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WOMAN AND HER HISTORICAL SUCCESS

Editorial Message

WOMAN – abbreviated for Wonderful Outstanding Marvellous Adorable and Nice. It is always a pride to describe the success of a woman. She in her way always completes the presence of being, be it anywhere at home or work place. Though many countries still suffer gender equity, woman has made her mark in all fields. Pharmacy professional is no less to her acquittance. The 20th century reperesents the era of many spectacular and innovative changes in the profession of pharmacy. One among them was the rapid growth in the numbers of women entering the pharmacy profession. It was observed that more than 40% of girls are studying in the pharmacy institutions across the country. Time has come for the women to realize their potential and make the most of their skills and experiences to serve the noble profession i.e., healthcare.

Women can contribute at various platforms from policy making to the ground root reality of the country. They are being represented at all levels and sectors of pharmacy. Women can advance within pharmacy and make a difference in the profession. She has represented the best of best not only in healthcare but man major fields. History has proved women to be successful administrators, which again and again has been shown at every era, they possess skill to think in an organization - as an individual and as an organization.

Women are represented in transformation and revolutionizing pharmacy at all levels and across all sectors. The top companies, healthcare system, community entrepreneur, public health, academic everywhere the woman are representing. Empowering woman can change the look of the society. She has to overcome patriarchal society, woman can be supported by motivation rather than sympathy.

This month we are celebrating Women's Day, KRPA editors have taken immense effort in projecting the right and strong quality of woman. This issue is to motivate our woman partners and congratulating them for the success achieved.

Wishing you all a HAPPY WOMEN'S DAY

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MEDICAL DEVICE SAFETY

A Necessity

INTRODUCTION

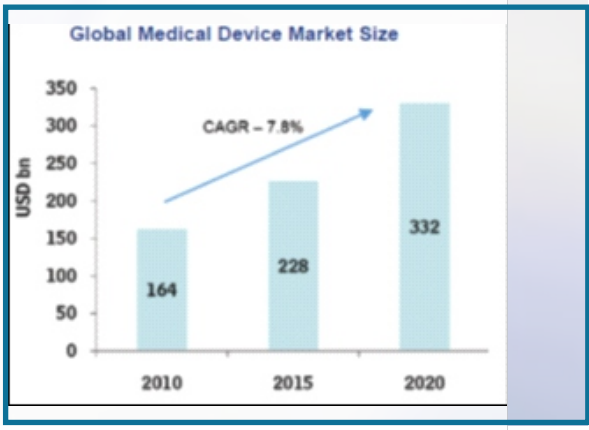
Good quality, safe, and affordable healthcare services are the priorities of regulatory bodies and healthcare providers to promote better patient care and safety, building a healthier population. The focus has customarily been on the drug aspects of adverse events in the healthcare system especially in the developing country scenario and the medical device aspect has been neglected.

The World Health Organization has defined a medical device as any "instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- Investigation, replacement, modification, or support of the anatomy or a physiological process,
- Cupporting or sustaining life,
- Control of conception, disinfection of medical devices
- Providing information utilizing in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means."

There are over an estimated two million different kinds of medical devices in the world market, that are categorized as over 22,000 generic devices groups. The estimation of the global market for medical devices increased from 260 billion United States dollars (US$) in 2006 to over US$ 380 billion in 2016.



With all the pros to mention the medical devices equally carry a significant potential risk that can lead to unexpected and serious safety problems. Therefore, it is vital to assess and ascertain the risks and benefits associated with the devices at all stages of pre- and post-marketing phases to ensure the quality and evaluate the safety and performance of medical devices. Materiovigilance deals with the identification, collection, reporting, estimating the undesirable occurrence, and the possible management of adverse events associated with the use of medical devices, thus promoting patient health by preventing its recurrences.

The United States enacted the Food and Drug Administration (FDA) Modernization Act 1970 under section 522 for the post-marketing surveillance of medical devices. In 1993, Global Harmonization Task Force (GHTF) was established by the European Union, USA, Japan, Australia, and Canada. The GHTF aimed to bring uniformity in the regulatory system related to safety, performance, and quality of medical devices. A new forum in 2011, International Medical Device Regulators Forum (IMDRF) was conceived to build on the commendable work of GHTF and to accelerate the medical device regulatory harmonization and convergence.

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MEDICAL DEVICE SAFETY IN INDIA

Initially, the medical devices were regulated under the Indian Drugs and Cosmetics Act (1940) and no systematic structure was in place to collate adverse events associated with medical devices. The numerous reports of deaths and hospitalization due to faulty hip implants, cardiac stents, and poor-quality devices, gained attention for the need of a parallel system for surveillance of medical devices. In July 2015, the Indian health ministry approved the establishment of the materiovigilance program, with the Indian Pharmacopoeia Commission as the national coordinating center. In 2017, the government of India issued the Medical Devices Rules 2017 for regulating medical devices used throughout the country. The rules came into effect on 1 January 2018.

Drugs Controller General India (DCGI) launched Materiovigilance Programme of India (MvPI) at Indian Pharmacopeia Commission (IPC), Ghaziabad on July 6, 2015. The fundamental aim of this program is to monitor medical device-associated adverse events (MDAE), create awareness among health-care professionals about the importance of MDAE reporting, and generate independent credible evidence-based safety data of medical devices, and to share it with the stakeholders. The IPC functions as the National Coordination Centre (NCC) and Central Drug Standard Control Organization (CDSCO) functions as the regulator of MvPI.

DISCUSSION

In the US the reported medical devices related adverse events between 2001 and 2009, had an estimated increase of 15% per year, with 57,000 reported adverse events in 2001 to 207,000 reported adverse events in 2009 alone. Further the serious adverse events such as death, life-threatening disability or hospitalization, reported in 2002 were 8000 which rose to 28,000 in 2009.

Brockton et.al. conducted a first-ever national estimates of medical device–associated adverse events reported an estimated 454,383 emergency department visits in a 12-month period in the United States associated with a medical device. 13% of the total cases involved patient hospitalization, with the highest among the patients using invasive or implanted devices.

The Indian Pharmacopoeia Commission received a total of 1931 medical device-associated adverse events from July 2015 to October 2019. Of which, 1277 (66.13%) events were classified as serious and 654 (33.86%) as non-serious cases.

926 (47.95%) events were associated with cardiac stents; 226 (11.7%) with intrauterine contraceptive devices; 179 (9.2%) with orthopaedic implants; 75 (3.8%) with intravenous cannulae; 76 (3.9%) with catheters; and 449 (23.25%) with other types of device.

1439 (74.5%) events were reported by marketing authorization holders; 419 (21.7%) by medical device adverse event monitoring centres; 70 (3.6%) by adverse drug reaction monitoring centres and 3 (0.15%) by consumers.

John Cherf, the chief medical officer of Lumere stated in his perspective on the challenges facing healthcare stakeholders in the journey to improve patient safety that, “Every year, over 600,000 patients are admitted to hospitals for device complications, costing health systems nearly $12 billion. However, the true costs to a hospital extend beyond the initial admission. Fifteen to twenty percent of patients with device complications will be readmitted for various reasons, and the cost of those readmissions are typically significantly more expensive than the cost of the initial index admission. Additionally, a patient going through extensive revision and diagnostic processes following a device complication is likely to adversely impact patient satisfaction scores, leading to potential adverse impact to the institution”.

CONCLUSION

Materiovigilance being in its infancy in a developing country like India with a large population poses a great challenge. The system has to gain considerable knowledge for the development of tools and inculcating reporting culture within the healthcare system. Regular training programs to educate health-care professionals are needed to foster a sense of responsibility and generate awareness on what, how, and where to report medical device adverse events. A database for medical device adverse events is necessary for optimal analyses and management of adverse events.

PHARMACISTS AND DENTAL SENSITIVITY PAIN

Lifestyle has a major impact on quality of life, longevity and disease patterns. The modern day lifestyle full of material comforts and consumption of sugary foods, acidic drinks, alcohol consumption, smoking, and increasing incidence of hyperglycemia or impaired glucose tolerance, has created vulnerability to oral disease - particularly sensitivity pain. When teeth are sensitive to hot or cold drinks causing a sharp pain sensation or even discomfort in the gums – this is called dental sensitivity pain. In dental literature this pain is technically called dentin hypersensitivity.

THE WORLD DENTAL FEDERATION DEFINES DH AS FOLLOWS:

Dentin hypersensitivity (DH) is characterized by short sharp pain arising from exposed dentin most commonly at the tooth cervical area (neck region of tooth) in response to stimuli - typically thermal, evaporative, tactile, osmotic or chemical, but which cannot be ascribed to any other dental defects, diseases or restorative treatments.

The onset and progress of DH is a gradual process. The wear and tear of outermost enamel exposing the second layer called dentin results in occurrence of dentin hypersensitivity pain. There are thousands of microscopic dentinal tubules in the second dentine layer. Below the dentine layer is the soft pulp cavity containing blood vessels and nerves. The cause of dentin hypersensitivity is the movement of dentinal fluid in the dentinal tubules. The movement occurs due to hot or cool liquids coming in touch with the dentinal fluid or sticky foods like caramel chocolate stimulating the dentinal fluid movement. Essentially, the movement of liquid contained in the exposed dentinal tubules of the dentin, results in dentin hypersensitivity pain.

There is another protective layer called the cementum below the gums in root of the tooth. This too is required to keep dentinal channels from getting exposed. Thus, enamel and cementum are both protecting the dentine and the pulp layer below the dentine.

When the enamel and cementum deteriorate due to various factors, exposing the lower dentine layer and the enclosed dentinal tubules to the oral cavity environment, DH pain starts. So the idea is to have a robust enamel and cementum layers, and healthy gums to prevent occurrence of DH.

SOME FACTORS CAUSING DH ARE:

- Gingivitis (inflammation of gums) that results in exposing the neck of tooth and gradual breakdown of enamelocementum junction
- Dental caries (dental infection) that causes enamel breakdown and exposure of the dentinal tubules
- Non caries lesions of the enamel due to hard brushing (abrasion), clenching and grinding of teeth as in bruxism (attrition), chipping of teeth and exposure of neck of teeth, dentine exposure thus leading to hypersensitivity pain (abfraction), and enamel breakdown due to chemical reasons like GERD (gastro oesophageal reflux disorder) in alcoholics, elderly subjects and others – this is called erosion (thus non – caries lesions are due to abrasion, attrition, abfraction and erosion)

CLOSING REMARKS:

The chief role of pharmacists is to help the patient experience good health through identification of problem areas, offer guidance, give support and recommend products that are useful and legally possible such as appropriate toothpastes and mouthwashes in dental sensitivity management. Pharmacists can also enhance revenues through recommendation of such oral care products. When a patient is satisfied with the pharmacist's recommendation, greater are the chances of his repeat visits to the pharmacy and repeat buying occurs to strengthen pharmacy revenues. The intangible feel good factor through a pharmacist's right behavior is a great draw for repeat patient visits. Giving sound advice to patients on oral care products is also an important avenue for improving pharmacy business outcomes.

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Elizabeth Gooking Greenleaf

The Mother of Pharmacy

Elizabeth Gooking Greenleaf, the Mother of Pharmacy has promised to devote herself to a lifetime of services for the betterment in the field of pharmacy. She was recognized as the first female pharmacist in the United States and one among the 17 women to be recognized posthumously by the American Pharmacists Association in 2012 for her contributions in the field of pharmacy. She was also listed as one among the 32 apothecaries in New England during the late 1600s.

Mrs. Greenleaf was born in Cambridge, Massachusetts Colony in 1681. In 1727, she left her hometown and moved to Boston to start an apothecary with her husband, Mr. Daniel Greenleaf, who was a Harvard graduate. She assisted her husband in the compounding and dispensing of medicines for the patients. In those days, these roles use to be taken up by men however, with her bravery and entrepreneurship; she stood as an inspiration for other women to take up pharmacy as a profession. Her contributions to the field of pharmacy have created a growth in the future aspiring women to become pharmacists.

During the mid-1960s, the number of female pharmacists was 8% only and rose to 55% today (National Bureau of Economic Research, Issue no-2). This rise in the number of women in the field of pharmacy has been a result of her hard work. The statistical increase in the number of female pharmacists is inspiring, and they have served as a trusted healthcare professional ever since.

In 2012, the American Pharmacists Association honoured Elizabeth Greenleaf for 'contributions to the profession and advancement of women in pharmacy'. Elizabeth proved that in any professional aspect women are capable of exploring, representing leadership qualities and continuing as a strong role model for the future pharmacist. Elizabeth Greenleaf passed away in 1762 but her legacy lived on and manifested to women across everywhere as a career in pharmacy as possible. Following which many other women pharmacists have engraved their names in the history of pharmacy.

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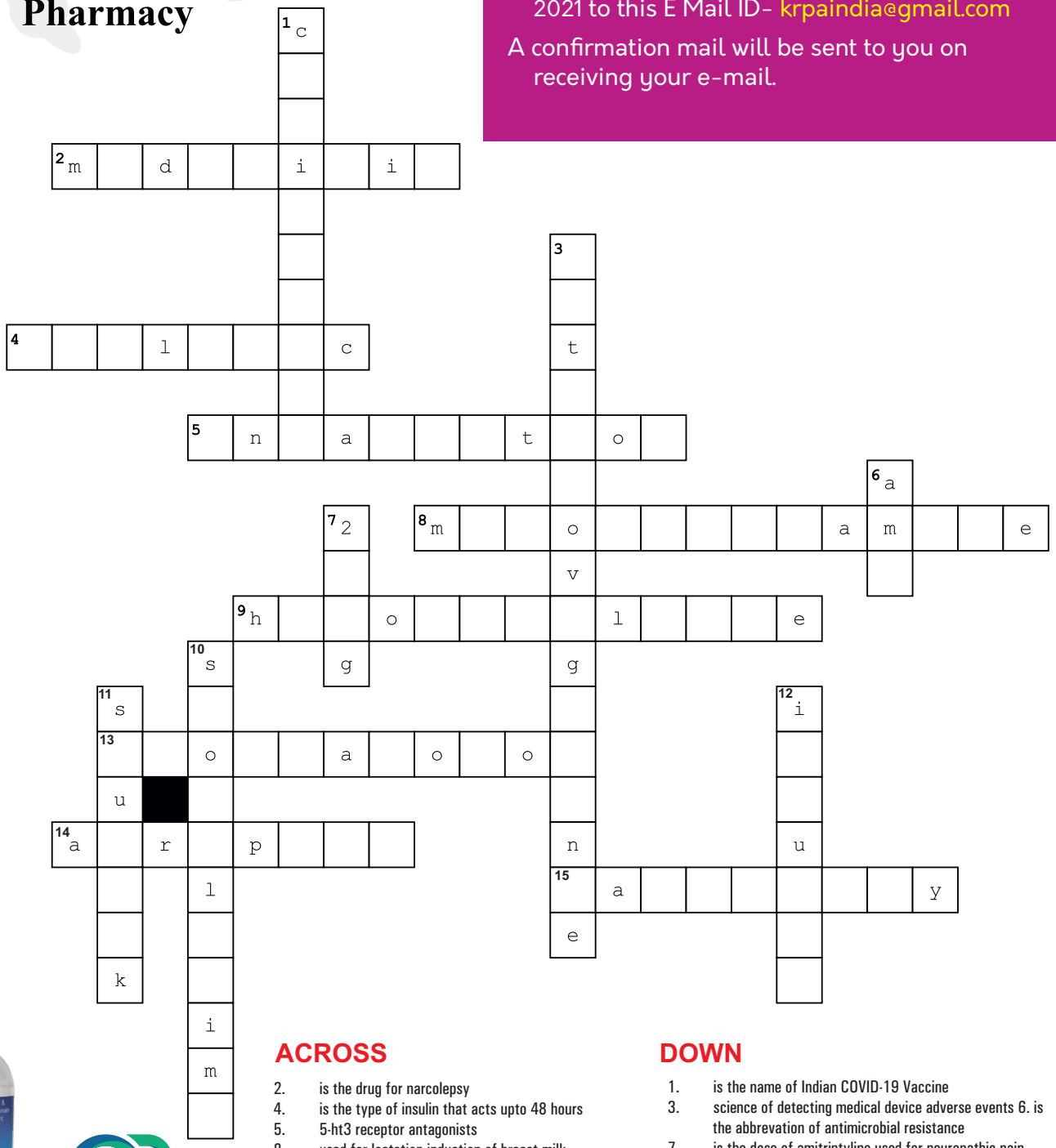
Quiz

Pharmacy

RULES

1. Correct answers will be rewarded 1 point each (10 marks)
2. Answer of the quiz will be evaluated by panel of judges and their decision is final.
3. Those who get the highest marks, their photo will be published in our next bulletin and also a cash prize of Rs.500/- will be rewarded to them
4. The answer must be sent within 20th February 2021 to this E Mail ID- krpaindia@gmail.com

A confirmation mail will be sent to you on receiving your e-mail.



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ACROSS

2. is the drug for narcolepsy
4. is the type of insulin that acts upto 48 hours
5. 5-ht3 receptor antagonists
8. used for lactation induction of breast milk
9. science of detecting and reporting of adverse events related to blood and blood products
13. is the anti-hypertensive drug that is also used in managing anxiety
14. is the antidote for organophosphorus poisoning
15. is a sudden, brief loss of voluntary muscle tone triggered by strong emotions such as laughter

DOWN

1. is the name of Indian COVID-19 Vaccine
3. science of detecting medical device adverse events 6. is the abbrevation of antimicrobial resistance
7. is the dose of amitriptyline used for neuropathic pain
10. is also called as devil's breath
11. is the name of Russian COVID-19 vaccine
12. is the drug of choice in managing gestionational diabetes

DISCLAIMER

The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. Neither the people associated with the publication of the Newsletter nor the organization shall be liable for any damage incurred as a result of use of the contents of this publication. The brand names of medicines, if mentioned, are for illustration only and the newsletter does not endorse them.

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