

New In Medicine Issue 141

Editorial

There have been several recent medical advancements, with promising developments across the spectrum of drugs, clinical research, devices, and healthcare administration. This editorial highlights some of the most significant breakthroughs.

On the Drug Front:

- Relief for women: The FDA approved *Pivva*, a new treatment for uncomplicated urinary tract infections (UTIs) in women. This offers a new option for managing this common and often frustrating condition.
- A broader spectrum antibiotic: *Zevtera*, a new antibiotic, received FDA approval for treating three different kinds of infections, including bloodstream infections and pneumonia. This broadens the arsenal available to doctors and could improve patient outcomes.

Clinical Research Shines a Light:

- Personalized Oxygen Therapy: Researchers explored the use of machine learning to personalize oxygen targets for critically ill patients. This could potentially lead to a reduction in mortality rates.
- Reassuring News for Pregnant Mothers: A study in JAMA found no association between acetaminophen use during pregnancy and an increased risk of autism, ADHD, or intellectual disability in children. This can alleviate concerns for many expecting mothers.
- Promising Results for Kidney Cancer: A study showed that Pembrolizumab, an immunotherapy drug, significantly improved overall survival rates in patients with kidney cancer at high risk of recurrence. This offers new hope for this patient population.
- COVID Treatment Update: While *Nirmatrelvir* did not show a significant benefit for all COVID-19 patients, further research on its effectiveness continues.
- Migraine Relief on the Horizon: Studies suggest new calcitonin gene-related peptide antagonists may be a first-line preventive treatment for migraine, offering relief to patients with severe or frequent migraines.
- Hope for Duchenne Muscular Dystrophy: A study on *Givinostat* showed a potential benefit in slowing the progression of muscle weakness in boys with Duchenne Muscular Dystrophy. Further research is ongoing.

New Devices and Guidelines:

- Digital Tools for COPD Management: Research explored the use of digital technologies to deliver pulmonary rehabilitation programs for patients with chronic obstructive pulmonary disease (COPD). This holds promise for improving accessibility and convenience of these programs.
- Blood Culture made Easier: The Kurin Lock device simplifies blood collection for infection testing, potentially improving efficiency and reducing errors.
- Focus on Women's Health: The NICE released updated guidelines on diagnosing and managing endometriosis, aiming to raise awareness and improve treatment options for women experiencing this condition.
- Expanding Treatment Choices for Skin Cancer: NICE guidelines now include the use of rhenium-188 paste for treating non-melanoma skin cancer, offering another option for patients.

Healthcare Administration Takes Center Stage:

- Implementing Continuous Monitoring: Studies explored the challenges and benefits of implementing continuous patient monitoring systems in hospitals. This research highlights the importance of user education and patient experience when introducing new technologies.
- Simulation for Safety: A study demonstrated the effectiveness of in situ simulation for identifying human errors and safety threats in adult tracheostomy care. This approach can inform the development of interventions to improve patient safety.

I. Drugs

FDA Approves New Treatment for Uncomplicated Urinary Tract Infections

Source: The FDA, April 2024

Link: <https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-uncomplicated-urinary-tract-infections>

Pivya (pivmecillinam) tablets for the treatment of female adults with uncomplicated urinary tract infections (UTIs) caused by susceptible isolates of Escherichia coli, Proteus mirabilis and Staphylococcus saprophyticus.

FDA Approves New Antibiotic for Three Different Uses

Source: The FDA, April 2024

Link: <https://www.fda.gov/news-events/press-announcements/fda-approves-new-antibiotic-three-different-uses>

Zevtera (ceftobiprole medocaril sodium for injection) for the treatment of adults with Staphylococcus aureus bloodstream infections (bacteremia) (SAB), including those with right-sided infective endocarditis; adults with acute bacterial skin and skin structure infections (ABSSSI); and adult and pediatric patients three months to less than 18 years old with community-acquired bacterial pneumonia (CABP).

II. Clinical Research

Individualized Treatment Effects of Oxygen Targets in Mechanically Ventilated Critically Ill Adults

Source: The JAMA, April 2024

Link: <https://jamanetwork.com/journals/jama/article-abstract/2816677>

Oxygenation targets that are individualized using machine learning analyses of randomized trials may reduce mortality for critically ill adults.

Acetaminophen Use During Pregnancy and Children's Risk of Autism, ADHD, and Intellectual Disability

Source: The JAMA, April 2024

Link: <https://jamanetwork.com/journals/jama/article-abstract/2817406>

Acetaminophen use during pregnancy was not associated with children's risk of autism, ADHD, or intellectual disability in sibling control analysis.

Overall Survival with Adjuvant Pembrolizumab in Renal-Cell Carcinoma

Source: The JAMA, April 2024

Link: <https://www.nejm.org/doi/full/10.1056/NEJMoa2312695>

Adjuvant pembrolizumab was associated with a significant and clinically meaningful improvement in overall survival, as compared with placebo, among participants with clear-cell renal-cell carcinoma at increased risk for recurrence after surgery.

Nirmatrelvir for Vaccinated or Unvaccinated Adult Outpatients with Covid-19

Source: The JAMA, April 2024

Link: <https://www.nejm.org/doi/full/10.1056/NEJMoa2309003>

The time to sustained alleviation of all signs and symptoms of Covid-19 did not differ significantly between participants who received nirmatrelvir–ritonavir and those who received placebo.

Calcitonin gene-related peptide antagonists as a first-line preventive therapy for migraine

Source: The Uptodate, April 2024

Link: <https://www.uptodate.com/contents/whats-new-in-drug-therapy>
https://www.uptodate.com/contents/preventive-treatment-of-episodic-migraine-in-adults?sectionName=Choosing+pharmacologic+therapy&topicRef=8360&anchor=H382445576&source=see_link#H382445576

Several calcitonin gene-related peptide (CGRP) antagonists available for migraine prevention have frequently been reserved for patients with an inadequate response to initial therapy. They may be effective for patients with severe symptoms or frequent migraines and may provide earlier benefit than other preventive agents, and the formulations given by injection may also be helpful for those who have difficulty with daily dosing.

Safety and efficacy of Givinostat in boys with Duchenne muscular dystrophy (EPIDYS): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial

Source: The Lancet, April 2024

Link: [https://www.thelancet.com/journals/laneur/article/PIIS1474-4422\(24\)00036-X/abstract](https://www.thelancet.com/journals/laneur/article/PIIS1474-4422(24)00036-X/abstract)

Among ambulant boys with Duchenne muscular dystrophy, results of the four-stair climb assessment worsened in both groups over the study period; however, the decline was significantly smaller with Givinostat than with placebo. The dose of Givinostat was reduced after an interim safety analysis, but no new safety signals were reported. An ongoing extension study is evaluating the long-term safety and efficacy of Givinostat in patients with Duchenne muscular dystrophy.

TRIFLURIDINE/TIPIRACIL (FTD/TPI) with or without bevacizumab in previously treated patients with esophago-gastric adenocarcinoma, a randomised phase III trial

Source: The Lancet, April 2024

Link: [https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(24\)00100-7/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(24)00100-7/fulltext)

In patients with pre-treated metastatic esophago-gastric cancer, trifluridine-tipiracil plus bevacizumab, compared to trifluridine-tipiracil monotherapy, did not significantly prolong progression-free survival. The combination of trifluridine-tipiracil with bevacizumab was well tolerated without increase in severe neutropenia and no new safety signals.

III. Devices

Digital technologies to deliver pulmonary rehabilitation programmes for adults with COPD: early value assessment

Source: The NICE, April 2024

Link: <https://www.nice.org.uk/guidance/hte18>

Digital technologies to deliver pulmonary rehabilitation for chronic obstructive pulmonary disease (COPD) provide parts of face-to-face pulmonary rehabilitation. Pulmonary rehabilitation programmes should last at least 6 weeks and include an in-person assessment before starting and after completion, physical training, disease education, and nutritional, psychological and behavioral interventions.

Kurin Lock for blood culture collection

Source: The NICE, April 2024

Link: <https://www.nice.org.uk/guidance/mtg77>

Kurin Lock (Iskus Health Ltd) is a CE-marked class IIa medical device, intended for use in collecting blood samples to check for the presence of infections. The Kurin Lock device consists of a needle, a flash chamber to collect,

isolate and display the first 0.15 ml of blood drawn, and a tube to collect the remaining blood sample, which goes on to be cultured and analysed.

IV. Treatment Guidelines

Endometriosis: diagnosis and management

Source: The NICE, April 2024

Link: <https://www.nice.org.uk/guidance/ng73>

This guideline covers diagnosing and managing endometriosis. It aims to raise awareness of the symptoms of endometriosis, and to provide clear advice on what action to take when women and people with signs and symptoms first present in healthcare settings. It also provides advice on the range of treatments available.

Epidermal radiotherapy using rhenium-188 paste for non-melanoma skin cancer

Source: The NICE, April 2024

Link: <https://www.nice.org.uk/guidance/ipg784>

Epidermal radiotherapy using rhenium-188 paste for non-melanoma skin cancer. This involves radioactive paste being spread on foil over the top of the cancer, to destroy the cancer cells.

V. Healthcare Administration

Implementation of a Continuous Patient Monitoring System in the Hospital Setting: A Qualitative Study

Source: The JCI, April 2024

Link: [https://www.jointcommissionjournal.com/article/S1553-7250\(23\)00267-2/abstract](https://www.jointcommissionjournal.com/article/S1553-7250(23)00267-2/abstract)

In addition to understanding the pre-implementation anticipated barriers to implementation and establishing shared value before implementation, future recommendations include studying strategies for optimal tailoring of education to each user group, identifying and reinforcing positive process changes after implementation, and including patient experience as the overarching element in frameworks for digital tool implementation.

Harnessing In Situ Simulation to Identify Human Errors and Latent Safety Threats in Adult Tracheostomy Care

Source: The JCI, April 2024

Link: [https://www.jointcommissionjournal.com/article/S1553-7250\(23\)00287-8/abstract](https://www.jointcommissionjournal.com/article/S1553-7250(23)00287-8/abstract)

An in situ simulation-based quality improvement approach shed light on human errors and LSTs associated with tracheostomy care across multiple settings in one health system. This method of engaging frontline health care provider key stakeholders will inform the development, adaptation, and implementation of interventions.