SOP Magazine

Volume 5 Issue 3 | **Spring** 2018

“A little **knowledge that acts** is worth infinitely more than much knowledge that is idle.”

Gibran Kahlil Gibran

SOP Magazine

ABOUT THE SCHOOL OF PHARMACY

One of the highly ranked private schools of pharmacy nationwide, the Lebanese International University School of Pharmacy maintains an elegant reputation for innovative educational programs and skillful training through both degrees it offers, the BPharm and PharmD. Over the past few years the School has strived to establish a structure which enables our graduates to become an added quality to the healthcare system. The School focuses on clinical pharmacy, community outreach, and training on the optimal use of medication therapy through didactic as well as clerkship/internship courses. Today, our School is acknowledged by private, public, and international institutions. Our graduates attain high success rate in the national pharmacy examination (colloquium), and are highly recognized by national and international pharmaceutical companies.

The SOP Magazine, published tri-annually, delivers drug and health information news from the School's Faculty members and highlights some of the School's events.

Dean of the School of Pharmacy
Dr. Mohamad Rahal

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Design & Execution
LIU PRINTING PRESS

Dean's Message To Graduates

Pharmacist's role has evolved from being compounder and dispenser to that of being an EXPERT in medicines within multidisciplinary healthcare team. The WHO and the International Federation of Pharmacists (FIP) define pharmacists as " specifically educated and trained health professionals who are charged by their national or other authorities with the management of the distribution of medicines and to assure their safe and efficacious use."

The Center for Advancement of Pharmaceutical Education (CAPE) has Future Pharmacists must be capable of:

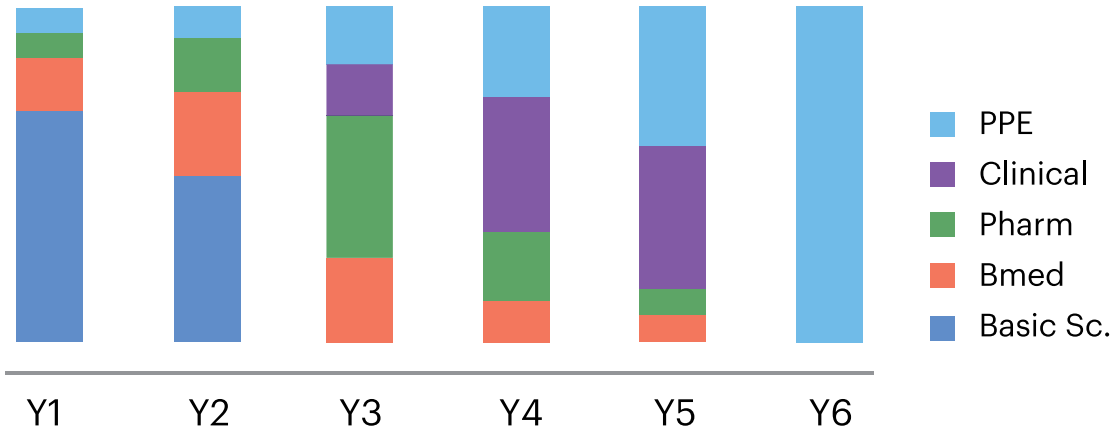
- Functioning collaboratively as member of inter professional team
- Advocating for patients and demonstrating leadership
- Providing care for diverse patient populations
- Contributing to the health and wellness of indi viduals and communities
- Educating a broad range of constituents
- Effectively managing a highly technical workplace

A pharmacy program should prepare pharmacists to have the knowledge and skills to optimize patient care and treatment outcomes as an effective member of the health care team.

The program should provide a strong educational basis in the biomedical, pharmaceutical, social, administrative and clinical sciences that will equip graduates with the appropriate competencies to excel in various fields of pharmacy and be dedicated to lifelong professional development.

The program should categorize the Intended Educational Outcomes that provide a structured framework for promoting and guiding curricular change, inspiring innovation, meeting challenges facing pharmacy education, and mapping and measuring programmatic outcomes.

Pharmacy educators should be committed to planning and applying quality assurance and improvements in their curriculum towards achieving national and international recognition and accreditation.



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Overview of Dementia

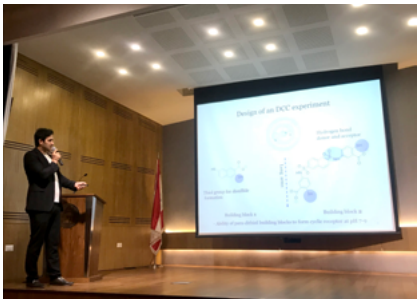
By: Dr. Etwal Bou Raad

The Lebanese International University, School of pharmacy and the extracurricular committee organized in December 12, 2017 a seminar entitled “Overview of Dementia”. The presentation was delivered by Dr. Nabil Naja, the head and the medical director of Dar Al Ajaza Islamia Hospital. Dr. Naja has founded many organizations including but not limited to the Lebanese Geriatric Society, the Lebanese Alzheimer association and the center of studies on aging (CSA). The seminar took place at Beirut campus and attended by pharmacy students and faculty. The seminar conveyed important information including disease risk factors, diagnosis, and clinical management. In order to enhance the attendee understanding about the disease manifestations, he presented a video of a real case scenario at the end of the presentation. Moreover, Dr. Nabil explained to the audience about the burden of the disease on the patient, the family care givers and the society.

Synthetic Receptors for Ammonium Ions Using Dynamic Combinatorial Chemistry

By: Dr. Dalal Hammoudi

A Seminar on "Synthetic Receptors for Ammonium Ions using Dynamic Combinatorial Chemistry" was delivered at the school of Pharmacy, Beirut Campus, by Dr. Saleh Hamieh, PhD in Chemistry, University of Groningen, The Netherlands. Dr. Hamieh elaborated on the role of such chemistry method in discovery of new drug entities. He explained how it is possible using such innovative modality to get multiples of molecules that can be screened for medicinal activity, within a significantly shorter time than that needed for conventional methods. The seminar was attended by the Dean, faculty, and third year students, and was concluded by an open discussion.



Breast Cancer Awareness Campaign

By: Dr. Mariam Dabbous

October is the **World Breast Cancer** Awareness Month.

The School of Pharmacy at Lebanese International University organized a full day on Thursday October 19, 2017 to raise awareness about breast cancer at the International University of Beirut.

The aim of this day is to remind people to be screened for breast cancer, the second leading cause of cancer death among women after lung cancer.

We, school of pharmacy, think every little bit of awareness and exposure will certainly help the cause. Our day started with a poster session, where the professional communication students highlighted on the importance of screening to detect breast cancer on early stage. The pharmacy club performed several activities during this day started by pink yoga then forming the human ribbon in support of Breast Cancer Awareness month in collaboration with the marketing department.

The day was ended with a seminar entitled "Breast Cancer Screening and Prevention" delivered by Dr. Hazem Assi. Dr Assi, is an assistant Professor and Director of Hematology- Oncology Division, Department of Internal Medicine at the American University of Beirut Medical Center. He focused on the risk factors of breast cancer, signs and symptoms, and ended with the screening methods used to find breast cancer as early as possible.

At the end, Dr. Mohamad Rahal, dean of School of Pharmacy, gave Dr. Assi a trophy of appreciation for the informative and interactive lecture.

Diabetes Awareness Campaign

By: Dr. Mariam Dabbous

World Diabetes Day is the primary global awareness campaign focusing on diabetes mellitus and is held on November 14 each year. The School of Pharmacy at Beirut Campus organized a diabetes awareness campaign on Tuesday, November 14, 2017 to draw attention to issues of paramount importance to the diabetes world. The professional communications students and pharmacy club were educating LIU students and faculty about their risk of developing diabetes and give them tips to reduce their risks.

First, a risk assessment sheet was given to each participant in order to calculate his/her risk of diabetes. Random blood glucose, blood pressure, weight, and height were measured and the risk was calculated.Patients with moderate and high risk were given a diet plan by the health club members to help reduce weight and emphasize on importance of exercise, and following healthy life style.

At the end, all faculty and students were blue cloves and took common photo.

Christmas Fundraising Campaign

By: Dr. Mariam Dabbous

Under the Christmas Spirit, the students at the school of pharmacy held a Fundraising Campaign on Thursday, December 21st, 2017 to support CHANCE (Children Against Cancer) Association, which helps in the treatment of children who have been diagnosed with cancer.

The donations that were given by the students, faculty members, and administrative staff summed up to a total of one thousand dollars. Dr. Rola Farah, the founder and president of CHANCE Association, visited the School of Pharmacy the day of the event to personally thank our students for helping the children in their fight. Mr. Sharif Kayes, a motivational speaker, gave the students a speech to encourage them to support cancer patients. He focused on the role of humanity in helping sick patients by organizing such events.

The event was ended by a Secret Santa reveal for the students and instructors. The team, who organized this event, including the students and faculty members, has always been passionately committed to looking for noble causes to help those in need. And in fact, they have actually fulfilled the slogan of this association which is: Let's all join hands and efforts to "Give them a CHANCE"..

LUND University- Sweedens

By: Dr. Mariam Dabbous

The School of Pharmacy at the Lebanese International University represented by the Dean Dr. Mohammad Rahal, participated in the Al Kitab University College First International Scientific Conference In Cooperation with LUND University- Sweedens on 13th and 14th of December 2017 at Iraq/ Baghdad.

Dr. Rahal delivered a presentation entitled: 'Shaping Pharmacy Education: Achieving Professional Competencies". Dr. Rahal emphasized on the "Imperatives for Evolving the Pharmacy Profession," through introducing the LIU school of Pharmacy experience. Dr. Rahal started his presentation with a brief introduction about pharmacy evolution and major roles of pharmacists with a plan for future pharmacists according to the World Health Organization (WHO) and International Pharmaceutical

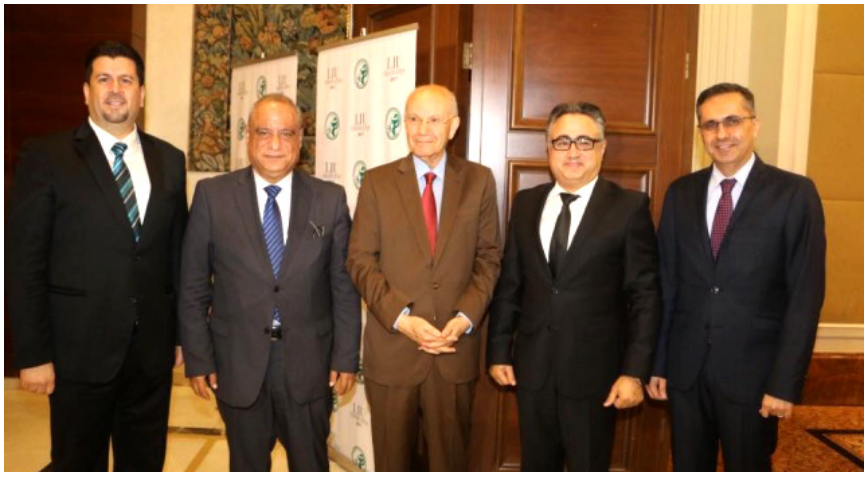
Federation (FIP) guidelines. Then he fully described the Pharmacy Program Learning and Educational Outcomes to answer the question: "Does Our Pharmacy Program Equip Future Pharmacists with Essential Competencies?" Dr. Rahal continued to present the mission and vision of the school of pharmacy at LIU, competencies of pharmacy graduates, degrees offered, curricular philosophy, curricular design, and how the pharmacy practice clerkship is integrated within the curriculum as an essential part of the educational process. Dr. Rahal ended his presentation with the school's future plans and activities.

Dr. Mohamad Rahal was highly acknowledged by the conference organizers for his valuable contribution, and his presence was considered "part of the success" of the conference.

Graduate Dinner

By: Dr. Mariam Dabbous

The School of Pharmacy at Lebanese International University held its 12th annual graduate dinner at Ramada Plaza Hotel Raouche on Thursday, October 26th, 2017. The attendees included the representative of the Minister of Education and Higher Education, Professor Naeem Al Owaini; President of the Lebanese International University H.E. Mr. Abdul Rahim Murad; President of the Lebanese Order of Pharmacists Dr. Georges Sili and the opl members; Secretary of the Committee of Equations and Colloquium in the Ministry of Education and Higher Education, Dr. Abdul Mawla Shihabuddin; LIU Family: Vice-Presidents: Dr. Samir AbouNassif, Dr. Ali Tarbay, and Dr. Ahmad Faraj, Deans, Academic Directors; Faculty and Pharmacy Graduates 2017.



This event is considered as one of the traditional annual events to celebrate the achievements of our students. The organizer, Dr. Mariam Dabbous, gave the opening speech to welcome the attendees. She highlighted on the importance of such events, since it enriched in its deliberations and discussions the pharmacy practice. Dr. Mohammad Rahal, the Dean of the SOP, encouraged the graduates to be committed to pharmacy profession, and to assure the safe and effective use of medications for the benefit of the patient and society. The graduates' speech was delivered by the student of the highest GPA within the graduates 2017 Mr. Ahmad Sinno, who expressed his gratitude to God, his Professors, and University administrative. Mr. Sinno said "Our success and that our hard work has paid off". A video was then played to demonstrate most of the activities done by the School of Pharmacy for the academic year 2016-2017. The president H.E. Mr. Abdul Rahim Mourad, congratulated the graduates on their achievements that are shown year after year in the national colloquium results. Mr. Mourad said "All LIU graduates are showing achievements at Local and International Levels". He continued 'I am proud of our School of Pharmacy, and it is a star on my shoulders".

Finally, at the end of dinner, the graduates cut the cake with the president and the school faculty and took pictures.

Blood Donation Campaign

By: Dr. Mariam Dabbous

The School of Pharmacy at Lebanese International University organized a blood donation activity with the collaboration of the AUBMC and the Donner Sang Compter (DSC) on Thursday, January 11, 2018 in Beirut campus.

A total of 160 volunteers were screened for donation eligibility; and we were able to break the previous record of 70 donations by collecting 95 donated bloods at the end of the day. This overwhelming response shown by all students and staff was appreciated by the blood donation organization

LIU donors were glad to be part of this community service, and enjoyed the feeling of accomplishment by knowing that they help in saving lives.

Honor Ceremony

By: Dr. Mariam Dabbous

The School of Pharmacy organized the Dean's Honor Ceremony on Tuesday, November 28, 2017 from 1:00 till 2:30 at Amphitheater/ Beirut Campus.

Dean of School of Pharmacy Dr. Mohamad Rahal, congratulated the students on president's list and Dean's list for excellent academic performance during Spring 2016/2017. "This is one of favorite event at the school of pharmacy since it is about you, the students, your achievements and success" said Dr. Rahal.
Then Dr. Rahal distributed the certificates for all involved students.

At the end, the students cut the cake with the dean and faculty members of the school and took some pictures.

World Polio Day

By: Dr. Dalal Hammoudi

In the event of the World Polio Day, the School of Pharmacy at Bekaa campus hosted a seminar entitled: "Polio Eradication: Are We Close to Ending the Second Disease in Human History? - Highlights from Lebanon and the World".

The seminar was delivered by Dr. Abdullatif Alwaqedi, MD, who is the WHO Global Polio Eradication Initiative consultant in Lebanon since July 2016, and the WHO STOP-polio team consultant in Lebanon since May 2014. Dr. Alwaqedi's work especially involves the surveillance of polio, where he participated in detection and mitigation of polio outbreak in Yemen, and supervised WHO and UNICEF polio awareness campaigns. In Lebanon, Dr. Alwaqedi participated in several polio activities including: update of standard guidelines for polio surveillance, preparation of national standard operations in response to polio virus importation, planning and improvement of polio campaigns, as well as training and supervision of vaccination programs. In his presentation, Dr. Alwaqedi highlighted main properties of polio, and discussed the comprehensive Polio Eradication Strategic Plan that was internationally launched by health authorities, scientific experts, health initiatives, and other stakeholders. This plan aims at eradication of polio by bringing together the latest scientific knowledge on the virus, tracking its epidemiologic status, and preventing infection through immunization.

He elaborated the use of polio vaccines and how it has changed the history of the disease, and cited many live examples about his experience with polio cases.

WAAW

By: Dr. Dalal Hammoudi

In parallel with World Health Organization (WHO) week on antibiotic resistance awareness, scheduled in November of each year, pharmacy students at LIU Bekaa Campus organized the campaign WAAW! – World Antibiotic Awareness Week. This activity aimed at raising public knowledge about enormous rise and global spread of "superbugs" that are multiresistant to antibiotics, and emphasizing that these drugs should not be misused or overused, in order to retain their effectiveness. Students started by showing a cartoon movie to illustrate resistance, then they displayed a set of posters from the WHO theme of this year: "Think twice, seek advice". Students also organized role plays and sketches to describe antibiotic misuse in a comic and explicable manner, and they promoted natural remedies that can be used in treatment of common colds and simple viral infections, without resorting to antibiotics. The activity was concluded by a game to search for most resistant microbes and identify them, and by a battle of humans versus superbugs.

Effective Medical Literature Searching for Evidence and Systematic Reviews

By: Dr. Etwal Bou Raad

The Lebanese International University, School of pharmacy and the extracurricular committee organized on 18 of January a workshop entitled "Effective Medical Literature Searching for Evidence and Systematic Reviews". The objective of this workshop was to provide the SOP faculty the skills to search for reliable online resources. The workshop covered basic and advanced techniques for effective and efficient searching of the medical/health literature. The trainer also covered an introduction to evidence based medicine (EBM) and how to get information to design a systematic reviews.

Dr. Aida Farha, is the medical information specialist and the chief medical Librarian for the Saab Medical Library at AUB. In addition to the courses she teaches regularly at AUB, Dr. Farha conducted similar workshops at AUB, and in regional countries (Syria, Saudi Arabia, Morroco, Cairo, Cyprus and others).

The trainer was very impressed with the SOP faculty member "I have done many similar workshops in Lebanon and in the Region and I must admit that the workshop held at LIU School of Pharmacy was one of the best and most rewarding one I have done in more than thirty years! In particular the attendees - mainly LIU Pharmacy Faculty - were all keen to learn these new essential skills for effective medical literature searching, and this was something I rarely see and it was really impressive for me! This in addition to the comfortable setting and superb hospitality/food! Finally I would like to thank LIU administration and in particular, Dr. Etwal Bou Raad for inviting me".

All of the 20 attendees who filled the workshop evaluation form highly agreed that workshop covered important information, and the trainer was knowledgeable. Moreover they all recommended similar workshops.

The school of pharmacy would like to thank Dr. Samir Abou Nassif for his continuous support to all activities that promote faculty evolvement. We also want to thank Dr. Mohamad Rahal for his trust and support.

Third Regional Pharmacy Faculty Development Workshop On Best Practices For Planning and Evaluation Of Experiential Education in Al Ain University of Science and Technology

By: Dr. Diana Malaeb

The School of Pharmacy at the Lebanese International University represented by the Dean Dr. Mohammad Rahal, Dr. Diana Malaeb, Dr. Marwan Akel, and Dr. Fouad Sakr participated in the 3rd Regional Pharmacy Faculty Development Workshop On Best Practices For Planning and Evaluation Of Experiential Education in Al Ain University of Science and Technology on 4rth and 5th of March 2018 in Abu Dhabi.

The workshop was organized by Al Ain University of Science and Technology (AAU), Commission for Academic Accreditation in Ministry of Education (CAA), Accreditation Council for Pharmacy Education (ACPE), and American Association of Colleges of Pharmacy (AACP).

The workshop was delivered by Craig D. Cox, who is an Associate Professor of Pharmacy Practice & Vice Chair of Experiential Programs, at Texas Tech University Health Sciences Center School of Pharmacy and Susan S. Vos, who is a Clinical Associate Professor & Director of the Professional Experience Program at The University of Iowa College of Pharmacy.

This workshop was designed to help teams of 3 to 5 pharmacy faculty members and administrators from a university work together to evaluate their experiential education program. Expert faculty led discussions and activities to assist in developing and evaluating experiential education program. Sessions focused on the importance, assessment and best practice of experiential education. In addition, the participants were invited to present posters to allow faculty members in the region to present their experiences with experiential education.


BEST PRACTICES FOR
PLANNING AND EVALUATION
OF EXPERIENTIAL EDUCATION

Faculty Highlights

Focus on Hematologic Diseases

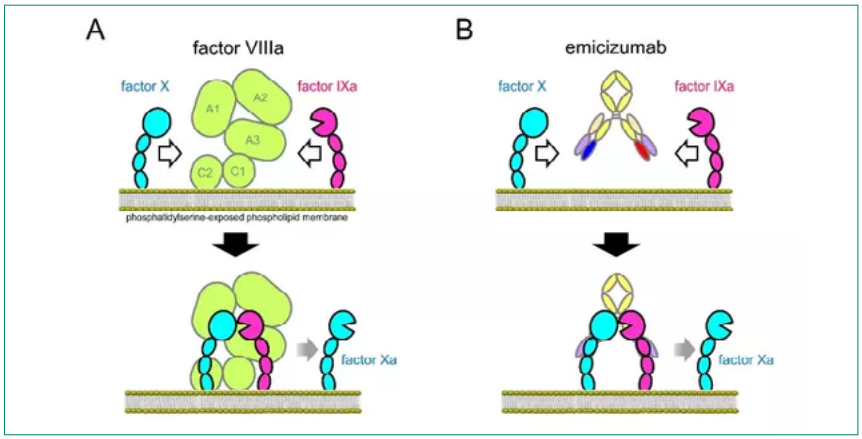
FDA Approves Emicizumab-kxwh for Prevention and Reduction of Bleeding in Patients with Hemophilia A with Factor VIII Inhibitors

Ahmad Dimassi, BSc, PharmD, MSc.

Key point: On November 16, 2017, the U.S. Food and Drug Administration (FDA) approved Emicizumab-kxwh (HEMLIBRA®, Genentech, Inc.) a new treatment for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A with factor VIII inhibitors.

Finer points: Hemophilia A is an inherited disorder that primarily affects males, in which the blood does not clot properly, leading to uncontrolled and spontaneous bleeding. It affects around 320,000 people worldwide, 50-60% of whom have a severe form of the disorder. Hemophilia A is due to factor VIII deficiency that brings together the clotting factors IXa and X. Affected patients bleed frequently, especially into their joints or muscles. The standard treatment for hemophilia A includes regular prophylaxis and episodic treatment with intravenous infusion of recombinant or plasma-derived factor VIII. However, the main barrier to this treatment is the induction of anti–factor VIII alloantibodies (factor VIII inhibitors). The inhibitors block the efficacy of replacement factor VIII.

Approval of emicizumab was based on data from two clinical trials. The first was HAVEN 1, a randomized, multicenter, open-label, phase 3 trial in 109 adult and adolescent males (aged 12 to 75 years) with hemophilia A with Factor VIII inhibitors who previously received either episodic (on-demand) or prophylactic treatment with bypassing agents. Patients on prior episodic treatment were randomized 2:1 to weekly emicizumab-kxwh prophylaxis (3 mg/kg once weekly for the first 4 weeks followed by 1.5 mg/kg once weekly, thereafter) or no prophylaxis. Patients randomized to no prophylaxis could switch to emicizumab-kxwh prophylaxis after 24 weeks. For patients receiving emicizumab-kxwh prophylaxis, the annualized bleeding rate (ABR) requiring treatment with coagulation factors was 2.9 (95% CI; 1.7, 5.0) compared with 23.3 (95% CI: 12.3, 43.9) for patients not receiving prophylaxis



corresponding to an 87% ABR reduction (95% CI: 72.3%, 94.3%), p<0.0001.
The second trial was HAVEN 2, a single-arm, multicenter, open-label, clinical trial in pediatric males (age < 12 years, or 12-17 years) with hemophilia A with Factor VIII inhibitors. Patients received emicizumab-kxwh prophylaxis at the dose and schedule described above. In 23 patients evaluated at the interim analysis, ABR for treated bleeds was 0.2 (95% CI: 0.1, 0.6). ABR for all bleeds was 2.9 (95% CI: 1.8, 4.9).

Emicizumab-kxwh is a humanized monoclonal modified immunoglobulin G4 (IgG4) antibody with a bispecific antibody structure binding factor IXa and factor X that mimics the function of the coagulation Factor VIII. The "kxwh" is a four-letter suffix designated by the FDA to help in distinguishing related biologic products thus the letters have no meaning.

Recommended dose is 3 mg/kg by subcutaneous injection once weekly for the first 4 weeks, followed by 1.5 mg/kg once weekly thereafter.
Common side effects of emicizumab include injection site reactions, headache and arthralgia.
The labeling for Hemlibra® contains a boxed warning to alert healthcare professionals and patients that severe blood clots (thrombotic microangiopathy and thromboembolism) have been observed in patients who were also given a rescue treatment (activated prothrombin complex concentrate) to treat bleeds for 24 hours or more.

Take home message: Emicizumab is a first-in-class therapy that works by bridging other factors in the blood to restore blood clotting in adult and pediatric patients with hemophilia A with factor VIII inhibitors. Hemlibra® is a prophylactic treatment given once weekly and self-administered via subcutaneous injection.

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Focus on Infectious Diseases

Juluca: The ART of Two

Hawraa Kisserwan, Pharm D

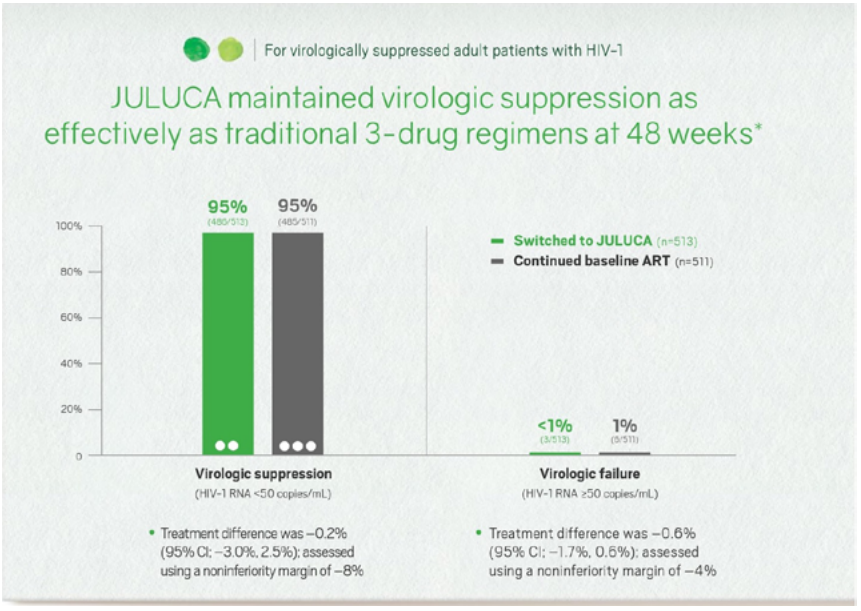
Key point: On November 21, 2017 the U.S. Food and Drug Administration (FDA) has approved dolutegravir and rilpivirine (Juluca®, GlaxoSmithKline) as a complete, once- daily regimen in a small pill to treat human immunodeficiency virus type- 1 (HIV-1) infection in adults.

Finer points: According to Central Intelligence Agency (CIA) World Factbook, an estimated 1% of the whole Lebanese population till the beginning of January 2018 are living with HIV. HIV-1 is the principle cause for almost all cases of acquired immunodeficiency syndrome (AIDS) worldwide. The most effective treatment for HIV is antiretroviral therapy (ART) where the standard treatment includes three or more drugs to control the amount of the virus in the body. The aim of researchers is to limit the number of drugs in any HIV treatment regimen to reduce toxicity as much as they can. Juluca® is a new approved drug that will allow patients to reduce the number of antiretrovirals (ARVs) that they take.

Juluca® is ViiV Healthcare's first 2- drug regimen that combines the integrase strand transfer inhibitor (INSTI) dolutegravir, with the non- nucleoside reverse transcriptase inhibitor (NNRTI) rilpivirine. Juluca® is considered as a complete regimen for the maintenance treatment of HIV-1 infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/ml) on a stable ARV regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Juluca®.

The effectiveness of Juluca® was studied in two pivotal phase III clinical trials, SWORD-1 and SWORD-2 of 1024 adult participants whose virus was suppressed on their current anti- HIV drugs. Patients were randomly assigned to continue their current anti-HIV drugs or to switch to Juluca®. Results showed Juluca® was effective in keeping the virus suppressed and comparable to those who continued their current anti-HIV drugs.
The recommended dose for adult patients is one tablet (dolutegravir 50mg/ rilpivirine 25mg) orally once daily with a meal. FDA summarized the most common side effects by diarrhea and headache. Due to drug interactions, risk of adverse reactions, loss of virologic response or risk of Torsade de Pointes may be encountered.

What you need to know: HIV remains the main reason of death and Juluca® is considered as a new option to treat adults with HIV-1.



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Focus on Gene Therapy

Viral Gene Therapy to Normalize Blood Glucose Levels!!

Iqbal Fahs, BSc, PharmD

Key points: Researchers from the University of Pittsburgh have shown that alpha cells can be reprogrammed into beta cells to restore blood glucose levels in diabetes.

Finer points: Approximately 9% of the world's adult population has diabetes, which can cause serious micro- and macrovascular complications. Type 1 diabetes is a chronic autoimmune disease that destroys insulin-producing beta cells in the pancreas, resulting in high blood glucose levels. Hence, restoring and preserving beta cells and thereby replenishing insulin levels is a fundamental goal of diabetes treatment. But in patients with type 1 diabetes, beta-cell replacement therapy is a challenge likely doomed to failure because the new cells might be destroyed as the original cells. A potential solution to this problem is to reprogram other cells into functional beta-like cells that produce insulin but are distinct from beta cells and therefore are not recognized by the immune system. For example, alpha cells are plentiful, resemble beta cells, and are in the correct location, all of which could facilitate reprogramming. To explore the feasibility of this approach, researchers of the University of Pittsburgh School Of Medicine engineered an adeno-associated viral (AAV) vector to deliver to the mouse pancreas proteins (Pdx1 and MafA), which support beta cell maturation, proliferation, and function. Thus, functional beta-like cells from pancreatic alpha cells were generated, and this strategy restored normal blood glucose levels in diabetic mice for an extended period of time, typically around four months.

This approach can be translated and applied to humans. The viral vectors can be delivered directly to the human pancreas through a routinely performed non-surgical endoscopic procedure. Moreover, immunosuppression is not required, so patients would avoid related side effects. One major concern with this approach was that the mice did eventually return to the diabetic state, suggesting that this treatment would not represent a definitive cure for the disease. However, according to the researchers, processes in mice are highly accelerated, so four months in mice might translate to several years in humans.

Currently, the researchers are testing their approach in primates, and if they were able to show efficacy in non-human primates, they would begin working with the FDA to get approval for the use of this viral gene therapy in type 1 and 2 diabetic patients.

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Focus on Market

Drug Shortage in Lebanon: Current Situation 2018

Katia Iskandar, BSc, MS, PharmD

Drug shortage is a major international problem that has hit crisis proportions. It is a complex, multi-faceted issue considered a patient safety issue, a clinical, economic and regulatory issue.

Drug shortage is a widespread problem worldwide with multiple stakeholders involved including patient, healthcare professionals, hospitals, community pharmacies, pharmaceutical industry and regulatory affairs.

In Lebanon, external cause of drug shortages may be due to the manufacturer related quality issues, manufacturing and supply chain issues or to some delays, the company has experienced receiving raw materials and components from suppliers or it may be due to discontinuations of older drugs in favor of newer, more profitable ones. Drug shortages can be also due to change in the manufacturer or product formulation that delays production or to an unexpected increase in demand for a drug when a new indication has been approved or usage changes due to new therapeutic guidelines or to a substantial disease outbreak. Other causes includes manufacturer mergers that may narrow the focus of product lines, causing discontinuation of certain products or moving production of a drug to a new facility, causing production delays or manufacturer's business decision to halt production of a drug due to availability of generic products, patent expiration, market size, drug approval status

Regulatory compliance requirements, anticipated clinical demand or reallocation of resources to other products. On the other hand, internal causes can be related to poor inventory ordering practices, stockpiling before price increases, and hoarding caused by rumors of an impending shortage. It can be due to drug repricing and the absence of a national strategic plan to manage the crisis pro-actively. There is currently no law or unit that can intervene on national level and every stakeholder is trying to solve this issue independently. Whatever the cause is, drug shortages have become a key PATIENT SAFETY concern in healthcare today. Why? Because uses of alternative medications may enhance risk of errors and/or adverse outcomes due to clinicians unfamiliarity with dosing, administration, or monitoring of the alternative therapy , in addition, the use of different package sizes can lead to over or under dosing. In addition, compounding of unavailable therapies can also lead to errors or sterility issues and supply of alternative products can quickly become exhausted, leading to a secondary shortage of the alternative medication.

Other problems related to the alternative medication, are patients allergy to the medication or one of its component or a history of adverse reactions to the medication, which leaves the patient without an effective treatment option. On economic level, secondary markets seem to be able to gain access to drugs that are no longer available to healthcare providers through usual sources and advertise availability of scarce drugs, often at exorbitant prices with questionable quality breaching ethical lines, particularly when the drug in short supply is an essential lifesaving medication. Other difficulties reported include the lack of information about causes or duration of drug shortage, lack of advanced warning and suggested alternative in addition to difficulty obtaining suitable alternatives and substantial resources educating practitioners on the use of alternatives and possible loss of prior safety safeguards put in place.

The solution can be early notification, communication, transparency and collaboration between different stakeholders.

Focus on Critical Illness

FDA Approves Angiotensin II (Giapreza®) for Critically Low Blood Pressure in Septic Shock

Nermine Chouman, BSc, PharmD

In the United States, septic shock, a life-threatening condition and most common form of distributive shock, is the leading cause of non-cardiac death in intensive care units.Distributive shock results from excessive vasodilation and the impaired distribution of blood flow leading to organ failure and death.

On December 21, 2017, the US Food and Drug Administration (FDA) approved angiotensin II (Giapreza®, La Jolla Pharmaceutical Company) for intravenous infusion to treat dangerously low blood pressure in adults with septic or other distributive shock.

Giapreza® is a sterile, aqueous solution of synthetic human angiotensin II that causes vasoconstriction and an increase in blood pressure starting a dose of 20 ng/kg/min.
The approval is based on a double-blind, "The Angiotensin II for the Treatment of High-Output Shock" (ATHOS-3), clinical trial of 321 critically ill patients who continued to have a dangerously low blood pressure despite receiving standard therapies. The trial was conducted in 128 centers in the United States, Europe, Australia and New Zealand.
The benefit of Giapreza® was measured by the proportion of patients who achieved the target blood pressure after 3 hours of treatment with the drug or placebo. During this period, the dose of other drugs used to raise blood pressure was kept constant. Target blood pressure was either a pre-specified blood pressure or a pre-specified increase in blood pressure to assure adequate circulation to vital organs.

According to the FDA, significantly more patients responded to treatment with Giapreza® than those treated with a placebo in an intensive care unit and this angiotensin II injection effectively increased blood pressure when added to conventional high-dose vasopressors. However, prophylactic treatment should be used with angiotensin II, as it may cause dangerous blood clots with serious resulting in deep vein thrombosis.

La Jolla plans to make Giapreza® available for patients in the USA in March 2018.

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Focus on Nutrition

The Fats that you Need!

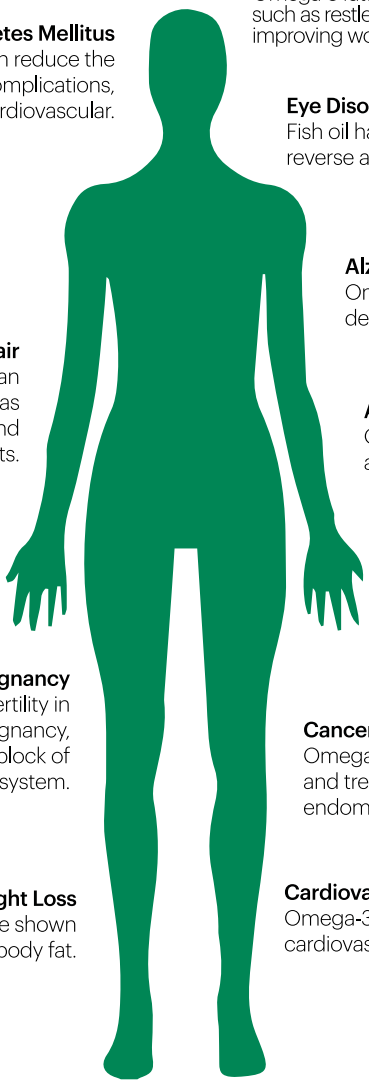
Nisreen Mourad, BSc, PharmD

Omega-3 fatty acids, also known as polyunsaturated fatty acids (PUFAs) are three types docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA), and α-linolenic acid (ALA). Omega-3 fatty acids are not produced by the body, as such we tend to rely on diet to acquire them.

Food	Weight (g)	Measure	DHA (g) Per Measure	EPA (g) Per Measure
Fish, mackerel, salted	80.0	1.0 piece	2.372	1.295
Fish, herring, Atlantic, cooked, dry heat	143.0	1.0 fillet	1.580	1.300
Fish, salmon, coho, farmed, cooked, dry heat	143.0	1.0 fillet	1.246	0.583
Fish, shad, american, raw	85.0	3.0 oz	1.123	0.923
Fish, tilefish, cooked, dry heat	150.0	0.5 fillet	1.099	0.258
Fish, whitefish, mixed species, cooked, dry heat	85.0	3.0 oz	1.025	0.345
Fish, tuna, fresh, bluefin, cooked, dry heat	85.0	3.0 oz	0.970	0.309
Fish, bass, striped, cooked, dry heat	124.0	1.0 fillet	0.930	0.269
Fish, sablefish, cooked, dry heat	85.0	3.0 oz	0.782	0.737
Fish, bluefish, raw	150.0	1.0 fillet	0.779	0.378
Fish, bluefish, cooked, dry heat	117.0	1.0 fillet	0.778	0.378
Fish, anchovy, european, raw	85.0	3.0 oz	0.774	0.457
Fish, sardine, Pacific, canned in tomato sauce, drained solids with bone	89.0	1.0 cup	0.769	0.473

Food	Weight (g)
Flaxseed	80.0
Butternuts (dried)	143.0
English walnuts	143.0
Soybeans (raw)	150.0
Wheat germ	85.0
Almonds	124.0
Chickpeas	85.0
Avocados	150.0
Strawberries	117.0
Peanuts	85.0

The term essential fatty acids that was given for Omega-3 fatty acids came from the fact that they are very beneficial for various conditions.



Attention Deficit Hyperactivity Disorder (ADHD)
Omega-3 fatty acids may reduce symptoms of ADHD such as restlessness and aggressiveness, while improving work completion and academic performance.

Diabetes Mellitus
Omega-3 fatty acids can reduce the development of diabetes complications, both microvascular and cardiovascular.

Eye Disorders
Fish oil has been shown to reverse age-related eye disorders.

Alzheimer's Disease
Omega-3 fatty acids were shown to slow cognitive decline, and help prevent brain atrophy.

Skin and Hair
Omega-3 fatty acids deficiency can contribute to some skin conditions, such as dandruff, hair thinning, eczema and psoriasis, as well as age and sun spots.

Anxiety and Depression
Omega-3 fatty acids were shown to reverse all anxiety and depression-like behavioral changes.

Arthritis
Omega-3 fatty acids were shown to reduce arthritis pain and overall disease activity.

Fertility and Pregnancy
Omega-3 fatty acids can improve fertility in both men and women. While in pregnancy, omega-3 DHA is a critical building block of the fetal brain, eyes and nervous system.

Cancer
Omega-3 fatty acids can help in the prevention and treatment of various cancers, including colon, endometrial, prostate and breast.

Weight Loss
Omega-3 fatty acids were shown to decrease body fat.

Cardiovascular Diseases
Omega-3 fatty acids can help prevent many cardiovascular diseases

References

1- *https://ndb.nal.usda.gov/ndb/nutrients/report/nutrientsfrm?max=25&offset=0&totCount=0&nutrient1=621&nutrient2=629&nutrient3=204&subset=0&fg=15&sort=c&measureby=m*

2- *Harper CR, Jacobson TA. The fats of life: the role of omega-3 fatty acids in the prevention of coronary heart disease.Arch Intern Med 2001;161:2185–92.*

3- *https://draxe.com/fish-oil-benefits-health/*

Focus on Respiratory Disease

FDA Approves First Nebulized Long Acting Muscarinic Antagonist Inhaler for Chronic Obstructive Pulmonary Disease

Nour Chamsine, BSc, PharmD

Key Points: On December 5, 2017, the US Food and Drug Administration (FDA) approved glycopyrrolate inhalation solution 25 mcg twice daily (Lonhala Magnair, Sunovion Pharmaceuticals) for maintenance treatment of airflow obstruction in adults with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Finer points: Approximately 15.7 million adults in the U.S. report they have been diagnosed with COPD. The main risk factor for COPD is tobacco smoking, but other environmental exposures may contribute. The disease makes it hard for people to breathe and subsequently may limit their ability to perform some routine activities, including the proper inhalation of medication. This improper medication technique may impact treatment over time and may also result in an inadequate amount of the drug reaching the lungs, potentially worsening a person's COPD. For people with moderate-to-very-severe COPD, nebulized treatments offer an alternative to inhalers, allowing a person to breathe normally while taking their medicine. Lonhala Magnair® is the first nebulized long-acting muscarinic antagonist (LAMA) approved by the FDA for the treatment of COPD. It is the first time the Magnair eFlow technology system, developed by PARI Pharma GmbH, has been used. This technology is a virtually silent, portable, closed system nebulizer that is designed to deliver the drug in two to three minutes and allows people to breathe normally while using the device.

The approval is based on data from the clinical trials in the Glycopyrrolate for Obstructive Lung Disease via Electronic Nebulizer (GOLDEN) program, which included GOLDEN-3 and GOLDEN-4. In the 12-week trials, glycopyrrolate was compared with placebo in adults with moderate to very severe COPD.

The GOLDEN-3 trial enrolled 653 individuals who were at least 40 years old, and the GOLDEN-4 trial enrolled 641 individuals who were at least 40 years old. Glycopyrrolate 25 mcg, glycopyrrolate 50 mcg, or a placebo was administered twice daily in both studies. Both studies included individuals who were taking effective background long-acting bronchodilator therapy and individuals with very severe disease and co-existing cardiovascular illness. Patients treated with glycopyrrolate showed statistically and clinically significant changes from baseline in trough forced expiratory volume in 1 second (FEV1) at 12 weeks.

In addition, the GOLDEN-5, a phase 3 study demonstrated the long-term safety and tolerability of Lonhala Magnair® (glycopyrrolate) in comparison with Spiriva® (tiotropium bromide) delivered by the HandiHaler® device in adults with moderate to very severe COPD. Overall, treatment-emergent adverse events were similar for patients receiving glycopyrrolate and those receiving tiotropium during a 48-week period

Glycopyrrolate should not be started in patients with acutely deteriorating COPD or to relieve sudden symptoms of COPD and should not be used more than twice daily. It is contraindicated in patients with hypersensitivity to glycopyrrolate or any of the ingredients.

Take Home Message: Glycopyrrolate offers an important new option that combines the efficacy of a proven medication for COPD with the attributes of a unique handheld nebulizer that allows a person to breathe normally while taking their medication. The FDA is currently considering approval of a second nebulized LAMA, revefenacin, which has been investigated as a once-daily COPD treatment.

Sources:

1. *Kerwin E, Donohue JF, Goodin T, et al.Efficacy and safety of glycopyrrolate/eFlow® CS (nebulized glycopyrrolate) in moderate-to-very-severe COPD: Results from the glycopyrrolate for obstructive lung disease via electronic nebulizer (GOLDEN) 3 and 4 randomized controlled trials. Respir Med. 2017 Nov;132:238-250.*

2. *Fereguson GT, Goodin T, Tosiello R, et al. Long-term safety of glycopyrrolate/eFlow® CS in moderate-to-very-severe COPD: Results from the Glycopyrrolate for Obstructive Lung Disease via Electronic Nebulizer (GOLDEN) 5 randomized study. Respir Med. 2017 Nov;132:251-260.*

3. *GOLD Guidelines 2017. Retreived from http://www.goldcopd.org/guidelines-global-strategy-for-diagnosis-management.html.*

4. *Sunovion receives FDA approval for Lonhala Magnair inhalation solution to treat COPD [news release]. Marlborough, MA: December 5, 2017. Retreived from news.sunovion.com/press-release/sunovion-receives-fda-approval-lonhala-magnair-inhalation-solution-treat-copd*

Focus on Natural Medicine

The Bioactivity of Pomegranate Impact on Health and Disease

Rima Boukhary, RPh, MSC, PhD

Key points: Pomegranate (Punica granatum L.) is a widely used plant having medicinal properties due to its functional metabolites known as phytoestrogens structurally similar to steroid hormone. They play an important role in the treatment of menopausal symptoms and in the protection of DNA from oxidant-induced damage. Moreover, flavonoids and phenolic acids present in different parts of pomegranate plant exert a higher antioxidant activity than α-tocopherol and ascorbic acid. For this reason, Research on pomegranate occupies an important place due to its valuable nutritional and therapeutic properties including diabetes, Alzheimer's disease, cardiovascular disorders, cancer and AIDS.

Oxidative stress may induce damage to cellular bio-molecules. Recent studies emphasize the involvement of free radical in many diseases. These radicals produce damage to cellular proteins, nucleic acids and certainly death of cells. Phenolic compounds derived from plants have received high attention during recent years owing to their positive effects on diet health interaction in human nutrition. Research on breast cancer cell lines demonstrated that pomegranate constituents efficiently inhibited angiogenesis, invasiveness and growth. In a paper published on April 10th , 2014 its antiproliferative effect using human breast (MCF-7, MDA MB-231) was proved.

Finer points: Collaborators in the study proved that its anti-invasive, antiproliferative and antimetastatic effects were attributed to the modulation of Bcl-2 proteins, upregulation of p27 and p21 and downregulation of cyclin-cdk network. Pomegranate constituents inhibit angiogenesis via downregulation of vascular endothelial growth factor (VEGF) in human umbilical vein endothelial and MCF-7 breast cancer cell lines. Biological effects of PME was found to be antiestrogenic in breast, exhibited cardioprotective and osteoprotective effects, and had no estrogenicity in uterus.

In conclusion, pomegranate fruit is a source of biologically active compounds acting against several diseases including cancer, heart diseases….

References:

1. *Sreeja S, Hima S, Parvathy M, Juberiya MA, and Sreeja Sreeharshan. Pomegranate fruit as a Rich source of Biologically active Compounds. BioMed Research International April 2014.*

2. *Larrosa M et al. Anti-inflammatory properties of a pomegranate extract and its metabolite urolithin-A in a colitis rat model and the effect of colon inflammation on phenolic metabolism. Metabolism. The Journal of Nutritional Biochemistry. 2010; 21(8): 717–725.*

Focus on Oncologic Diseases

Abemaciclib A New Horizon In Breast Cancer Treatment

Sahar Haydar, BSc, PharmD

Key Points: Cyclin-dependent kinase CDK (4& 6) inhibitors are novel drugs targeting breast cancer, that block retinoblastoma tumor suppressor protein phosphorylation and prevents progression through the cell cycle, resulting in arrest at the G1 phase

Finer Points: On September the FDA approved abemaciclib, the third CDK4 & 6 inhibitor. In combination with fulvestrant for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in women with disease progression following endocrine therapy.

As monotherapy for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer in patients with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

Results of Abemaciclib in Combination with Fulvestrant in Women with HR+/HER2− Advanced Breast Cancer Who Had Progressed While Receiving Endocrine Therapy MONARCH 2 study.

	Abemaciclib 150 mg BID Fluvestrant 500 mg **446 patients**	**Placebo** Fluvestrant 500 mg **223 patients**
Progress free survival	16.4 months	7.2 months
Objective response rate	35.2 %	16.1 %
12 month Duration of response	67.8%	66.9%
Clinical benefit rate	72.2 %	56.1 %
Change in tumor size	−62.5%	−32.8%
Safety	15.9 % of patients discontinued treatment due to side effect Diarrhea, nausea, fatigue, and abdominal pain. Severe neutropenia	3.1 % patients discontinued treatment due to side effect

Take Home Message: Abemaciclib is the only CDK inhibitor that can be used as monotherapy. And can be used for men and women breast cancer.

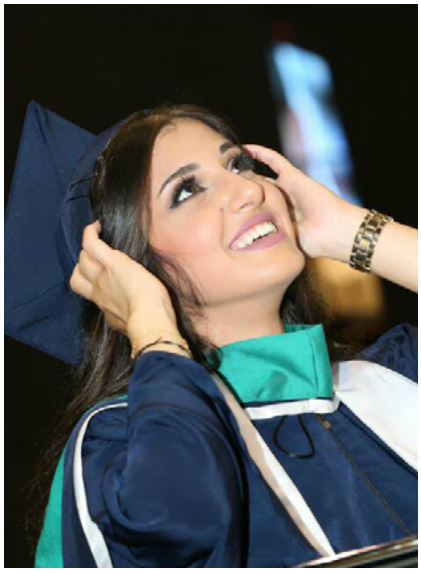
Hanaa Saeed

Clinical pharmacists often work in collaboration with physicians, nurse practitioners, and other healthcare professionals.

From my experience as a PharmD candidate in the PharmD program at LIU, I highly sense the importance of pharmacists, and the appreciation of our presence. As LIU students we are proud now more than any time since we really have extended knowledge and updated information.

We are given the skills and knowledge to critically evaluate patients' cases, seek an individual-based treatment approach, monitor any drug related consequence, and provide counseling tips upon patient discharge. Besides, it was a chance to practically apply the conventional guidelines, discussed on the floor with physicians and nurses, and intervene when appropriate.

Briefly, clinical pharmacy is the substantial branch of pharmacy that broadens our roles as pharmacists beyond the ordinary tasks. At last, special thanks go to our professional and well experienced instructors and preceptors who are constantly guiding us for the high level performance.



Mia Faraj

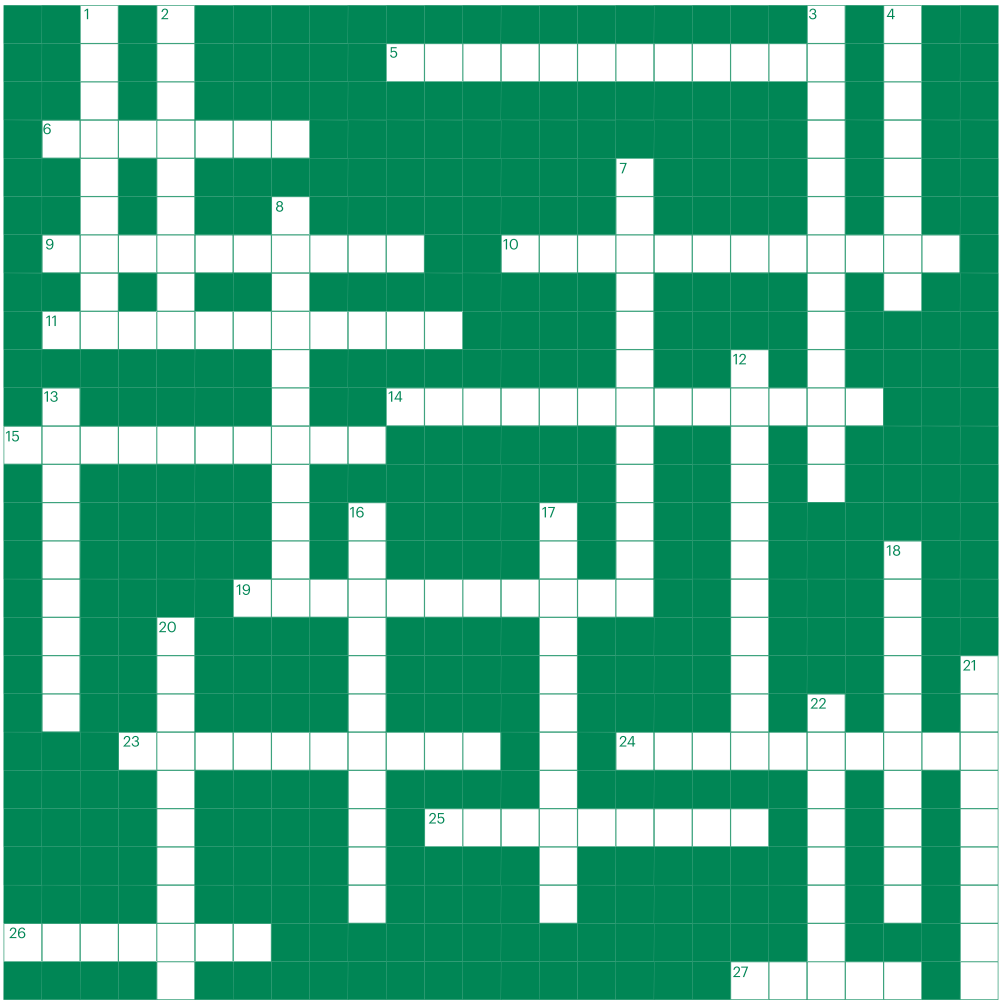
A medical team is never complete without a drug expert orienting the choice of drug, monitoring side effects, and adjusting the drug dose.

The PharmD program at LIU offered us the opportunity to be an essential member in the health care professional team at the Lebanese hospitals. Our role as PharmD Candidates was to aid in the clinical decision making through the application of evidence based literature we already acquired during our BS degree in pharmacy. As part of the medical team, we had to ensure patient›s safety by monitoring drug-drug interactions, side effects, lab values and by following up patient's medical progress. These tasks are applied through the critical utilization of the international adopted guidelines.

Besides providing the candidates with a great experience through on-ground interactions, the PharmD program helped us develop our presentation skills, research skills and clinical thinking. PharmD is a great opportunity for highly motivated students to explore, where every scene is a lesson and every case is a new challenge. On a personal level, I advise every student to attain this degree as it enhances the critical thinking and broadens the scope of pharmacy practice.

Pharmaco-Crossword Puzzle

Susana Abdel Fattah, RPh, MBA, PharmD



Down

1. To treat gastroenteropancreatic neuroendocrine tumors (GEP-NETs), Approved 2018
2. Antineoplastic, PARP Inhibitor, Approved 2016
3. To treat osteoporosis in postmenopausal women at high risk of fracture or those who have failed other therapies, Approved 2017
4. For the prevention of herpes zoster, Approved 2017
7. For the reversal of the anticoagulant effects of dabigatran, Approved 2015
8. For the treatment of multiple myeloma, Approved 2015
12. MEK inhibitor, Approved 2015
13. A monoclonal antibody, Approved 2017
16. To improve glycemic control in adults with type 2 diabetes mellitus, Approved 2017
17. For the treatment of opioid-induced constipation, Approved 2017
18. A CDK inhibitor, Approved 2017
20. To treat severe asthma, Approved 2016
21. The brand name of a combination therapy used in the management of hypertension, Approved 2016
22. Is a brand name of a combination therapy used to treat adults with complicated urinary tract infections, Approved 2017

Across

5. To treat urothelial carcinoma, Approved 2016
6. The brand name of edoxaban, Approved 2015
9. Is a factor Xa (FXa) inhibitor, Approved 2017
10. For the treatment of acute bacterial skin infections, Approved 2017
11. To treat adults with tardive dyskinesia, Approved 2017
14. The generic name of Steglatro®, Approved 2017
15. To treat multiple sclerosis, Approved 2016
19. To treat certain advanced or metastatic breast cancers, Approved 2017
23. A PCSK9 Inhibitor, Approved 2015
24. For the treatment of chronic heart failure, Approved 2015
25. For the treatment of hyperkalemia, Approved 2015
26. Parathyroid hormone analogue, Approved 2015
27. A combination therapy to treat DMII, Approved 2017

“**Live** as if you were to die tomorrow. **Learn** as if you were to live forever.”

Mahatma Gandhi

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