Drug Information Bulletin

Drug Information Centre (DIC)

Indian Pharmaceutical Association

Bengal Branch

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Regulatory Affairs Division (RAD), IPA

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Content

Editorial

Access to health care information especially in resource poor countries is a major impediment to reach quality health care to the people. There are isolated initiatives to reach the health care information to the health care providers and the general people, but there is a huge gap. Dr. Neil Pakenham-Walsh- Coordinator, HIFA2015 – Co-Director, Global Healthcare Information Network has said in an interview that- "It is tragic that so many children continue to die unnecessarily for want of simple, low-cost interventions that are often locally available. It is even more tragic that many of these children would have been saved if only their mothers, fathers, family caregivers and, indeed, health workers, had basic healthcare knowledge to recognize serious illness requiring urgent, appropriate, life-saving action."

Recently WHO has modified its Essential Medicine Information Portal. Through this portal Non-WHO publications are being included in the database – these can include journal articles, reports from other organizations and other books where permitted by copyright. Essential medicines documents are now combined with those on other health technologies. WHO partner organizations like - MSH, USAID, World Bank and UNICEF are also making available with their data base.

Now it is possible to find reports of MSF, articles from BMJ, meeting reports of ICDRA, required information from 'Managing Drug Supply" and so on as per available sources.

More such initiative will improve access to health care information and improve the quality of health care system.

As a recognition of continuous transmission of health care information by Drug Information Centre (DIC) run by IPA, Bengal Branch & publication of Drug Information Bulletin (DIB) HIFA invited DIC to join as supporting organization and now DIC is one of the supporting organizations of HIFA 2015, having its HQ at UK.

Dr. Subhash C. Mandal
Editor

Ministry of Health & Family Welfare released revised version of Guidelines on categorization of Seasonal Influenza A H1N1 cases during screening for home isolation, testing, treatment and hospitalization on 11.02.2015

In order to prevent and contain outbreak of Influenza-A H1N1 virus for screening, testing and isolation following guidelines are to be followed:
At first all individuals seeking consultations for flu like symptoms should be screened at healthcare facilities both Government and private or examined by a doctor and these will be categorized as under:

Category- A

☐ Patients **with mild fever plus cough / sore throat** with or without bodyache, headache, diarrhoea and vomiting will be categorized as Category-A. They **do not require** Oseltamivir and should be treated for the symptoms mentioned above. The patients should be monitored for their progress and reassessed at 24 to 48 hours by the doctor.

☐ **No testing of the patient for H1N1 is required.**

☐ Patients should confine themselves at home and avoid mixing up with public and high risk members in the family**.**

Category-B

(i) In addition to all the signs and symptoms mentioned under Category-A, if the patient has high grade fever and severe sore throat, may require home isolation and Oseltamivir;

(ii) In addition to all the signs and symptoms mentioned under Category-A, individuals having one or more of the following high risk conditions shall be treated with Oseltamivir:

☐ Children with mild illness but with predisposing risk factors.

☐ Pregnant women;

☐ Persons aged 65 years or older;

☐ Patients with lung diseases, heart disease, liver disease kidney disease, blood disorders, diabetes, neurological disorders, cancer and HIV/AIDS;
☐ Patients on long term cortisone therapy.

☐ **No tests for H1N1 is required for Category-B (i) and (ii).**

☐ All patients of Category-B (i) and (ii) should confine themselves at home and avoid mixing with public and high risk members in the family.

☐ Broad Spectrum antibiotics as per the Guideline for Community-acquired pneumonia (CAP) may be prescribed.

Category-C

In addition to the above signs and symptoms of Category-A and B, if the patient has one or more of the following:
☐ Breathlessness, chest pain, drowsiness, fall in blood pressure, sputum mixed with blood, bluish discolouration of nails;

☐ Children with influenza like illness who had a severe disease as manifested by the red flag signs (Somnolence, high and persistent fever, inability to feed well, convulsions, shortness of breath, difficulty in breathing, etc).

☐ Worsening of underlying chronic conditions.

All these patients mentioned above in Category-C require testing, immediate hospitalization and treatment.

Drug Profile: Oseltamivir phosphate

Tamiflu (Roche)
75 mg capsules
Approved indication: influenza
Australian Medicines Handbook Section 5.3.2

Oseltamivir is the second neuraminidase inhibitor to receive Australian approval for the treatment of influenza. Unlike its predecessor, zanamivir, oseltamivir is taken by mouth.

After absorption oseltamivir is converted to its active form, oseltamivircarboxylate. The plasma concentrations of this metabolite reach a peak within three hours and then decline with a half-life of 6-10 hours. Oseltamivir carboxylate is excreted in the urine, so the dose should be reduced if renal function is impaired.

In a clinical trial, twice-daily doses of 75 mg or 150 mg were compared with a placebo. The 629 adults involved in the trial had presented within 36 hours of developing a febrile respiratory illness. Laboratory testing confirmed the presence of influenza virus (mostly influenza A) in 374 cases. In these cases oseltamivir reduced the duration of illness by more than 30%.[1]

Patients given oseltamivir are more likely to experience gastrointestinal upsets than those given a placebo. In clinical trials 12% of patients suffered vomiting and a further 11% complained of nausea. There is potential for the influenza virus to develop resistance.

Although patients treated with oseltamivir recover significantly faster than those given a placebo, the difference is only about one day. Treating 1000patients reduces illness by 254 hours. However, patients given 75 mg twice a day were able to resume their normal activities 2-3 days sooner than those given a placebo. Giving a higher dose does not make patients recover more quickly.[1] As few elderly or debilitated people were included in the clinical trials, the best strategy for those at risk is still immunisation to prevent influenza. Little information is available about the efficacy of oseltamivir in influenzaB.

Reference

1. Treanor JJ, Hayden FG, Vrooman PS, Barbarash R, BettisR, Riff D, et al. Efficacy and safety of the oral neuraminidase inhibitor oseltamivirin treating acute influenza. JAMA 2000;283:1016-24.

Ref. *Aust Prescr 2001; 24:43-7*

(Oseltamivir (as phosphate) Capsule (75mg) & oral suspension (12mg/ml) approved by CDSCO for influenza on 25.10.2005 in India and available in Indian market in different brand names like-Antiflu, Fluvir etc.)

Ketamine control plan condemned as potential disaster for world's rural poor

A proposal that is about to come before the UN to restrict global access to ketamine, a drug abused in rich countries, would deprive millions of women of lifesaving surgery in poor countries, according to medicines campaigners.

Ketamine, known to clubbers by a variety of names including ket, Vitamin K and

Special K, is one of the most commonly used anaesthetics in the developing world. As it is injectable, it can be used in rural areas where anaesthetic gases are unavailable.

Surgery in parts of the developing world, and particularly caesarean sections without which women with difficult labours may die, would be reduced and sometimes even unavailable. Campaigners say the health of at least two billion people would be affected.

Source:
http://www.theguardian.com/world/2015/feb/27/raver-drug-ketamine-control-plan-at-un-condemned-as-potential-disaster

5,299 patents granted in Apr2014-Jan 2015 period

India granted as many as 5,299 patents and rejected 1,119 during the April-January period of the current fiscal, as reported in the Parliament recently. During the period, 35,431 patent application have been filed, Commerce and Industry Minister Nirmala Sitharaman said in a written reply to the Lok Sabha.

In 2013-14, 2012-13 and 2011-12, the country granted 4,225, 4.126 and 4,381 patents, respectively.

"The patents are granted after following the procedures as per the Patents Act 1970...Any Indian company aggrieved by the grant of this patent can also oppose the grant of patent," she said.

For details: www.DrugsControl.org

Job News:

Drugs Inspector (CDSCO): 147 (one hundred forty seven only)

For details:
http://www.upsc.gov.in/recruitment/advt/2015/Advt_04_2015.pdf

or

Employment News 28th February-6th March 2015

Forthcoming Events

National Workshop on Ensuring Quality through Good Laboratory Practice

Date: 8th March 2015 (Sunday)
Time: 9.30 am -5.00 pm
Venue: Floatel, Kolkata

Organized by:
Regulatory Affairs Division (RAD), IPA
Jointly with IPA, Bengal Branch

Faculties *:

- **Dr. Rao V.S.V. Vadlamudi**, President, IPA
- **Dr. P.L. Sahu,** Principal Scientific Officer, Indian Pharmacopoeia Commission(IPC)
- **Dr. Jayanta K. Chattopadhyay,** Former GM, Fresenius Kabi
- **Mr. Sankar Gupta**, Former Deputy Drugs Controller, Govt. of India

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- Confirmed till date