



Drug Information Bulletin

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Editorial

Access to essential medicines is a grave problem throughout the world, specially in the developing and under developed countries. India is not an exception and it varies from state to state, despite India being the third largest producer of medicines and is exporting to about 250 countries. Out-of-pocket (OOP) expenditure for health care and medicines account for about 70 percent of expenses of households in India and also in developed countries, due to spiraling medicine costs. This is also causing about 63 million populations to sink below poverty line, and this vicious cycle is not allowing them to surface again. In fact increased spending on health is putting its fangs on the budgets of families, forcing them to cut down on nutrition, and tragically even on medicines, leading to a grave socio-economically compromised system and a burden of sick individuals. Health care experts have identified a plethora of complex factors behind this scenario. One major reason for this situation is irrational use of medicines. So promoting concept of Rational Use of Medicines (RUM) could be an effective strategy. Three effective tools of implementing RUM are-Essential medicines list (EML), Standard Treatment Guidelines (STG), and Drug Formulary. The last tool is a concise book containing dose, dosage form, indication, contraindication, adverse drug reaction for ready reference for the prescriber and pharmacist. Every healthcare set up should have its own formulary so that authentic information is available to the prescribers and the pharmacists, but unfortunately all health care facility does not have such a book. Recent publication of "Drug Formulary for community based Health facilities" published by Community Development Unit and Shramajibi Swasthya Udyog is a laudable initiative. Hope other institutions will follow this example.



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Research findings:

Immunotherapy may get a big boost from softer cell growth method

Fewer than half of patients receiving immunotherapy for treatment of leukemia see results, but a new, softer mesh used in scaffolding to produce T cells may help by yielding a much higher proportion of functional cells. The development by Columbia University biomedical engineers Lance Kam and Helen Lu replaces the hard plastic beads now used to grow the cells.

Ref. [Alliance of Advanced BioMedical Engineering](#)

Blood test offers hope of detecting Cancers before symptoms develop

A new blood test that allows doctors to detect 10 types of cancer years before a person becomes sick with the disease has been developed by scientists. The breakthrough is being hailed as a tool to dramatically reshape the way that care for cancer and other inherited diseases is delivered.

Some 1,600 patients have already been tested with the procedure, producing a 90% accuracy rate in some cases. Of those tested, 749 were cancer-free, and 878 were newly diagnosed. The tests found warning signs for the disease at different rates, depending on the type of cancer. It was best at diagnosing pancreatic, ovarian, liver and gallbladder cancers, accurately pinpointing the diseases in at least four out of five patients.

The test was slightly less accurate at finding lymphoma and myeloma, at 77% and 73% respectively, and bowel cancer in two out of three patients. Lung cancer was correctly detected in 59% of patients, while head and neck cancer was detected in 56% of patients.

“This is potentially the holy grail of cancer research, to find cancers that are currently hard to cure at an earlier stage when they are easier to cure, and we hope this test could save many lives,” said Dr Eric Klein, the lead author of the study from the Cleveland Centre in Ohio.

“Most cancers are detected at a late stage, but this ‘liquid biopsy’ gives us the opportunity to find

them months or years before someone would develop symptoms and be diagnosed,” he continued. Klein and his fellow researchers plan on presenting their findings to the annual conference of the American Society of Clinical Oncology in Chicago.

The tests, once complete, are expected to produce results for patients within two weeks of taking them. The test is a “liquid biopsy”, which is a type of screening that is generally seen as having advantages over traditional biopsies, which require an actual tissue sample from parts of someone’s body.

Experts note that there is still a lot to be done to create a system of universal screening that could help save lives, but say the new tests are a step in the right direction because many cancers are detected too late for surgery or adequate treatments.

Source: ET Health world

Janssen stops Alzheimer's drug studies over unfavorable risk-benefit profile

Two clinical studies evaluating JNJ-54861911, or atabecestat, for Alzheimer's disease were stopped by Johnson & Johnson's Janssen Biotech because of an unfavorable risk-benefit profile for the beta-site amyloid precursor protein-cleaving enzyme inhibitor. Screening, randomization and dosing of atabecestat will be stopped by the company in a Phase IIb/III study in patients with late-onset preclinical-stage Alzheimer's and in a midstage European long-term safety study.

Ref. [Genetic Engineering & Biotechnology News](#)

Regulatory measures round the globe:

Clarithromycin Potential risk of heart problems or death in patients with heart disease

The US Food and Drug Administration (FDA) has added a new warning about an increased risk of death in patients with heart disease to the drug labels for Clarithromycin (Baxin®). In addition, the FDA has added the results of a clinical trial that indicate this increased risk to Clarithromycin drug

labels. Clarithromycin is used to treat a variety of infections and is not approved to treat heart disease. The FDA's recommendation is based on a review of the results of a 10-year follow-up study of patients with coronary heart disease from a large clinical trial that first observed this safety issue. Results from the trial provide evidence of the increased risk compared to placebo. Other observational studies showed mixed findings. The FDA is unable to determine why the risk of death is greater for patients with heart disease.

Reference: Safety Alerts for Human Medical Products, US FDA, 2 February 2018 (www.fda.gov)

Clopidogrel and selexipag interaction Co-administration is contraindicated due to increased blood concentrations of selexipag

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the package inserts for clopidogrel containing products (Plavix®, ComPlavin®) and selexipag (Uptravi®) should be revised to include that coadministration of selexipag and clopidogrel is contraindicated. Selexipag is indicated for pulmonary arterial hypertension. Clopidogrel is indicated for suppression of recurrent ischemic cerebrovascular disorder. Clopidogrel is a potent CYP2C8 inhibitor and there is a possibility of an onset of adverse drug reactions and/or symptom exacerbation arising from an increase in blood concentrations of selexipag and its active metabolite. MHLW and PMDA have conducted an investigation and have concluded that the revision of the package inserts of both products should include language regarding the risks associated with coadministration of clopidogrel.

Reference: Revision of Precautions, MHLW/PMDA, 20 March 2018 (www.pmda.go.jp/english/)

Miconazole and warfarin interaction Reminder of reduced warfarin clearance

TGA has requested that a warning statement about the potential interaction with warfarin is added to product labels for miconazole containing products. In addition, TGA will also work with manufacturers to strengthen warnings

in the patient information (PI) and consumer medicines information (CMI) documents. Miconazole is an antifungal medication used to treat ringworm, pityriasis versicolor, and yeast infections of the skin or vagina.

Miconazole inhibits one of the main cytochrome P450 isoenzymes involved in warfarin metabolism (CYP2C9), which can result in reduced warfarin clearance and an enhanced anticoagulant effect. This can lead to supratherapeutic international normalised ratio (INR) values and subsequent bleeding complications. Bleeding events can have fatal outcomes. The TGA has reminded health professionals that, while the number of Australian reports of warfarin and miconazole interactions are low, the potential of an interaction can be life-threatening.

Reference: Medicines Safety Update, TGA, Vol. 9, No. 1, February-March 2018 (www.tga.gov.au)

Retinoids: Updated measures for pregnancy prevention and potential risk of neuropsychiatric disorders

EMA's PRAC has completed a review of retinoid medicines and has recommended that pregnancy prevention measures need to be updated. In addition, prescribing information for oral retinoids should be updated to include a warning on the possibility of neuropsychiatric disorders.

Oral retinoids are used to treat various forms of severe acne, severe hand eczema that does not respond to treatment with corticosteroids, severe forms of psoriasis and other skin conditions, and certain types of cancer. Retinoids applied to the skin are used to treat various skin conditions including mild to moderate acne.

The review confirmed that oral retinoids can harm the unborn child and must not be used during pregnancy. Data on neuropsychiatric adverse events was not sufficient to assess the risk with retinoid use. However, considering that patients with severe skin conditions may be more vulnerable to neuropsychiatric disorders due to the nature of the disease, the prescribing information for oral retinoids will be updated to include a warning about this possible risk.

Reference: EMA, 23 March 2018 (www.ema.europa.eu)

China grants priority review to Innovent's Hodgkin lymphoma drug

China's State Drug Administration accepted under priority review status Innovent Biologics' new drug application for IBI308, or sintilimab, which is being developed as a treatment of relapsed or refractory classical Hodgkin lymphoma. In a midstage trial, the candidate achieved a disease control rate of 97.9% and an overall response rate of 79.2%.

Ref. BioCentury

Ministry of Health, Govt. of India to make it mandatory to set up MDR TB Centres at all Govt. Hospitals as Patient Numbers Surge

The Central government is getting ready to make it mandatory for all government medical colleges and hospitals in the country to set up multi-drug resistant (MDR) tuberculosis centres. The health ministry has recently made the proposal to the Medical Council of India (MCI) as the number of people suffering from drug resistant TB is climbing steadily. In a letter to the MCI, the health secretary requested the council to incorporate the obligatory requirement of establishing MDR-TB centre for treatment initiation of patients as per revised national TB control programme guidelines at each medical college for recognition of medical college. According to official data, as many as 1.5 lakh people in India are suffering from MDR TB.

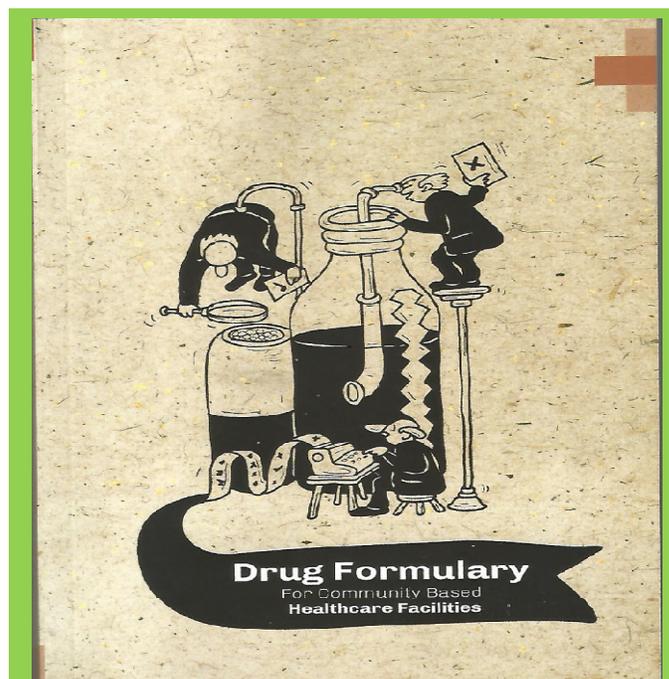
Once the proposal is implemented, it will be mandatory for all the government medical colleges and hospitals to set up such centres for obtaining recognition from MCI. India, with 27.9 lakh tuberculosis cases, 4.23 lakh disease-related deaths, and an average of 211 new infections diagnosed per 100,000 people, has the highest number of TB patients in the world. There are 147

MDR-TB treatment centres in the country at present, and the new clause is expected to help create enough centres for treatment.

According to the central government's TB India Report 2018, the country saw 18,27,959 TB patients in 2017, of which 1,92,458 were from Maharashtra. Mumbai saw 45,675 TB patients in 2017, and the average rise in TB patients in Mumbai is 30 per cent every year.

The ministry has recently made non-reporting of TB cases to the government a criminal offence to get a more realistic picture of the disease's incidence and prevalence in the country and help track the 'missing million' unregistered or undetected patients. As per the new regulations, clinical establishments, including those in the private sector, will face punitive action if they fail to notify TB cases to the local public health authority District Health Officer or Chief Medical Officer. Moreover, all pharmacies, chemists and druggists dispensing anti-TB medications must provide details of the patient, prescription and medical practitioner concerned to the nodal officer of the district failing which action will be taken against them.

Source: Pharmabiz



Book published by: Community Development Medicinal Unit & Shramajibi Swasthya Udyog

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