

Seqirus Media Monitoring

1st May 2018

Seqirus mentions

No News Recorded

Industry News

EMA Updates Flu Vaccine Recommendations

On April 30, 2018, the European Medicines Agency updated the European Union list of recommendations for influenza virus strains that manufacturers should include in vaccines for the autumn 2018 season. The update contains a decision on suitable strains for live, attenuated vaccines. EMA also updated the list of reagents for vaccine standardization.

<http://www.pharmtech.com/ema-updates-flu-vaccine-recommendations>

New EMA guideline for development of vaccines

The European Medicines Agency has produced a new draft guideline for the clinical development of vaccines. The guidelines, which have been put out for a six-month public consultation, include specific considerations for clinical trials of vaccines in special populations, such as pregnant women or older people. The revised version of the guidelines also adds considerations to priming and boosting strategies.

<https://www.pharmaceutical-journal.com/news-and-analysis/news-in-brief/new-ema-guideline-for-development-of-vaccines/20204777.article>

Bill Gates Pledges \$12 Million to End the Pandemic Flu Threat

The Bill & Melinda Gates Foundation's new \$12 million Universal Influenza Vaccine Development Grand Challenge is committed to funding bold, innovative ideas that stem from a place of collaboration. "Our collective belief is that innovation is catalyzed through rigorous collaboration and enriching of ecosystems, and we hope this Grand Challenge will stimulate creative thinking beyond the traditional influenza community," the foundation announced. In addition to being completely transformative research rather than incremental steps, study proposals for the Grand Challenge should include vaccines that have the potential to be used in all age groups around the world, especially in developing countries.

<http://www.laboratoryequipment.com/news/2018/04/bill-gates-pledges-12-million-end-pandemic-flu-threat>

BiondVax Announces Fourth Quarter and Full Year 2017 Financial Results and Update

BiondVax announced its fourth quarter and full year financial results for the year ended December 31, 2017 and provided a business update. Earlier this month, the first participant was enrolled in the United States in a Phase 2 clinical trial of the BiondVax's universal flu vaccine candidate, M-001. The trial is sponsored by the US National Institute of Allergy and Infectious Diseases (NIAID).

<http://markets.businessinsider.com/news/stocks/biondvax-announces-fourth-quarter-and-full-year-2017-financial-results-and-update-1022926796>

NHS England's Simon Stevens - no Trump drug price rhetoric here

The UK pharmaceutical industry is beginning crucial talks with the government on the future of drug pricing for the next four years, and this time around NHS England is set to make it very much a three-way conversation. Speaking at the annual conference of UK pharma association the ABPI, Simon Stevens reiterated that NHS England would enter into the Pharmaceutical Price Regulation

Scheme (PPRS) negotiations in “good faith”, with the goal of seeking a “triple win” for the industry, NHS and patients.

http://www.pmlive.com/pharma_news/nhs_englands_simon_stevens_-_no_trump_drug_price_rhetoric_here_1233513

Pandemic Influenza News

Health and Human Services Biodefense Budget Oversight

In the U.S., The House Appropriations Subcommittee on Labor, Health and Human Services, and Education held an oversight hearing focused on the FY2019 Budget for Health and Human Services Biodefense Activities on April 18, 2018. NIAID is partnering with BARDA to support the development of vaccine candidates for influenza strains with the potential to cause a pandemic, including H7N9 avian influenza. NIAID also is working to develop broadly protective, or “universal,” influenza vaccines that could protect against multiple strains of seasonal and pandemic influenza. NIAID recently developed a Strategic Plan to guide research efforts focused on the design and development of universal influenza vaccines.

<https://globalbiodefense.com/2018/04/29/health-and-human-services-biodefense-budget-oversight/>

Academic studies

Flu vaccine, even when just 20% effective, saves tens of thousands of lives

Each winter, many people wonder whether its worth getting a flu shot while health officials repeatedly warn against not getting one. Now a new study sheds light on the benefit of doing so. Even when the flu shot is just 20% effective it can still reduce US doctor visits due to illness by an estimated 20 million in a single year, the new report says. A mathematical model shows that for example, at just 43% coverage (the average rate of Americans who received a flu shot for the years 2012 through 2017), a vaccine with just 20% effectiveness could avert more than 20 million infections or illnesses as compared to not getting the vaccine. In addition, 129,000 hospitalizations and 61,000 deaths could be prevented.

<https://www.cnn.com/2018/04/30/health/vaccine-low-effectiveness-study/index.html>

Additional sources: ([Health Day](#))

Pediatric influenza news

No News Recorded

Over 65's influenza news

No News Recorded

General Influenza News

Bill Gates got President Trump fired up about a universal flu vaccine — and also (maybe) got a job offer

Bill Gates was talking to President Trump in the Oval Office last month when the conversation turned to the notion of a universal flu vaccine — probably, as Gates recalled in an interview, “the longest conversation about universal flu vaccine that the president’s ever had.” The Gates Foundation is offering \$12 million in seed money for projects that would help the world develop a universal flu vaccine. Gates said he thinks that when a universal flu vaccine is developed, it will be made in one of the newer vaccine constructs attracting so much research attention these days. “The RNA, DNA technologies are extremely likely to be where you get the universal flu vaccine,” he said. He name-checked a few biotechs working in that space: Inovio, Moderna, and CureVac.

<http://www.statnews.com/2018/04/30/bill-gates-vaccine-trump-meeting/>

Additional sources: ([Politico](#)) ([Quartz](#))

Life insurers count cost of deadly flu season

US life insurers are counting the cost of one of the worst flu seasons in modern history as deaths prompt payouts to the victims' survivors. The flu is estimated to have claimed more than 12,000 lives in the US so far this year. The predominant strain, H3N2, is particularly virulent and vaccines against it have an unusually low success rate. Insurance executives will face questions this week about the financial implications of the outbreak, especially after it caused an unexpectedly big hit to profits at Reinsurance Group of America. Anna Manning, chief executive, on Friday blamed an "especially harsh" winter after the reinsurer took a \$40m charge for "adverse mortality" trends. The company's first quarter net income fell almost a third from a year ago.

<http://www.ft.com/content/4cbd2718-4a4b-11e8-8ee8-cae73aab7ccb>

Call to vaccinate as flu season nears

In Australia, a free influenza vaccine is now available for South West residents to access under the Federal Government's National Immunisation Program. With last year seeing the highest influenza activity in Australia in almost a decade, Forrest MHR Nola Marino urged everyone in the region to consider getting a flu shot this year.

<http://thewest.com.au/news/south-western-times/call-to-vaccinate-as-flu-season-nears-ng-b88817028z>

Trump Says He's "Super Interested" in a Universal Flu Vaccine. His Budget Says Otherwise

President Trump, who in the past was skeptical of immunizations, has now expressed enthusiasm about the development of a universal flu vaccine. Does Trump's alleged enthusiasm bode well for researchers? Michael Osterholm, a flu researcher and the director of the Center for Infectious Disease Research and Policy at the University of Minnesota, doesn't want to speculate. "It's gratifying to see many parties now talking about the need for a game-changing influenza vaccine—we've come a long way in this discussion," he said. "Just \$10 million here and \$10 million there is not going to do it," Osterholm said

<http://www.motherjones.com/politics/2018/04/trump-says-hes-super-interested-in-a-universal-flu-vaccine-his-budget-says-otherwise/>

State leaders to discuss flu shot information bill

In Louisiana, a bill that looks to curb some of the dangers school students face when it comes to the flu is up for debate. Representative Paula Davis has introduced a bill that would require schools to provide up-to-date information on the flu vaccinations to parents. It also proposes that the Louisiana Department of Education do the same for parents of homeschooled children. The bill passed the House last month in a 90 to 1 vote. The information schools would be required to share would include the causes, symptoms of the flu, and how it is spread. Parents would also be able to learn where vaccinations are available.

<http://www.wbrz.com/news/state-leaders-to-discuss-flu-shot-information-bill/>

European Commission moves to boost vaccination cover across the continent

The European Commission has tabled wide ranging recommendations to increase the uptake of vaccinations against preventable diseases. These aim to reassure the public of the safety and benefits of vaccines and to tackle the upsurge in Europe of infectious diseases. Vaccination programmes have become increasingly fragile, the commission notes, because of low uptake of vaccines, vaccine hesitancy, increasing costs, and production and supply shortages.

<https://www.bmj.com/content/361/bmj.k1889.short>

Guard against the flu season

In Australia, the 2018 flu season is just around the corner and medical centres are urging people to get vaccinated. The Department of Health advises that because the protection from vaccination may reduce after three to four months, vaccination should be timed to achieve the highest level of

protection during the flu season. As the peak flu season is usually from June to September, the Forbes Medical Centre recommends vaccinations occur from late April to early May.

<http://www.forbesadvocate.com.au/story/5361759/guard-against-the-flu-season/>

Ground-breaking flu vaccines now available

In Australia, Central Coast residents who are most at risk of getting sick during this year's flu season can now access a free influenza vaccine under the Federal Government's National Immunisation Program. Member for Robertson, Ms Lucy Wicks, said 2017 had the highest influenza activity in Australia in almost a decade, mirroring a global trend, with more than 250,000 Australians testing positive for influenza, and double the normal hospitalisations.

<http://coastcommunitynews.com.au/central-coast/news/2018/04/ground-breaking-flu-vaccines-available/>

44% of the most at-risk group of people still need to be vaccinated against H1N1, according to SES

According to the Secretary of State for Health (SES), Goias still needs to immunize 590,949 people who are part of the most at risk group of the vaccination campaign against the H1N1 virus. About 54.61% of the target group of 1,302,902 people have already received flu vaccine, according to the partial health team balance sheet completed last Friday (April 27th). According to Clecia Vecci Menezes the number of people vaccinated may be higher as some cities do not pass on updated data about the vaccination campaign. The Secretariat said that this Friday another 178,000 new doses would arrive after a quality review by the Ministry of Health. Of these new doses, approximately 38,000 will be available in Goiania to continue the vaccination campaign, which will resume on Wednesday (02/05).

<http://www.dm.com.br/cotidiano/2018/04/44-do-grupo-de-risco-ainda-precisa-ser-vacinado-contr-o-h1n1-segundo-se.html>

Vaccination plea after Acacia Hills teen Thomas Snell's tragic death from total organ failure

Last week in Australia, NT chief health officer Dr Sara Watson also told Territorians to get a flu vaccine. "The most effective way to prevent the disease is by vaccination," she said. "Flu season can be variable and everyone should get an annual flu vaccine anytime from mid-April onwards to be protected. It's never too late to be vaccinated as the flu can spread all year round."

<http://www.ntnews.com.au/lifestyle/vaccination-plea-after-acacia-hills-teen-thomas-snells-tragic-death-from-total-organ-failure/news-story/146a77860a9f89684e182cc83468b89a>

News Scan for Apr 30, 2018

In a speech at the annual meeting of the Massachusetts Medical Society on Apr 27, philanthropist and Microsoft cofounder Bill Gates announced the launch of a \$12 million Grand Challenge to speed the development of a universal flu vaccine. He said the Lucy and Larry Page family is a partner in the challenge and is also supporting Sabin Vaccine Institute efforts to encourage new approaches to curb the pandemic flu threat

<http://www.cidrap.umn.edu/news-perspective/2018/04/news-scan-apr-30-2018>

Patient hospitalized with H1N1 flu shows improvement, says FMS

The local Municipal Health Foundation reported on Sunday (29th) that a 13-year-old girl is the first patient to be diagnosed with the Influenza A virus in Teresina this year and they added that treatment seems to be improving her clinical condition. According to FMS, the patient is no longer under sedation and the infection has been controlled. Despite this, the girl is still in the Teresina Emergency Hospital ICU (HUT) and is not expected to be discharged any time soon. The adolescent has an associated comorbidity and chronic lung disease, that is, pulmonary disease that lasts for more than three months and even with proper treatment, and in some cases, there is no cure. Since the beginning of the year, the FMS has recorded 52 cases of Severe Acute Respiratory Syndrome, of

these, seven cases were confirmed as H1N1. In addition to the young woman, six other people have been diagnosed with the virus; two sisters aged 19 and 22, two elderly women, a 54-year-old woman and a pregnant woman who was hospitalized in Buenos Aires hospital. At present, all patients, except the adolescent, have managed to recover at home.

<http://www.portalodia.com/noticias/saude/paciente-internada-com-h1n1-apresenta-melhora,-diz-fms-317633.html>

Maitland doctors and pharmacists flat out vaccinating patients against the flu

In Australia, the number of Maitland people rolling up their sleeve this season for the annual flu jab has increased significantly as awareness of this year's deadly strain spreads. There has been conflicting information about when to vaccinate, some believing they should hold off until May, others saying to vaccinate sooner rather than later. NSW Health is urging people to get their flu shot by the end of May.

<http://www.maitlandmercury.com.au/story/5367873/panicking-patients-needle-gps-for-flu-shots/>

Authorities find empty and out of date bottles of H1N1 flu vaccine discarded in Luziania street

Empty and out of date bottles of H1N1 flu vaccine have been found discarded in a Luziania street. Additionally there were medicine records, tablets, needles and syringes found. The material has been picked up and sent for incineration. The bottles had an expiration date of 2014. After cross-checking the manufacture lot number of the vaccines, the local Municipal Health Department assured the public that the materials had not been thrown away by any public unit. "In the public network, we hire a waste disposal company that does all the collection and incineration of any discarded material. So that stuff is not ours," said the city's Health Secretary, Whaterson Roriz.

<http://g1.globo.com/go/goias/noticia/frascos-vazios-e-vencidos-de-vacinas-contr-h1n1-sao-descartados-em-rua-de-luziania.gh.html>

Burden of disease

5 More Flu-Related Deaths Reported in Connecticut As Flu Activity Begins to Decrease

Connecticut public health officials say they are beginning to see a decrease in flu activity, but five more flu deaths have been reported within a week. According to officials, flu activity has decreased since its peak in early February, but it remains elevated and is considered widespread. An increase in the circulation of influenza B virus has contributed to increased flu activity previously, but experts are now beginning to see the activity decrease.

<http://www.nbcconnecticut.com/news/local/5-More-Flu-Related-Deaths-Reported-in-Connecticut-As-Flu-Activity-Begins-to-Decrease--481189851.html>

Additional sources: (New Haven Register) (Fairfield Citizen)

Flu Deaths Rose Sharply In The Carolinas

More than 600 people have died from flu-related illnesses in the Carolinas, according to state health department reports. The flu season officially runs through the end of May. Dr. Charles Bregier, a medical director with Novant Health in Charlotte, says this was the worst flu season since the swine flu pandemic in 2009-2010.

<http://wfae.org/post/flu-deaths-rose-sharply-carolinas>

Harsh flu season winding down, but it left its mark: Highest child death count in at least 5 years

In the U.S., a brutal flu season is finally on its last legs, but it has taken a heavy toll, including the highest death count among children in at least five years, health officials say. The CDC has previously estimated that a severe season can kill up to 56,000 people, hospitalize up to 710,000 and sicken up to 35 million. This season "may have been worse than that," Lynnette Brammer, head of domestic influenza surveillance at CDC, said. Flu vaccines typically prevent 40% to 60% of flu

connection with H1N1

A 6-month-old baby has been hospitalized in Goiania with a perforated bowel. The doctor Zacharias Calil, who is managing this case, believes it could well be a complication linked to the H1N1 virus. According to the pediatrician, the child has symptoms of the disease and was even being medicated for it before. The case is considered to be very rare. At the request of the family, the doctor did not disclose in which unit the baby is hospitalized nor the identity of the family and relatives. The baby lives in Montes Claros de Goias and was admitted on the 20th, in Goiania. "A quick test pointed towards influenza being present in this case. However, influenza has some sub-divisions, such as H1N1, H3N2. Even though the baby is already being treated, due to this complication he had to be operated on," said the doctor.

<http://g1.globo.com/go/goias/noticia/bebe-tem-intestino-perfurado-e-medico-suspeita-que-caso-tenha-ligacao-com-h1n1-em-goianaia.ghtml>

Flu Surveillance in Animals

New highly pathogenic H5N6 avian flu cases found in wild birds in Sweden

In Sweden, a total of 3 new cases of H5N6 bird flu have been identified after analysis at the National Veterinary Office. They were a sea eagle, a pigeon and a buzzard found in the areas surrounding Morrum and Bromolla in southern Sweden. This virus has not been found to present a risk to humans, unlike the H5N6 virus that circulates in Asia.

<http://www.mesvaccins.net/web/news/12256-nouveaux-cas-de-grippe-aviaire-hautement-pathogene-a-h5n6-chez-des-oiseaux-sauvages-en-suede>

US Storing Viral Pathogens for Biological Attacks: Iranian Official

Head of Iran Veterinary Organization Alireza Refiepour highlighted Iran's efforts to control avian flu over the past two years, urging collective efforts to prevent an epidemic of bird flu this year. As regards the preventive measures by the Veterinary Organization, he pointed to stricter control over transportation, handling of illegal poultry farms, and constant monitoring of the country's lagoons. In comments earlier this month, the official announced that more than 25 million birds in 22 provinces of the country had been culled to curb avian flu.

<https://www.tasnimnews.com/en/news/2018/04/28/1711918/us-storing-viral-pathogens-for-biological-attacks-iranian-official>