sciencepro ACADEMY

Empowering Patient Advocacy Groups (PAGs) in Pharmacovigilance

مجموعات مناصرة المرضى وتعزيز دورهم من خلال مشاركتهم في اليقظة الدوائية

TOPICS

- Overview of Cancer Treatment Approaches and Associated Adverse Events/Side Effects
- Pharmacovigilance Practices According to Lebanese Guidelines
- Addressing the Threat of Counterfeit and Falsified Medications
- Exploring Medication Safety: Interactive Training

Practice Based 1 day training

For more information,
contact us at academy@sciencepro.me

SCIENCE PRO ACADEMY – AN OVERVIEW

Science PRO Academy, a division of Science PRO launched in 2024 to serve local and regional communities through comprehensive programs, tailored training modules, and educational initiatives in the health sector. Our mission while simple, is profound: to equip both healthcare professionals and patients with the tools, knowledge, and confidence needed to navigate the complexities of modern healthcare systems through partnerships with leading healthcare institutions, organizations, and experts. This enhances the depth of our educational offerings, ensuring that participants stay updated with cutting-edge knowledge and practices.

We offer a variety of specialized training modules that cover a wide range of medical disciplines, and our curriculum includes workshops, seminars, and hands-on training sessions led by key experts, fostering a robust learning environment.

Science PRO Academy also fosters a sense of community among healthcare professionals, encouraging the exchange of experiences, insights, and support. Our programs are designed to facilitate networking and collaboration, helping participants build valuable professional relationships.

Our commitment to education extends beyond the health care professionals, recognizing the invaluable role of patient education in their own healthcare journey. We offer targeted programs aimed at increasing patient awareness and empowering individuals to make informed healthcare decisions, contributing to improved healthcare outcomes.

Science PRO Academy strive to create a dynamic and inclusive educational environment, ultimately contributing to enhanced healthcare knowledge sharing standards.

About Science PRO

Science PRO, established in 2012, is a medical communication company dedicated to advancing healthcare through a range of specialized services and initiatives. Our divisions— Science PRO Medical Affairs, Science PRO Events, Science PRO Academy, and Science PRO Research and Registry—collaborate to provide comprehensive solutions that address the evolving needs of bio-pharmaceutical stakeholders, healthcare professionals, patients.

INTRODUCTION

Pharmacovigilance, encompassing the science and activities dedicated to detecting, assessing, understanding, and preventing adverse effects and other drug-related issues, is pivotal for ensuring the safety and efficacy of medications[1]. Historically, healthcare professionals and regulatory authorities have been the main drivers of pharmacovigilance. However, recent years have witnessed a growing acknowledgment of the vital role patients play in these processes[2].

Patients, being the ultimate recipients of healthcare interventions, including medications, offer unique perspectives and experiences that contribute invaluable insights beyond the pure view of healthcare professionals. Consequently, involving patients in pharmacovigilance processes ensure a comprehensive understanding of real-world medication impacts, improves adverse event reporting, and enriches decision-making[3].

INITIATIVES IN PATIENT INVOLVEMENT

Despite being the most affected stakeholders with information on safety issues, patients seldom assume a central role in shaping and leading pharmacovigilance initiatives. For that, initiatives that aim to address this gap and promote patient engagement in pharmacovigilance are crucially needed. In that aspect, regulatory bodies, alongside patient organizations and advocacy groups, are instrumental in championing patient involvement. These organizations serve as platforms for patients to share experiences, report adverse events, and collaborate with researchers and regulatory bodies. By equipping patients with tools and resources, they will be empowered for active participation in monitoring medication safety and contributing to the development of safer therapies[3].

Such involvement ensures that the patient's perspective is integral to decision-making, leading to more patient-centered outcomes.

BEST PRACTICES FOR PATIENT EMPOWERMENT IN PHARMACOVIGILANCE

Effective patient involvement necessitates the adoption of certain best practices. Firstly, there is a need to enhance health literacy among patients. Initiatives such as providing clear and accessible information and organizing awareness campaigns can empower patients to understand medication-related risks, benefits, and the importance of reporting adverse events. This can be delivered as part of a focused patient awareness training[4].

Secondly, healthcare professionals must adapt an environment conducive to patient reporting. Open communication channels encourage patients to discuss concerns or side effects confidently, facilitating timely reporting and promoting a culture of safety. That is why, involving healthcare providers in focused patient awareness training is important to encourage such communication[3].

Additionally, technological advancements present new opportunities for patient involvement. Mobile Safety Application and digital platforms, such as the e-reporting link, are two examples that have been adapted at the Lebanese National Pharmacovigilance Program aiming to enable a real-time reporting of adverse events and providing instant feedback on medication safety. Integrating patient-generated data with existing pharmacovigilance systems enhances surveillance capabilities and facilitates rapid detection of potential safety issues[3].

PATIENT ADVOCACY GROUPS IN LEBANON

Patient Advocacy Organizations or Patient Advocacy Groups (PAGs) provide patient and caregiver-oriented education, advocacy, and support services. In Lebanon, PAGs are formally organized, nonprofit groups that concern themselves with medical conditions or potentially life-threatening medical conditions. Their mission is to support people affected by those medical conditions or to support their families. These organizations advocate for and provide services to people with physical and mental conditions such as cancer, mental illnesses, diabetes, and cardiovascular disease via different platforms, including outreach programs, meetings, counseling sessions, Web sites, and published materials.

A PAG usually seeks to raise public awareness of a disease's symptoms, risk factors, and treatment options and promotes research to cure or to prevent that disease. Additionally, patient organizations and advocacy groups should be involved in empowering patients, providing resources and platforms for monitoring medication safety.

OBJECTIVES OF THE WORKSHOP

World Patient Safety Day, observed annually on September 17, serves as a call from the World Health Organization (WHO) for solidarity and concerted action to improve patient safety. In 2023, the focal theme was "Engaging Patients for Patient Safety", with the accompanying slogan, "Elevate the voice of patients!" This underscores the crucial role patients play in ensuring their own safety and emphasizes the importance of actively involving them in healthcare decision-making processes[5].

The objective of this workshop is to empower oncology patients and PAGs in pharmacovigilance through awareness, education, and open discussion.

ACTIVITY PLAN

Objective: To empower oncology patients and PAGs representatives in pharmacovigilance through awareness, education, and open discussion.

Target Audience: Oncology Patient Advocacy Group and cancer survivors.

Speakers and Facilitators: Oncology Physician and Lebanese Pharmacovigilance team.

Educational Materials: Visually appealing and informative materials including pamphlets, presentations, and handouts.

Language: Arabic and English

COURSE DIRECTOR AND CHAIR

Dr. Rita KARAM

Dr. Rita Karam, a Pharmacist with a Ph.D. in pharmaceutical sciences, is a professor at the Lebanese University and holds key roles in healthcare governance as the director of quality assurance of pharmaceutical products program (QAPPP) and national pharmacovigilance program coordinator. She is an active member of ISoP (International Society of Pharmacovigilance) and chairs the ISPOR-Arabic network (The Professional Society for Health Economics and Outcome Research). With more than one hundred scientific articles and reports, her contribution span various fields in healthcare, including health technology assessment, health economics, and pharmacovigilance. This extensive body of work establishes her as a significant figure in academia and public health.

DISCUSSION TOPICS

1. "Empowering Patients: Understanding the Vital Role of Pharmacovigilance in Adverse Event Reporting for Safer Healthcare Journeys"
2. "Navigating the Path: An In-Depth Overview of Cancer Treatment Approaches and Associated Adverse Events/Side Effects"
3. "Patient Safety Through Product Quality"
4. "Safety First"
5. "Protecting Patients: Addressing the Threat of Counterfeit and Falsified Medication"
6. "Exploring Medication Safety: Interactive Training"

PATIENT FOCUSED TRAINING WORKSHOP
جدول أعمال ورشة عمل

TIME / التوقيت	TOPIC / الموضوع	SPEAKER /المحاضر
Moderators: Dr. Amani Ghadban, Dr. Ali Mrad مشرفو الجلسة: د. أماني غضبان, د. علي مراد		
8:30 – 9:00	Registration and welcome استقبال وتسجيل	
9:00 – 9:30	Empowering Patients: Understanding the Vital Role of Pharmacovigilance in Adverse Event Reporting for Safer Healthcare Journey 1. Who are we? 2. What do we do? 3. Why are we here? **تعزيز دور المرضى: فهم الدور الحيوي لليقظة الدوائية في الإبلاغ عن الآثار الجانبية للأدوية واللقاحات لتحقيق رعاية صحية أكثر أمانا** ١- من نحن؟ ٢- ماذا نفعل؟ ٣- لماذا نحن هنا اليوم؟	**Dr. Rita Karam** د. ريتا كرم
9:30 – 10:00	Overview of Cancer Treatment Approaches and Associated Adverse Events/Side effects. **شرح الآثار الجانبية للأدوية وخيارات العلاج المتاحة**	**Dr. Roula Farah** د. رولا فرح
10:00 – 10:30	Empowering Patients: Understanding the Vital Role of Pharmacovigilance in Adverse Event Reporting for Safer Healthcare Journey 1. How to Recognize Adverse Drug Reactions 2. What to Do if You Experience Adverse Drug Reactions? **تعزيز دور المرضى: فهم الدور الحيوي لليقظة الدوائية في الإبلاغ عن الآثار الجانبية للأدوية واللقاحات لتحقيق رعاية صحية أكثر أمانا** ١- كيفية التعرف على الآثار الجانبية للأدوية ٢- ماذا تفعل إذا تعرضت لأثر جانبي ؟	**Dr. Abeer Zeitoun** د. عبير زيتون
10:30 – 10:45	**Coffee break /** إستراحة	
10:45 – 11:30	I. Patient safety through product quality 1. Introduction to product quality 2. Measures taken in the pharmaceutical industry to ensure product quality 3. Reporting of product quality complaints **ا. سلامة المريض من خلال جودة الدواء** ١. مقدمة عن جودة الدواء ٢. التدابير التي تتخذها شركة الأدوية لضمان جودة الدواء ٣. التبليغ عن شكوى تخص جودة الدواء	**Dr. Maswa Mansour** د. مسوى منصور

TIME / التوقيت	TOPIC / الموضوع	SPEAKER /المحاضر
11:30 – 12:00	II. Safety First 1. What is pharmacovigilance and the importance of safety reporting? 2. What to report? 3. How are cases processed? **II.السلامة أولا** ١. ما هو التيقظ الدوائي وأهمية الإبلاغ عن الآثار الجانبية؟ ٢. ما هي المعلومات التي يجب عليك الإبلاغ عنها ٣. كيف تتم معالجة تقارير الأحداث الجانبية ؟	**Dr. Badiha Masri** د. بديعة مصري
11:30 – 12:00	Protecting Patients: Addressing the Threat of Counterfeit and Falsified Medication 1. Overview of Substandard/Falsified (SF) and Counterfeit (C) Medicinal Products 2. Managing Substandard/Falsified and Counterfeit Cases **حماية المرضى: التعاطي مع خطر الأدوية المزيفة والمزورة** ١.لمحة عامة على المنتجات الطبية المتدنية الجودة/المغشوشة والمزورة/المقلدة ٢.التعامل مع المنتجات الطبية المتدنية الجودة/المغشوشة والمزورة/المقلدة	**Dr. Rita Karam** د. ريتا كرم
12:00 – 12:20	Exploring Medication Safety: Interactive Training 1. What are Educational Materials? 2. Scope of Educational Materials 3. Types of Educational Materials **التعرف على السلامة الدوائية: تدريب تفاعلي** ١. ما هي المواد التعليمية ٢. نطاق المواد التعليمية ٣. أنواع المواد التعليمية	**Dr. Abeer Zeitoun** د. عبير زيتون
12:20 – 12:55	Exploring Medication Safety: Interactive Training How to Use the Reporting Tools 1. VigiMobile E Forms: AEFI and ADRs 2. E-Reporting **التعرف على السلامة الدوائية: تدريب تفاعلي** كيفية استخدام وسائل الإبلاغ ١. تطبيق ٢. نموذج التبليغ الإلكتروني	**Dr. Aya Ibrahim** د. آية إبراهيم
12:55 – 1:00	Closing of the day كلمة الختام	**Dr. Rita Karam** د. ريتا كرم
1:00 – 1:30	**LUNCH**	

REFERENCES

1. World Health Organization. Regulation and Prequalification-Definition of Pharmacovigilance [Internet]. [cited 2023 Dec 12]. Available from: https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance
2. Inácio P, Cavaco A, Airaksinen M. The value of patient reporting to the pharmacovigilance system: a systematic review. Br J Clin Pharmacol. 2017 Feb;83(2):227–46.
3. Ho R. Patient Involvement and Empowerment in Pharmacovigilance: A Commentary on Current Initiatives and Best Practices. Available from: https://www.walshmedicalmedia.com/open-access/patient-involvement-and-empowerment-in-pharmacovigilance-a-commentary-on-current-initiatives-and-best-practices.pdf
4. Van Hoof M, Chinchilla K, Härmark L, Matos C, Inácio P, van Hunsel F. Factors Contributing to Best Practices for Patient Involvement in Pharmacovigilance in Europe: A Stakeholder Analysis. Drug Saf. 2022 Oct;45(10):1083–98.
5. World Health Organization. World Patient Safety Day campaign [Internet]. [cited 2023 Dec 12]. Available from: https://www.who.int/campaigns/world-patient-safety-day