements as from 2007.
Asthma Myths

Ali M. Arabi

1. Director General Dr Gafar Ibnouf Paediatric Tertiary Hospital Khartoum, Sudan.

Is asthma controllable?

That depends. There are four categories of asthma: intermittent, mild persistent, moderate persistent and severe persistent. People who have mild, moderate or severe persistent asthma need a daily long-term controller medicine, usually an inhaled corticosteroid, to control inflammation and minimize asthma attacks.

Asthma Medicines Are Habit-Forming

Medications used to treat asthma are not addictive; however, because asthma is a chronic disease, long-term use of medicine is often needed to manage the condition and prevent asthma attacks. It’s important to follow doctor’s recommendations for treatment, even when symptoms are well controlled.

Inhaled steroids are dangerous

There is a common belief that the long-term use of inhaled steroids will make a child short. These drugs do affect how fast a child grows, but there is no proof they have any effect on a person’s final adult height. and evidence shows that children who are undertreated are shorter. They also have more potentially life-threatening asthma attacks. Inhaled steroids are preventer medications, and are the best way to keep moderate or severe asthma under control.

People Can Outgrow Asthma!

Asthma is a chronic, treatable condition that develops in childhood. It’s no longer considered a disease that children “outgrow;” however, symptoms may improve during adolescence and adulthood. When asthma is diagnosed for the first time in an adult, it’s likely the condition was present, but mild and undetected earlier.

People with Asthma Shouldn’t Exercise!

In most cases, nothing could be further from the truth. Regular exercise can improve lung function and help you maintain a healthy weight, reducing your asthma risk or if you already have the disease, helping you breathe easier. Consultation with the treating doctor is important before beginning an exercise program.

Moving to a Dry Climate Can Cure Asthma!

A change in the environment can temporarily improve asthma symptoms, but it won’t cure the disease. To reduce asthma triggers at home: air conditions, carpets, curtains, etc. should be cleaned. Keep windows closed during pollen season and dusty wind.

Asthma can be cured

FALSE! Asthma is a treatable health condition. Despite great advances in treatments over the years, unfortunately we still don’t have a cure. However, with appropriate diagnosis and good management, just about everyone with asthma can lead normal, active lives.

It’s normal to puff on my blue reliever salbutamol inhaler at least once a day

NO WAY! If reliever medication (salbutamol) is used to deal with asthma symptoms more than twice a week, then asthma is not under control. If a preventer medication is used, then make sure it’s taken every day, or perhaps a higher dose needed. Frequently use of reliever medication is a strong indicator of a coming asthma attack.
Pharmacovigilance of Herbal Products

Randa A. Almahdi

The concern of pharmacovigilance includes beside drugs; herbals, traditional and complementary medicines, blood products, biological, medical devices and vaccines.

The problem with use of herbal medicines is complicated by the misconception that "natural" always mean "safe", which is proved not to be the case in a number of instances. Therefore, the monitoring of the safety of herbal medicines usually been considered before their efficacy mainly due the growing use of herbs worldwide. This is why different member countries in Uppsala Drug Monitoring Center are sending their requests to the World Health Organization (WHO) to assist them in strengthening their national capacities in monitoring safety of herbal medicines. WHO has responded by the development of guidelines as a joint project between the traditional medicines team, with special reference to the safety of medicines. These guidelines were developed within the current pharmacovigilance schemes for general medicines by enhancing and broadening the system to allow for successful monitoring of herbal medicines.

Herbal medicines present a special case that need specialized reporting form, since the spontaneous reporting of adverse events remain to be the main method for generation and detection of potential signals of safety concern of herbs. The general Adverse Drug Reactions (ADR) form used to report ADR of drugs have important limitations, specially with unlicensed herbal products which have, questioned pharmaceutical quality, unknown methods of extraction from crude herbal material beside that herbs contain several ingredients. To overcome the problem, the existing ADR form should be modified to include important details about the herbal medicines.

Use of herbal medicines in Sudan is very common.

Herbs are sold in herbal shops by herbalists, who have long experiences moved from one generation to another. Currently, Sudan is in the stage of developing guidelines for controlling the use of herbs, which will be based on the general guidelines of the WHO.

The WHO specified that, for a properly functioning pharmacovigilance system for herbs, the system should be linked to the national program for monitoring general drugs safety, and has recommended four complementary actions to be taken;

1. Clear identification of the nature of the adverse event.
3. Institution of measures to prevent the event.
4. Good communication of the risks and benefits of herbal medicines.

References:


1. Lecturer of pharmacy practice, Faculty of Pharmacy, University of Sciences and Technology.
Antibiotic resistance is expressed by different modes; enzymes (ESBLs, carbapenemases), efflux pump, (affecting carbapenems and quinolones) and target modification affecting aminoglycosides. Certain pathogenic organisms have shown different mechanisms through which they develop resistance towards the antibiotics they used to be sensitive to; examples are:

**Staphylococcus aureus:** Which is one of the most commonly encountered pathogens in the community as well as in healthcare settings and is the most important cause of blood stream infection associated death. Today almost all Staphylococci are resistant to penicillin and ampicillin by virtue of production of β-lactamase enzyme that hydrolyses penicillin and ampicillin. Infection with *S. aureus* is treated with penicillinase-resistant penicillins e.g. cloxacillin.

Methicillin resistant *Staphylococcus aureus* (MRSA) was first reported in 1960, but it became prevalent in hospitals in the 1980s. MRSA is resistant to all β-lactam antibiotics including penicillinase-resistant penicillins, due to alteration of penicillin binding protein. This is facilitated by a gene *MecA* that encodes for a different penicillin binding protein, that does not accept β-lactam antibiotics. MRSA infection is treated with glycopeptides e.g. vancomycin. Methicillin resistant Glycopeptide intermediate *S. aureus* (GISA), was first described in 1997 is insusceptible to glycopeptides. GISA produce excessive peptidoglycan cell wall material that traps vancomycin (glycopeptide) molecules.

**Enterococcus spp.** is the most common cause of bloodstream infection in the United States and Europe. *Enterococcus spp.* is intrinsically resistant to several antibiotics including cephalosporins. The treatment of enterococcal infection is limited to ampicillin, co-amoxiclav and vancomycin. Being least costly and associated with least side effects, ampicillin should be the preferred antibiotic in treating all infections with susceptible enterococci. Alteration in the glycopeptide binding site in the cell wall renders *Enterococcus spp.* fully resistant to glycopeptides (vancomycin). Glycopeptide binds to the D-alanyl-D-alanine terminus of the peptidoglycan. Enterococci that exhibit high level resistance to glycopeptides produce a new dipeptide terminus, either D-alanyl-D-lactate or D-alanyl-D-serine, that do not accept glycopeptides. Such strains are known as vancomycin resistant *Enterococcus* (VRE). They are treated with linezolid or daptomycin.

**Streptococcus pneumoniae:** The burden of pneumococcal invasive disease in the Arab peninsula remains significant with incidence rates of 3.4 to 53.5 /100,000/ year. Due to alteration in penicillin binding protein, some strains of *Streptococcus pneumoniae* have developed partial or full resistance to penicillin, erythromycin or cephalosporins. Pneumococcal resistance to penicillin is rather high in the Middle East, North Africa and South Europe.

**Gram-negative bacilli:** Common resistance among Gram negative bacilli is mostly caused by production of inactivating enzymes such as β-lactamases that inactivate β-lactam antibiotics and aminoglycoside modulating enzymes that inactivate aminoglycosides.

**Enterobacteriaceae:** Shortly after launching of 3rd generation cephalosporins in the 1980, *Klebsiella spp.* and *E. coli* underwent mutational modifications on β-lactamases to produce broad spectrum enzymes that could hydrolyse all penicillins, monobactams and cephalosporins including 3rd generation. These

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1. Consultant Microbiologist, Soba University Hospital, Khartoum.
enzymes were called Extended Spectrum β-lactamases (ESBL)\(^7\).

**Pseudomonas aeruginosa and related organisms (non-fermenters):** *P. aeruginosais* naturally resistant to several antibiotics. It is susceptible to aminoglycosides, uredopenicillins, carbapenems, ceftazidime, quinolones and polymyxins. However, it can acquire resistance to these antibiotics by several mechanisms, such as efflux for meropenem and ciprofloxacin, ESBL production and metallo-β-lactamase (VIM) that inactivates all β-lactam antibiotics including meropenem. Multi-resistant strains of *P. aeruginosa* are encountered in hospital areas where antibiotics are excessively used e.g. ICU. Multi-resistant *P. aeruginosa* can be treated with colistin.

Other mode of carbapenems resistance is intrinsic such as that with *Stenotrophomonasmaltophilia*. These organisms as well as other multi resistant bacteria such as *Burkholderia cepacia*, although resistant to meropenem and colistin they are susceptible to cotrimoxazole.

**Acinetobacterbaumannii:**

*Acinetobacter baumannii* is a bad organism to have in any hospital ward. It can acquire multiple resistances by several mechanisms. It resists harsh environmental conditions, spreads widely and difficult to contain. *A. baumannii* has multiple extra chromosomal mobile elements containing resistance genes (plasmids, transposomes, and integrons). *A. baumannii* can sometimes become resistant to virtually all antibiotics.

References:

Development of Sudan National Traditional and Herbal Medicines Policy

Sarah A. Kareem

Sudan, where there is a long-term practice of traditional medicine outside the dominant health care system, interest has been increasing for a national traditional and herbal medicines (THM) policy framework.

In January 2015, the Undersecretary, FMoH has issued administrative decree to establish a national committee entrusted with the formulation of Sudan Herbal/Traditional Medicines Policy. The committee included 12 members representing experts and some stakeholders.

A number of consecutive and systematic consultations were convened with all interested parties which were preceded by a couple of brainstorming sessions to evaluate the current situation of THM practice in Sudan. Accordingly, the committee developed a comprehensive THM policy draft taking into consideration similar countries experiences, WHO strategy for Herbal and Traditional medicines 2014 – 2023, besides the National Health Sector Strategy 2012 – 2016 with explicit bias towards the Sudan National Medicines Policy 2014. The draft of the suggested policy was discussed with all parties concerned to create sense of collective ownership of the final policy.

Therefore, this policy is part of the government effort in acknowledging and preserving herbal and traditional medicines practices as integral components of a comprehensive national health system to ensure appropriate, safe and effective use of TM.

The overall goal of the policy is to guide and regulate THM practice while protecting indigenous knowledge, intellectual property, consumer and other rights and medicinal resources in addition to stimulate strategic research into THM by providing support for clinical research projects on its safety and effectiveness; and encourage the industrialization of finished medicinal products using local herbal medicines.

The Policy is focusing on building the knowledge base around this theme through appropriate national policies; strengthen quality assurance, safety, proper use, and effectiveness of THM by regulating products, practices, and practitioners, and the promotion of universal health coverage by integrating TM services appropriately.

The overall objective of the current policy is to make THM of acceptable quality, safety and effectiveness at affordable price available to the community with a certain emphasis on the rational uses of these resources. A policy’s implementation plan is fully detailed and it stresses the need for a comprehensive and functional administrative structure of TM to coordinate, oversee and advise practitioners, manufacturers, distributors and other beneficiaries. It is anticipated that this policy will be launched in the second half of 2016.

Guide for authors

Scope of the journal:
Rational use of medicines (RUM) issues directed to health care providers and medical students.

Suitability of publication:
All topics related to the different aspects of RUM will be evaluated by the editorial board. Prospective authors with a subject(s) or questions about the suitability of their papers or materials are invited to request an opinion from the Editorial Board. (sjrum@khmic.org).

Avoid plagiarism

How to submit materials:
Manuscripts can be handed over directly to the Directorate General of Pharmacy as soft copy or by e-mail (sjrum@khmic.org).

Types of manuscripts:
1. Research papers.
2. Case reports.
3. Thematic topics.
4. Success stories.

Preparation of manuscripts
All manuscripts must be typed in Arial font size 12, with 1.5 line spacing. Manuscripts must be in Word. Page margins on all sides must be at least 2.5 cm wide. You can use either English or American spelling but not both on the same manuscript.

1. Research papers
Original research will have the priority of publications. Author(s) name and affiliations should be clearly written. Contact person, telephone number and e-mail address should be included.
Total words count should not exceed 800 words including references, tables, table captions, figure legends, and footnotes. Maximum of three tables and figures are accepted.
The manuscript should be divided into sections. Each section should have a separate heading. Subheadings take the form of paragraph lead-ins (should be bold case), indented and run in with the text, separated by a period.

Introduction: This section should provide the reader with sufficient background information to evaluate the results of the research. An extensive review of the literature is not needed in this section. It should also give the rationale for and objectives of the study that is being reported.

Methods: Sufficient information must be provided so that the reader will understand the methodology and be able to repeat the experiment.

Results: The results section should be written in such a manner to provide information by means of text, tables and figures. Results and discussion may be combined or there may be a separate discussion section. If a discussion section is included, place extensive interpretations of results in this section. Do not repeat the results. Give numbers to figures and tables in the order in which they are mentioned in the text. All figures and tables must be cited in the text.

Conclusions and recommendations: Acknowledge personal, financial and institutional assistance at the end of this section.

References: Use the Vancouver reference system. Cite 6 references maximum.

Ethical clearance is a requirement for all researches from 2012 onward.

2. Case reports
Any case that is related to RUM will be considered. The manuscript should include the following setting: complete description of the case, consequences and outcome and finally follow up if applicable. Suggestions for solutions should be included.
Words count should not exceed 400 words.

3. Thematic topics
Any topic related to rational medicine use is considered. The manuscript should not exceed 400 words.

4. Success stories
Any story that reflects rational use of medicine and positive changes towards rational medicines use is welcomed. The manuscript should not exceed 400 words.

NOTE: Accepted manuscripts may be subjected to minor/appropriate changes prior to publishing. Please check the website for previous issues and updates www.sjrum.sd
Highlights on some of the NMICRL activities in 2015

Building states capacity: River Nile state’s pharmacists training on medicines information June 2015.

NMICRL Participation in the Khartoum international exhibition Oct. 2015.

NMICRL Open seminar in Quality assurance of pharmaceutical services Jan. 2015.

Development & endorsement of the national antibiotic prescribing policy Sept. 2015.

World’s antimicrobial resistance week activities 16-22 Nov. 2015

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