# 1. News

## EPA and DKT-Ethiopia Conduct Training on Family Planning and Methods of Contraception

Five rounds of family planning and methods of contraception trainings have been conducted by the Ethiopian Pharmaceutical Association in collaboration with DKT Ethiopia. The trainings were conducted in Addis Ababa (two), Adama, Bahrdar and Jimma from May 10 to June 23, 2012. The objective of these trainings was to fill the current knowledge gaps among pharmacy professionals (pharmacists and druggists) during the provision of family planning and contraception services at their practice sites. A total of 301 pharmacy professionals, 231 of which are males took part in the training. All the trainings were conducted

## EPA, MSH/SIAPS Join Hands to Offer Basic ART Training for Pharmacists

The Ethiopian Pharmaceutical Association in collaboration with MSH/SIAPS conducted two rounds of “Basic ART Trainings for pharmacists” in Adama and Mekelle from April 25 to May 01 and from May 14 to 20, 2012 respectively. The objective of the training was to provide pharmacy professionals with the basic skills and knowledge in ARV drugs management. Of the total, 53 were males and 15 were female participants.

## EPA, MSH/SIAPS Conduct a Pharmaceutical Ethics Training

The Ethiopian Pharmaceutical Association in collaboration with MSH/SIAPS conducted a two-days training on familiarizing pharmaceutical ethics to pharmacy professionals from 11-12 June 2012 in Bahrdar. The objective of the training was to update pharmacy professionals with the basic standards of ethical practice in different practice settings. A total of 40 participants took part in the training of whom, 37 participants were males and 3 were females.

## Anti malarial Drug Management and Rational Use Training Conducted

The Ethiopian Pharmaceutical Association in collaboration with MSH/SIAPS conducted a four-days training on anti-malarial drug management and rational drug use in Bahrdar from 10 to 13 July 2012. The training aimed to enhance the rational use and proper management of

medicines with special emphasis to antimalarial drugs. A total of 44 pharmacy professionals benefited from the training program.

## Continuing Medical Education on TB/HIV Co-infection update

The Ethiopian Pharmaceutical Association in collaboration with the Ethiopian Medical Association conducted a one-day continuing medical education on 21 July 2012 on TB/HIV Co-infection update in Jimma for health professionals with special consideration to pharmacy professionals. The training was financially supported by CDC/PEPFAR and it aimed to update health professionals with new developments on the management of TB/HIV Co-infection. A total of 148 health professionals of which 126 males and 22 females attended the session, of which 92 were pharmacists, 37 druggists and 17 nurses.

## FMHACA Collaborates with UNODC to Strengthen and Establish New Rehabilitation Centers for Drug Addicts

Apart from prevention and control of drug abuse, Rehabilitating and re-integrating the drug addicts to the society is one part of UN conventions that countries have signed including Ethiopia. As part of drug addicts Rehabilitation and re-integration program, the Federal Government of Ethiopia has established rehabilitation centers for drug addicts in five regional hospitals of the country (Dilchora Hospital, Felegehiwot Hospital, Mekele Referal Hospital, Jimma University Teaching hospital, Hawasa University Teaching hospital) and two federal hospitals St. Paul General Hospital and Amanuel Psychiatric Specialized Hospital. To build the capacity of professionals working in these rehabilitation centers the Food ,Medicine and Healthcare Administration and Control Authority (FMHACA) in collaboration with United Nations Office on Drugs and Crime (UNODC) country office has given five rounds training for a total of 88 health professionals and including those from regional health bureaus. A team of trainers who participated in the Training of Trainers (ToT) program organized by UNDOC in Mombasa, Kenya conducted the trainings in Ethiopia.

## National Strategic Framework on Prevention and Containment of Anti-Microbial Resistance (AMR) Familiarized to Stakeholders

Since their discovery in the 1930s, antimicrobial agents have saved billions of lives and have had considerable public health impact. However, emergence and spread of resistant microorganisms has reduced the life saving power of these medications. Preserving the efficacy of antimicrobial agents for the future generation is the public health agenda that the world has given priority. Based on the global strategy on prevention and containment of AMR, launched by the World Health Organization in 2001 countries are expected to devise their own strategy based on the global strategy and harmonize the combat against AMR.

Taking this in to consideration, Ethiopia has developed national strategy on AMR prevention and containment of AMR that can synergize the stakeholders to enable use the available resources and expertise for effective prevention and containment of AMR. The strategy will be supported by implementation plan of action.

Food, Medicine and Healthcare Administration and Control Authority (FMHACA) of Ethiopia in collaboration with MSH/SIAPS conducted a Familiarization workshop on National Antimicrobial Resistance prevention and Containment Strategy and plan of action. The objective of the familiarization workshop was to bring the stakeholders together, discuss on the implementation status of the national strategy, and enrich implementation plan of action and to sensitize and promote National Antimicrobial Resistance Prevention and containment Strategy and enrich implementation plan of action on prevention and containment of antimicrobial resistance.

Participants were drawn from different institutions including those from Ministry of Health, Ministry of Agriculture, Regional Health Bureaus and Agricultural Bureaus, Universities, Research institutions, Diagnostic laboratories, public and private health care facilities, Professional associations, Media and Development partners.

## Training on Prevention and Containment Antimicrobial Resistance Given to Journalists Working on Health

The prevention and containment of antimicrobial resistance has a common approach and requires integrated and well- coordinated efforts at the national level. It is a biological, behavioral, economic, regulatory and educational problem, and requires a comprehensive response employing evidence based strategy.

Media plays a significant role in public awareness creation, advocacy, and public education. In attempt to tap into this potential, the FMHACA in collaboration with MSH/SIAPS conducted a training for media personnel on promotion of rational medicines use and prevention and containment of Antimicrobial Resistance. The trained journalists are expected to advocate and educate the public on prevention and containment of antimicrobial resistance.

## 39 Minimum Health Facility Standards Approved By Ethiopian Standards Authority as Mandatory

Ethiopian Standards Authority has approved 39 Health Facility Standards prepared by FMHACA as mandatory standards for health facilities in Ethiopia. Application of the standards is expected to bring fundamental changes to quality of the health facility services. Familiarizations of these standards are on the move by FMHACA and a grace period of six months to one and half years depending on the type of the level of the health facility is given before starting to enforce the standards. The standards are comprehensive and set minimum requirements in terms of human resource requirement, service quality, management, equipment etc.

The following are list of health facilities that minimum mandatory requirements are currently set and approved by national standards Authority:

1. Health Post
2. Health Center
3. Primary Hospital
4. General Hospital
5. Compressive Specialized Hospital
6. Maternal & Child Health (MCH) Center
7. Internal Medicine Center
8. Surgery Center
9. Pediatric Center
10. Orthopaedic Center
11. Cardiac Center
12. Oncology Center
13. Neurology Center
14. Gastroenterology
15. Renal Center
16. Eye/Ophthalmology Clinic
17. Dental Specialty Clinic
18. Medium Dental Clinic
19. Dental Laboratory
20. Obstetrics & Gynaecology Speciality Clinic
21. Paediatric Specialty Clinic
22. Dermatology Specialty Clinic
23. Psychiatric /Mental Health Speciality Clinic
24. Oto-Rhino Larengo(ORL)(ENT)Specialty Clinic
25. Surgery Specialty Clinic
26. Orthopedic Specialty Clinic

27. Internal Medicine Specialty Clinic
28. Neurology Specialty Clinic
29. Cardiovascular Specialty Clinic
30. Gastroenterology Specialty Clinic
31. Rheumatology Specialty Clinic
32. Nephrology Specialty Clinic
33. Physiotherapy Specialty Clinic
34. Chest Specialty Clinic
35. Nursing Home
36. Primary Clinic
37. Medium Clinic
38. Basic Medical Laboratory
39. Advanced Medical Laboratory

## The Efficacy of Niclosamide under Investigation in Ethiopia

Niclosamide 500mg tablet has been used in Ethiopia for decades as an effective anthelmintic drug. It has been the drug choice for treatment of infections with *Taenia Saginata* (beef tapeworm) and *Taenia solium* (pork tapeworm). However, FMHACA has been receiving many efficacy problem reports of the drug from all corners in the last two years. The Authority tried all sorts to investigate the root source of the problem, from physical inspection to laboratory analysis. There was no quality problem in raw material and production process as checked by FMHACA inspectors and FMHACA quality control laboratory. FMHACA further dealt with the sole manufacturing company, Addis Pharmaceutical Factory (APF), and informing the company that the problem may be due to emergence of resistance. The company has since stopped producing the drug for the time being and has planned conduct a clinical research to investigate into the problem in collaboration with Mekele University. The batches all ready in the market will go until it will stock out in regions where the drug is still active. A new decision will be passed based on the investigation results, it is expected.

## International day against drug abuse and illicit trafficking celebrated

According to the UNODC, nearly 200 million people are using illicit drugs such as cocaine, cannabis, hallucinogens, opiates and sedative hypnotics worldwide. Many countries, including Ethiopia, ratified conventions to control cultivation, production, usage and trafficking of such drugs. In December 1987 the UN General Assembly decided to observe June 26 as the International Day against Drug Abuse and Illicit Trafficking. And it has been held annually since 1988 on 26 June and the day was commemorated for 24 years internationally and for 19 years in Ethiopia.

This year's International day against drug abuse and illicit trafficking has been commemorated internationally under the theme "global action for healthy communities without drugs". Ethiopia also celebrated this day under international theme and country specific themes using the local language.

A taskforce composed of FMHACA, WHO, EPHA and Federal police successfully coordinated the 2012 event. With the objective to create awareness for the general public about the devastating consequences of drug abuse and illicit trafficking in Ethiopia, plenary discussion, a press conference, message displays on banners, and a mass walk have been part of the ceremony for this year.


*Mass walk at Hawasa town.*

## Discussion on the cohort event monitoring (CEM) proposed to be carried out on the safety of Anti retroviral medicines in Ethiopia

The FMHACA as part of its commitment to ensuring public health, follows upon the safety profile of medicines not only before marketing but also after distributed to the people. The National pharmacovigilance center at FMHACA follows up and investigates safety of medicines marketed within the country. The cornerstone of this pharmacovigilance system used currently is Spontaneous reporting which is  a passive surveillance system that uses voluntary reporting of an encountered adverse drug event by a health provider with the main objective being able to provide signals about potentially serious, previously unknown safety problems with marketed drugs.

According to a summary of spontaneous reports sent to the pharmacovigilance center from 2001-2003E.C, (77%) of the adverse drug events were caused by drugs of antiretroviral therapy. Though this primary data is obtained through passive surveillance, the system has got various limitations in identifying and assessing injuries related to these drugs. For this purpose various countries are employing other additional active surveillance methods that could compliment the drug safety information obtained from the passive surveillance system to obtain a high quality data and result into proper decision making.

The FMHACA has planned to carry out one of these effective methods which is Cohort Event Monitoring (CEM) on ARV medicines in collaboration with the relevant stakeholders and partners so that it would be possible to evaluate the safety for use of medicines of Anti Retroviral Therapy in Ethiopian population and come up with intervention strategies and also generate baseline data. For this purpose, a proposal was developed and introduced to stakeholders and partners on a workshop held on June 6, 2012 at Siyonat Hotel, Addis Ababa. The proposal was oriented to the participants and their involvement the study was initiated by establishing a task force that coordinates and follows the activities in carrying out the Cohort Event Monitoring together with the Pharmacovigilance center.

## Launch of a pharmacovigilance database

A pharmacovigilance database that was developed with the objective of storing, and analysis of drug safety information sent from health providers was launched at Siyonat Hotel on April 23, 2012. Participants present were stakeholders from regional health bureaus, teaching institutions, professional associations, health facilities and other partners such as the WHO. The development and launch of this database was possible through the collaborative activity of strengthening the National pharmacovigilance system between FMHACA and Management Sciences for Health System for Improved Access to Pharmaceuticals and Services (MSH/SIAPS).

The database Pharmacovigilance data management system (PVDMS 1.0) was developed by the IT Unit of MSH/SIAPS according to the Scope of work specified by the National Pharmacovigilance center at FMHACA. The database captures all kinds of necessary information i.e. data on Adverse drug reaction, medication error, product quality defect including safety reports obtained from Adverse Events following Immunization (AEFI) and Market

Authorization holders (MAH) needed for a comprehensive monitoring and analysis of drug related reactions using user friendly and consistent input taking interfaces.

***Market Recall of some Anti malarials after Post marketing surveillance***

Based on the joint project of FMHACA and USP-PQM for surveillance of anti-malarial products circulating in Ethiopia, FMHACA conducted post marketing surveillance on different types of anti- malarial medicines. A total of 170 samples have been collected from different parts of the country and are being analyzed for compliance with the the quality requirements by the national quality control laboratory of the Authority. The products under analysis are solid oral dosage forms of: Artemether +Lumefantrine (20mg +120mg), Chloroquine (250mg), Sulfadoxine +Pyrimethamine (500mg +25mg), Quinine 300mg, primaquine 15mg and Mefloquine 250mg.

On the previous phase of this same project, regulatory decisions were taken on anti malarials that did not meet the requirement of assay for the parameters tested as per USP-2011. These were Artemether 20+ Lumefanthrine 120mg [coartem 20/120 (batch no. F1954)], Sulfadoxine + Pyrimethamine [PYRALFIN (batch no. DM00040)] and Sulfadoxine + Pyrimethamine [GOMAL (batch no. SGMT1003)]. The local importers of these products were officially notified to recall the products from market and periodically send their progress reports to the Authority.

## 2. Current Issues

The five year growth and transformation (GTP) plan of Ethiopia has put, in the forefront, pharmaceutical industry as one of the priority areas the government will be working to expand. Currently there are very few industries in the country catering to a very small portion of the country's drug needs. The health sector in Ethiopia at present heavily depends on imported drugs and medical supplies consuming a hard-earned foreign currency.

We sat down with Ms. Etenesh Abraha, the chairperson for the Pharmaceuticals and Medical Supply Manufacturers' Association, to have firsthand information regarding the current challenges and efforts to improve access to pharmaceuticals and medical supplies.

Happy reading!

**Pharmaforum**: First of all, on behalf of the Pharmaforum and the Ethiopian Pharmaceutical Association, we would like to thank you for your willingness to do the interview with us.

**Pharmaforum:** Would like you to introduce yourself and tell us about your role in the Association of Local Pharmaceuticals' Manufacturing Factories.

***Ms. Etenesh:*** My name is Etenesh Abraha. By profession, I am an accountant. After graduation, I used to work in different Institutions in the field of accounting until I started

my own project of a small export enterprise followed by Import & Manufacturing Companies in Pharmaceuticals & Medical Supplies. Since then, I have been leading my Company ETAB INTER-MEDICA as a General Manager. I am the chairperson of the Pharmaceuticals & Medical Supply Manufacturers'' Association.

**Pharmaforum:** When was the first local pharmaceutical factory established? How does the development look like? How many factories are there currently in Ethiopia? What percentage of the country's consumption of pharmaceuticals is covered by these local factories? What are the major challenges that the sector faces?

***Ms. Etenesh:*** The first Pharmaceutical Manufacturing Company to be produce pharmaceuticals in Ethiopia is Ethiopian Pharmaceuticals Manufacturing (commonly known as EPHARM). It was established as a joint venture of a foreign company and the Ethiopian government in1964 G.C. and after ups & downs it was nationalized by the then Dergue Regime.

The development in the manufacturing sector was stagnant during The Imperial & Dergue Regime with only one company dealing with very limited generic products (mostly antibiotics, pain killers, vitamins, some simple syrups, ointments and a few Injectables & powders). Following the overthrow of the Dergue Regime, new pharmaceutical companies have mushroomed encouraged by the incentives put forth by the new government and currently the number has reached to 11 operational pharmaceutical plants

As far as local coverage is concerned, though it is very difficult to tell the exact percentage (as there is no efficient database in the country) it is estimated that local manufacturing companies contribute to not more than 30% of the total consumption (In Value).

Previously local manufacturers had a lot of problems related to finance, technology, taxation, procurement obstacles, skilled man power and others. Now, some of the problems have been resolved due to the collaborative efforts done by the association, and the government stake holders Such as MOH, MOI, FMHACA, PFSA and Others**.**

**Pharmaforum:** When was the Association of the Local Pharmaceuticals Manufacturing factories established? And How? What has it accomplished since its establishment? What were the major challenges that it faced? How many of the factories are members? To what extent do these factories support the Association?

***Ms. Etenesh:*** The Official Establishment date in its current form, Ethiopian Pharmaceuticals & Medical Manufacturers' Association" is August 04, 2004 (Hamle 28,1996), However some of the current members including ***ETAB*** had been members of the then "Ethiopian Private Manufacturers Association".

Under the Ethiopian Private Manufacturers association, as I put earlier we were very few, who are engaged in the Pharmaceuticals & Medical Manufacturing sector. We use to regularly discuss the peculiar problems related to our sector, in fact we used to reflect the consolidated problems to government Institutions such as the then DACA, MOFED & others, seeking solutions. Finally we established our own association in line with the revised proclamation which clearly indicated The Pharmaceutical Sector as an independent entity.

Since its establishment, the association has tried its best to resolve problems of its members; to be specific:

We actively participated in the development of the five years strategic plan of the Pharmaceutical Manufacturing sector. We were able to negotiate with the government regarding tax problems related to raw materials and this has resulted in reduction of tax rates to the lowest and down to 0% now by the MOFED. Also, our efforts resulted in convincing the government in general and the specific institutions such as PFSA/ Ministry of Health to give priority to local products.

However, we still have challenges that affect the development of the local manufacturers (partly internal and partly external). The government is committed to support the sector. But there are problems here and there in implementation which I hope shall be resolved with time.

Currently we have more than 14 members and are supporting their association in finance as membership fee though it is limited to cover the obligations of the association.

**Pharmaforum:** What can you tell us about the Import of Pharmaceuticals? i.e.,its contribution to the supply of Pharmaceuticals? Its market share? Its impact on the development of the local manufacturing?

***Ms. Etenesh:*** As I put it earlier, currently most of the demand of the country is covered by Import. Therefore it is unfair to deny the contribution of import while playing on less than 30% coverage in local production.

The best and fair approach that should be taken is that with establishment of new local manufacturers and entry of products with sufficient amount priority should be given to locals so as to encourage self reliance.

**Pharmaforum:** What can you tell us about the country's policies and legislations on the supply of drugs with regard to the development of the local manufacturing sector? What about the role of the regulatory body?

***Ms. Etenesh*:** The government, I believe is in the right track. The government wanted to see as many manufacturers as possible in the country. As organs of the government the Ministry of Health & the Ministry of Industry are working towards this goal. In fact, very recently the Ministry of Health has taken its own initiative to organize a permanent forum which is composed of the association members and other stake holders such as PFSA, FMHACA and others to strictly identify the problems of the sector and accordingly seek solutions in collaboration with other government offices.

We do not have policy problems. But we have to monitor the practices that are being followed in the implementing offices if they are really doing in line with the policies.

Regulatory bodies are indispensable. They have to be serious in regulation. But at the same time they should support the local Industries in GMP and other technical needs.

**Pharmaforum:** I would like to give you the chance if there is any message that you would like to pass to the pharmacy professionals regarding what has been discussed about.

***Ms. Etenesh*:** Pharmacy profession plays an important role in the development of the sector. It means, the professional Pharmacists are stake holders. Thus, they should be active in supporting their association so that it plays its role in the development.

Thank you very much. Best regards!

**Pharmaforum:** Thank you

## 3. Pharmacy practice

**CLINICAL PHARMACY AT ALERT HOSPITAL**

Over the past few years there has been a trend for pharmacy practice to move towards not only of medicine supply but also towards a more inclusive focus on patient care. The role of pharmacists has evolved from the compounder and supplier of pharmaceutical products towards that of a provider of services and information and ultimately that of a provider of patient care.

A one-month training on “a course on clinical pharmacy in-service training for pharmacists” was organized by the pharmaceutical fund and supply agency in collaboration with MSH/SIAPS and Jimma University. Pharmacists drawn from 21 hospitals took park and ALERT Hospital was among those who had the opportunity for its pharmacists to participate.

ALERT Hospital is a specialized hospital with a specialty service in Dermatology, ophthalmology and TB/HIV. It is also the third treatment center for MDR/TB next to St. Peter and University of Gondar Teaching Hospital. The hospital has more than 250 beds.

The clinical Pharmacy service has been delivered in three units of the Hospital-Medical, Pediatric, and TB/HIV wards. Depending on the success and the experience to be gathered, the service will expand to other units of the hospital.

Early in the morning pharmacists who are assigned in each ward review their patient card before a major round begins at 10 AM. During the major round participating pharmacists discuss drug related issues on each patient with respective physicians. In the afternoon there is also a round in which only pharmacists participate (a pharmacy round). In this round pharmacists assess each card and identifies drug therapy problem. In addition, there is also a pharmacist-only morning session conducted twice weekly.

The clinical pharmacy team at the hospital has developed its own documentation form which includes information such as patients specific date, prescribers information, categorization of drug related problems (DPR) ,Pharmacist comment on DPR, pharmacist recommendation on current DPR, copy of original prescribed medication, prescriber review and comments (response) pharmacist action plan and finally the outcome.

Early experience has indicated that such service fosters the pharmacist-physician interaction and narrows the communication gap to a great extent. In addition, it is created an opportunity to effectively manage medication related problems of patients and monitor medicine related illness effectively.

Finally, the hospital and pharmacists believe that pharmacist have the potential to improve the therapeutic out come and patients quality of life with in available resources and must position themselves at the forefront of health care system ,the movement towards pharmaceutical care is a critical factor in this process.

Contributed by: ALERT Hospital Clinical Pharmacy Team

## 4. Continuing Education

**An Overview of the Treatment and Management of Rhinosinusitis**

Every year rhinosinusitis accounts for a significant morbidity in the population resulting in lost days to work/school due to illness. National data in Ethiopia regarding the disease burden is lacking however observations reveal that it accounts to large number of illnesses contributing to irrational use of antimicrobial agents. Primary care clinicians and pharmacists are challenged to differentiate between viral and bacterial sinusitis, which have nearly identical symptoms, and recommend appropriate therapy for patients. Due to these concerns, in March 2012 the Infectious Diseases Society of America (IDSA) published its first clinical practice guidelines on the treatment of acute bacterial sinusitis. A community pharmacist is poised to help treat this public health concern through education and proper recognition of when to treat symptoms or an underlying bacterial infection.

**Definition and Etiology**

*Sinusitis*, or *rhinosinusitis*, is defined as inflammation of the paranasal sinuses and nasal cavity. The term rhinosinusitis is preferred because sinusitis is typically associated with inflammation of the nasal mucosa. Rhinosinusitis can be categorized based on the duration of infection, and then further subdivided by the causative pathogen. Regarding duration of symptoms, rhinosinusitis can be classified as acute rhinosinusitis (<4 weeks), subacute rhinosinusitis (4-12 weeks), chronic rhinosinusitis (>12 weeks), or recurrent acute rhinosinusitis (four or more cases per year). When categorizing based on causative organism, the majority of cases are viral in

origin, but a small minority are caused by bacterial and/or fungal pathogens. Acute rhinosinusitis is typically subdivided into acute bacterial rhinosinusitis (ABRS) or acute viral rhinosinusitis (AVRS).

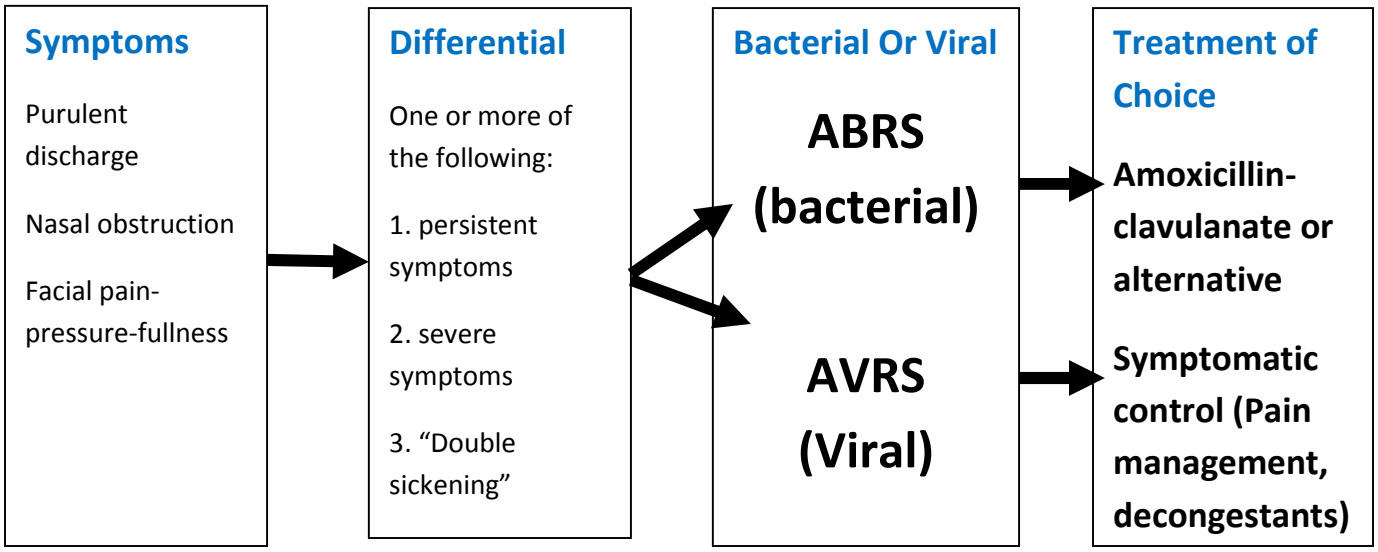


Figure 1. Diagnosis and Treatment of Rhinosinusitis

The most common etiology for rhinosinusitis is the *rhinovirus*, also known as the *common cold*. AVRS is the most common type of rhinosinusitis, accompanying upper respiratory tract infections when viral inoculation occurs via contact with nasal mucosa or conjunctiva. The virus causes inflammation in the nasal passages and sinus cavities, impairing mucociliary clearance and leading to the obstruction of the sinuses. ABRS most often occurs when the inflamed mucosa is secondarily infected by bacteria. Regardless of the causative organism, this mucosal inflammation causes the typical symptoms of acute rhinosinusitis.

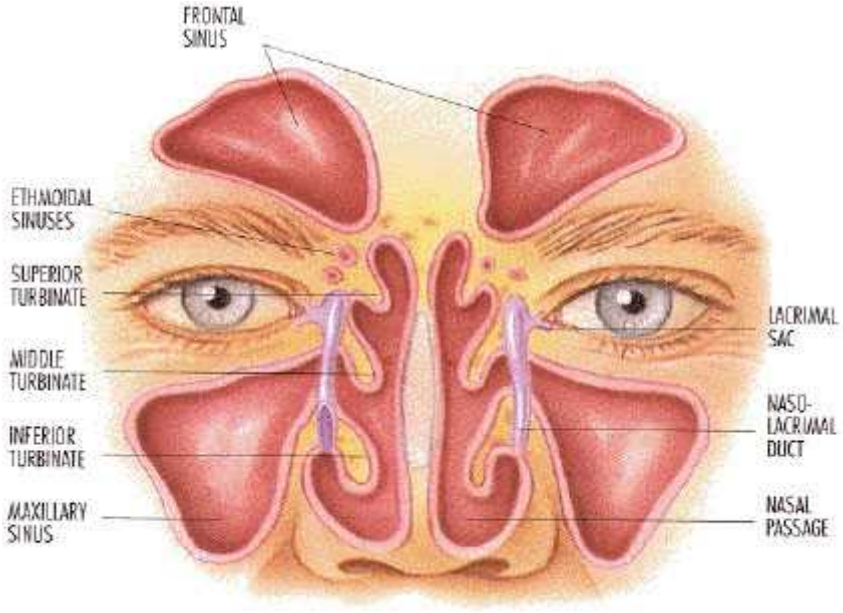


Figure: Sinuses

**Symptoms**

Rhinosinusitis has three cardinal symptoms: purulent nasal discharge, nasal obstruction, and facial pain-pressure-fullness. Purulent nasal discharge is cloudy or colored in appearance; nasal obstruction is defined by the patient as obstruction, congestion, blockage, or stuffiness; and facial pain-pressure-fullness involves the anterior face and periorbital region or manifests with headache that can be localized or diffuse. Secondary symptoms can include fever, cough, fatigue, hyposmia, anosmia, maxillary dental pain, and ear fullness or pressure. The 2012 Infectious Disease Society of America (IDSA) guidelines help distinguish between viral and bacterial rhinosinusitis by defining three clinical presentations that may be present in bacterial but not viral infections: persistent and nonimproving symptoms, severe symptoms, or a worsening (i.e., “double sickening”).

Some risk factors that predispose patients to rhinosinusitis include anatomical abnormalities, nasal allergic reactions, dental infections, mucosal abnormalities (such as in subjects with cystic fibrosis), chemical irritants, and immunodeficiency. Some conditions that present similarly to rhinosinusitis warrant urgent referral due to possible complications, including intracranial and orbital infections. Symptoms that indicate urgent referral are diplopia, blindness, change in mental status, and periorbital edema.

**Categorization of Illnesses**

***Acute:*** As mentioned previously, acute rhinosinusitis can be divided into two categories depending on the causative organism-AVRS and ABRS. Symptoms of AVRS and ABRS can be identical, so distinguishing the two can be difficult. AVRS is normally self-limiting and typically resolves without treatment in 7 to 10 days. Bacterial complications occur in a few percentage of AVRS cases when the virally inflamed sinus cavity becomes secondarily infected. AVRS can promote bacterial infection by obstructing sinus drainage, promoting growth of bacteria, and depositing bacteria into the sinus cavity during nose blowing. Typical pathogens include *Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis*, and *Staphylococcus aureus*, with the majority of cases in adult patients caused by the first two bacteria.

The 2012 IDSA guidelines help differentiate AVRS from ABRS by defining three clinical presentations that identify bacterial infections: symptoms for ≥10 days without improvement, severe symptoms, or worsening symptoms after initial improvement. Severe symptoms are defined as high fever (≥ 39°C) and purulent nasal discharge or facial pain lasting for at least 3 to 4 consecutive days. Worsening symptoms, also called “double sickening,” are defined as the new onset of fever, headache, or nasal discharge following an upper respiratory tract infection that lasted 5 to 6 days, when initially symptoms were improving.

***Subacute:*** Subacute rhinosinusitis is a designation used to define the time period between acute rhinosinusitis (<4 weeks) and chronic rhinosinusitis (>12 weeks). No clinical data exist for the evaluation or treatment of subacute rhinosinusitis. As such, no specific recommendations can be made on the treatment of subacute rhinosinusitis.

***Chronic:*** Chronic rhinosinusitis (CRS) is characterized by greater than 12 weeks of sinus inflammation regardless of appropriate medical management. The four cardinal signs of CRS include anterior and/or posterior mucopurulent drainage, nasal obstruction, facial pain, and decreased sense of smell. CRS may involve nasal polyps or allergic fungal infection, and many different patient-specific factors can contribute to the disease. CRS needs to be evaluated by a physician via endoscopy and/or CT imaging, and some patients may need endoscopic surgery; therefore, treatments for patients with rhinosinusitis symptoms lasting longer than 12 weeks are outside the scope of the community pharmacy practice.

**Treatment**

The goals of therapy for both acute and chronic rhinosinusitis are to control infection, reduce tissue edema, facilitate drainage, maintain patency of the sinus ostia, and break the pathologic cycle that leads to CRS. Acute viral rhinosinusitis is a self-limiting condition. Since no pharmacotherapeutic interventions are proven to reduce the duration of illness, the goals of medical management are to relieve the symptoms of nasal obstruction and rhinorrhea.

Treatment of ABRS may include antibiotics to eliminate the infection, but, as stated before, the majority of bacterial infections will clear spontaneously. Since ABRS cannot generally be differentiated from its viral counterpart in the first 10 days, antibiotic therapy should be reserved for patients with severe symptoms for at least 3 to 4 consecutive days, signs of double sickening, and illness persisting for longer than 10 days without evidence of clinical improvement.

Patients with facial swelling, edema around the eyes, abnormal vision, or mental status alterations may be experiencing intracranial or intraorbital extension of sinusitis, and should be referred immediately for urgent medical attention.

***Acute Viral Rhinosinusitis:*** Supportive therapy for AVRS should be tailored to an individual's symptom profile. Nonsteroidal anti-inflammatory drugs (NSAIDs) and paracetamol are recommended for the pain and discomfort associated with mucosal swelling. Oral and topical decongestants reduce symptoms of rhinosinusitis by constricting the blood vessels of the nasal mucosa, thereby reducing edema and inflammation. Topical decongestants, such as oxymetazoline, can provide more relief than systemic decongestants due to their increased potency and local administration, but they should be used for no more than 3 days to avoid rebound congestion. Systemic decongestants should be used with caution in patients with cardiovascular disease or uncontrolled hypertension.

Intranasal corticosteroids reduce edema and inflammation and have been shown to reduce symptoms of acute rhinosinusitis.

Antihistamines are often prescribed for symptom relief due to their drying effect, but there is no evidence to support their use in infectious rhinosinusitis. Overdrying the mucous membrane can impair mucus clearance and cause additional discomfort. Antihistamines should only be recommended to patients with symptoms suggesting a significant allergic component.

Saline nasal rinses are used to soften viscous secretions and improve mucous clearance.

***Acute Bacterial Rhinosinusitis:*** The symptoms of bacterial and viral rhinosinusitis are almost indistinguishable within the first 10 days. As such, patients presenting with fewer than 10 days of nonsevere symptoms, including mild pain and fever ≤38.3˚, should be managed symptomatically as previously discussed. Antibiotics should be initiated when signs and symptoms of acute rhinosinusitis do not improve within 10 days, in patients who experience a secondary worsening after initial improvement of symptoms (double sickening), or in patients with severe symptoms lasting for 3 to 4 days.

Initial antibiotic choice should be based on a number of factors including safety, cost, and efficacy against microorganisms likely to cause ABRS. The most commonly isolated organisms include *S pneumoniae , H influenzae*, and *M catarrhalis*. To prevent bacterial resistance, antibiotics with a narrow spectrum of activity are preferred. The 2012 IDSA guidelines for the treatment of ABRS suggest amoxicillin-clavulanate as first-line therapy for patients requiring antibiotics. Previously, amoxicillin alone had been recommended for initial therapy. For patients with a penicillin allergy, doxycycline or a respiratory fluoroquinolone (levofloxacin, moxifloxacin) should be used.

The recommended duration of therapy is 5 to 7 days for adults and 10 to 14 days for pediatric patients, based on the typical therapy used in randomized, controlled trials of antibiotics in ABRS; however, no significant differences in cure rates are obtained with a shorter, 3- to 4-day course of therapy.

Some other factors may dictate the use of alternative therapy. A history of antibiotic use in the previous 4 to 6 weeks increases the risk of antibiotic-resistant microorganisms. Guidelines suggest a fluoroquinolone or high-dose amoxicillin-clavulanate (2,000 mg/125 mg by mouth twice a day) for such patients.

Treatment failure is defined as progression of symptoms during antibiotic therapy or no improvement after 7 days of therapy. These patients should be reevaluated for a nonbacterial cause or infection with drug-resistant bacteria. If treatment with narrow-spectrum antibiotics is insufficient, a more broad-spectrum fluoroquinolone or high-dose amoxicillin-clavulanate should be considered. Refractory cases should be referred to an otolaryngologist, who may obtain endoscopic cultures to guide therapy.

***Chronic Rhinosinusitis:*** The symptoms of CRS, regardless of origin, can be managed similarly to those of acute rhinosinusitis. CRS sufferers using once-daily saline nasal rinses for 6 months used less nasal spray, required fewer antibiotics, and experienced fewer 2-week periods with sinus-related symptoms.

As previously discussed, patients with symptoms of rhinosinusitis lasting more than 12 weeks require medical management, including imaging studies, endoscopy, and potentially surgery. Therefore, these patients should be referred to a physician.

## Conclusion

Rhinosinusitis contributes to a significant morbidity each year and accounts for a major cause of antibiotic preseciptions on an outpatient basis. A significant majority of patients improve without antibiotics. Community pharmacists are poised to play a significant role in the appropriate treatment of rhinosinusitis through proper recognition of cardinal symptoms and clinical manifestations, patient education, and evidence-based pharmacotherapy.

## Resources


1. Rosenfeld RM, Andes D, Bhattacharyya N, et al. Clinical practice guideline: adult sinusitis. *Otolaryngol Head Neck Surg*. 2007;137(suppl):S1-S31.
2. Fokkens W, Lund V, Mullol J; European Position Paper on Rhinosinusitis and Nasal Polyps Group. EP30S 2007: European position paper on rhinosinusitis and nasal polyps 2007. A summary for otorhinolaryngologists. *Rhinology*. 2007;45:97-101.
3. Young J, DeSutter A, Merenstein D, et al. Antibiotics for adults with clinically diagnosed acute rhinosinusitis: a meta-analysis of individual patient data. *Lancet*. 2008;371:908-914.
4. Chow AW, Benninger MS, Brook I, et al. IDSA clinical practice guidelines for acute bacterial rhinosinusitis in children and adults. *Clin Infect Dis*. 2012;54:e1-e45.
5. Gorbach SL, Falagas M, eds. *The 5-Minute Infectious Diseases Consult*. Boston, MA: Wolters Kluwer; 2001.
6. Ah-See KW, Evans AS. Sinusitis and its management. *BMJ*. 2007;334:358-361.
7. Cooper DH, Krainik AJ, Lubner SJ, et al, eds. *The Washington Manual of Medical Therapeutics*. 32nd ed. St. Louis, MO: Wolters Kluwer; 2007.