What's new in

کتابخانه بیمارستان کوثر

نوامبر-دسامبر ۲۰۲۵

GENERAL DRUG THERAPY

Fish oil supplements for patients on maintenance dialysis

(November 2025)

Patients on dialysis are at high risk of cardiovascular (CV) morbidity and mortality. In a trial in which over 1200 patients on maintenance hemodialysis were randomly assigned to either high-dose fish oil supplementation or placebo, the rate of serious CV events (ie, CV death, nonfatal myocardial infarction, nonfatal stroke, and peripheral vascular disease leading to amputation) was lower in the fish oil group during 3.5 years of follow-up (0.31 versus 0.61 per 1000 patient-days) [1]. The benefit in patients without a history of CV disease (approximately two-thirds of the study population) was similar to that in patients with such a history. However, fish oil did not lead to a statistically significant reduction in all-cause mortality. Based on these data, we now suggest fish oil supplements for patients on maintenance dialysis. (See "Secondary prevention of cardiovascular disease in end-stage kidney disease (dialysis)", section on 'Fish oil'.)

ong-term antiplatelet therapy after percutaneous coronary intervention in patients taking oral anticoagulation (November 2025)

LPatients with an indication for oral anticoagulation (OAC) who undergo percutaneous coronary intervention (PCI) often receive combination antithrombotic therapy (ie, OAC plus an antiplatelet medication) indefinitely; however, it is uncertain whether long-term antiplatelet therapy is necessary. Two recent trials addressed this question:

- A trial in over 800 patients with stent placement >6 months prior to enrollment and current treatment with long-term OAC found that participants randomly assigned to aspirin had higher rates of death and major bleeding compared with those assigned to placebo [2].
- A trial in over 900 patients with stent placement >12 months prior to enrollment found that patients randomly assigned to direct oral anticoagulant (DOAC) monotherapy had lower rates of a composite endpoint of death, myocardial infarction, stent thrombosis, stroke, systemic embolism, and clinically important bleeding compared with those assigned to combination therapy (DOAC plus clopidogrel); this difference was driven primarily by a reduction in bleeding [3].

For most patients on long-term OAC, we now suggest not continuing antiplatelet therapy indefinitely, and typically stop 6 to 12 months after PCI. However, for selected patients at very high risk of thrombotic events, it is reasonable to continue a single antiplatelet drug. (See "Coronary artery disease patients requiring combined anticoagulant and antiplatelet therapy", section on 'Long-term therapy studies'.)

ADVERSE REACTIONS AND WARNINGS

Immune thrombocytopenia from immune checkpoint inhibitors (December 2025)

Immune checkpoint inhibitors (ICIs) are a special case of drug-induced immune thrombocytopenia (DITP) because the drug may be critical for cancer therapy and there may not be an obvious alternative. In a new report evaluating over 86,000 individuals treated with an ICI, including 214 cases of DITP (incidence 0.25 percent), risk factors for DITP included lower baseline platelet count, combination ICI therapy, stage 4 cancer, and additional immune-related adverse events [8]. Platelet counts recovered in three-fourths, with glucocorticoids as the most common treatment. Approximately one-third were retreated with an ICI, and approximately one-third of those had recurrent DITP. Mortality was higher in individuals with ICI-associated DITP and correlated with thrombocytopenia severity. These data may be useful when weighing the risks and benefits of restarting an ICI. (See "Drug-induced immune thrombocytopenia", section on 'Immune checkpoint inhibitors'.)

Labeling changes to low-dose vaginal estrogen boxed warning
(December 2025)

Low-dose vaginal estrogen is the most effective treatment for moderate to severe symptoms of vaginal atrophy. Despite a lack of adverse safety data linking vaginal estrogen to an increased risk of breast or endometrial cancer, cardiovascular disease, venous thrombosis, or stroke, low-dose vaginal estrogen carried the same box warning as systemic hormone therapy. In November 2025, in addition to other changes, the US Food and Drug Administration advised manufacturers to remove the boxed warning from low-dose vaginal estrogen products [9]. In our practice, we counsel patients that the change in labeling highlights that low-dose vaginal estrogen is a safe treatment option for most patients with genitourinary syndrome of menopause, as well as other patients with hypoestrogenism (eg, those who are postpartum and/or lactating). (See "Genitourinary syndrome of menopause (vulvovaginal atrophy): Treatment", section on 'Serum absorption'.)

Increased United States Emergency Department visits for cannabinoid hyperemesis syndrome (December 2025)

Previous studies have reported rising rates of cannabinoid hyperemesis syndrome (CHS), which causes episodic vomiting and intense abdominal pain in some individuals with prolonged, nearly daily cannabis use. A cross-sectional study of over 188 million United States emergency department (ED) visits found that from 2016 to 2020, visits for CHS sharply increased from 4 to 33 per 100,000 visits, and have since plateaued but remain elevated [10]. These findings highlight the medical burden of CHS, can help inform policy, and should remind ED clinicians to ask about cannabis use in patients with cyclic vomiting and abdominal pain. (See "Cannabinoid hyperemesis syndrome", section on 'Epidemiology'.)

Antidepressants and treatment-emergent insomnia in youth
(November 2025)

- Insomnia, which is a symptom of pediatric major depression, may also be precipitated or exacerbated by antidepressants. In a meta-analysis of 20 randomized trials, the incidence of treatment-emergent insomnia was modestly greater in youth treated with selective serotonin reuptake inhibitors (SSRIs) or serotonin-norepinephrine reuptake inhibitors (SNRIs) than with placebo (6 percent versus 4 percent) [11]. Additional analyses found that the risk of insomnia with SSRIs or SNRIs was comparable, and that the risk was greatest with sertraline and least with duloxetine. Youth receiving antidepressants for depression should be assessed for insomnia at baseline and subsequently monitored for changes in insomnia, as well as other symptoms. (See "Pediatric unipolar depression and pharmacotherapy: General principles", section on 'Treatment-emergent insomnia'.)

RECENT APPROVALS - ANTIMICROBIALS

Gepotidacin and zoliflodacin for urogenital gonorrhea

(December 2025)

The emergence of *Neisseria gonorrhoeae* with decreased susceptibility to cephalosporins underscores the need for new antibiotic therapies. The US Food and Drug Administration recently approved two novel oral antibiotics, gepotidacin [18] and zoliflodacin [19], for uncomplicated urogenital gonorrhea in individuals 12 years and older. In randomized trials comparing these agents with ceftriaxone plus azithromycin, microbial cure rates were similar with gepotidacin [20] and were within the prespecified noninferiority margin with zoliflodacin [21]. Efficacy for extragenital infection has not been established. The optimal role of these agents is uncertain; we reserve them for urogenital gonorrhea in nonpregnant individuals when ceftriaxone and other alternative agents cannot be used. (See "Treatment of uncomplicated gonorrhea (*Neisseria gonorrhoeae* infection) in adults and adolescents", section on 'Novel alternative agents'.)

RECENT APPROVALS
DERMATOLOGIC AND ALLERGY THERAPIES

Two new agents for prophylaxis in hereditary angioedema

(July 2025, Modified November 2025)

- **ECENT APPROVALS - DERMATOLOGIC AND ALLERGY THERAPIES**
- Hereditary angioedema due to C1 inhibitor deficiency is a rare genetic disorder characterized by recurrent episodes of angioedema affecting the skin or mucosal linings of the gastrointestinal tract and throat. In 2025, two new prophylactic agents received regulatory approval for patients 12 years of age and older, increasing options for control of this disease (table 2) [25,26]. Studies directly comparing the new drugs with each other or existing drugs are not available.
- ●Garadacimab is a novel monoclonal antibody that inhibits activated factor XII and prevents excessive bradykinin formation. In a six-month randomized trial comparing monthly subcutaneous garadacimab or placebo in 64 patients, mean attack rates were 0.27 and 2.01 per month in the garadacimab and placebo groups, respectively [27]. (See "Hereditary angioedema (due to C1 inhibitor deficiency): General care and long-term prophylaxis", section on 'Garadacimab'.)
- ●Donidalorsen is a ligand-conjugated antisense oligonucleotide that inhibits prekallikrein expression. In a randomized trial comparing monthly or bimonthly subcutaneous donidalorsen or placebo in 90 patients, the time-normalized number of confirmed attacks per month was 0.44, 1.02, and 2.26 in the four-week, eight-week, and placebo groups, respectively; it was well tolerated [26,28]. (See "Hereditary angioedema (due to C1 inhibitor deficiency): General care and long-term prophylaxis", section on 'Donidalorsen'.)

RECENT APPROVALS
HEMATOLOGIC AND ANTICOAGULANT

R2 plus either tafasitamab or epcoritamab for relapsed follicular lymphoma (July 2025, Modified December 2025)

Lenalidomide plus rituximab (R^2) is one of our preferred regimens for the treatment of relapsed follicular lymphoma (FL). Data from two international, randomized trials suggest that the addition of the anti-CD19 antibody tafasitamab or the anti-CD3xCD20 bispecific antibody epcoritamab to R^2 improves progression-free survival, albeit with an increase in toxicity, primarily infectious complications [32-35]. Tafasitamab and epcoritamab now have regulatory approval in the United States for the treatment of relapsed or refractory FL when given in combination with R^2. The decision to incorporate these agents is individualized, weighing the improved efficacy versus the burden of frequent infusions, increased cost, and potential toxicity. Select fit patients may elect to receive R^2 plus either tafasitamab or epcoritamab, recognizing that the data are limited. (See "Treatment of relapsed or refractory follicular lymphoma", section on 'Efficacy and toxicity'.)

Investigational use of mitapivat in thalassemia

(June 2025, Modified December 2025)

- Mitapivat is a small molecule that activates pyruvate kinase (PK), originally developed for individuals with PK deficiency but with potential use in other anemias. Mitapivat was approved for adults with alpha or beta thalassemia in December 2025 based on a randomized trial in 194 patients with non-transfusion-dependent alpha or beta thalassemia and hemoglobin <10 g/L [36]. The dose is 100 mg twice daily. Compared with the placebo arm, individuals on the mitapivat arm were more likely to have a hemoglobin increase (42 percent versus 2 percent with placebo) and to have improvements in fatigue scores; there were no serious adverse events.
(See "Management of thalassemia", section on 'Mitapivat'.)

RECENT APPROVALS
ONCOLOGIC

Perioperative chemoimmunotherapy for locally advanced resectable gastric and gastroesophageal junction adenocarcinoma (August 2025, Modified December 2025)

- The US Food and Drug Administration (FDA) approved durvalumab plus fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) as perioperative treatment, followed by single-agent durvalumab, for adult patients with resectable gastric or gastroesophageal junction (GEJ) adenocarcinoma [45]. This approval is based on a randomized trial of approximately 950 such patients, in whom perioperative durvalumab plus FLOT improved two-year event-free survival (67 versus 59 percent) relative to perioperative placebo plus FLOT, and was well tolerated [46]. This benefit was mostly driven by patients with tumor area positivity (TAP) score ≥1 percent. For patients with locally advanced resectable gastric and GEJ adenocarcinoma that is mismatch repair proficient and has a combined positive score (CPS) ≥1 or TAP score ≥1 percent, we suggest the addition of perioperative durvalumab to FLOT. (See "Neoadjuvant and adjuvant therapy for gastric cancer", section on 'Durvalumab plus FLOT' and "Neoadjuvant and adjuvant therapy for locally advanced resectable gastroesophageal junction and gastric cardia adenocarcinoma", section on 'Durvalumab plus FLOT'.)

RECENT APPROVALS
OTHER

Guselkumab approved for treatment of psoriatic juvenile idiopathic arthritis (November 2025)

There are growing treatment options for psoriatic juvenile idiopathic arthritis (psJIA), a form of chronic inflammatory arthritis that can lead to irreversible joint damage and disability. In September 2025, the US Food and Drug Administration approved guselkumab, a human monoclonal antibody targeting interleukin 23, for children with psJIA ≥6 years of age [52]. Approval was based upon extrapolation from efficacy data in adult psoriatic arthritis and safety and pharmacokinetic data in pediatric plaque psoriasis. Guselkumab can be used in psJIA as an alternative to tumor necrosis factor inhibitors in patients with persistent peripheral arthritis despite treatment with methotrexate or sulfasalazine, and as a third-line therapy for refractory axial arthritis. (See "Psoriatic juvenile idiopathic arthritis: Management and prognosis", section on 'Peripheral arthritis'.)

Vaccines and autism spectrum disorder (December 2025)

The United States Centers for Disease Control has published a statement calling for a re-examination of the possibility that infant vaccines may cause autism, suspending its prior conclusion that vaccines do not cause autism [66]. In a new systematic review of data from over 30 studies conducted in multiple countries from 2010 to 2025, the World Health Organization's Global Advisory Committee on Vaccine Safety concluded that the evidence does not support a causal relationship between vaccines, vaccine constituents, and autism [67]. These findings reaffirm results of prior high-quality studies. Given the extent of existing evidence, we concur with the American Academy of Pediatrics and other scientific societies that vaccines are not a contributing factor in the development of autism spectrum disorder. (See "Autism spectrum disorder and chronic disease: No evidence for vaccines or thimerosal as a contributing factor", section on 'Public concern about a potential association between vaccines and ASD'.)

Respiratory syncytial virus vaccination in patients at risk for severe disease (December 2025)

- Evidence to support respiratory syncytial virus (RSV) vaccination in older adults is mounting. In a randomized trial of over 130,000 adults ≥60 years old, vaccine efficacy against hospitalization for RSV was 83 percent [68]; in a meta-analysis of three trials of adults ≥75 years old, it was 77 percent against RSV-associated lower respiratory tract illness [69]. These support our suggestion to vaccinate adults ≥75 years of age and those 60 to 74 years of age at risk for severe disease (table 3). We also suggest vaccination for younger adults with moderate to severe immunocompromise (table 4), particularly lung transplant and hematopoietic cell recipients. This approach for immunocompromised patients is consistent with recent guideline recommendations from the Infectious Disease Society of America [70]; however, some clinicians may choose to defer vaccination in such patients <50 years of age, since data on the efficacy and the long-term durability of vaccination are more limited. (See "Respiratory syncytial virus infection in adults", section on 'Persons ≥18 to 59 at risk for severe disease'.)

AAP continues to recommend a universal birth dose of hepatitis B vaccine (December 2025)

Universal hepatitis B vaccination at birth has been a long-standing element of the United States' strategy to eliminate hepatitis B infection and has been associated with substantial decreases in the incidence of childhood infection. The Centers for Disease Control and Prevention recently withdrew the recommendation in favor of individualized decision-making on when and whether to vaccinate children born to mothers with a negative hepatitis B surface antigen because of their low risk of exposure [71]. However, hepatitis B vaccination at birth serves as an important safety net when maternal infection is not accurately identified or when there is other risk for infection in early childhood, and no new data have emerged to challenge its safety and efficacy. We agree with the American Academy of Pediatrics (AAP) and other expert organizations that continue to recommend universal infant hepatitis B vaccination, including a dose within 24 hours of birth. (See "Hepatitis B virus immunization in infants, children, and adolescents", section on 'Efficacy and effectiveness' and "Hepatitis B virus immunization in infants, children, and adolescents", section on 'In the United States'.)

Single-dose HPV vaccine schedule (December 2025)

Human papillomavirus (HPV) vaccination effectively prevents cervical cancer, but vaccine hesitancy and logistical barriers limit vaccine uptake globally. While the United States recommends a two- or three-dose HPV vaccine series, growing evidence lends support to a single-dose approach. In a randomized trial of over 20,000 girls aged 12 to 16 years old in Costa Rica, single-dose or two-dose vaccination similarly prevented incident HPV16 or HPV18 infection over five years (97 percent vaccine efficacy or higher) [72]. The single-dose HPV vaccine schedule is an option recommended by the World Health Organization and in other countries. (See "Human papillomavirus vaccination", section on 'Immunization schedule'.)

Vaccine effectiveness against respiratory viruses

(November 2025)

Severe infections with influenza, respiratory syncytial virus (RSV), and coronavirus disease 2019 (COVID-19) are all preventable by vaccination. A systematic review of over 500 trials and observational studies estimated pooled vaccine effectiveness against infection-associated hospitalization in various populations from 2023 to mid-2025: 67 and 48 percent for influenza vaccination in children and adults 18 to 64 years old, respectively; 79 percent for RSV vaccination in adults 60 years and older; and 46 to 50 percent for COVID-19 vaccination in adults [73]. Potential safety issues identified have been well described (rare risks of myocarditis with COVID-19 vaccines and Guillain-Barre with the RSVpreF vaccine). Concomitant administration of the vaccines was not associated with adverse immunogenicity or safety outcomes. These data highlight the benefits of vaccination against respiratory viruses and support our recommendations on each of these vaccines. (See "Seasonal influenza vaccination in adults", section on 'Overall efficacy'.)

High-dose influenza vaccine in older adults
(September 2025, Modified November 2025)

- Among patients ≥65 years, most studies comparing high-dose (HD) with standard-dose (SD) inactivated influenza vaccine have observed reductions in hospitalization with the HD vaccine, but sometimes the number of events was small. In a randomized trial among more than 100,000 adults ≥65 years in Spain, HD vaccine reduced hospitalization for influenza or pneumonia compared with SD vaccine (relative vaccine effectiveness 24 percent) [74]. In a similar trial among more than 330,000 adults ≥65 years in Denmark, hospitalization rates were similar between the groups (relative vaccine effectiveness 6 percent) [75]. In a prespecified pooled analysis of data from these two trials, HD vaccine reduced hospitalization for influenza or pneumonia compared with SD vaccine (relative vaccine effectiveness 8.8 percent) [76]. We continue to favor HD over SD vaccine for this patient group. (See "Seasonal influenza vaccination in adults", section on 'Patients 65 years and older'.)