

# New in Medicine Issue 129

February 2023

## Editorial

Dear Colleagues

Despite the three long years of Covid-19 pandemic, this viral infection has not yet completely gone. Moreover, there are new and recurrent infections being reported worldwide (despite prior infection or post vaccination). However, there have been few positive developments regarding the diagnosis, treatment and prevention of COVID-19. FDA has approved the first over-the-counter (OTC) at-home diagnostic test (*Lucira COVID-19 & Flu Home Test*) that can differentiate and detect influenza A and B, commonly known as the flu, and SARS-CoV-2. This single-use at-home test kit provides results from self-collected nasal swab samples in roughly 30 minutes. Some drugs have been used clinically to treat adults with mild-to-moderate Covid-19, who were at risk for progression. In a study, *VV116* was found noninferior to *nirmatrelvir-ritonavir* with respect to the time for sustained clinical recovery and with fewer safety concerns. The safety of the fourth COVID-19 *BNT162b2 mRNA (second booster) vaccine* was found to be safe in a prospective and retrospective cohort study. Such assurances can help the high-risk individuals who opt to receive this booster vaccine and thereby prevent severe outcomes associated with COVID-19.

It is estimated that 1 in 10 of the population may suffer with chronic kidney disease (CKD) and it is common in older individuals. Anemia is a common association of CKD. FDA has recently approved the first oral treatment, *Jesduvraq (Daprodustat)*, for anemia caused by CKD for adults who are on dialysis for at least four months. It is not approved for patients who are not on dialysis. An oral targeted-release formulation of the glucocorticoid budesonide (*TRF-budesonide*) has been designed to release the drug in the distal ileum in patients with immunoglobulin A nephropathy (IgAN). It targets the presumed site of production of aberrantly galactosylated IgA1 while limiting systemic glucocorticoid absorption. Treatment with *TRF-budesonide*, compared with placebo, resulted in a greater reduction in proteinuria from baseline and a slower rate of estimated glomerular filtration rate decline at nine months; while rates of adverse effects were similar between the groups, rates of adverse events leading to treatment discontinuation were higher in the TRF-budesonide group.

The tremendous progress in Genomics and Gene therapy has enabled the clinicians to apply its utility for their patients. Gene therapy focuses on genetic modification of the cells to produce a therapeutic effect for a disease, either by repairing or reconstructing the defective genetic material. Now, it is not only possible to treat the monogenic and chromosomal disorders but many other diseases like cancers, and infectious diseases. *Tranacogene Dezaparvovec* gene therapy was found superior to prophylactic factor IX with respect to the annualized bleeding rate, and it had a favorable safety profile for Hemophilia B.

The diagnosis and treatment options of various cancers are evolving at a rapid speed, with significant research output and clinical experience. In a study, omission of *radiotherapy* was found to be associated with an increased incidence of local recurrence in early breast cancer, but had no detrimental effect on distant recurrence as the first event or overall survival among women 65 years of age or older with low-risk, hormone receptor-positive. In patients with peripheral, smaller non-small-cell lung cancer (2cm or less) and pathologically confirmed node-negative disease, *sublobar resection* was not inferior to *lobectomy* with respect to disease-free survival.

Health care management is a behind-the-scenes role that is responsible for overseeing the direction of health care facilities. In a statement of Joint Commission International (JCI), it was reported that the *patient's recall* of their inpatient care after discharge, despite modern facilitators, remains poor, and further efforts are needed to enhance or implement facilitators based on patient feedback. *Diagnostic Errors (DE)* are a cause of concern for the clinicians, as well as the healthcare administrators. A study concluded that the health care organizations should consider the key factors when trying to create a culture that engages clinicians and patients in reducing DEs.

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### I. Drugs

#### **FDA Approves first oral treatment for anemia caused by chronic kidney disease for adults on dialysis**

Source: The FDA, February 2023

Link: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-oral-treatment-anemia-caused-chronic-kidney-disease-adults-dialysis>

Jesduvroq tablets (daprodustat) as the first oral treatment for anemia caused by chronic kidney disease for adults who have been receiving dialysis for at least four months. Jesduvroq is not approved for patients who are not on dialysis. Other FDA-approved treatments for this condition are injected into the blood or under the skin.

### II. Clinical Research

#### **Gene Therapy with Etranacogene Dezaparvovec for Hemophilia B**

Source: The NEJM, February 2023

Link: <https://www.nejm.org/doi/full/10.1056/NEJMoa2211644>

Tranacogene dezaparvovec gene therapy was superior to prophylactic factor IX with respect to the annualized bleeding rate, and it had a favorable safety profile.

#### **Breast-Conserving Surgery with or without Irradiation in Early Breast Cancer**

Source: The NEJM, February 2023

Link: <https://www.nejm.org/doi/full/10.1056/NEJMoa2207586>

Omission of radiotherapy was associated with an increased incidence of local recurrence but had no detrimental effect on distant recurrence as the first event or overall survival among women 65 years of age or older with low-risk, hormone receptor–positive early breast cancer.

#### **Respiratory Syncytial Virus Prefusion F Protein Vaccine in Older Adults**

Source: The NEJM, February 2023

Link: <https://www.nejm.org/doi/full/10.1056/NEJMoa2209604>

A single dose of the RSVPreF3 OA vaccine had an acceptable safety profile and prevented RSV-related acute respiratory infection and lower respiratory tract disease and severe RSV-related lower respiratory tract disease in adults 60 years of age or older, regardless of RSV subtype and the presence of underlying coexisting conditions.

#### **Lobar or Sublobar Resection for Peripheral Stage IA Non–Small-Cell Lung Cancer**

Source: The NEJM, February 2023

Link: <https://www.nejm.org/doi/full/10.1056/NEJMoa2212083>

In patients with peripheral NSCLC with a tumor size of 2 cm or less and pathologically confirmed node-negative disease in the hilar and mediastinal lymph nodes, sublobar resection was not inferior to lobectomy with respect to disease-free survival. Overall survival was similar with the two procedures.

#### **VV116 versus Nirmatrelvir–Ritonavir for Oral Treatment of Covid-19**

Source: The NEJM, February 2023

Link: <https://www.nejm.org/doi/full/10.1056/NEJMoa2208822>

Among adults with mild-to-moderate Covid-19 who were at risk for progression, VV116 was noninferior to nirmatrelvir–ritonavir with respect to the time to sustained clinical recovery, with fewer safety concerns.

### **Safety of the fourth COVID-19 BNT162b2 mRNA (second booster) vaccine: a prospective and retrospective cohort study**

Source: The Lancet, February 2023

Link: [https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(22\)00407-6/fulltext](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(22)00407-6/fulltext)

The safety of the second booster, with our findings reflecting physicians' diagnoses, patients' objective physiological measures, and patients' subjective reactions. These assurances can help increase the number of high-risk individuals who opt to receive this booster vaccine and thereby prevent severe outcomes associated with COVID-19.

### **Targeted-release budesonide for IgA nephropathy**

Source: The Uptodate, February 2023

Link: <https://www.uptodate.com/contents/whats-new-in-drug-therapy>  
[https://www.uptodate.com/contents/iga-nephropathy-treatment-and-prognosis?sectionName=Other%20regimens&topicRef=8360&anchor=H3987571880&source=see\\_link#H3987571880](https://www.uptodate.com/contents/iga-nephropathy-treatment-and-prognosis?sectionName=Other%20regimens&topicRef=8360&anchor=H3987571880&source=see_link#H3987571880)

An oral targeted-release formulation of the glucocorticoid budesonide (TRF-budesonide) has been designed to release the drug in the distal ileum in patients with immunoglobulin A nephropathy (IgAN) to target the presumed site of production of aberrantly galactosylated IgA1 while limiting systemic glucocorticoid absorption. Treatment with TRF-budesonide, compared with placebo, resulted in a greater reduction in proteinuria from baseline and a slower rate of estimated glomerular filtration rate decline at nine months; while rates of adverse effects were similar between the groups, rates of adverse events leading to treatment discontinuation were higher in the TRF-budesonide group.

## **III. Devices**

### **FDA Authorizes First Over-the-Counter At-Home Test to Detect Both Influenza and COVID-19 Viruses**

Source: The FDA, February 2023

Link: <https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-over-counter-home-test-detect-both-influenza-and-covid-19-viruses>

The first over-the-counter (OTC) at-home diagnostic test that can differentiate and detect influenza A and B, commonly known as the flu, and SARS-CoV-2, the virus that causes COVID-19. The Lucira COVID-19 & Flu Home Test is a single-use at-home test kit that provides results from self-collected nasal swab samples in roughly 30 minutes.

## **IV. Treatment Guidelines**

### **Cardiovascular disease: risk assessment and reduction, including lipid modification**

Source: The NICE, February 2023

Link: <https://www.nice.org.uk/guidance/cg181>

This guideline covers the assessment and care of adults who are at risk of or who have cardiovascular disease (CVD), such as heart disease and stroke. It aims to help healthcare professionals identify people who are at risk of cardiovascular problems including people with type 1 or type 2 diabetes, or chronic kidney disease. It describes the lifestyle changes people can make and how statins can be used to reduce their risk.

### **Barrett's oesophagus and stage 1 oesophageal adenocarcinoma: monitoring and management**

Source: The NICE, February 2023

Link: <https://www.nice.org.uk/guidance/ng231>

This guideline covers monitoring, treatment and follow-up for people aged 18 and over with Barrett's oesophagus and stage 1 oesophageal adenocarcinoma. It includes advice on endoscopic and non-endoscopic techniques. It aims to improve outcomes by ensuring the most effective investigations and treatments are used.

#### **Transvenous obliteration for gastric varices**

Source: The NICE, February 2023

Link: <https://www.nice.org.uk/guidance/ipg751>

This involves inserting a tube with a tiny balloon on the end into a vein in the thigh or neck. The tube is then passed into the enlarged vein in the stomach (gastric varix) and the balloon is inflated to stop blood flowing into the vein. The vein is then blocked using one of several techniques. The aim is to reduce the risk of bleeding.

#### **Joint guideline on integrative medicine for pain management in oncology**

Source: The Uptodate, February 2023

Link: <https://www.uptodate.com/contents/whats-new-in-oncology>  
[https://www.uptodate.com/contents/rehabilitative-and-integrative-therapies-for-pain-in-patients-with-cancer?sectionName=Clinical%20practice%20guidelines&topicRef=8361&anchor=H1283537498&source=see\\_link#H1283537498](https://www.uptodate.com/contents/rehabilitative-and-integrative-therapies-for-pain-in-patients-with-cancer?sectionName=Clinical%20practice%20guidelines&topicRef=8361&anchor=H1283537498&source=see_link#H1283537498)

A joint guideline that provides evidence-based recommendations on integrative medicine for pain management in oncology patients. The evidence quality was judged low to intermediate for most interventions, and most recommendations were weak or moderate.

## **V. Healthcare Administration**

#### **Assessment of Patient Retention of Inpatient Care Information Post-Hospitalization**

Source: The JCI, February 2023

Link: [https://www.jointcommissionjournal.com/article/S1553-7250\(22\)00267-7/fulltext](https://www.jointcommissionjournal.com/article/S1553-7250(22)00267-7/fulltext)

Patient recall of their inpatient care after discharge, despite modern facilitators, remains poor. Further efforts are needed to enhance or implement facilitators based on patient feedback.

#### **Providers' and Patients' Perspectives on Diagnostic Errors in the Acute Care Setting**

Source: The JCI, February 2023

Link: [https://www.jointcommissionjournal.com/article/S1553-7250\(22\)00288-4/fulltext](https://www.jointcommissionjournal.com/article/S1553-7250(22)00288-4/fulltext)

The study findings represent an important supplement to our understanding of DEs in acute care settings and the advancement of a culture of patient safety in the context of patient-centered care and patient engagement. Health care organizations should consider the key factors identified in this study when trying to create a culture that engages clinicians and patients in reducing DEs.