Drug Information Bulletin

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Content

Editorial

Starting of Refresher Course for Registered Pharmacist which is a pre requisites for renewal of registration as per Sec. 4.2 of the Pharmacy Practice Regulation 2015 has been started by a few Institutions / Organizations including Indian Pharmaceutical Association (IPA), Bengal Branch considered as a landmark in the pharmacy profession of India.

Practice in Pharmacy is existing in India since long back, with a different name and structure and it has got a regulated structure since implementation of Pharmacy Act 1948. Engagement of Pharmacist in serving the prescription of a registered practitioner has been made mandatory by an amendment of sec 42 of Pharmacy Act 1940, in the year of 1984 and it was further bolstered by the amendment of Rule 65 of Drugs and Cosmetics Rules 1945 in the same year. Framing and notification of Pharmacy Practice Regulation 2015(PPR-2015) in the month of January 2015 is a landmark event in the history of Pharmaceutical Profession in India, which will certainly help in giving proper shape to the unorganized state of Pharmacy Practice in India. In the present regulation the Pharmacy Practice is well defined and the same has set up certain regulation to regulate the same.

In the mean time a few states like Kerala have implemented the same through notification by the state Government. Hope all professional organizations will take up the issue with the concerned authorities, so that all state governments implement the act immediately for improving the health care outcome.

IPA has sent several memorandums to all state Health Secretaries and State/UT Drugs Controllers for proper implementation of PPR-2015 and the present step for providing refresher course showed its commitment for implement of PPR-2015.

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New Drug: Clofarabine Injection

It was first approved by USFDA under brand name Clolar.

INDICATIONS AND USAGE: Clofarabine injection is a purine nucleoside metabolic inhibitor indicated for the treatment of pediatric patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens. This indication is based upon response rate. There are no trials verifying an improvement in disease-related symptoms or increased survival.

DOSAGE AND ADMINISTRATION: Administer the recommended pediatric dose of 52 mg/m2 as an intravenous infusion over 2 hours daily for 5 consecutive days of a 28-day cycle. Repeat cycles every 2-6 weeks. Provide supportive care, such as intravenous infusion fluids, antihyperuricemic treatment, and alkalinization of urine throughout the 5 days of Clolar administration to reduce the risk of tumor lysis and other adverse events. (2.1) Discontinue Clolar if hypotension develops during the 5 days of administration. (2.1) Reduce the dose in patients with renal impairment.

DOSAGE FORMS AND STRENGTHS: 20 mg/20 mL single-dose vial.

WARNINGS AND PRECAUTIONS:

Myelosuppression: May be severe and prolonged. Monitor complete blood counts and platelet counts during Clolar therapy. Hemorrhage: Serious and fatal cerebral, gastrointestinal and pulmonary hemorrhage. Monitor platelets and coagulation parameters and treat accordingly. Infections: Severe and fatal sepsis as a result of bone marrow suppression. Monitor for signs and symptoms of infection; discontinue Clolar and treat promptly. Tumor Lysis syndrome: Anticipate, monitor for signs and symptoms and treat promptly. Systemic Inflammatory Response Syndrome (SIRS) or Capillary Leak Syndrome: Monitor for and discontinue Clolar immediately if suspected. Venous Occlusive Disease of the Liver: Monitor for and discontinue Clolar if suspected. Hepatotoxicity: Severe and fatal hepatotoxicity. Monitor liver function, for signs and symptoms of hepatitis and hepatic failure. Discontinue Clolar immediately for Grade 3 or greater liver enzyme and/or bilirubin elevations. Renal Toxicity: Increased creatinine and acute renal failure; monitor renal function and interrupt or discontinue Clolar. Enterocolitis: Serious and fatal enterocolitis, occurring more frequently within 30 days of treatment and with combination chemotherapy. Monitor patients for signs and symptoms of enterocolitis and treat promptly. Skin Reactions: Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), including fatal cases. Discontinue for exfoliative or bullous rash, or if SJS or TEN is suspected.

ADVERSE REACTIONS: vomiting, nausea, diarrhea, febrile≥Most common adverse reactions (neutropenia, pruritus, headache, bacteremia, pyrexia, rash, tachycardia, abdominal pain, chills, fatigue, anorexia, pain in extremity, hypotension, epistaxis, and petechiae. (6) To report SUSPECTED ADVERSE REACTIONS, contact Genzyme Corporation at 1-800-RX-CLOLAR or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS: Embryo-fetal Toxicity: fetal harm can occur when administered to apregnant woman. Women should be advised to avoid becoming pregnant when receiving Clofarabine.

Ref. USFDA

Status in India: CDSCO approved Clofarabine Bulk & Injection 20 mg/20ml vial for the treatment of patients 1 to 21 years old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens. This indication is based upon response rate on 16.01.2018.

WHO's new Global Antimicrobial Surveillance System (GLASS) reveals widespread occurrence of antibiotic resistance

WHO's first release of surveillance data on antibiotic resistance reveals high levels of resistance to a number of serious bacterial infections in both high- and low-income countries.

WHO's new Global Antimicrobial Surveillance System (GLASS) reveals widespread occurrence of antibiotic resistance among 500 000 people with

suspected bacterial infections across 22 countries.

The most commonly reported resistant bacteria were Escherichia coli, Klebsiella pneumoniae, Staphylococcus aureus, and Streptococcus pneumoniae, followed by Salmonella spp. The system does not include data on resistance of Mycobacterium tuberculosis, which causes tuberculosis (TB), as WHO has been tracking it since 1994 and providing annual updates in the Global tuberculosis report.

Among patients with suspected bloodstream infection, the proportion that had bacteria resistant to at least one of the most commonly used antibiotics ranged tremendously between different countries – from zero to 82%.

Resistance to penicillin – the medicine used for decades worldwide to treat pneumonia – ranged from zero to 51% among reporting countries. And between 8% to 65% of E. coli associated with urinary tract infections presented resistance to ciprofloxacin, an antibiotic commonly used to treat this condition.

Dr Marc Sprenger, director of WHO's Antimicrobial Resistance Secretariat said, "The report confirms the serious situation of antibiotic resistance worldwide. Some of the world's most common – and potentially most dangerous – infections are proving drug-resistant," adds Sprenger. "And most worrying of all, pathogens don't respect national borders. That's why WHO is encouraging all countries to set up good surveillance systems for detecting drug resistance that can provide data to this global system."

To date, 52 countries (25 high-income, 20 middle-income and 7 low-income countries) are enrolled in WHO's Global Antimicrobial Surveillance System. For the first report, 40 countries provided information about their national surveillance systems and 22 countries also provided data on levels of antibiotic resistance.

Dr Carmem Pessoa-Silva, who coordinates the new surveillance system at WHO said, "The report is a vital first step towards improving our understanding of the extent of antimicrobial resistance. Surveillance is in its infancy, but it is vital to develop it if we are to anticipate and tackle one of the biggest threats to global public health."

Data presented in this first GLASS report vary widely in quality and completeness. Some countries face major challenges in building their national surveillance systems, including a lack of personnel, funds and infrastructure.

WHO is supporting more countries to set up national antimicrobial resistance surveillance systems that can produce reliable, meaningful data. GLASS is helping to standardize the way that countries collect data and enable a more complete picture about antimicrobial resistance patterns and trends.

Solid drug resistance surveillance programmes in TB, HIV and malaria have been functioning for many years and have helped estimate disease burden, plan diagnostic and treatment services, monitor the effectiveness of control interventions, and design effective treatment regimens to address and prevent future resistance. GLASS is expected to perform a similar function for common bacterial pathogens.

Ref. BioSpectrum Asia

Study evaluates PET/CT-based treatment strategy in Hodgkin lymphoma

Italian researchers found that patients with advanced Hodgkin lymphoma with positive PET/CT scans after two cycles of treatment with doxorubicin, vinblastine, vincristine and dacarbazine who were switched to stronger BEACOPP treatment had a 60% three-year progression-free survival rate and an 89% three-year overall survival rate, compared with an 87% three-year PFS and 99% three-year OS among those with negative PET/CT scans who continued ABVD treatment. The findings in the Journal of Clinical Oncology "showed that a PET-driven switch from ABVD to escalated BEACOPP can be safely done in advanced-stage Hodgkin lymphoma," said researcher Dr. Alessandro Rambaldi.

Ref. OncLive

WHO List Of Epidemic-Prone Diseases That Need More R&D Investment

For the purposes of the R&D Blueprint, WHO has developed a special tool for determining which

diseases and pathogens to prioritize for research and development in public health emergency contexts. This tool seeks to identify those diseases that pose a public health risk because of their epidemic potential and for which there are no, or insufficient, countermeasures. The diseases identified through this process are the focus of the work of R& D Blueprint. This is not an exhaustive list, nor does it indicate the most likely causes of the next epidemic.

The first list of prioritized diseases was released in December 2015.

Using a published prioritization methodology, the list was first reviewed in January 2017.

The second annual review occurred 6-7 February, 2018. Experts consider that given their potential to cause a public health emergency and the absence of efficacious drugs and/or vaccines, there is an urgent need for accelerated research and development for*:

- Crimean-Congo haemorrhagic fever (CCHF)
- Ebola virus disease and Marburg virus disease
- Lassa fever
- Middle East respiratory syndrome coronavirus (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS)
- Nipah and henipaviral diseases
- Rift Valley fever (RVF)
- Zika
- Disease X

Disease X represents the knowledge that a serious international epidemic could be caused by a pathogen currently unknown to cause human disease, and so the R&D Blueprint explicitly seeks to enable cross-cutting R&D preparedness that is also relevant for an unknown "Disease X" as far as possible.

A number of additional diseases were discussed and considered for inclusion in the priority list, including: Arenaviral hemorrhagic fevers other than Lassa Fever; Chikungunya; highly pathogenic coronaviral diseases other than MERS and SARS; emergent non-polio enteroviruses (including EV71, D68); and Severe Fever with Thrombocytopenia Syndrome (SFTS).

These diseases pose major public health risks and further research and development is needed, including surveillance and diagnostics. They should be watched carefully and considered again at the next annual review. Efforts in the interim to understand and mitigate them are encouraged.

Although not included on the list of diseases to be considered at the meeting, monkey pox and leptospirosis were discussed and experts stressed the risks they pose to public health. There was agreement on the need for: rapid evaluation of available potential countermeasures; the establishment of more comprehensive surveillance and diagnostics; and accelerated research and development and public health action.

Several diseases were determined to be outside of the current scope of the Blueprint: dengue, yellow fever, HIV/AIDs, tuberculosis, malaria, influenza causing severe human disease, smallpox, cholera, leishmaniasis, West Nile Virus and plague. These diseases continue to pose major public health problems and further research and development is needed through existing major disease control initiatives, extensive R&D pipelines, existing funding streams, or established regulatory pathways for improved interventions. In particular, experts recognized the need for improved diagnostics and vaccines for pneumonic plague and additional support for more effective therapeutics against leishmaniasis.

For details: WHO News Release