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NEWS LETTER
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# Cancer Burden Rises to 18.1 Million New Cases and 9.6 Million Cancer Deaths in 2018

The International Agency for Research on Cancer (IARC) estimated 18.1 million new cases and 9.6 million deaths across the globe in 2018. This translates to one out of six deaths globally and far exceeding the number of deaths from HIV and Aids, malaria and tuberculosis combined. Cancers of the breast, colorectum, lung, cervix uteri and thyroid are most prevalent among females while those of the lung, prostate, colorectum, stomach and liver are top among males.

The disease burden is greatest in low-income and middle-income countries (LMICs), where 70 per cent of cancer deaths occur with the sub-Saharan Africa projected to have more than an 85 per cent increase in cancer incidence by 2030. This sharp increase is being attributed to demographic changes such as ageing and population growth, changing prevalence of cancer risk factors and increased exposure to risk factors such as environmental carcinogens, urbanisation, unsafe food and water, infectious agents, lifestyle changes such as obesity, alcohol and tobacco use.

Many cancers can be prevented. Others can be diagnosed early in their development, treated and cured. However, there is a limited public awareness on cancer symptoms. This coupled with geographical inaccessibility of services, cost of treatment, social cultural factors, poor referral and post referral follow ups and other social determinants of health delay timely diagnosis. The consequence is physical, financial and emotional strain on cancer patients and their families. Ultimately, prolonged disability and premature mortality have social and economic impact on LMICs.

In May 2017, world governments made a commitment to further invest in cancer control as a public health priority, passing the World Health Assembly Resolution 70.12 on cancer prevention and control. However, historically, cancer has received little attention from global policymakers and donors with only 5 per cent of global spending on cancer directed to LMICs while 1 per cent of global health financing is directed to Non-Communicable Dis eases. Thus, LMICs are finding it difficult to respond to the cancer challenge on national health systems.

**Behavioural interventions**

At an individual level; avoid tobacco use; eat a healthy diet; if you choose to take alcohol, do so only in moderation; limit processed foods; maintain a healthy weight and be physically active; avoid tanning beds and sunlamps while at the same time protecting yourself from intense midday sun; get vaccinated against Hepatitis B and Human Papilloma Virus; avoid risky behaviors such as unsafe sex and sharing of injectable drug needles; lastly, get regular medical checkups -- regular self-exams and screenings for various types of cancers can increase your chances of “catching it early”-ask your doctor about the best cancer-screening schedule.

**Biomedical interventions**

The first step in the event of a diagnosis with cancer would be to find the right doctor for the specific disease followed by designing of a treatment plan and creation of a social support system. Treatment aims to cure disease, prolong life, and improve the quality of life. The most effective and efficient treatment is linked to early detection programmes and follows evidence-based standards of care.

**Structural interventions**

In view of the complex nature of the disease and the fragmented and uncoordinated interventions in LMICs, taking a systems approach in cancer control plans tailored to regional and national priorities would address the challenge more holistically.

**Future research priorities in oncology**

Moving forward, research on oncology in LMICs needs to focus on: (1) risk reduction and early detection aimed at determining specific genetic, biological, and behavioral risk factors for cancer and evaluating innovative models to improve screening and increase early diagnosis and (2) survivorship and symptom science aimed at reducing treatment-related symptoms and enhancing survivorship. (Source:WHO)

## Skin Patch to Make Cancer Treatment Painless

**New York:** Massachusetts Institute of Technology (MIT) researchers have developed a fast-acting skin patch that efficiently delivers medication to attack cells in melanoma — a deadly form of skin cancer. Topical ointments can impart medications to the skin, but they can only penetrate a small distance through it.

While syringes are an effective drug delivery mode, they can be painful. Syringes can also be inconvenient for patients, leading to non-compliance. "Our patch has a unique chemical coating and mode of action that allows it to be applied and removed from the skin in just a minute while still delivering a therapeutic dose of drugs," says Yanpu He, a graduate student who helped develop the device.

The researchers believe that the skin patch, tested in mice and human skin samples, is an advance toward developing a vaccine to treat melanoma, a deadly form of skin cancer. "Our patches elicit a robust antibody response in living mice and show promise in eliciting a strong immune response in human skin," He said. "But we are excited by the possibility that the patch is another tool in the oncologists' arsenal against cancer, specifically melanoma," Hammond said. (Source: The Free Press Journal)

## Experimental drugs show 90 percent survival rates for Ebola patients

The deadly Ebola hemorrhagic fever is not incurable anymore. Scientists are a step closer to being able to cure the deadly Ebola fever after two experimental drugs showed survival rates of nearly 90 percent in a clinical trial in the Democratic Republic of Congo (DRC).

Two experimental drugs — REGN-EB3 developed by Regeneron and a monoclonal antibody called mAb114 — will now be offered to all patients infected with the viral disease. Ebola has been spreading in eastern Congo since August 2018, with the outbreak killing at least 1,800 people.

The drugs showed "clearly better" results, according to the US National Institute of Allergy and Infectious Diseases (NIAID), in a trial of four potential treatments being conducted during the second-largest Ebola outbreak in history, now entering its second year in DRC.

The drugs improved survival rates from the disease more than the two other treatments being tested — ZMapp (manufactured by Mapp Biopharmaceutical) and Remdesivir (made by Gilead Sciences). The agency said 49 percent of the patients on ZMapp and 53 percent on Remdesivir died in the study. In comparison, 29 percent of the patients on REGN-EB3 and 34 percent on mAb114 died. ZMapp and Remdesivir will now be dropped.

Jean-Jacques Muyembe, director general of Congo's Institut National de Recherche Biomédicale in DRC, who co-led the trial, said: "From now on, we will no longer say that Ebola is incurable…these advances will help save thousands of lives."
(Source: PharmaCompass)

## US Senator seeks "Unannounced" FDA inspections of plants overseas

In a letter sent to Alex Azar, secretary, Department of Health and Human Services (HHS), and Norman Sharpless, acting commissioner, US Food and Drug Administration (FDA), Chuck Grassley, chairman of the US Senate Committee on Finance, highlighted that the committee has an obligation to ensure that FDA upholds its responsibility to protect public health by properly overseeing the nation's drug supply and ensuring that the drugs Americans use are safe and effective.

Referencing the valsartan drug safety issues that made headlines in the past year and an interview with ex-FDA investigator Motammed Masoud who "had tried to sound the alarm on what he flagged as potential systemic problems at two facilities in China and India that produce the API in generic valsartan and other blood pressure medications", the letter also highlights that the "FDA only inspected one in five registered human drug manufacturing facilities abroad last year."

As the Trump administration is pushing for drug imports from overseas in an effort to lower drug prices in the US, the letter states "the FDA does not track in its databases whether a foreign inspection was subject to an announced or unannounced visit." Further, Grassley said he has learned that the FDA generally does not perform unannounced visits of drug manufacturing facilities in foreign countries but does perform unannounced visits at facilities based in the US.

The letter goes on to mention that in 2013 the FDA created a pilot program in India that eliminated advanced notice and instead used short notice or unannounced visits. In 2015, the pilot program was shut down without explanation. It is unclear why the Obama administration shut the pilot program.

However, because of its reported successes, Grassley said he would strongly encourage the administration's demonstration projects to include unannounced inspections in foreign manufacturing facilities to determine "if they meet the required API and drug quality and safety standards to include sufficient record-keeping, testing, and protections against counterfeiting".
Meanwhile, following data accuracy issues with Novartis' recently approved gene therapy — Zolgensma, Grassley has asked Novartis to provide details on data manipulation related to its US$ 2 million gene therapy.

Grassley wants Novartis to submit additional details, including the date when it came to know that it issued manipulated data to the FDA as well as the number of employees whose services were terminated due to this issue. Novartis said it has received the Senator's letter and was reviewing the request.(Source: PharmaCompass)

## Indian Pharma Wants a Booster Fund to Push Innovation

AHMEDABAD/MUMBAI: The Indian Pharmaceutical Alliance, a group of top research-based pharmaceutical companies, has urged policy think tank Niti Aayog and the Department of Pharmaceuticals to set up a large fund to boost technological innovation in pharma and healthcare startups. “We have approached the government to set up dedicated funds to boost innovation and startups in the pharma space in India,” said Sudarshan Jain, secretary-general, IPA.

Last month, the IPA submitted its Vision 2030 document that highlights opportunities and challenges in the Indian pharma sector. The document seeks to promote innovation backed by risk capital to further boost pharma and health technology innovation in India. “IPA is advocating and advising the government to set up a startup VC fund to boost innovation in pharma,” said Pankaj Patel, CMD of Cadila Healthcare, one of the top five pharma companies in India in terms of revenue.

Patel, who is also former IPA president, said the sector has to innovate to grow faster. IPA has also asked the government to boost its investment share in private sector R&D to 35% from 25%. This could be done by allocating more funds to R&D projects in life sciences and startups, it said.

Co-funding research projects and startups is common in developing countries, including China which has allocated $12 billion for drug development in 2010-15, it said. “Indeed, this is a great step. Like BIRAC (Biotechnology Industry Research Assistance Council) funds biotech innovation, it’s high time pharma and the med-tech sector, which are also heavily dependent on R&D, get risk funding support to position India as an innovation-based economy,” said Vishal Gandhi, founder, BIORx Venture A ..

India already has a Biotechnology Ignition Grant Scheme (BIG) that provides assistance of up to $5 million to biotech startups to establish and validate proofs-of-concept and to enable the creation of spin-offs. “The pharmaceutical industry expects similar and larger funds to be created across all innovations in the pharma space,” IPA said.

Past efforts to set up a funding institution to fuel pharmaceutical innovation have not taken off. Except for BIRAC and funding assistance from the Technology Development Board, which grants financial assistance to biotechnology-based startups, these attempts have drawn little interest from the government. “At least from the optics, innovation is getting importance from the government but if that will go to the level of making funding available is doubtful,” a veteran venture capitalist told ET, ..

Innovation programmes, in addition to funding, should attract Indian scientists who have worked in international research labs, he said. Ten years ago, China initiated the Thousand Talents Program that had roped in Chinese scientists from external research institutes, mostly from the US and that has spurred its research effort in the life sciences segment, he said. (Source: Economic Times)

## Genetically Manipulating Protein Level in Colon Cancer Cells Can Improve Effectiveness of Chemotherapy, Mayo Clinic

Colorectal cancer outcomes may improve by genetically altering an immune-regulatory protein in cancer cells, making the cells more vulnerable to chemotherapy. That's according to new Mayo Clinic research.The findings, published this month in Oncogene, indicate that increasing the expression of the PD-L1 protein in colorectal cancer cells can improve the effectiveness of chemotherapy.

"These findings, if verified by subsequent research, suggest that the level of tumor cell PD-L1 may be important in drug sensitivity and suggest that enhancing PD-L1 expression may be a potential strategy to improve treatment outcomes in this malignancy," says Frank Sinicrope, M.D., a Mayo Clinic medical oncologist and gastroenterologist. Dr. Sinicrope is co-director of the Gastrointestinal Cancer Program at Mayo Clinic and corresponding author of the study.

PD-L1 is an immune checkpoint protein that interacts with another protein, PD-1, to negatively affect cell functions and enable tumor cells to evade the body's immune system. Research has shown that interrupting the PD-L1/PD-1 interaction can enhance attacks on anti-tumor immunity.

However, the Mayo Clinic study describes another function of PD-L1: its effect on proteins that regulate tumor cell death. Deleting the PD-L1 gene suppressed two proteins that are associated with increased chemotherapy-induced cell death. In contrast, restoring PD-L1 expression reversed the suppression of these proteins.

"We sought to determine the relevance of our findings for PD-L1 in patients with colorectal cancer," Dr. Sinicrope says. "To do so, we utilized the Cancer Genome Atlas database of the National Cancer Institute to examine the association of PD-L1 expression with the survival of patients with colon cancer."

The study found that increased tumor cell PD-L1 expression was associated with better survival among patients expected to have received chemotherapy, which is the standard of care for patients with stage 3 and stage 4 cancers, according to Dr. Sinicrope.

"This suggests a broader role for PD-L1 as a possible predictive biomarker for how patients will respond to cancer treatment, though more research is needed to address this issue," he says.
The study also found that the BRAF oncogene, a gene that can transform a cell into a cancer cell, can regulate the expression of PD-L1. When the BRAF oncogene is mutated, it can increase PD-L1 expression in colorectal cancer cells, according to the study.

"Current therapies targeting PD-L1 are mainly focused on blocking or disrupting its function in tumor cells," says Haidong Dong, M.D., Ph.D., a Mayo Clinic tumor immunologist and co-author of the study. "This work suggests that enhancement of PD-L1 expression in tumor cells may promote the efficacy of chemotherapy, at least in colon cancer. It is an idea-changing discovery that, if validated in clinical trials, would bring more benefit to patients with colon cancer that is resistant to current chemotherapy."

The study, conducted by researchers at Mayo Clinic in Rochester and Mayo Clinic in Florida, was supported in part by a grant from the National Cancer Institute. Co-author Daofu Feng, M.D., was supported by the Scientific Research Training Program for Young Talents of Tianjin Medical University General Hospital in China. Co-author Lei Sun was supported by Second Affiliated Hospital of Guangzhou Medical University in Guangzhou, China. (Source: News Wise)

## Government Mulling Price Cap on Sanitary Pads, Adult Diapers, Handwash

**New Delhi**: The government is actively considering to bring personal hygiene items such as handwash, sanitary napkins, disinfectants and adult diapers under price regulation. Several hygiene products are likely to find a place in the revised National List of Essential Medicines (NLEM) with medicines, medical devices and other vital health products.

The health ministry is reassessing the NLEM to add relevant products and exclude a few items. It is also making separate lists for medical devices, disposables and hygiene products. Medicines and medical devices listed in the NLEM must be sold at the price fixed by the National Pharmaceutical Pricing Authority (NPPA).

It is worth noting that the Centre controls prices of around 384 essential drugs, including medical devices such as stents, by imposing a cap on profit margins on their maximum retail price. Plus, pharmaceutical companies are allowed to increase prices for other medicines by up to 10 per cent per year, on a 12-month moving average basis. The government has also put a lid on trade margins for 42 cancer drugs. The trade margin is the difference between the price at which the manufacturers sell to stockists and the price charged to buyers.

"The list of essential hygiene products is in its final stages and is likely to be released over the next two months," an official told a leading national daily. The list will have two categories — primary and secondary. The products in the primary category will be price -regulated, and the Centre will also ensure availability of drugs at reasonable prices included in the secondary list.

A Niti Aayog panel will take a final decision on whether there will be an overarching ceiling price or a cap on trade margins after the list of products is notified. The daily mentioned, citing an unnamed official, that it may be a combination of both. There could a price control for products on the primary list, while trade margin limits likely to be fixed for those on the secondary list.

"The idea is to ensure that all these products are available and affordable to the common people as they play a crucial role in disease control and maintaining health and hygiene. Some of these products will be available for free at primary and community health centres," the daily quoted the official as saying.

Many of these items such as sanitary pads, diapers and sanitisers are highly-priced with increasing trade margins. The list is being drafted by a sub-panel constituted under the standing national committee on medicine and health headed by, Balram Bhargava, secretary, department of health research and director-general of the Indian Council of Medical Research.(Source: etnownews.com)

## *South Asia's First Signa Artist Wide Bore 96 Channel Digital MRI system has been launched to leverage technological advancement for better clinical outcomes and patients' comfort*

**Pune,** India: To maintain the lead in providing world-class healthcare by adopting newer and advanced technology in its model, BLK Super Specialty Hospital today introduced South Asia's First Signa Artist Wide Bore 96 Channel Digital MRI system. This most advanced technology delivers a new level of clinical performance with additional research-focused capabilities, especially for Neurology, Cardiology, Orthopaedics and Oncology.

The state of the art new MRI system with wide bore helps ease anxiety concerns with tight spaces and reduces claustrophobia.This machine can scan any body part going head or feet first. This works wonder in reducing patient anxiety. Feet first scanning is available for all body parts and that helps in making the procedure less claustrophobic for many patients.

"From the patients perspective this advanced machine significantly reduces scan time. A brain scan with Magic sequence can be done in five minutes which would have otherwise taken at least 20 minutes. "As a standard biomarker in oncology diffusion imaging plays a critical role in cancer detection and staging, the whole body diffusion can be done in 20 minutes which is a major achievement also SIGNA Artist uses intelligent quantitative solutions to automatically detect and correct distortion, artefacts and motion.," said Dr. Prem Kumar Ganesan– Director & HOD, Radiology and Imaging, BLK Super Speciality Hospital.

The New System offers multiple startling advances in imaging with Tractography and advanced Functional Imaging. Another unique feature is the reduction of noise inside the MRI machine. The quieter machine and the new in bore experience which allows the patients to choose music and videos of their choice to be viewed during scan makes the overall patient experience much more enjoyable and allows the technicians to smoothly and efficiently complete the scan.

"The spatial and temporal resolution of Signa Artist is amazing providing much clearer and sharper images there by increasing the confidence of the radiologist in making correct and accurate diagnosis" added Dr Prem Ganesan. (Source: NRI News 24x7)

**Global Pharma Logistics Summit returns to Mumbai where it began in 2017 with a tailor-made agenda designed to empower and enable logistics and supply chain professionals in pharmaceutical manufacturing and temperature-controlled transport.**

Join the highly engaging discussions with top professionals of pharma manufacturing, directors of supply chain, quality management, logistics, packaging and transportation along with innovators of temperature-controlled products and solutions on ensuring end-to-end supply chain management and integrity of pharma products on the move.

India is the third largest exporter of pharmaceutical products in terms of volumes. Country's pharmaceutical production in 2018-19 stood at $39 billion, of which $19 billion, half of total production, were exports. Supply chain and logistics play a crucial role for India's pharmaceutical exports. The conference takes place in Mumbai, the city that has the best gateway airport in India for pharmaceutical export and the closest one to the country's pharma manufacturing hubs.