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Editorial

Dear Colleagues

It is encouraging to note that several new therapies have been approved recently, for various medical conditions e.g. **Reybota** for the prevention of recurrence of Clostridioides difficile infection (CDI) in adults, **Tzielid** to delay the onset of stage 3 type 1 diabetes in adults and in pediatric patients, 8 years and older who currently have stage 2 type 1 diabetes. Apart from this, **Selpercatinib** has been approved to treat adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged transfection (RET) gene fusion. It has been reported that the addition of **Brentuximab Vedotin** to standard chemotherapy for Pediatric High-Risk Hodgkin's Lymphoma, resulted in superior efficacy, with a 59% lower risk of an event or death, and no increase in the incidence of toxic effects at three years.

Gene therapy is penetrating slowly into the clinical practice for many diseases. FDA has approved the first Gene therapy to treat adults with Hemophilia B, using **Hemgenix**, an adeno-associated virus vector-based gene therapy. Trials are being done on different vaccines to evaluate their efficacy in multiple conditions. In a multi-centre study, it was found that a third dose of COVID-19 vaccine induced a boost in antibody binding in immunosuppressed patients with Inflammatory Bowel Disease but these responses were reduced in patients taking infliximab, infliximab plus thiopurine, and tofacitinib. Tofacitinib was also associated with reduced T-cell responses. A study from Bangladesh reported that the **RotaTeq** induced a higher magnitude and longer duration of rotavirus IgA response than **Rotarix** in this setting, where child mortality is high. Additional vaccination strategies should be evaluated to overcome the suboptimal performance of current oral rotavirus vaccines in these settings.

Newer devices are coming to the foray of surgeons and physicians to use for their patients. Recently, **Optilume** (a urethral balloon coated with paclitaxel), has been indicated for managing urethral stricture disease in 'adult males'. It is designed to be used as a drug-coated dilation balloon for a urethral stricture that is 3 cm or less in length. A newer laser vaporisation technique (**GreenLight XPS**) to treat Benign Prostatic Hyperplasia works by removing excess prostate tissue using laser vaporization (a procedure known as photoselective vaporization of the prostate [PVP]). A laser fibre is passed through a cystoscope to vaporize the enlarged prostate, leaving a clear urethral channel. In 'coagulation' mode, it can also seal (cauterize) any bleeding vessels that may result from PVP.

New treatment guidelines are being developed on a regular basis to help optimize various treatments. NICE has published guidelines for diagnosing and treating an **aneurysmal subarachnoid haemorrhage** and its complications. It provides recommendations to improve diagnosis and ensure that the most effective treatments are offered. It includes guidance on follow-up care and information for people (aged 16 and over) who have had an aneurysmal subarachnoid haemorrhage, their families and carers. Similarly, guidelines for **percutaneous ultrasound-guided microwave ablation** for symptomatic benign thyroid nodules has been published by NICE. This involves inserting a thin wire into the nodule under local anaesthetic and guiding it into position using ultrasound. Microwaves from the wire heat the nodule to ablate it.

Health care administration policies play a crucial role in the prevention and management of **sepsis**. It is suggested that the Emergency Department (ED) performance in sepsis care may exceed overall hospital performance inclusive of all inpatients. Sepsis quality measurement and sepsis QI efforts may be best guided by separating ED sepsis cases from in-hospital sepsis cases as is done for other acute time-sensitive conditions. The role of hospital administration in reducing the **diagnostic errors** is critical. In a research, 10 safety practices were identified to help organizations conduct a proactive, systematic assessment of risks to timely and accurate diagnosis.

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I. Drugs

FDA Approves First Fecal Microbiota Product

Source: The FDA, November 2022

Link: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-fecal-microbiota-product>

Rebyota is approved for the prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older. It is for use after an individual has completed antibiotic treatment for recurrent CDI.

FDA Approves First Gene Therapy to Treat Adults with Hemophilia B

Source: The FDA, November 2022

Link: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-treat-adults-hemophilia-b>

Hemgenix, an adeno-associated virus vector-based gene therapy for the treatment of adults with Hemophilia B who currently use Factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes.

FDA Approves First Drug That Can Delay Onset of Type 1 Diabetes

Source: The FDA, November 2022

Link: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-can-delay-onset-type-1-diabetes>

Tzield injection to delay the onset of stage 3 type 1 diabetes in adults and pediatric patients 8 years and older who currently have stage 2 type 1 diabetes.

II. Clinical Research

Selpercatinib Receives Regular Approval for Non–Small Cell Lung Cancer

Source: The JAMA, November 2022

Link: <https://jamanetwork.com/journals/jama/article-abstract/2797894>

Selpercatinib was granted regular approval to treat adults with locally advanced or metastatic non–small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion.

COVID-19 vaccine-induced antibody and T-cell responses in immunosuppressed patients with inflammatory bowel disease after the third vaccine dose (VIP): a multicentre, prospective, case-control study

Source: The Lancet, November 2022

Link: [https://www.thelancet.com/journals/langas/article/PIIS2468-1253\(22\)00274-6/fulltext](https://www.thelancet.com/journals/langas/article/PIIS2468-1253(22)00274-6/fulltext)

A third dose of COVID-19 vaccine induced a boost in antibody binding in immunosuppressed patients with IBD, but these responses were reduced in patients taking infliximab, infliximab plus thiopurine, and tofacitinib. Tofacitinib was also associated with reduced T-cell responses.

Head-to-head comparison of the immunogenicity of RotaTaq and Rotarix rotavirus vaccines and factors associated with seroresponse in infants in Bangladesh: a randomised, controlled, open-label, parallel, phase 4 trial

Source: The Lancet, November 2022

Link: [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(22\)00368-1/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00368-1/fulltext)

RotaTeq induced a higher magnitude and longer duration of rotavirus IgA response than Rotarix in this high child mortality setting. Additional vaccination strategies should be evaluated to overcome the suboptimal performance of current oral rotavirus vaccines in these settings.

Brentuximab Vedotin with Chemotherapy in Pediatric High-Risk Hodgkin's Lymphoma

Source: The NEJM, November 2022

Link: <https://www.nejm.org/doi/full/10.1056/NEJMoa2206660>

The addition of brentuximab vedotin to standard chemotherapy resulted in superior efficacy, with a 59% lower risk of an event or death, and no increase in the incidence of toxic effects at 3 years.

Evaluation of mRNA-1273 Vaccine in Children 6 Months to 5 Years of Age

Source: The NEJM, November 2022

Link: <https://www.nejm.org/doi/full/10.1056/NEJMoa2209367>

Two 25- μ g doses of the mRNA-1273 vaccine were found to be safe in children 6 months to 5 years of age and elicited immune responses that were noninferior to those in young adults.

III. Devices

Optilume for treating recurrent bulbar urethral strictures

Source: The NICE, November 2022

Link: <https://www.nice.org.uk/guidance/mtg73/chapter/2-The-technology>

Optilume is a urethral balloon coated with paclitaxel. It is indicated for managing urethral stricture disease in 'adult males'. It is designed to be used as a drug-coated dilation balloon for a urethral stricture that is 3 cm or less in length.

GreenLight XPS for treating benign prostatic hyperplasia

Source: The NICE, November 2022

Link: <https://www.nice.org.uk/guidance/mtg74/chapter/2-The-technology>

GreenLight XPS is a 180 W, 532 nm wavelength laser system intended to treat benign prostatic hyperplasia (BPH). It works by removing excess prostate tissue using laser vaporisation (a procedure known as photoselective vaporisation of the prostate [PVP]). A laser fibre is passed through a cystoscope to vaporise the enlarged prostate, leaving a clear urethral channel. In 'coagulation' mode, GreenLight XPS can also seal (cauterise) any bleeding vessels that may result from PVP.

IV. Treatment Guidelines

Subarachnoid haemorrhage caused by a ruptured aneurysm: diagnosis and management

Source: The NICE, November 2022

Link: <https://www.nice.org.uk/guidance/ng228>

Diagnosing and treating an aneurysmal subarachnoid haemorrhage and its complications. It provides recommendations to improve diagnosis and ensure that the most effective treatments are offered. It includes guidance on follow-up care and information for people (aged 16 and over) who have had an aneurysmal subarachnoid haemorrhage, their families and carers.

Percutaneous ultrasound-guided microwave ablation for symptomatic benign thyroid nodules

Source: The NICE, November 2022

Link: <https://www.nice.org.uk/guidance/ipg743>

Percutaneous ultrasound-guided microwave ablation for symptomatic benign thyroid nodules . This involves inserting a thin wire into the nodule under local anaesthetic and guiding it into position using ultrasound. Microwaves from the wire heat the nodule to destroy it (ablation).

CDC updates opioid prescribing guidelines

Source: The Uptodate, November 2022

Link: <https://www.uptodate.com/contents/whats-new-in-anesthesiology>

The guideline is intended for clinicians who prescribe opioids to outpatients ≥ 18 years of age and does not apply to pain related to sickle cell disease, cancer, palliative care, or end of life care

V. Healthcare Administration

Improving Sepsis Management Through the Emergency Quality Network Sepsis Initiative

Source: The NICE, November 2022

Link: [https://www.jointcommissionjournal.com/article/S1553-7250\(22\)00179-9/fulltext](https://www.jointcommissionjournal.com/article/S1553-7250(22)00179-9/fulltext)

Preliminary benchmarking results demonstrate a weak, statistically significant correlation with subsequent publicly reported CMS SEP-1 scores and suggest that ED performance in sepsis care may exceed overall hospital performance inclusive of all inpatients. Sepsis quality measurement and sepsis QI efforts may be best guided by separating ED sepsis cases from in-hospital sepsis cases as is done for other acute time-sensitive conditions.

Developing the Safer Dx Checklist of Ten Safety Recommendations for Health Care Organizations to Address Diagnostic Errors

Source: The NICE, November 2022

Link: [https://www.jointcommissionjournal.com/article/S1553-7250\(22\)00180-5/fulltext](https://www.jointcommissionjournal.com/article/S1553-7250(22)00180-5/fulltext)

The researchers identified 10 safety practices to help organizations conduct a proactive, systematic assessment of risks to timely and accurate diagnosis. The Safer Dx Checklist can enable HCOs to begin implementing strategies to address diagnostic error.