Drug Information Bulletin

Drug Information Centre (DIC)

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Content

Editorial

Scientific studies show, that an estimated 4.8 million people suffering from moderate to severe cancer pain do r receive treatment. Similarly, about 1.4 million people suffering from moderate to severe pain at terminal stages of H annually, remain untreated. In India, a million people with cancer and an unknown number of people with oth incurable and disabling diseases like HIV/AIDS, need opioids for pain relief and only a minute fraction (0.4%) of t population in need of opioids have access to the drugs. Major barriers to gain access to opioids are complicat regulations and problems related to attitude and knowledge among health professionals, regulators, administrators a the public regarding pain relief and opioids. As a result of collaborative efforts among the WHO, certain Palliative Ca Organizations and Pain & Palliative care activists, the Government of India has taken some steps like - asking all sta governments to modify the narcotic rules & regulations following a model, extended schedule K exemption to Morphi Tablets. Currently, more than 15 states and union territory in India have simplified regulations, but opioid availability medical use has improved only in a minority of these states. Establishment of simple standard operating procedures implement the simplified regulations, advocacy, and aggressive and improved education of professionals are essent for further improvement of the situation.

In the mean time Govt. of India has amended NDPS Act 1985 to improve access to opoids for medical purpose vi THE NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES (AMENDMENT) ACT, 2014 dated 10th March 2014. It expected that the same will help to improve palliative care of millions of patients suffering from pain.

Dr. Subhash C. Mandal
Editor

Seasonal Influenza A (H1N1): Guidelines for Vaccination of Health Care Workers , updated on 14th February 2015 by Ministry of Health and Family Welfare

1. World Health Organization recommends vaccination of high risk groups with Seasonal Influenza Vaccination.
2. In India, neither the actual disease burden of Influenza, nor differentials
on the way influenza impacts high risk groups are known. Hence, evidence based decision is not possible for all high risk groups.
3. Health Care Workers working in close proximity to influenza patients are at higher risk of acquiring the disease. Hence, vaccination is recommended for them. Such category would include:

☐ Health Care Workers working in casualty/ emergency department of identified hospitals treating Influenza cases.

☐ Heath Care Workers working in ICU and Isolation Wards managing influenza patients.

☐ Health Care Workers identified to work in screening centres that would be set up for categorization of patients during Seasonal Influenza outbreak.

☐ Health Care workers treating/managing the High Risk Group

☐ Laboratory personnel working in virological laboratories testing Influenza samples.

☐ Rapid Response Team members identified to investigate outbreaks of Influenza.

☐ Drivers and staff of vehicles/ambulances involved in transfer of
Influenza patients.

4. The vaccine should be used every year.
5. Influenza vaccination is most effective when circulating viruses are well-matched with vaccine viruses. Even with appropriate matching, efficacy of vaccine may be about 70% to 80%, especially in geriatric age group. In case the locally circulating virus is different from vaccine virus recommended by WHO, it may not be effective at all. Hence, vaccine should not give a false sense of security. Considering the risk perspective, the preventive modality of infection prevention and control practices like use of PPEs should be strictly adhered to. The available vaccine takes about 2-3 weeks for development of immunity. The use of chemoprophylaxis during this period may be considered.

Germany's Boehringer loses India patent on lung drug to Cipla

India has revoked a patent on German pharmaceutical company Boehringer Ingelheim's lung drug Spiriva and ruled in favour of domestic drugmaker Cipla Ltd, in the latest setback for a multinational drug maker operating in India.

Cipla, India's fourth-largest drug maker by sales, filed an opposition to Boehringer's patent on Spiriva in 2013, claiming the drug was "obvious" and did not constitute an invention under India's patent laws.

Spiriva is a respiratory drug used in the treatment of chronic obstructive pulmonary disease.

India's patent office ordered the revocation in a decision posted on its website on Thursday.

A spokeswoman at Boehringer's India office said the company will be "evaluating carefully the basis for the recent decision once the detailed reasons thereof are available."

A Cipla spokesman declined to comment.

The move adds to the woes of Western drug makers who covet a large share of India's fast-growing $15 billion pharmaceuticals market, and have expressed frustration over a series of drug patent-related decisions taken by the government to improve affordability.

India is working on revamping its intellectual property rights policy, but has maintained its patent rules are compliant with international patent protection law.

Source: The Economic Times

A German agency says it has a better way to assess prescription drug value

Seeking a better way to assess the value of a prescription drug? A German agency chartered with assessing cost effectiveness has a suggestion – require drug makers to provide complete dossiers, including clinical study reports, which it uses to assess benefits and risks. Why? The dossiers contain more complete information than is available otherwise publicly, according to a new study in BMJ.

Here's the background: Four years ago, German regulators began requiring drug makers to submit dossiers to determine the value of newly approved medicines with comparative treatments. The idea was to make it easier for authorities to assess benefits and harms as they looked to negotiate pricing. The clinical study reports included in these dossiers may contain previously unpublished data.

And so, the Institute for Quality and Efficiency in Health Care, or IQWIG, which makes recommendations about drug effectiveness to German regulators, sought to determine whether this approach may yield more useful information about value than can be obtained from public sources. As part of its review, IQWIG publishes dossiers online and notes that no other country does so when assessing value.

So what IQWIG find?

IQWIG examined dossiers for 15 drugs it received between January 2011 and February 2013 containing study results and methods from 22 different clinical trials. The agency considered about 90% of the required dossiers to be complete. But other sources of information, such as publicly available journal publications and registry reports, were lacking compared with the dossiers submitted to IQWIG – only 75% had sufficient data on study methods and 52% had sufficient data on study results.

As a result, the agency found that conventional, publicly available sources provide "insufficient information on new drugs," especially for outcomes in subpopulations of patients for which a medicine was approved, according to the. "This approach could be used internationally to develop a comprehensive publication model for clinical studies and, thus, represents a key open access measure."

The findings tie together a pair of contentious issues confronting the pharmaceutical industry. One is the rising cost of some prescription medicines, which has alarmed some public and private payers in many countries. The other issue is growing demand for disclosure of clinical trial data, which some researchers and regulators believe could make it easier to detect drug safety or effectiveness concerns.

In effect, the study underscores how wider access to such data may alleviate issues raised in both debates. For instance, IQWIG explains that dossiers could be used by different groups for different purposes. Cost-effectiveness agencies could use clinical study reports for determining value. Researchers, meanwhile, could use the information to lay the groundwork for treatment decisions.

Whether the approach advocated by IQWIG catches on remains to be seen. In the U.S., of course, cost effectiveness is not viewed by regulators. And in general, the pharmaceutical industry has balked over the extent to which commercial information should become accessible. Drug makers argue that disclosing certain data may compromise trade secrets or patient privacy. Consumer groups say such information is kept out of reach at the expense of patients.

The issue is playing out in Europe, where there is a growing clash over rules for managing a European Union database of clinical study information, which will be overseen by the European Medicines Agency. IQWIG, by the way, is arguing for a very broad definition of confidential commercial information.

Pics from "National workshop on Ensuring Quality through Good Laboratory Practice"

Organized by Regulatory Affairs Division of IPA

jointly with IPA, Bengal Branch

8th March 2015, Kolkata

Dr. Rao V.S.V. Vadlamudi, President, inaugurating the workshop

Faculty members with organizers

Participants engrossed listening to the lecture

IPA, Bengal Branch President & Chairman, RAD honouring women participants on the occasion of "Women's Day"

Forthcoming Event

61st IPSF World Congress – Hyderabad, India

International Pharmaceutical Students' Federation (IPSF) World Congress is for the first time in 60 years being hosted in India by Indian Pharmaceutical Association – Students' Forum (IPA-SF).

IPSF aims to promote improved public health and pharmacy education through the provision of information, education, networking, and a range of publications and professional activities.61st IPSF world congress will serve as a common platform to discuss issues related to the field of pharmacy globally, the forum presents information on pharmacy education, public health campaigns and professional initiatives by various workshops and symposia which can help in attaining unification of the pharmacy education across the globe. The conference will also include social events to let the delegates experience the cultural exchange. The event will be held at the Marriott hotel, Hyderabad, India, from 30th July to 9th august.

For any further details visit www.ipsf2015.org or write to us on secretary@ipsf2015.org