

Advancing quality use of medicines in NSW

TAG Mail: January to June 2024 Cumulative Listing of Reports, Publications, Medication Safety

Fortnightly TAG Mail – resources list

20th June 2024

NSW TAG ACTIVITIES

Current Email Discussions

- -Local protocols for COVID-19 antivirals. Closes 28th June 2024
- -Feedback for TGA Proposed Updates to Medicine Labelling Rules. Closes 8th July 2024
- -Implementation of the Guiding Principles for Transition of Young People on Complex and/or Costly Medicines from Paediatric to Adult Care. Closes 12th July 2024

Recently Completed Email Discussions

- -Virtual Pharmacy Service for Patients being discharged from Hospital
- -Shingrix (updated following TAG General meeting 19th July)

Coming soon: Survey about protocols for critical care medicines.

Contact Sasha Bennett at <u>sasha.bennett@svha.org.au</u> for further information about any email discussions, publications or upcoming meetings.

EDITOR'S PICKS

AA: Clinical Decision Support as a Prevention Tool for Medication Errors in the Operating Room - link

AJHP: Evaluation of an electronic health record Drug Interaction Customization Editor (DICE) - link

AJHP: Practice-enhancing publications about the medication-use process in 2021 - link

AJHP: Critical care pharmacist perspectives on optimal practice models and prioritization of professional activities- link

AP: Editorial: Quality use of medicines: who owns it now? - link

AP: Deprescribing antihypertensive drugs in frail older adults - link

BJCP: Navigating methotrexate toxicity: Examining the therapeutic roles of folinic acid and glucarpidase - link

BJCP: Challenges for the improvement of valganciclovir prophylaxis in solid organ transplantation and the possible role of therapeutic drug monitoring in adults - <u>link</u>

BMJ: Wider use of tranexamic acid to reduce surgical bleeding could benefit patients and health systems - link

BMJ: Exploring different objectives in non-inferiority trials - link

BMJ: How an opioid giant deployed a playbook for moulding doctors' minds - link

BMJ QS: Editorial: Improving medication safety in both adults and children: what will it take? - link

CADTH: Infliximab for Immune Checkpoint Inhibitor Therapy-Related Toxicities - link

CADTH: Anticytokine Therapy and Corticosteroids for CRS and for Neurotoxicity Following T-Cell Engager or CAR T-Cell Therapy - <u>link</u>

DrugSaf: Risk factors associated with medication administration errors in children - link

EHJ: Low-dose aspirin for the prevention of atherosclerotic cardiovascular disease - link

EHJ: When cardiovascular medicines should be discontinued - link

EJCP: Inpatient case characteristics of SGLT2 inhibitor-associated diabetic ketoacidosis- link

IJCP: Characterising pharmacists' interventions in chronic non-cancer pain care-link

JAGS: Clinical impact of medication review and deprescribing in older inpatients- link

JAMA: Prolonged vs Intermittent Infusions of $\,\beta$ -Lactam Antibiotics in Adults with Sepsis or Septic Shock- $\underline{\text{link}}$

JAMA: Continuous vs Intermittent β -Lactam Antibiotic Infusions in Critically III Patients with Sepsislink JAMA: Povidone Iodine vs Chlorhexidine Gluconate in Alcohol for Preoperative Skin Antisepsis - <u>link</u> JPPR: Surface contamination of cytotoxic medicine in preparation and patient care areas in Australian hospitals- <u>link</u>

MDPI: Decoding Clozapine-Induced Agranulocytosis: Unraveling Interactions and Mitigation Strategies - link

PJ: - Pregabalin prescribing increases by almost 25% since restrictions imposed - link

OTHER NEWS

Australian Commission on Safety and Quality in Health Care (ACSQHC)

- Heavy Menstrual Bleeding Clinical Care Standard - report - media release - poster

NSW Health

- People aged 65 and over urged to book in for free flu vaccine as cases surge across NSW link
- Treatment of UTIs link
- Continuing Education Allowances in the Public Health System Nurses' And Midwives' (State) Award (PD2024_018)

TGA

- Update on the Vaping Reforms Bill 2024 link
- Update on the glucagon-like peptide-1 receptor agonists (GLP-1 RAs) pharmacy compounding changes $\underline{\text{link}}$

REPORTS AND PUBLICATIONS - AUSTRALIA

Agency for Clinical Innovation, NSW (ACI)

- The latest weekly Evidence Digest can be found here
- Management of traumatic haemorrhagic shock: Quick reference quide
- Clinical principles for specialist bereavement care in NSW link
- Perioperative care toolkit launched in new digital format link

Australian Commission on Safety and Quality in Health Care (ACSQHC)

- Introduction to High Risk Medicines - Updated eLearning Module - link

Australian Government Department of Health

- National 'Give Up For Good' campaign launched to tackle smoking and vaping - link - young people

Australian Institute for Health and Welfare (AIHW)

- National bowel cancer screening program monitoring report 2024 link factsheet
- Health of veterans: Australia's Health topic summary link
- Alcohol and other drug treatment services in Australia annual report link
- Chronic conditions and risk factors <u>updates</u>: Overweight & obesity; Heart, stroke & vascular diseases; Diabetes; Chronic kidney disease; Chronic musculoskeletal conditions; Chronic respiratory conditions; back problems; asthma; COPD; chronic conditions; gout; diet; OA; RA; multimorbidity; physical activity; alcohol & drug use treatment; veteran health

Australian Institute of Health Innovation (AIHI)

- Issue 20: The dangers of copying a previous order. Don't be a copycat
- Issue 21: The curious case of the 100-fold overdose

Deeble Institute

- Perspectives Brief No.31: Engaging stakeholders in healthcare innovation: How hard can it be?
- Issues <u>Brief No.55</u>: Harnessing data to improve patient care and prevent hospital-acquired complications
- Issues <u>Brief No.56</u>: Integrating oral health into primary healthcare for improved access to oral health care for rural and remote populations

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

PBS

- Update: Substitution for new brand of Budesonide + Formoterol listings - link

Pharmacy Council of NSW

- Cold Chain Management - link

TGA

- Update to listed medicine ingredients in June 2024 link
- Database of section 19A approvals to import and supply medicines to address medicine shortages

REPORTS AND PUBLICATIONS - INTERNATIONAL

Agency for Healthcare Research and Quality (AHRQ)

- Making Healthcare Safer IV—Summary of Findings on Year 1 Topics - link

Canadian Agency for Drugs and Technologies in Health

- Choline Supplementation for Infants, Children, and Pregnant People link
- Interferons, Glatiramer Acetate, and Minocycline for Relapsing-Remitting Multiple Sclerosis and Clinically Isolated Syndrome <u>link</u>
- Nabilone for Chronic Non-Cancer Pain link
- Infliximab for Immune Checkpoint Inhibitor Therapy-Related Toxicities link
- Anticytokine Therapy and Corticosteroids for Cytokine Release Syndrome and for Neurotoxicity Following T-Cell Engager or CAR T-Cell Therapy <u>link</u>

electronic Medicines Compendium (eMC) (UK)

- New products
- -- Finlee (dabrafenib mesilate) 10 mg dispersible tablets indicated in combination with trametinib for patients ≥ 1 year old with: low-grade glioma with a BRAF V600E mutation, or high-grade glioma with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment -- Spexotras (trametinib dimethyl sulfoxide) 0.05 mg/ml powder for oral solution indicated in combination with dabrafenib for patients ≥ 1 year old with: low-grade glioma with a BRAF V600E mutation, or high-grade glioma with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment
- Revised SPCs
- -- BOTOX Allergan includes paediatric neurogenic detrusor overactivity and overactive bladder under posology with corresponding data updated in the undesirable effects and pharmacodynamic sections -- Brilique (ticagrelor) data included from two RCTs which found continuing single antiplatelet therapy for 9 and 12 months, respectively, post PCI has been shown to decrease the risk of bleeding with no observed increase in risk of major adverse cardiovascular events vs continued DAPT -- Nilemdo (bempedoic acid) and Nustendi (ezetimibe, bempedoic acid) licensed in adults with
- -- Nilemdo (bempedoic acid) and Nustendi (ezetimibe, bempedoic acid) licensed in adults with established/high risk of atherosclerotic cardiovascular disease, as an adjunct to correction of other risk factors in patients on a maximum tolerated dose of a statin and not adequately controlled with additional ezetimibe
- -- Timodine (hydrocortisone, dimeticone, benzalkonium chloride, nystatin) cream is a mild steroid and now labelled as such to simplify advice for patients in line with regulatory requirements

European Medicines Agency (EMA)

- Faster access to clinical trial information in Europe - link

Food and Drug Administration (FDA) USA

- FDA updates guidance on interchangeability link
- 9 Things to Know About Biosimilars and Interchangeable Biosimilars link
- FDA issues agency-initiated proposed order regarding OTC monograph drugs containing acetaminophen link
- Approvals
- -- pembrolizumab with chemotherapy for primary advanced or recurrent endometrial carcinoma

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au An initiative of NSW clinical pharmacologists & pharmacists

- -- repotrectinib for adult and pediatric patients with NTRK gene fusion-positive solid tumors
- -- <u>imetelstat</u> for low- to intermediate-1 risk myelodysplastic syndromes with transfusion-dependent anemia
- -- Sofdra (sofpironium) to treat primary axillary hyperhidrosis
- -- <u>Elevidys</u> (delandistrogene moxeparvovec-rokl) expanded approval for patients with Duchenne muscular dystrophy
- -- Durvalumab expanded to Endometrial Cancer
- -- Sarilumab for Polyarticular JIA
- -- Iqirvo (<u>elafibranor</u>) for adults with primary biliary cholangitis who do not respond to or cannot tolerate ursodeoxycholic acid

NHS Scotland

- Accepted for use:
- -- Epcoritamab (Tepkinly®) for relapsed or refractory diffuse large B-cell lymphoma
- -- Etrasimod (Velsipity®) for ulcerative colitis
- -- Glofitamab (Columvi®) for relapsed or refractory diffuse large B-cell lymphoma
- -- Momelotinib (Omjjara®) for myelofibrosis-related splenomegaly or symptoms
- Accepted for restricted use:
- -- <u>Tirzepatide</u> (Mounjaro®) for weight management
- -- Voxelotor (Oxbryta®) for anaemia due to sickle cell disease (SCD)

National Institute for Health and Care Excellence (NICE) UK

- Pembrolizumab with trastuzumab and chemotherapy for untreated locally advanced unresectable or metastatic HER2-positive gastric or gastro-oesophageal junction adenocarcinoma (TA983)
- Voxelotor for treating haemolytic anaemia caused by sickle cell disease (TA981)
- Tafamidis for treating transthyretin amyloidosis with cardiomyopathy (TA984)

Specialist Pharmacy Services NHS UK

- Using and prescribing thiamine in alcohol dependence link
- New product evaluations May 2024 update
- Purchasing for safety link

The King's Fund (UK)

- Productivity in the NHS and health care sector - link

World Health Organisation (WHO)

- WHO releases report on state of development of antibacterials - link

MEDICATION SAFETY

electronic Medicines Compendium (eMC) (UK)

- Revised SPCs
- -- Alzain (pregabalin) suicidal ideation and behaviour reported in patients treated with anti-epileptic agents. Medical advice should be sought if signs emerge and consideration given to discontinuation
- -- Avelox (moxifloxacin) photosensitivity reactions and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) added to SPC as ADRs of unknown frequency
- -- Bimzelx (bimekizumab) treatment of active moderate to severe hidradenitis suppurativa (HS; acne inversa) in adults with an inadequate response to conventional systemic HS therapy added
- -- Dulcolax (bisacodyl) new trial data as main effect is on the distal part of gut bisacodyl is ineffective in altering digestion or absorption of calories or essential nutrients in the small intestine
- -- Epistatus (midazolam) may have enhanced effects and prolonged duration in elderly patients, with a half-life that may be prolonged up to 4 times therefore use with caution in these patients
- -- Jemperli (dostarlimab) maximum dilution volume for infusion solution (250mL) for 500mg & 1000mg doses; corresponding minimum concentration for 1000mg dose (from 2 mg/mL to 4mg/mL)

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- -- Lemsip (paracetamol, pseudoephedrine hydrochloride) addition of 'uncontrolled hypertension' and 'severe acute or chronic kidney disease or renal failure' as contraindications. Also cases of posterior reversible encephalopathy syndrome and reversible cerebral vasoconstriction syndrome reported
- -- Locoid (hydrocortisone butyrate) warning not to smoke or go near naked flames due to risk of severe burns as fabric in contact burns more easily & is a serious fire hazard. Washing clothing & bedding may reduce product build-up but not totally remove it. Also now labelled as moderate steroid.
- -- Magnevist (gadopentetic acid dimeglumine) must not be used intrathecally; serious, life-threatening and fatal cases, primarily with neurological reactions (e.g. coma, encephalopathy, seizures) reported
- -- Onpattro (patisiran sodium) list of premedication that should be given at least 60 minutes prior to the start of each infusion has been amended, to replace ranitidine 50mg with famotidine 20mg
- -- Oxbryta (voxelotor) pruritis (common) and angioedema (frequency not known) added as ADRs
- -- Robitussin (guaifenesin, pseudoephedrine hydrochloride) posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS) as ADRs which are rare pseudoephedrine adverse effects. Symptoms include sudden severe headache, nausea, vomiting & visual disturbances. Discontinue product if PRES/RCVS suspected
- -- Qdenga (dengue tetravalent vaccine live, attenuated) warning dengue diagnostic tests may be positive during vaccine viremia and cannot be used to distinguish vaccine viremia from wild type dengue infection
- -- Sivextro (tedizolid phosphate) following post-marketing experience that co-administration of tedizolid with serotonergic agents can increase risk of serotonin syndrome. These patients should be monitored for cognitive dysfunction, hyperpyrexia, hyperreflexia & incoordination
- -- Testavan (testosterone) transdermal gel updated to note the product contains 46.84%w/w ethanol, and it may cause a burning sensation on damaged skin. Because alcohol-based products are flammable, avoid fire, flame or smoking until the gel has dried
- -- Vitaros (alprostadil) cream updated to highlight that Vitaros contains 50mg/g (5%w/w) ethanol, and may cause a burning sensation on damaged skin
- -- Zinforo (ceftaroline fosamil) reports of hypersensitivity reactions which progressed to Kounis syndrome (acute allergic coronary arteriospasm that can result in myocardial infarction) with other beta-lactam antibiotics

EMA

- CAR T-cell medicines: PRAC identifies risk of secondary malignancies of T-cell origin link
- PRAC to perform a safety review of metamizole, a painkiller medicine link

Medicines and Healthcare products Regulatory Agency (MHRA) UK

- Drug Safety Update May 2024
- -- Topical steroids: introduction of new labelling and a reminder of the possibility of severe side effects, including Topical Steroid Withdrawal Reactions link

Specialist Pharmacy Services NHS UK

- Anticoagulant suggestions for adults with swallowing difficulties link
- Antiplatelet suggestions for adults with swallowing difficulties link
- PPI suggestions for adults with swallowing difficulties link

TGA

- Shortages of Vyvanse (lisdexamfetamine dimesilate) capsules link
- Serious Scarcity Substitution Instruments (SSSIs) link
- Making therapeutic goods safer for everyone new ADR reporting system link
- Compounded weight-loss medicines public awareness campaign link

PAPERS OF INTEREST

American Journal of Cardiology

- P2Y12 Inhibitor Monotherapy After Short-Term Dual Antiplatelet Therapy in Acute Coronary Syndrome - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

American Journal of Health-System Pharmacy (AJHP)

- Evaluation of an electronic health record Drug Interaction Customization Editor (DICE) link
- Determining QTc in acute care settings: What we (don't) know link
- A pilot project implementing a team-based approach for remote physiologic monitoring in an accountable care organization link
- How critical is it? Integrating critical care into the pharmacy didactic curriculum link
- Practice-enhancing publications about the medication-use process in 2021 link
- Critical care pharmacist perspectives on optimal practice models and prioritization of professional activities: A cross-sectional survey link
- Critical care clinical pharmacy value-based metrics: Time to terminate widget counting link
- Pharmacist consult to prevent hypoglycemia in adult inpatients with renal dysfunction link

Anesthesia & Analgesia

-Clinical Decision Support as a Prevention Tool for Medication Errors in the Operating Room: A Retrospective Cross-Sectional Study -<u>link</u>

Annals of Internal Medicine

- COVID-19 Vaccine Side Effects and Long-Term Neutralizing Antibody Response: A Prospective Cohort Study link
- In the clinic: Type 2 Diabetes link
- Metformin Use in the First Trimester of Pregnancy and Risk for Non-live Birth and Congenital Malformations: Emulating a Target Trial Using Real-World Data link
- Paternal Use of Metformin During the Sperm Development Period Preceding Conception and Risk for Major Congenital Malformations in Newborns <u>link</u>

Arthritis & Rheumatology

- Hydroxychloroquine Dose and Hospitalizations for Active Lupus - link

Australian Health Review

- Exploring palliative care practice and learning needs of allied health professionals in the Loddon Mallee region of Victoria: a cross-sectional survey link.google.com/
- Using emergency department data to define a 'mental health presentation' implications of different definitions on estimates of emergency department mental health workload <u>link</u>

Australian Prescriber

- Editorial: Quality use of medicines: who owns it now? link
- New and emerging drug therapies for Alzheimer disease link
- Controversies in the management of community-acquired pneumonia in adults link
- Deprescribing antihypertensive drugs in frail older adults link
- Medicinal mishap: Thiopurines and risk of lymphoproliferative disorders link
- Letter: Lipid-lowering therapy in patients with a 'normal' LDL-C link
- Letter: Additional preconception considerations for patients with diabetes link
- Latest News: Medicines Repurposing Program supporting new uses for existing medicines link
- New drug: Inclisiran for hypercholesterolaemia; Recombinant respiratory syncytial virus (RSV) vaccines for older adults, and pregnant women to prevent disease in their infant; Nirsevimab for prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in neonates and infants
- TGA Medicines Safety Update summary: Updated warnings about persistent sexual dysfunction for antidepressants $\underline{\mathsf{link}}$

British Journal of Clinical Pharmacology

- 'Under pressure': The role of therapeutic drug monitoring in the treatment of hypertension link
- Drug-drug interactions between gender-affirming hormone therapy and antiretrovirals for treatment/prevention of HIV $\underline{\text{link}}$
- In depth: The drug interaction between trimethoprim-sulfamethoxazole and folic acid/folinic acid link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Past, present and future of drug safety link
- Impact of CYP2D6*2A, CYP2D6*4 and CYP3A5*3 genetic polymorphisms on bisoprolol peak concentration and clinical response in acute coronary syndrome patients link
- Navigating methotrexate toxicity: Examining the therapeutic roles of folinic acid and glucarpidase link
- Challenges for the improvement of valganciclovir prophylaxis in solid organ transplantation and the possible role of therapeutic drug monitoring in adults <u>link</u>
- A potential novel treatment for cirrhosis-related ascites: Empagliflozin is safe and tolerable in advanced chronic liver disease link

British Journal of General Practice

- Interventions to improve medication adherence in adults with mental–physical multimorbidity in primary care: a systematic review link
- Estimating the prevalence of potential and actionable drug-gene interactions in Irish primary care: A cross-sectional study <u>link</u>

British Medical Journal (BMJ)

- Mailed feedback to primary care physicians on antibiotic prescribing for patients aged 65 years and older: pragmatic, factorial randomised controlled trial <u>link</u>
- Analysis: Why digital innovation may not reduce healthcare's environmental footprint link
- When I use a word .. .The languages of medicines—trade names, proprietary names, or brand-names link
- Antiplatelet therapy after coronary artery bypass surgery: five-year follow-up of randomised DACAB trial link
- Pigmented skin lesions link
- How an opioid giant deployed a playbook for moulding doctors' minds link
- Global burden of type 1 diabetes in adults aged 65 years and older, 1990-2019: population based study link
- Vitamin B12 deficiency: NICE guideline summary link
- Wider use of tranexamic acid to reduce surgical bleeding could benefit patients and health systems link
- Exploring different objectives in non-inferiority trials link
- Recognition, diagnosis, and early management of suspected sepsis: summary of updated NICE guidance link

BMJ Quality and Safety

- Global, regional and national time trends in incidence of adverse effects of medical treatment, 1990–2019: an age–period–cohort analysis from the Global Burden of Disease 2019 study link
- Systematic review: Rapid response systems, antibiotic stewardship and medication reconciliation: a scoping review on implementation factors, activities and outcomes <u>link</u>
- Editorial: Improving medication safety in both adults and children: what will it take? link
- Raising the barcode: improving medication safety behaviours through a behavioural science-informed feedback intervention <a href="https://link.gov/link.

Circulation

- Effect of Sacubitril/Valsartan on Cognitive Function in Patients with Heart Failure with Preserved Ejection Fraction: A Prespecified Analysis of PARAGON-HF - Link

Cochrane

- Immunosuppressive therapy for IgA nephropathy in children - link

Diabetes Care

- Efficacy and Safety of GLP-1 Medicines for Type 2 Diabetes and Obesity - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Impact of COVID-19 and Non-COVID-19 Hospitalized Pneumonia on Longer-Term Cardiovascular Mortality in People With Type 2 Diabetes: A Nationwide Prospective Cohort Study From Scotland - link

Drug Safety

- Risk factors associated with medication administration errors in children: a prospective direct observational study of paediatric inpatients - <u>link</u>

Drug and Therapeutics Bulletin

- DTB select: Safety update- psychiatric and sexual adverse effects with finasteride link
- DTB select: Switching frail older people with AF from a vitamin K antagonist to a DOAC link
- Republished case reports
- -- Angioedema without urticaria after recent initiation of celecoxib link
- -- Diagnostic dilemma: drug-induced vasculitis versus systemic vasculitis link
- -- Steroid-induced glaucoma: an avoidable cause of irreversible blindness link
- -- Methylphenidate-associated chest pain in a child link
- -- Acute eosinophilic pneumonia-like syndrome post-initiation of vortioxetine link

European Heart Journal

- Low-dose aspirin for the prevention of atherosclerotic cardiovascular disease link
- When cardiovascular medicines should be discontinued link
- Office measurement vs. ambulatory blood pressure monitoring: associations with mortality in patients with or without diabetes link
- Alcoholic cardiomyopathy: an update link
- Evinacumab in homozygous familial hypercholesterolaemia: long-term safety and efficacy link
- Perinatal depression and risk of maternal cardiovascular disease: a Swedish nationwide study link

European Journal of Hospital Pharmacy

- Inpatient case characteristics of SGLT2 inhibitor-associated diabetic ketoacidosis: a retrospective study link
- Harm to a child caused by the off-label use of prochlorperazine maleate tablets due to the discontinuation of licensed prochlorperazine mesilate liquid in the UK link
- Letter: HMGCR-associated myopathy in polymorbid patients with polypharmacy should not be attributed solely to statins <u>link</u>
- Physical compatibility of ceftriaxone and cefepime in 0.45% sodium chloride, Ringer's lactate solution, and Plasma-Lyte A \underline{link}
- Medication safety strategies in European adult, paediatric, and neonatal intensive care units: a cross-sectional survey link

Explor Res Clin Social Pharm

- Incidence of drug-related adverse events related to the use of high-alert drugs: a systematic review of randomized controlled trials - link

International Journal of Clinical Pharmacy

- Impact of pharmacist-evaluated clinical decision support system alerts on potentially missing or inappropriately prescribed proton pump inhibitors at hospital discharge: a retrospective cross-sectional study link
- Comparative efficacy and safety of six angiotensin II receptor blockers in hypertensive patients: a network meta-analysis $\underline{\text{link}}$
- Optimizing vancomycin dosing in pediatrics: a machine learning approach to predict trough concentrations in children under four years of age link
- Characterising pharmacists' interventions in chronic non-cancer pain care: a scoping review link
- Diagnostic evaluation of hypersensitivity reactions to arylpropionic acid derivatives: a descriptive observational study focusing on clinical characteristics and potential risk factors in children link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

International Journal for Quality in Health Care

- Prescribing antibiotics for children with dengue infection in Taiwan: Who are at risk and who are high prescribers? - link

JAGS

Clinical impact of medication review and deprescribing in older inpatients: A systematic review and meta-analysis- link

JAMA

- Prolonged vs Intermittent Infusions of β -Lactam Antibiotics in Adults with Sepsis or Septic Shock: A Systematic Review and Meta-Analysis \underline{link}
- Continuous vs Intermittent β -Lactam Antibiotic Infusions in Critically III Patients With Sepsis: The BLING III Randomized Clinical Trial link
- Management of Depression in Adults: A Review link
- Patient Page: What Should I Know About Recurrent UTIs in Older Women? link
- JAMA Guide to Statistics and Methods: Test-Negative Study Designs for Evaluating Vaccine Effectiveness <u>Link</u>
- Low-Dose Corticosteroids for Critically III Adults with Severe Pulmonary Infections: A Review link
- Dapagliflozin for Critically III Patients with Acute Organ Dysfunction: The DEFENDER Randomized Clinical Trial Inital <a href="In
- Povidone Iodine vs Chlorhexidine Gluconate in Alcohol for Preoperative Skin Antisepsis: A Randomized Clinical Trial Link
- Interventions for High Body Mass Index in Children and Adolescents: US Preventive Services Task Force Recommendation Statement <u>link</u>

JAMA Cardiology

- Climate Change and Cardiovascular Health: A Systematic Review link
- Postpartum Ambulatory Blood Pressure Patterns Following New-Onset Hypertensive Disorders of Pregnancy $\underline{\text{link}}$
- Multifaceted Intensive Blood Pressure Control Model in Older and Younger Individuals with Hypertension: A Randomized Clinical Trial link

JAMA Dermatology

- Clinical Characteristics Associated With Response to Biologics in the Treatment of Psoriasis: A Meta-analysis - <u>link</u>

JAMA Internal Medicine

- Nirmatrelvir-Ritonavir and Symptoms in Adults With Postacute Sequelae of SARS-CoV-2 Infection: The STOP-PASC Randomized Clinical Trial link
- Electronic Cigarettes vs Varenicline for Smoking Cessation in Adults: A Randomized Clinical Trial link
- Overdose, Behavioral Health Services, and Medications for Opioid Use Disorder After a Nonfatal Overdose link

JAMA Neurology

- Acetaminophen and Ibuprofen in Pediatric Central Nervous System Malaria: A Randomized Clinical Trial link
- Angiotensin Receptor Blockers for Hypertension and Risk of Epilepsy link

JAMA Oncology

- Cardiovascular Events and Androgen Receptor Signaling Inhibitors in Advanced Prostate Cancer: A Systematic Review and Meta-Analysis <u>link</u>
- Comprehensive Audiologic Analyses After Cisplatin-Based Chemotherapy link
- Home Time Among Older Adults with Acute Myeloid Leukemia Following Chemotherapy link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au An initiative of NSW clinical pharmacologists & pharmacists

Journal of Pharmacy Practice and Research (JPPR)

- Surface contamination of cytotoxic medicine in preparation and patient care areas in Australian hospitals: a retrospective cross-sectional study - link

Lancet

- Long-term colchicine for the prevention of vascular recurrent events in non-cardioembolic stroke (CONVINCE): a randomised controlled trial $\underline{\text{link}}$
- Persistent physical symptoms: definition, genesis, and management link
- Peptic ulcer disease link

Lancet Diabetes & Endocrinology

- Call for effective therapies for preventing dementia in people with type 2 diabetes - link

Lancet Gastroenterology and Hepatology

- Clinical management of liver cyst infections: an international, modified Delphi-based clinical decision framework - link

Lancet Haematology

- Thrombotic risk and features of patients with inferior vena cava agenesis: a multicentre, retrospective, observational study - link

Lancet Infectious Diseases

- Effectiveness and safety of modified fully oral 9-month treatment regimens for rifampicin-resistant tuberculosis: a prospective cohort study - link

Lancet Neurology

- Recent advances in diagnosing, managing, and understanding the pathophysiology of cluster headache <u>link</u>
- Tenecteplase versus alteplase for thrombolysis in patients selected by use of perfusion imaging within 4·5 h of onset of ischaemic stroke (TASTE): a multicentre, randomised, controlled, phase 3 non-inferiority trial link

Lancet Psychiatry

- Incidence of antidepressant discontinuation symptoms: a systematic review and meta-analysis - link

Lancet Public Health

- Early adulthood BMI and cardiovascular disease: a prospective cohort study from the China Kadoorie Biobank - link

Lancet Oncology

- Bortezomib, thalidomide, and dexamethasone with or without daratumumab and followed by daratumumab maintenance or observation in transplant-eligible newly diagnosed multiple myeloma: long-term follow-up of the CASSIOPEIA randomised controlled phase 3 trial - link

Lancet Respiratory Medicine

- Long-term outcomes of early exposure to repeated general anaesthesia in children with cystic fibrosis (CF-GAIN): a multicentre, open-label, randomised controlled phase 4 trial $\underline{\text{link}}$
- Editorial: Respiratory syncytial virus vaccines: the future is bright link
- Biological and therapeutic implications of the cancer-related germline mutation landscape in lung cancer link
- Potential for personalised and biomarker-quided COPD self-treatment approaches link

Molecular Diversity Preservation International (MDPI)

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

- Decoding Clozapine-Induced Agranulocytosis: Unraveling Interactions and Mitigation Strategies - link

Medical Journal of Australia

- A summary of the 2023 Society of Obstetric Medicine of Australia and New Zealand (SOMANZ) hypertension in pregnancy guideline <u>link</u>
- Dying of heart failure: how do we improve the experience? link

Nature

- Combined use of Donepezil and Memantine increases the probability of five-year survival of Alzheimer's disease patients - link

New England Journal of Medicine

- Bulevirtide Combined with Pegylated Interferon for Chronic Hepatitis D link
- Magnesium Disorders link
- Tirzepatide for Metabolic Dysfunction-Associated Steatohepatitis with Liver Fibrosis link
- A randomized trial of intravenous amino acids for kidney protection link
- Risk of Second Tumors and T-Cell Lymphoma after CAR T-Cell Therapy link
- Diets <u>lin</u>k
- Community-Based Cluster-Randomized Trial to Reduce Opioid Overdose Deaths link
- Reteplase versus Alteplase for Acute Ischemic Stroke link
- Stress Ulcer Prophylaxis during Invasive Mechanical Ventilation link
- Tenecteplase for Ischemic Stroke at 4.5 to 24 Hours without Thrombectomy link

Pediatrics

- Modification of Electronic Nicotine Delivery Systems Among Adolescents and Young Adults link
- Acute Kidney Injury in Neonates: A Meta-Analysis link
- Acute Kidney and Liver Injury Associated With Low-Dose Liraglutide in an Obese Adolescent Patient link
- Emergency Department Antibiotic Prescribing for Pediatric Urinary Tract Infections, 2011–2020 link
- Hospital Quality Indicators for Opioid-Exposed Infants: Results From an Expert Consensus Panel link

Pharmacotherapy

- Incidence of serious infections in the working-age Japanese adult population with rheumatoid arthritis treated with tumor necrosis factor- α inhibitors and interleukin-6 inhibitors: A nationwide retrospective cohort study - link

Pharmaceutical Journal

- Pregabalin prescribing increases by almost 25% since restrictions imposed link
- Conference report: Bariatric surgery produces greater and more durable weight loss than glucagon-like peptide-1 receptor agonists (GLP-1 RAs) and lifestyle interventions <u>link</u>
- Number of patients at risk of type 2 diabetes increases by half a million in one year link

Stroke

- Anticoagulation Versus Antiplatelets in Spontaneous Cervical Artery Dissection: A Systematic Review and Meta-Analysis - link

Thorax

- Early menopause and hormone therapy as determinants for lung health outcomes: a secondary analysis using the PLCO trial link
- Undertreating cardiovascular disease in people with chronic obstructive pulmonary disease (COPD)
- link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au An initiative of NSW clinical pharmacologists & pharmacists

- Quantifying sustained health system benefits of primary care-based integrated disease management for COPD: a 6-year interrupted time series study - link

CONSULTATIONS

Pharmacy Board of Australia

- Have your say on the draft Criminal history registration standard and supporting materials, closes 30 July 2024 - <u>link</u>

TGA

- Consultation: updates to Australian medicine labelling rules to support medicine safety, closes 11 July 2024 - <u>link</u>

WEBINARS & PODCASTS

Australian Prescriber Podcasts

- Episode 165 - Assessing, communicating and managing cardiovascular disease risk

FDA Division of Drug Information is presenting a series of CE webinars

- FDA Drug Topics: Fraudulent Drugs: You're Using What? - May 21, 2024

MJA Podcasts

- Episode 20: What patients need to know about gastric and oesophageal cancer

Purple Pen Podcast

- PPP 162 - Impetigo

UPCOMING EVENTS

Australian Commission on Safety and Quality in Health Care (ACSQHC)

- NMS 2024 - save the date, 19 November 2024 - link

Australian Government Department of Health

- Delivering high quality, person-centred palliative care in aged care, webinar, 25 June 2024 14:00-15:00 AEST - link - register

FDΔ

- Rx Drug Promotion and the Clear, Conspicuous, and Neutral Final Rule, virtual, 26 Jun 2024
- Understanding Current Use of Ketamine for Emerging Areas of Therapeutic Interest, hybrid, 27 June

Society of Hospital Pharmacists (SHPA)

- Medicines Management 2024 MM2024, Adelaide, 14-16 November 2024 – abstract submission closes 15 July 2024 - early-bird registration closes 11:59pm AEST Thursday 3 October 2024

Fortnightly TAG Mail - resources list 6th June 2024

NSW TAG ACTIVITIES

Recently Completed Email Discussions

Virtual Pharmacy Service for Patients being discharged from Hospital

Upcoming TAG meeting dates

NSW TAG Management Committee 14th June 8.30am NSW TAG General Meeting 20th June 2.30 -4pm

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Contact Sasha Bennett at <u>sasha.bennett@svha.org.au</u> for further information about any email discussions, publications or upcoming meetings.

EDITOR'S PICKS

AJHP: Incorporating project management into the profession of pharmacy - link

AJHP: Parenteral medication use in hospital at home: Challenges and opportunities - link

AJHP: Implementation of a pharmacist-developed, indication-based order panel for outpatient prescribing of direct-acting oral anticoagulants - link

AIM: Benefits and Risks Associated with Statin Therapy for Primary Prevention in Old and Very Old Adults: Real-World Evidence From a Target Trial Emulation Study - link

BJCP: Determinants of pharmacists' confidence to participate in antimicrobial stewardship: A confirmatory factor analysis - link

BJCP: Acute kidney injury, renal impairment and renal failure associated with sodium glucose cotransporter-2 inhibitors in at-risk groups: A systematic review - <u>link</u>

BJCP: Long-term prescribed opioid use after hospitalization or emergency department presentation among opioid naïve adults (2014–2020) - <u>link</u>

BJCP: Removing the physician from the equation: Patient-controlled, home-based therapeutic drug self-monitoring of tacrolimus - <a href="https://link.nih.gov/link.gov/link.nih.gov/link.nih.gov/link.nih.gov/link.nih.gov/link.nih.gov/link.nih.gov/link.nih.gov/link.nih.gov/link.nih.gov/link.gov/link.gov/link.gov/link.gov/link.gov/link.gov/link.gov/link.gov/

BJCP: A retrospective analysis of perioperative medications for opioid-use disorder and tapering additional postsurgical opioids via a transitional pain service - link

BJP: Shifting paradigms in dementia care: navigating new therapies and prevention strategies - <u>link</u> BMJ: Summary of WHO infection prevention and control guideline for covid-19: striving for evidence based practice in infection prevention and control - <u>link</u>

BMJ: Does platelet rich plasma (PRP) treatment really work? - link

BMJ: State of the art review: Advances in diagnosis and management of cancer of the esophagus - BMJ Open: Pharmacist-led medication management services: a qualitative exploration of transition-of-care cardiovascular disease patient experiences - link

BMJ QS: What do clinical practice guidelines say about deprescribing? A scoping review - <u>link</u> Cochrane: Continuous infusion versus bolus injection of loop diuretics for acute heart failure - <u>link</u> EHJ: Great Debate: SGLT2 inhibitors should be first-line treatment in heart failure with reduced ejection fraction - <u>link</u>

EJHP: EAHP guidance on the pharmacy handling of in vivo gene therapy medicinal products - <u>link</u> EHJP: Contribution of hospital pharmacists to sustainable healthcare: a systematic review - <u>link</u> EMJ: Pharmacists in Trauma: a randomised controlled trial of emergency medicine pharmacists in trauma response teams - <u>link</u>

IMJ: Prevalence of risk factors for venous thromboembolism and aspirin resistance in Australian patients undergoing total hip and knee arthroplasty - <u>link</u>

JCO: Cardiac dysfunction among breast cancer survivors: role of cardiotoxic therapy and cardiovascular risk factors - <u>link</u>

Neurology: Teratogenesis, Perinatal, and Neurodevelopmental Outcomes After In Utero Exposure to Antiseizure Medication- <u>link</u>

OTHER NEWS

NSW Health

- Public health warning: severe opioid overdoses related to nitazene use link
- People aged 65 and over urged to book in now for free flu vaccine link
- Investment in Restricted Financial Assets (PD2024 017)

Pharmacy Board of Australia

- Concerns raised over emerging models of care - link

REPORTS AND PUBLICATIONS – AUSTRALIA

Agency for Clinical Innovation, NSW (ACI)

The latest weekly Evidence Digest can be found here

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

AHHA

- Improving access to restorative and wellbeing care for older Australians - link

Australian Government Department of Health

- Dispensing medicines under the Eighth Community Pharmacy Agreement link fact sheets
- Strategic Agreement on Pharmacist Professional Practice link
- User guide Active ingredient prescribing link
- National Aged Care Mandatory Quality Indicator Program Manual link

Australian Institute for Health and Welfare (AIHW)

- Congenital anomalies in Australia link
- The health and wellbeing of First Nations people in Australia's prisons 2022 link
- National opioid pharmacotherapy statistics annual data collection update
- GEN: Younger people in residential aged care link
- Climate change and environmental health indicators: reporting framework link
- Deaths in Australia; General Record of Incidence of Mortality (GRIM) books; Mortality Over Regions and Time (MORT) books (<u>updates</u>); What do Australians die <u>from</u>?

Deeble Institute

- Issues Brief No.54: Restorative and wellbeing care in Australian RACs

MIMS monthly updates

- New Products
- -- Avacopan (<u>Tavneos</u>) in combination with a rituximab or cyclophosphamide-based regimen, is indicated for adults with anti-neutrophil cytoplasmic autoantibody-associated vasculitis (granulomatosis with polyangiitis and microscopic polyangiitis)
- -- Clascoterone (<u>Winlevi</u>), an androgen receptor inhibitor, for topical treatment of acne vulgaris in patients 12 years of age and older
- -- Teclistamab (<u>Tecvayli</u>) as monotherapy has provisional approval for the treatment of adults with relapsed or refractory multiple myeloma who have received at least three prior therapies, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody
- New indications
- -- Bimekizumab (<u>Bimzelx</u>) adults with active psoriatic arthritis who have had an inadequate response to or who have been intolerant to previous disease modifying antirheumatic drug therapy; with active nonradiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C reactive protein and/or magnetic resonance imaging who have had an inadequate response to or are intolerant to nonsteroidal anti-inflammatory drugs; and with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy
- -- Somatropin (rmc) (Saizen) is now also indicated for growth disturbance (current height standard deviation score (H SDS) < -2.5 and parental adjusted H SDS < -1) in short children born small for gestational age with a birth weight and/or length below -2 standard deviations, who failed to show catch-up growth (height velocity SDS < 0 during the last year) by 4 years of age or later

PBS

- PBS restriction changes to type 2 diabetes mellitus (T2DM) medicines 1 June 2024
- 1 June 2024 updates as part of the Digital Transformation of Authority Required (Written) PBS listings <u>link</u>
- PBS Website Update 1 June 2024

TGA

TGA

- Extension to fluoxetine substitution instrument <u>link</u>
- Database of section 19A approvals to import and supply medicines to address medicine shortages
- Australian prescription medicine decision summaries:

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au An initiative of NSW clinical pharmacologists & pharmacists

- -- <u>NELARABINE-REACH</u> (Nelarabine) approved for the treatment of relapsing/refractory T-cell acute lymphoblastic leukaemia and T-cell lymphoblastic lymphoma
- -- <u>HEMGENIX</u> (Etranacogene dezaparvovec) approved for the treatment of adults with haemophilia B (congenital factor IX deficiency)
- -- <u>Lokelma</u> (Sodium zirconium cyclosilicate hydrate) for hyperkalaemia in adult patients. Lokelma binds to potassium in the gut.

Victorian Institute of Forensic Medicine

- Residential Aged Care Communiqué Volume 19 Issue 2 May 2024

REPORTS AND PUBLICATIONS - INTERNATIONAL

Agency for Healthcare Research and Quality (AHRQ) USA

- Measuring Documentation Burden in Healthcare - link

All Wales Medicines Strategy Group

- Alglucosidase alfa (Myozyme®) recommended as an option for use within NHS Wales for long-term enzyme replacement therapy in patients with a confirmed diagnosis of Pompe disease - Link

Alzheimer's Society, UK

- The economic impact of dementia - link

British Geriatrics Society

- Reablement, Rehabilitation, Recovery: Everyone's business - link

Canadian Agency for Drugs and Technologies in Health

- Alemtuzumab, Cladribine, Fingolimod, and Natalizumab as First-Line Treatments in Adult Patients With Highly Active Relapsing Multiple Sclerosis <u>update</u>
- Utilization of Antidiabetic Drugs During Pregnancy update
- Drugs for Metastatic Renal Cell Carcinoma: Utilization Analysis update

Department of Health and Social Care, UK

- Making prevention everyone's business - link

electronic Medicines Compendium (eMC) (UK)

- New products
- -- Exblifep 2 g/0.5 g (cefepime dihydrochloride monohydrate/enmetazobactam) powder for concentrate 4th generation cephalosporin combined with a penicillanic acid sulfone beta-lactamase inhibitor is licensed for complicated UTIs including pyelonephritis, hospital-acquired pneumonia, and treatment of bacteraemia in association (or potentially linked) with these infections
- -- Quadrivalent influenza vaccine split virion inactivated high-dose suspension for active immunisation in adults 60 years of age and older for the prevention of influenza disease
- -- Veklury (remdesivir) new preclinical data on the antiviral activity of remdesivir against the Omicron subvariants BF.7, BQ.1, XBB.1.5 and CH.1.1

EMA

- EU recommendations for 2024/2025 seasonal flu vaccine composition link
- First vaccine to protect adults from Chikungunya (Ixchiq)
- New gene therapy treatment for haemophilia B (Durveqtix)

European Medicines Agency (EMA)

- CHMP recommends approvals:
- -- Adzynma (rADAMTS13) for ADAMTS13 deficiency
- -- Akantior (polihexanide) for Acanthamoeba keratitis
- -- Avzivi (bevacizumab) for several types of cancer

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- -- Cejemly (sugemalimab) for metastatic non-small cell lung cancer
- -- Durvegtix (fidanacogene elaparvovec) for severe and moderately severe haemophilia B
- -- Fluenz (live attenuated nasal influenza vaccine) in children and adolescents
- -- GalliaPharm (Gallium chloride/Germanium chloride), a radionuclide generator
- -- Ixchiq (Chikungunya vaccine) for the prevention of chikungunya disease
- -- Pomalidomide Accord (pomalidomide) for multiple myeloma
- -- Zegalogue (dasiglucagon) for hypoglycaemia
- CHMP supports extension indication:
- -- apixaban (Eliquis) for the treatment and prevention of VTE in children
- -- dupilumab (Duxipent) for COPD
- -- maralixibat (Livmarli) for progressive familial intrahepatic cholestasis
- -- osimertinib (Tagrisso) for adults with advanced non-small cell lung cancer
- -- risankizumab (Skvrizi) for ulcerative colitis
- -- tislelizumab (Tevimbra) for non-small cell lung cancer
- -- <u>budesonide</u> (Kinpeygo) for adults with primary immunoglobulin A nephropathy with a urine protein excretion >1.0g/day (or urine-protein-creatinine ration ≥0.8g/g)

Food and Drug Administration (FDA) USA

- New Drug approvals
- -- lisocabtagene maraleucel for relapsed or refractory mantle cell lymphoma
- -- accelerated <u>selpercatinib</u> for pediatric patients two years and older with RET-altered metastatic thyroid cancer or solid tumors
- -- aflibercept intravitreal (Opuviz, Yesafili) 2 interchangeable biosimilars to Eylea
- -- belimumab (Benlysta) SC administration for children with SLE
- -- tarlatamab (Imdelltra) bispecific T-cell engager for small cell lung cancer
- -- <u>hydroxyurea</u> (Xromi) new oral solution approved for children aged 6 months to younger than 2 years with sickle cell anemia
- -- methoxy polyethylene glycol/epoetin beta (<u>Mircera</u>) for anemia due to CKD expanded to include children aged 3 months and older
- -- <u>Upadacitinib</u> approval in arthritis extended the JAK inhibitor's safety profile for patients as young as 2 years was similar to known to the known safety profile in adults
- -- Moderna's <u>RSV Vaccine</u> for the first time, an mRNA vaccine has been approved for an indication other than COVID-19. The vaccine will join other immunizations currently on the market for RSV
- -- Nonstimulant Liquid Onyda XR for ADHD the centrally acting alpha2-adrenergic agonist allows for night-time dosing and can be used with stimulants, the drug's manufacturer says

Food Standards Agency, UK

- Patterns and prevalence of adult food allergy (PAFA) - link

Health Services Safety Investigation Body, UK

- Investigation report: Keeping children and young people with mental health needs safe - the design of the paediatric ward - link

NHS England

- RightCare inflammatory bowel disease scenario - link

National Institute for Health and Care Excellence (NICE) UK

- Dabrafenib with trametinib for treating BRAF V600E mutation-positive glioma in children and young people aged 1 year and over (TA977)
- Ivosidenib with azacitidine for untreated acute myeloid leukaemia with an IDH1 R132 mutation (TA979)
- Setmelanotide for treating obesity and hyperphagia in Bardet-Biedl syndrome (HT31)

Royal Pharmaceutical Society

- Reclassification of medicines will help unlock access to medicines - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- calls for timely medication for hospital patients - link

Specialist Pharmacy Services NHS UK

- Switching strategies for antidepressants link
- SPS Spotlight Monthly Digest May 2024

MEDICATION SAFETY

electronic Medicines Compendium (eMC) (UK)

- Revised SPCs
- -- AmBisome (amphotericin B) Liposomal cases of hyperkalaemia (some of them leading to cardiac arrhythmias and cardiac arrest) reported. Most occurred in patients with renal impairment, and some after potassium supplementation in patients with previous hypokalaemia
- -- Efexor (venlafaxine) XL prolonged release capsules hypoglycaemia now included in overdose
- -- Genotropin (somatropin) headache added as an ADR of unknown frequency
- -- Imfinzi (durvalumab) immune-mediated myocarditis, which can be fatal, has occurred in patients who should be monitored for signs & symptoms and managed as recommended
- -- Myozyme (alglucosidase alfa) infusion of Myozyme at home may be considered for patients who are tolerating their infusions well and have no history of moderate or severe infusion associated reactions for a few months, upon recommendation by treating physician
- -- Oxyact (oxycodone hydrochloride) for adolescents (aged ≥ 12 years) for the treatment of severe pain, which can be adequately managed only with opioid analgesics. SPC warns that it should only be prescribed by a specialist experienced in managing severe pain in children
- -- Pirfenidone drug reaction with eosinophilia and systemic symptoms (DRESS), which can be lifethreatening or fatal, is a potential ADR (frequency unknown). If suggestive signs and symptoms appear, treatment should be discontinued immediately
- -- Provera (medroxyprogesterone acetate) meningiomas reported following long term administration of progestogens, including medroxyprogesterone acetate. Provera should be discontinued if a meningioma is diagnosed. Caution is advised when recommending Provera to patients with a history of meningioma
- -- Rinvoq (upadacitinib) may have a minor influence on the ability to drive and use machines because dizziness and vertigo may occur during treatment
- -- Targaxan (rifaximin) severe cutaneous adverse reactions including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis, which can be life-threatening or fatal, reported (frequency unknown). Stop, if they occur
- -- Xospata (gilteritinib fumarate) exposure may be increased in patients with severe renal impairment (as well as end stage renal disease) so patients should be closely monitored for toxicities and QT prolongation. However, dose adjustment is not necessary
- -- Xtandi (enzalutamide) severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome, which can be life-threatening or fatal, has been reported. Raised hepatic enzymes also added as an uncommon ADR
- Risk minimisation materials
- -- Lecigon (levodopa, carbidopa monohydrate, entacapone) intestinal gel A guide for HPs includes a recommended follow-up schedule for aftercare consultation for patients on Lecigon with PEG-J insertion. It also includes questions to ask patients and issues to consider during telephone calls and at home visits with patients
- -- Vanflyta (quizartinib dihydrochloride) A guide for HPs is provided to read before prescribing and administering this. It focusses on minimising the risk of QTc interval, interactions and monitoring. A patient card is also available this should be given to any patient receiving Vanflyta treatment

FDA

- FDA alerts health care professionals, compounders and patients of potential safety risks associated with sulfite-containing compounded drugs - $\underline{\text{link}}$

Health Canada - MedEffect Notice

- Health Product InfoWatch - May 2024

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Institute for Safe Medication Practices (ISMP) USA

- ISMP Issues Call to Action to Prevent Errors with Automated Dispensing Cabinets- link

Medicines and Healthcare products Regulatory Agency (MHRA) UK

- National Patient Safety Alert: Shortage of Pancreatic enzyme replacement therapy (PERT) link
- Topical steroids: introduction of new labelling and a reminder of the possibility of severe side effects, including Topical Steroid Withdrawal Reactions <u>link</u>

Medsafe (New Zealand Medicines and Medical Devices Safety Authority)

- Prescriber Update Vol. 45. No. 2 June 2024
- -- Medicines Monitoring: Calcium channel blockers and the possible risk of new-onset eczema link

Specialist Pharmacy Services NHS UK

- Medication Safety Update May 2024
- Treating lice during breastfeeding link

PAPERS OF INTEREST

American Journal of Cardiology

- Long-Term Efficacy and Safety of Once-Weekly Semaglutide for Weight Loss in Patients Without Diabetes: A Systematic Review and Meta-Analysis of Randomized Controlled Trials - <a href="https://link.pys.org/link.p

American Journal of Health-System Pharmacy (AJHP)

- Medication use evaluation of tocilizumab implementation in COVID-19 treatment guidelines: A causal inference approach $\underline{\text{link}}$
- Incorporating project management into the profession of pharmacy link
- Parenteral medication use in hospital at home: Challenges and opportunities link
- Implementation of a pharmacist-developed, indication-based order panel for outpatient prescribing of direct-acting oral anticoagulants link

Annals of Internal Medicine

- Benefits and Risks Associated with Statin Therapy for Primary Prevention in Old and Very Old Adults: Real-World Evidence From a Target Trial Emulation Study - link

Arthritis & Rheumatology

- Long-term follow-up of anti-infliximab antibodies in radiographic axial spondyloarthritis patients: a marker of drug survival and tapering link
- Risk of Gastrointestinal Perforation in Patients with Rheumatic Diseases Exposed to Janus Kinase Inhibitors Versus Adalimumab: A Nationwide Cohort Study <u>link</u>

British Journal of Clinical Pharmacology

- Acetazolamide-induced pulmonary oedema: A disproportionality analysis from the EudraVigilance database link
- Determinants of pharmacists' confidence to participate in antimicrobial stewardship: A confirmatory factor analysis <u>link</u>
- Acute kidney injury, renal impairment and renal failure associated with sodium glucose cotransporter-2 inhibitors in at-risk groups: A systematic review link
- Long-term prescribed opioid use after hospitalization or emergency department presentation among opioid naïve adults (2014–2020)—A population-based descriptive cohort study <u>link</u>
- The prevalence of polypharmacy in older Europeans: A multi-national database study of general practitioner prescribing link
- Afatinib-induced toxic epidermal necrolysis: A case report with a literature review link
- Evaluation of adherence to antipsychotics: A real-world data study using four different dosing assumptions link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- A retrospective analysis of perioperative medications for opioid-use disorder and tapering additional postsurgical opioids via a transitional pain service <u>link</u>
- Cardiovascular events of Bruton's tyrosine kinase inhibitors: A real-world study based on the United States Food and Drug Administration Adverse Event Reporting System database link
- Removing the physician from the equation: Patient-controlled, home-based therapeutic drug self-monitoring of tacrolimus <u>link</u>

British Journal of Psychiatry

- Shifting paradigms in dementia care: navigating new therapies and prevention strategies - link

British Medical Journal (BMJ)

- Association between exposure to antibiotics during pregnancy or early infancy and risk of autism spectrum disorder, intellectual disorder, language disorder, and epilepsy in children: population based cohort study link SPS commentary
- Epidural analgesia during labour and severe maternal morbidity: population based study link
- Pregnancy associated osteoporosis: NHS is "failing women" with rare but serious condition link
- Summary of WHO infection prevention and control guideline for covid-19: striving for evidence based practice in infection prevention and control <u>link</u>
- Tislelizumab plus chemotherapy versus placebo plus chemotherapy as first line treatment for advanced gastric or gastro-oesophageal junction adenocarcinoma: RATIONALE-305 randomised, double blind, phase 3 trial link
- When I use a word . . . The languages of medicines—International Nonproprietary Names (INNs) link
- Does platelet rich plasma (PRP) treatment really work? link
- Reducing the use of proton pump inhibitors in infants with reflux symptoms link
- State of the art review: Advances in diagnosis and management of cancer of the esophagus link
- Sterile water injections for back pain in labour link

BMJ Medicine

Regular use of fish oil supplements and course of cardiovascular diseases: prospective cohort study
 link

BMJ Open

- Pharmacist-led medication management services: a qualitative exploration of transition-of-care cardiovascular disease patient experiences <a href="https://link.google.com
- Preferences of people with chronic kidney disease regarding digital health interventions that promote healthy lifestyle: qualitative systematic review with meta-ethnography link
- Defining, identifying and addressing problematic polypharmacy within multimorbidity in primary care: a scoping review <u>link</u>
- Effects of primary or secondary prevention with vitamin A supplementation on clinically important outcomes: a systematic review of randomised clinical trials with meta-analysis and trial sequential analysis link

BMJ Quality and Safety

- What do clinical practice guidelines say about deprescribing? A scoping review - link

Circulation

- Atorvastatin Effect on Aortic Dilatation and Valvular Calcification Progression in Bicuspid Aortic Valve (BICATOR): A Randomized Clinical Trial link
- Evaluation and Management of Chronic Heart Failure in Children and Adolescents With Congenital Heart Disease: A Scientific Statement From the American Heart Association Link
- Pharmacogenetic influences over mavacamten pharmacokinetics: considerations for the treatment of individuals with hypertrophic cardiomyopathy <a href="https://link.gov/li
- Ertugliflozin for Functional Mitral Regurgitation Associated With Heart Failure: EFFORT Trial <u>link</u> <u>summary</u>

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Cochrane

- Interventions for postburn pruritus link
- Gene therapy for people with hepatocellular carcinoma link
- Metformin for preventing the progression of chronic kidney disease link
- Antioxidant supplementation for sickle cell disease link
- Continuous infusion versus bolus injection of loop diuretics for acute heart failure link

Drug and Therapeutics Bulletin

- Ritlecitinib for severe alopecia areata link
- DTB select: Prescribing changes following fluoroquinolone safety warning link

Emergency Medicine Journal

- Pharmacists in Trauma: a randomised controlled trial of emergency medicine pharmacists in trauma response teams - link

European Heart Journal

- Ischaemic stroke in women with atrial fibrillation: temporal trends and clinical implications link
- Great Debate: SGLT2 inhibitors should be first-line treatment in heart failure with reduced ejection fraction link
- Anticoagulation for post-operative atrial fibrillation after isolated coronary artery bypass grafting: a meta-analysis link

European Journal of Hospital Pharmacy

- Contribution of hospital pharmacists to sustainable healthcare: a systematic review link
- Complementary and alternative medicine in HIV care: frequency of consumption, risks and interactions with antiretroviral therapy <u>link</u>
- Patient safety culture and medication safety in European intensive care units: a focus group study link
- Assessing health outcomes: a systematic review of electronic patient-reported outcomes in oncology link
- European Association of Hospital Pharmacists (EAHP) guidance on the pharmacy handling of in vivo gene therapy medicinal products <u>link</u>
- Exploring susceptibility factors to medication dispensing errors through a retrospective study of patient-reported dispensing errors over 11 years: are dispensing errors indeed due to personal reasons for pharmacists? link
- Evaluation of the appropriateness of vancomycin therapeutic drug monitoring in the intensive care unit with a clinical pharmacy approach, a cross-sectional study $\underline{\text{link}}$
- Stability of clozapine tablets repackaged in dose administration aids using repackaging machines link
- Medication safety strategies in European adult, paediatric, and neonatal intensive care units: a cross-sectional survey $\underline{\text{link}}$

Health Policy

- The Impact of reference pricing on prescribing patterns, costs, and health services utilization of proton pump inhibitors: A quasi-experimental study in British Columbia, Canada - Link

Internal Medicine Journal

- Prevalence of risk factors for venous thromboembolism and aspirin resistance in Australian patients undergoing total hip and knee arthroplasty - $\underline{\text{link}}$

International Journal of Clinical Pharmacy

- Medication Literacy Test for Older Adults: psychometric analysis and standardization of the new instrument - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Impact of intra-patient variability of tacrolimus on allograft function and CD4 + /CD8 + ratio in kidney transplant recipients: a retrospective single-center study link
- Economic evaluation of camrelizumab plus rivoceranib versus sorafenib as first-line therapy for unresectable hepatocellular carcinoma in the United States and China Link
- Measuring the impact of pharmaceutical care bundle delivery on patient outcomes: an observational study link

JAMA

- Krill Oil for Knee Osteoarthritis: A Randomized Clinical Trial link
- Revisiting Race and the Benefit of RAS Blockade in Heart Failure: A Meta-Analysis of Randomized Clinical Trials link
- Global Production of Active Pharmaceutical Ingredients for US Generic Drugs Experiencing Shortages <u>link</u>
- Patient page: I Am Curious About Cannabis Edibles—What Should I Know? link
- Patient page: What Is Lynch Syndrome? link
- Chronic Pruritus: A Review link
- Stepped Palliative Care for Patients With Advanced Lung Cancer: A Randomized Clinical Trial link
- Is Weight Loss-Induced Muscle Mass Loss Clinically Relevant? link
- Interventions to prevent falls in community-dwelling older adults: US Preventive Services Task Force recommendation statement <a href="https://link.org/

JAMA Dermatology

- Antihypertensive Medications and Eczematous Dermatitis in Older Adults link
- Parental E-Cigarette Use and Pediatric Atopic Dermatitis link
- Gene-Environment Interaction Between CYP1B1 and Oral Contraception on Frontal Fibrosing Alopecia link
- Isotretinoin for Acne in Transgender and Gender-Diverse Individuals Receiving Masculinizing Hormone Therapy <u>link</u>

JAMA Internal Medicine

- Jinlida for Diabetes Prevention in Impaired Glucose Tolerance and Multiple Metabolic Abnormalities: The FOCUS Randomized Clinical Trial - link – SPS commentary
- Increasing Risk for Tick-Borne Disease: What Should Clinicians Know? link
- Caring for Hospitalized Patients with Opioid Use Disorder in the Era of Fentanyl. A Review <u>link</u> <u>summary</u>

JAMA Network Open

- Chlorthalidone vs Hydrochlorothiazide for Hypertension Treatment After Myocardial Infarction or Stroke: A Secondary Analysis of a Randomized Clinical Trial - <u>link</u>

JAMA Neurology

- Early Access to First-Seizure Clinics, Subsequent Outcomes, and Factors Associated With Attendance link
- Early vs Late Anticoagulation in Minor, Moderate, and Major Ischemic Stroke With Atrial Fibrillation: Post Hoc Analysis of the ELAN Randomized Clinical Trial link
- Immediate- or Delayed-Intensive Statin in Acute Cerebral Ischemia: The INSPIRES Randomized Clinical Trial link
- Time Windows Between Symptom Onset and Treatment—An Outdated Myth link
- Status epilepticus identification and treatment among emergency medical services agencies link

JAMA Oncology

- Obstacles to Biosimilar Acceptance and Uptake in Oncology: A Review - link

JAMA Ophthalmol

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au An initiative of NSW clinical pharmacologists & pharmacists

- Effect of Low-Dose Aspirin on the Course of Age-Related Macular Degeneration: A Secondary Analysis of the ASPREE Randomized Clinical Trial – <u>link</u>

JAMA Pediatrics

- Effect of Low-Dose Iron Supplementation on Early Development in Breastfed Infants: A Randomized Clinical Trial - <u>link</u>

JAMA Psychiatry

- Differential Outcomes of Placebo Treatment Across 9 Psychiatric Disorders: A Systematic Review and Meta-Analysis - <u>link</u>

Journal of Allergy and Clinical Immunology

- Intranasal antihistamines and corticosteroids in allergic rhinitis: A systematic review and metaanalysis - <u>link</u>

Journal of Clinical Oncology

- Fertility Preservation and Assisted Reproduction in Patients with Breast Cancer Interrupting Adjuvant Endocrine Therapy to Attempt Pregnancy link
- Cardiac dysfunction among breast cancer survivors: role of cardiotoxic therapy and cardiovascular risk factors link
- Olanzapine plus triple antiemetic therapy for the prevention of carboplatin-induced nausea and vomiting: A randomized, double-blind, placebo-controlled phase III trial <u>link</u>

Journal of Patient Safety

- Comparison of WHO-UMC and Naranjo Scales for Causality Assessment of Reported Adverse Drug Reactions <u>link</u>
- Enhanced Free-Text Search for Aggregated Medication Error Report Analysis and Risk Detection link
- Evolution of Intravenous Medication Errors and Preventive Systemic Defenses in Hospital Settings A Narrative Review of Recent Evidence <u>link</u>
- Implementation of Guidelines Limiting Postoperative Opioid Prescribing at a Children's Hospital link

Lancet

- The Lancet Series on Antimicrobial Resistance (AMR): The need for sustainable access to effective antibiotics Link
- Burden of bacterial antimicrobial resistance in low-income and middle-income countries avertible by existing interventions: an evidence review and modelling analysis link

Lancet Diabetes & Endocrinology

- Causes, prevention, and management of diabetes-related foot ulcers - link

Lancet Infectious Diseases

- Targeted next-generation sequencing to diagnose drug-resistant tuberculosis: a systematic review and meta-analysis <u>link</u> <u>SPS commentary</u>
- Critical illness due to infection in people living with HIV link

Lancet Oncology

- Projected environmental and public health benefits of extended-interval dosing: an analysis of pembrolizumab use in a US national health system link
- The burden of cardiovascular disease and risk for subsequent major adverse cardiovascular events in survivors of childhood cancer- <u>link</u>
- Consensus guidelines and recommendations for the management and response assessment of chimeric antigen receptor T-cell therapy in clinical practice for relapsed and refractory multiple myeloma: a report from the International Myeloma Working Group Immunotherapy Committee Link
- Recent advances and impending challenges for the radiopharmaceutical sciences in oncology link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

Lancet Psychiatry

- Psychosis as a disorder of muscarinic signalling: psychopathology and pharmacology - link

Molecular Diversity Preservation International (MDPI) – Pharmacy Journal

- The Role of a Clinical Pharmacist in the Identification of Potentially Inadequate Drugs Prescribed to the Geriatric Population in Low-Resource Settings Using the Beers Criteria: A Pilot Study Link
- Empowering Pharmacists: Strategies for Addressing the Opioid Crisis through a Public Health Lens link

Medical Journal of Australia

- The role of omega-3 polyunsaturated fatty acids in the prevention of preterm birth link
- Letters: Glucocorticoid-induced adrenal suppression: physiological basis and strategies for glucocorticoid weaning <u>link</u> <u>link</u>

New England Journal of Medicine

- Effects of Semaglutide on Chronic Kidney Disease in Patients with Type 2 Diabetes link
- Plozasiran, an RNA Interference Agent Targeting APOC3, for Mixed Hyperlipidemia link
- Zodasiran, an RNAi Therapeutic Targeting ANGPTL3, for Mixed Hyperlipidemia link
- Belantamab Mafodotin, Bortezomib, and Dexamethasone for Multiple Myeloma link
- Belantamab Mafodotin, Pomalidomide, and Dexamethasone in Multiple Myeloma link
- Asciminib in Newly Diagnosed Chronic Myeloid Leukemia link
- Efficacy and Safety of Donidalorsen for Hereditary Angioedema link
- Neoadjuvant Nivolumab and Ipilimumab in Resectable Stage III Melanoma link
- Oral Sebetralstat for On-Demand Treatment of Hereditary Angioedema Attacks link
- Osimertinib after Chemoradiotherapy in Stage III EGFR-Mutated NSCLC link
- Phase 3 Trial of Crinecerfont in Adult Congenital Adrenal Hyperplasia link
- Phase 3 Trial of Crinecerfont in Pediatric Congenital Adrenal Hyperplasia link
- Isatuximab, Bortezomib, Lenalidomide, and Dexamethasone for Multiple Myeloma link

Neurology

- Teratogenesis, Perinatal, and Neurodevelopmental Outcomes After In Utero Exposure to Antiseizure Medication: Practice Guideline From the AAN, AES, and SMFM - <u>link</u>

Pharmaceutical Journal

- 'Me and My Medicines' campaign to help identify patients at potential risk of harm from problematic polypharmacy nearly doubles number of structured medication reviews (SMRs) in one PCN link
- Everything you need to know about xylazine link
- NICE terminates appraisal of gefapixant (Lyfnua) for the treatment of persistent cough link
- Are prescribing restrictions for pregabalin working? link
- Making skill mix a reality: the advancing role of pharmacy technicians link

Pharmacotherapy

- Increasing the bioavailability of oral esketamine by a single dose of cobicistat: A case study link
- Vancomycin: An analysis and evaluation of eight population pharmacokinetic models for clinical application in general adult population <a href="https://link.gov/

Prescrire - June 2024 includes:

- Editorial: A tale of risk
- Faricimab (Vabysmo°) in age-related macular degeneration or diabetic macular oedema
- Semaglutide in secondary cardiovascular prevention in overweight or obese patients
- Paternal exposure to valproate drugs in the period prior to conception: neurodevelopmental disorders in children?

CONSULTATIONS (new additions in bold)

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Pharmacy Board of Australia

- Have your say on the draft Criminal history registration standard and supporting materials, closes 30 July 2024 - <u>link</u>

TGA

- Consultation: updates to Australian medicine labelling rules to support medicine safety, closes 11 July 2024 - <u>link</u>

WEBINARS & PODCASTS

Australian Prescriber Podcasts

- Episode 164 - Diagnosis and management of eosinophilic oesophagitis

MJA Podcasts

- Episode 18: a cardiology update exploring aortic stenosis and atrial fibrillation
- Episode 19: the need for adequate bowel preparation for colonoscopies

UPCOMING EVENTS

AHHA

- Joining up the care pathway: building a bundle of care, June 19, 2024 10:00-11:00 AEST - link

Australian Government Department of Health

- Delivering high quality, person-centred palliative care in aged care, webinar, 25 June 2024 14:00-15:00 AEST - link - register

Society of Hospital Pharmacists SHPA

- Medicines Management 2024 MM2024, Adelaide, 14-16 November 2024 – abstract submission closes 15 July 2024

Fortnightly TAG Mail – resources list

23rd May 2024

NSW TAG ACTIVITIES

Recently Completed Email Discussions

Virtual Pharmacy Service for Patients being discharged from Hospital

Upcoming TAG meeting dates

NSW TAG Finance Committee 13th June 2024 3pm

NSW TAG Management Committee 14th June 8.30am

NSW TAG General Meeting 20th June 2.30 -4pm

Contact Sasha Bennett at <u>sasha.bennett@svha.org.au</u> for further information about any email discussions, publications or upcoming meetings.

EDITOR'S PICKS

AHRQ: Making Healthcare Safer IV Report Expanded with New Evidence Reviews - link

AIM: Reporting Conflicts of Interest and Funding in Health Care Guidelines - link

AJHP: Defining the "ideal state": A primer on critical care pharmacy practice models - link

AJHP: Practice-enhancing publications about the medication-use process in 2022 - link

AJHP: Vital role of clinical pharmacy services within the hospital at home interdisciplinary team - link

AHHA: The Medicines Repurposing Program – a critical perspective - link

BMJ: Comparative effectiveness of 2nd line oral antidiabetic treatments in T2DM- link

BMJ: Cardiovascular toxicity of immune therapies for cancer - link

BMJ: Tackling the excesses of pharmaceutical marketing and promotion - link

Cochrane: Interventions for smoking cessation in hospitalised patients - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988

Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

IJCP: Development and Delphi consensus validation of the Medication-Related Fall screening and scoring tool - link

IJCP:_Medication errors in emergency departments - link

IJCP: Optimisation of medication reconciliation using queueing theory: a computer experiment - link IJQHC: Medication reuse programs: a narrative review of the literature - link

IMJ: TDM in anticancer agents: perspectives of Australian medical oncologists - link

JAMA: Survival Benefit Associated with Participation in Clinical Trials of Anticancer Drugs- link JAMA Oncology: Dual Checkpoint Inhibition in Melanoma With ≥1% PD-L1—Time to Reassess the Evidence - link

JCO: Palliative Care for Patients with Cancer: ASCO Guideline Update - link

JPPR: Prevention of venous thromboembolism after total hip and knee arthroplasties in Australian hospitals: what are we using? - link

JPPR: Design and development of the clinical pharmacy key performance indicators dashboard for equity of service provision at regional and rural hospitals in North Queensland, Australia - link JPS: Enhanced free-text search for aggregated medication error report analysis and risk detection -

Lancet Oncology: Overall survival benefits of cancer drugs initially approved by the FDA on the basis of immature survival data- link

NEJM: Andexanet for Factor Xa Inhibitor-Associated Acute Intracerebral Hemorrhage - link Pharmacotherapy: - Andexanet alfa versus PCC products for factor Xa inhibitor bleeding - link Paediatrics: Antimicrobial Stewardship Programs in Neonates: A Meta-Analysis – link - commentary SPS: Calculating and using the Child-Pugh score - link

SPS: Understanding enzyme or transporter-based drug interactions - link

WHO: Updated list of drug-resistant bacteria most threatening to human health - link

OTHER NEWS

NSW Health

- Measles alert for south western Sydney link
- Protect yourself and others from serious illness as flu season starts in NSW link
- Warning: High-dose MDMA tablets (ecstasy) circulating in NSW link
- Protocol Supply or Administration of Influenza Vaccine by Authorised Aboriginal Health Practitioners (PD2024 014)
- Occupational Assessment, Screening and Vaccination Against Specified Infectious Diseases (PD2024 015)
- Public Health Considerations for Major Evacuation Centres (GL2024_004)
- System-level patient safety risks: Response co-ordination and communication (PD2024 016)

REPORTS AND PUBLICATIONS – AUSTRALIA

Agency for Clinical Innovation, NSW (ACI)

The latest weekly Evidence Digest can be found here

- Health Budget 2024-25 reflects the cost of tinkering around the edges - link

Australian Commission on Safety and Quality in Health Care (ACSQHC)

- Psychotropic Medicines in Cognitive Disability or Impairment Clinical Care Standard link
- CARAlert annual report: 2023 link

Australian Government Department of Health

- Review of First Nations mental health and suicide prevention services and the Integrated Team Care program - Final report - link
- Palliative care education and training for allied health professionals Communication toolkit

Australian Institute for Health and Welfare (AIHW)

- Family, domestic and sexual violence subsite – update

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Social determinants of health among culturally and linguistically diverse people in Australia link
- New releases from the Department of Health and Aged Care: GEN Aged Care Data link
- Australia's hospitals at a glance link
- LGBTIQ+ Australians: suicidal thoughts and behaviours and self-harm link
- <u>National</u> palliative care measures ; <u>Palliative</u> care services in Australia ; <u>Palliative</u> care and health service use for people with life-limiting conditions

PBS

- DUSC utilisation analysis of medicines for type 2 diabetes 21 May 2024
- PBS subsidy arrangements for abatacept 125 mg SSSI link

TGA

- <u>Database</u> of section 19A approvals to import and supply medicines to address medicine shortages
- AusPARs:
- -- <u>Idefirix</u> for the desensitisation treatment of highly sensitised adult kidney transplant candidates prior to kidney transplantation
- Australian prescription medicine decision summaries:
- -- <u>Abrysvo</u> (recombinant respiratory syncytial virus pre-fusion F protein bivalent vaccine):approved for the prevention of lower respiratory tract disease caused by Respiratory Syncytial Virus (RSV) in certain patient groups
- -- Winlevi clascoterone 1% w/w cream for topical treatment of acne vulgaris in patients 12 years of age and older

REPORTS AND PUBLICATIONS - INTERNATIONAL

Agency for Healthcare Research and Quality (AHRQ) USA

- Weekly Issue May 15, 2024
- Making Healthcare Safer IV Report Expanded with New Evidence Reviews link
- Rapid Evidence Reports:
- -- Active Surveillance Culturing of Clostridiodes difficile and Multidrug-Resistant Organisms: Methicillin-Resistant Staphylococcus aureus, Carbapenem-Resistant Enterobacterales, and Candida auris <u>link</u>
- -- Fatigue and Sleepiness of Clinicians Due to Hours of Service link
- New Mental Health Resources from AHRQ link
- Hindsight is 20/20: Thrombolytics for Alcohol Intoxication link

Beyond Pills All-Party Parliamentary Group, UK

- Shifting the Balance Towards Social Interventions: A Call for an Overhaul of the Mental Health System - link

British National Formulary

- BNF/BNFc newsletter: May 2024

Canadian Agency for Drugs and Technologies in Health

- Health Technology Review: Exploration of the Risk of Suicidality and Self-Harm With Glucagon-Like Peptide-1 Receptor Agonists - <u>link</u>

Department of Health and Social Care, UK

- Government announces expansion of list of people who can administer naloxone without a prescription - link

electronic Medicines Compendium (eMC) (UK)

- New products
- -- Cufence (trientine) copper-selective chelator that enhances systemic elimination of divalent copper by forming a stable complex that is readily excreted by the kidneys licensed for the treatment of Wilson's disease in patients from age ≥5 years intolerant to D- Penicillamine therapy

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Revised SPCs

- -- Aldurazyme (laronidase) use for home infusion in patients who are tolerating their infusions well and have no history of moderate or severe infusion-associated reactions for a few months included
- -- Anastrozole new indication of primary prevention of breast cancer in postmenopausal women at moderate or high risk. Treatment duration is 5 years and should only be initiated by an experienced medical practitioner, and as part of a shared care pathway arrangement
- -- Aspaveli (pegcetacoplan) indicated as monotherapy in the treatment of adult patients with paroxysmal nocturnal haemoglobinuria who have haemolytic anaemia expanded to cover first line use based on Study APL2-PNH-308 (PRINCE)
- -- Keytruda (pembrolizumab) use in combination with platinum-containing chemotherapy as neoadjuvant treatment, then continued as monotherapy as adjuvant treatment of resectable non-small cell lung carcinoma at high risk of recurrence in adults

European Medicines Agency (EMA)

- European CHMP adopts change to existing indication for <u>bedaquiline</u> (Sirturo) in pulmonary tuberculosis (TB)
- European CHMP recommends approval for:
- -- entrectinib in younger patients
- -- Triumeq (abacavir sulfate/dolutegravir sodium/lamivudine) in younger patients
- -- <u>alectinib</u> for the treatment of non-small cell lung cancer
- -- amivantamab as first-line combination therapy for non-small cell lung cancer (NSCLC)
- -- nivolumab for treatment of urothelial carcinoma
- EMA confirms recommendation for non-renewal of authorisation of Duchenne muscular dystrophy medicine Translarna

Food and Drug Administration (FDA) USA

- New Drug approvals
- -- first interchangeable biosimilars to Eylea (aflibercept) to treat macular degeneration and other eye conditions Yesafili (aflibercept-jbvf) and Opuviz (aflibercept-yszy) link
- -- accelerated tarlatamab-dlle (Imdelltra label/PI) for extensive stage small cell lung cancer
- -- accelerated lisocabtagene maraleucel (Breyanzi) for follicular lymphoma
- -- belimumab (Benlysta) SC administration for children with SLE
- -- hydroxyurea (Xromi) new oral solution approved for children aged 6 months to younger than 2 years with sickle cell anemia
- -- methoxy polyethylene glycol/epoetin beta (<u>Mircera</u>) anemia due to CKD expanded to include children aged 3 months and older

Medicines and Healthcare products Regulatory Agency (MHRA)

- Innovation in regulation is shortening timelines for lowest risk clinical trials link
- MHRA announces dedicated new team to support the international community in tackling antimicrobial resistance <u>link</u>
- Proposals to expand access to take-home naloxone supplies link

MIMS, UK

- Medicines shortages from the pharmacist's perspective: private prescribing; switching powers; and WhatsApp groups link
- Generic 10mg, 15mg and 20mg rivaroxaban launched for stroke prevention in AF link

NHS England

- NHS expands 'soup and shake' diets across England to thousands more patients with type 2 diabetes and excess weight or obesity - <u>link</u>

NHS Scotland

- Accepted for restricted use:
- -- Budesonide/formoterol (Symbicort® Turbohaler®) as a reliever therapy for mild asthma

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Not recommended:
- -- Ruxolitinib (Opzelura®) for the treatment of non-segmental vitiligo

NHS Wales

- Opicapone (Ongentys®) recommended for Parkinson's disease

National Institute for Health and Care Excellence (NICE) UK

- Tumour profiling tests to guide adjuvant chemotherapy decisions in early breast cancer (DG58)
- Atogepant for preventing migraine (TA973)
- Selinexor with bortezomib and dexamethasone for previously treated multiple myeloma (TA974)
- Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people 25 years and under (TA975)
- Natalizumab for treatment of adults with highly active relapsing-remitting multiple sclerosis (TA127)
- Setmelanotide for treating obesity and hyperphagia in Bardet-Biedl syndrome (HST31)

National Institute for Health and Care Research (NIHR) Commentaries

- How to deprescribe in primary care - link

Office for Health Improvement and Disparities, UK

- Mental health data and analysis: a guide for health professionals - link

Scottish Intercollegiate Guideline Network (SIGN) UK

- SIGN 171: Management of diabetes in pregnancy

Specialist Pharmacy Services NHS UK

- New product evaluations - April 2024 update

UK Health Security Agency

- Hexavalent DTaP/IPV/Hib/HepB combination vaccine: information for healthcare practitioners (updated) - <u>link</u>

World Health Organisation (WHO)

- WHO updates list of drug-resistant bacteria most threatening to human health link
- WHO pregualifies new dengue vaccine link
- New guidance aims to reduce bloodstream infections from catheter use link
- World No Tobacco Day 2024, 31 May 2024

MEDICATION SAFETY

electronic Medicines Compendium (eMC) (UK)

- Revised SPCs
- -- Fentanyl (Effentora) toxic leukoencephalopathy observed with fentanyl overdose
- -- Gavreto (pralsetinib) updated with information on a pharmacokinetic study of subjects with moderate or severe hepatic impairment. The advice that no dose adjustment is needed in patients with hepatic impairment remains the same
- -- Ibrance (palbociclib) erythema multiforme added as an uncommon ADR with palbociclib treatment
- -- Iomeron (iomeprol) ADRs added: Contrast-induced encephalopathy, hyperthyroidism, severe cutaneous adverse reactions, vasospasm, ischaemia, and transient hypothyroidism in neonates and children. Guidance for thyroid function tests added
- -- Kynmobi (apomorphine hydrochloride) concomitant use with ondansetron is contraindicated due to reports of profound hypotension and loss of consciousness when subcutaneous apomorphine was administered with a 5HT3 antagonist. Additionally, transient sedation added as a common ADR
- -- Lioresal (baclofen) hypertonia included as symptom of withdrawal/abrupt discontinuation, 'other drugs known to lower blood pressure' included in the interactions section, & face swelling, peripheral oedema, alopecia, hypersensitivity, sexual dysfunction added as ADRs
- -- Opdivo (nivolumab) myelitis added as an immune-related side-effect (frequency unknown)

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- -- Protopic (tacrolimus) ointment warning and precaution for use for patients with pyoderma gangrenosum, a skin barrier defect that may result in increased systemic absorption of tacrolimus
- -- Quviviq (daridorexant) available data from a lactation study in 10 healthy lactating women receiving 50 mg daridorexant indicates that the presence of daridorexant in breast milk is low, with a fraction of the maternal dose of daridorexant excreted into breast milk of 0.02%
- -- Tecentriq (atezolizumab) data from observational studies in patients with pre-existing autoimmune disease (AID) suggest risk of immune-mediated ADRs after immune-checkpoint inhibitor therapy may be increased compared with risk in patients without pre-existing AID. Most AID flares were mild & manageable
- -- Tildiem (diltiazem) Lichenoid drug eruption added as a potential ADR, with unknown frequency
- -- Treposuvi (treprostinil) updated use as continuous IV infusion via central venous catheter using surgically placed fully internal implantable infusion pump, equipped with alarm (integrating occlusion and low battery alert), and internal 0.22 µ m filter to limit risk of blood stream infection
- -- Vocabria (cabotegravir) prolonged-release suspension for injection administration instructions updated to mitigate product leakage related to the correct use of the vial adapter, based on Human Factor studies.
- -- Yescarta (axicabtagene ciloleucel) infusion related reactions (common) added to ADR table
- -- Zolgensma (onasemnogene abeparvovec) thrombocytopenia may occur within 3 weeks of administration, increased risk of AST and/or ALT elevation added, and thrombocytopenia observed in a study in children weighing ≥8.5kg to ≤21 kg vs studies in children <8.5kg
- Risk minimisation materials
- -- <u>Lutathera</u> (lutetium [177Lu] oxodotreotide) Treatment Procedure Guide for patients: how the treatment works, considerations before treatment, how it is given, the precautions to take after treatment, and possible side effects

EMA

- Hydroxyprogesterone caproate (17-OPHC) medicines to be suspended from the EU market - link

Institute for Safe Medication Practices (ISMP) USA

- Medication Safety Alert! May 16, 2024 includes
- -- ISMP Urges Increased Action at the Practice Level to Halt the Growing Danger of Counterfeit Drugs

Medsafe (New Zealand Medicines and Medical Devices Safety Authority)

- Promethazine (oral): Do not use in children under 6 years of age due to the risk of psychiatric and central nervous system side effects - link

Specialist Pharmacy Services NHS UK

- Calculating and using the Child-Pugh score link
- Understanding enzyme or transporter-based drug interactions link

TGA

- Substitution approved for Orencia (abatacept) shortages link
- Updated warnings about persistent sexual dysfunction for antidepressants link

PAPERS OF INTEREST

American Journal of Health-System Pharmacy (AJHP)

- Defining the "ideal state": A primer on critical care pharmacy practice models link
- The times are changing: A primer on novel clinical trial designs and endpoints in critical care research link
- Impact of a health-system specialty pharmacy on time to upadacitinib initiation link
- Integration of a clinical pharmacist practitioner–led pharmacogenomics service in a Veterans Affairs hematology/oncology clinic <a href="https://link.org/link.or
- Practice-enhancing publications about the medication-use process in 2022 link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- The impact of sugammadex dosing and administration practices on potential cost savings for pharmacy departments link
- The vital role of clinical pharmacy services within the hospital at home interdisciplinary team link
- Pharmacy-driven performance improvement initiative to increase compliance with intravenous smart pump drug error reduction systems at a large urban academic medical center <u>link</u>

Annals of Internal Medicine

- Reporting Conflicts of Interest and Funding in Health Care Guidelines: The RIGHT-COI&F Checklist link
- Associations of Testosterone and Related Hormones with All-Cause and Cardiovascular Mortality and Incident Cardiovascular Disease in Men: Individual Participant Data Meta-analyses link
- Obesity link

Arthritis & Rheumatology

- Impact of glucocorticoid dose on complete response, serious infections, and mortality during the initial therapy of lupus nephritis: A systematic review and meta-analysis of the control arms of randomized controlled trials - link

Australian Health Review, Journal of the Australian Healthcare & Hospitals Association

- The Medicines Repurposing Program – a critical perspective - link

British Journal of Clinical Pharmacology

- Intranasal vitamin B12 administration in elderly patients: A randomized controlled comparison of two dosage regimens Link SPS commentary
- The impacts of undetected nonadherence in phase II, III and post-marketing clinical trials: An overview link
- Variability in the prevalence of inappropriate medication use among older adults: A review highlighting the importance of screening methods and database types link
- Glial modulators as novel therapeutics for comorbid pain and opioid use disorder link

British Journal of General Practice

- Breast cancer risk assessment for prescription of Menopausal Hormone Therapy in women who have a family history of breast cancer - <u>link</u>

British Journal of Psychiatry

- Lipid-modifying agents and risk of all-cause, natural and suicide mortality in schizophrenia: nationwide cohort study <u>link</u>
- Is it now time to prepare psychiatry for a psychedelic future? link

British Medical Journal (BMJ)

- Association of ultra-processed food consumption with all cause and cause specific mortality: population based cohort study link
- Comparative effectiveness of second line oral antidiabetic treatments among people with type 2 diabetes mellitus: emulation of a target trial using routinely collected health data link
- Ovarian cancer: identifying and managing familial and genetic risk—summary of new NICE guidance
- Clinical and healthcare use outcomes after cessation of long term opioid treatment due to prescriber workforce exit: quasi-experimental difference-in-differences study link
- Effect of the HPV vaccination programme on incidence of cervical cancer and grade 3 cervical intraepithelial neoplasia by socioeconomic deprivation in England: population based observational study <a href="https://link.ncb/l
- Long acting progestogens versus combined oral contraceptive pill for preventing recurrence of endometriosis related pain: the PRE-EMPT pragmatic, parallel group, open label, randomised controlled trial link
- Cardiovascular toxicity of immune therapies for cancer link
- What do we know about covid-19's effects on the brain? link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Tackling the excesses of pharmaceutical marketing and promotion - link

Circulation

- 2024 AHA/ACC/AMSSM/HRS/PACES/SCMR Guideline for the Management of Hypertrophic Cardiomyopathy <u>link</u>
- Effect of Cangrelor on Infarct Size in ST-Segment Elevation Myocardial Infarction Treated By
 Primary Percutaneous Coronary Intervention: A Randomized Controlled Trial (The PITRI Trial) link
 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the
 Management of Lower Extremity Peripheral Artery Disease-link
- Randomized, Multicenter Study to Assess the Effects of Different Doses of Sildenafil on Mortality in Adults With Pulmonary Arterial Hypertension <u>link</u>
- Early Versus Late Initiation of Direct Oral Anticoagulants After Ischemic Stroke in People With Atrial Fibrillation and Hemorrhagic Transformation: Prespecified Subanalysis of the Randomized-controlled ELAN Trial link
- Implementation of Obesity Science Into Clinical Practice: A Scientific Statement From the American Heart Association <u>link</u>

Cochrane

- Interventions for smoking cessation in hospitalised patients link
- Sodium-glucose co-transporter protein 2 (SGLT2) inhibitors for people with chronic kidney disease and diabetes link
- Early pharmacological interventions for prevention of post-traumatic stress disorder (PTSD) in individuals experiencing acute traumatic stress symptoms Link
- Interventions to prevent obesity in children aged 12 to 18 years old, aged 5 to 11 years old
- Oral vitamin A supplements to prevent acute upper respiratory tract infections in children up to seven years of age <u>link</u>
- Magnesium sulphate for women at risk of preterm birth for neuroprotection of the fetus link
- Calcium supplementation for people with overweight or obesity link
- Zinc for prevention and treatment of the common cold link

Critical Care Medicine

- Prophylactic Antibiotics Delivered Via the Respiratory Tract to Reduce Ventilator-Associated Pneumonia: A Systematic Review, Network Meta-Analysis, and Trial Sequential Analysis of Randomized Controlled Trials - link

European Heart Journal

- Semaglutide and Diuretic Use in Obesity-Related Heart Failure with Preserved Ejection Fraction: A Pooled Analysis of the STEP-HFpEF and STEP-HFpEF-DM trial link
- Ticagrelor monotherapy for acute coronary syndrome: an individual patient data meta-analysis of TICO and T-PASS trials <u>link</u>
- Risk of heart failure in inflammatory bowel disease: a Swedish population-based study link

European Journal of Hospital Pharmacy

- An essential component of antimicrobial stewardship during the COVID-19 pandemic in the intensive care unit: de-escalation <u>link</u>
- Editorial: Empowering European hospital pharmacists in the face of heart failure link
- Losartan potassium liquid formulation for paediatric hospital use: development and stability evaluation $\underline{\text{link}}$

Internal Medicine Journal

- Therapeutic drug monitoring in anticancer agents: perspectives of Australian medical oncologists link
- Letter: Successful use of empagliflozin in medically refractory post-bariatric surgery hypoglycaemia link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Heart

- Fabry disease: development and progression of left ventricular hypertrophy despite long-term enzyme replacement therapy - $\underline{\text{link}}$

International Journal of Clinical Pharmacy

- Development and Delphi consensus validation of the Medication-Related Fall screening and scoring tool link
- Preliminary feasibility assessment of a targeted, pharmacist-led intervention for older adults with polypharmacy: a mixed-methods study link
- Developing a machine learning model for predicting venlafaxine active moiety concentration: a retrospective study using real-world evidence <u>link</u>
- Medication errors in emergency departments: a systematic review and meta-analysis of prevalence and severity <u>link</u>
- Personalized venlafaxine dose prediction using artificial intelligence technology: a retrospective analysis based on real-world data link
- Optimisation of medication reconciliation using queueing theory: a computer experiment link
- Global trends in pharmacovigilance-related events: a 30-year analysis from the 2019 global burden of disease study <u>link</u>

International Journal for Quality in Health Care

- A scoping review of the methodological approaches used in retrospective chart reviews to validate adverse event rates in administrative data link
- Medication reuse programs: a narrative review of the literature link

JAMA

- Causal Inference About the Effects of Interventions from Observational Studies in Medical Journals <a href="https://link.org/
- Ponatinib vs Imatinib in Frontline Philadelphia Chromosome—Positive Acute Lymphoblastic Leukemia: A Randomized Clinical Trial <u>link</u>
- Acetaminophen for Prevention and Treatment of Organ Dysfunction in Critically III Patients with Sepsis: The ASTER Randomized Clinical Trial link
- Bisoprolol in Patients with Chronic Obstructive Pulmonary Disease at High Risk of Exacerbation: The BICS Randomized Clinical Trial <a href="https://link.pubm.nih.gov/link
- Pamrevlumab for Idiopathic Pulmonary Fibrosis: The ZEPHYRUS-1 Randomized Clinical Trial link
- Survival Benefit Associated with Participation in Clinical Trials of Anticancer Drugs: A Systematic Review and Meta-analysis <u>link</u>

JAMA Dermatology

- Hematologic Abnormalities in Patients with Hidradenitis Suppurativa Receiving Adalimumab - link

JAMA Internal Medicine

- Mortality of Patients with Sepsis Administered Piperacillin-Tazobactam vs Cefepime - link

JAMA Network Open

- Physician Antipsychotic Overprescribing Letters and Cognitive, Behavioral, and Physical Health Outcomes Among People with Dementia - link

JAMA Neurology

- Antithrombotic Treatment for Cervical Artery Dissection: A Systematic Review and Individual Patient Data Meta-Analysis <u>link</u>
- Treatment of Refractory Status Epilepticus with Continuous Intravenous Anesthetic Drugs: A Systematic Review link
- Contemporary Prestroke Dual Antiplatelet Use and Symptomatic Intracerebral Hemorrhage Risk After Thrombolysis link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

JAMA Oncology

- Metastatic Hormone-Sensitive Prostate Cancer and Combination Treatment Outcomes link
- Systemic Anticancer Therapy and Overall Survival in Patients with Very Advanced Solid Tumors link
- Dual Checkpoint Inhibition in Melanoma With ≥1% PD-L1—Time to Reassess the Evidence link

Journal of the American College of Cardiology

- Left Ventricular Function, Congestion, and Effect of Empagliflozin on Heart Failure Risk After Myocardial Infarction - Link

Journal of Clinical Oncology

- Palliative Care for Patients with Cancer: ASCO Guideline Update link
- Evolution of the Innovative Therapies for Children with Cancer Consortium Trial Portfolio for Drug Development for Children With Cancer Link

Journal of Infection

- Effectiveness of autumn 2023 COVID-19 vaccination and residual protection of prior doses against hospitalisation in England, estimated using a test-negative case-control study - <u>link</u>

Journal of Orthopaedic Trauma

- The Utilization of Preoperative Steroids Safely Decreases the Risk of Postoperative Delirium in Geriatric Patients After Hip Fracture Surgery: A Systematic Review and Meta-analysis of Randomized Controlled Trials - link

Journal of Patient Safety

- Enhanced free-text search for aggregated medication error report analysis and risk detection - link

Journal of Pharmacy Practice and Research (JPPR)

- Prevention of venous thromboembolism after total hip and knee arthroplasties in Australian hospitals: what are we using? link
- Design and development of the clinical pharmacy key performance indicators dashboard for equity of service provision at regional and rural hospitals in North Queensland, Australia Link

Lancet

- Ductal carcinoma in situ of the breast: finding the balance between overtreatment and undertreatment link
- Hypopituitarism <u>link</u> Stroke <u>link</u>
- Adding 6 months of androgen deprivation therapy to postoperative radiotherapy for prostate cancer: a comparison of short-course versus no androgen deprivation therapy in the RADICALS-HD randomised controlled trial link
- Duration of androgen deprivation therapy with postoperative radiotherapy for prostate cancer: a comparison of long-course versus short-course androgen deprivation therapy in the RADICALS-HD randomised trial link
- Tenecteplase versus standard of care for minor ischaemic stroke with proven occlusion (TEMPO-2): a randomised, open label, phase 3 superiority trial <u>link</u>
- Post-trial monitoring of a randomised controlled trial of intensive glycaemic control in type 2 diabetes extended from 10 years to 24 years (UKPDS 91) <u>link</u>

Lancet Diabetes & Endocrinology

- Effect of SGLT2 inhibitors on heart failure outcomes and cardiovascular death across the cardiometabolic disease spectrum: a systematic review and meta-analysis - link

Lancet Gastroenterology and Hepatology

- Infections in cirrhosis - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Lancet Haematology

- Immune effector cell-associated haematotoxicity after CAR T-cell therapy: from mechanism to management - $\underline{\text{link}}$

Lancet HIV

- Relative vaccine protection, disease severity, and symptoms associated with the SARS-CoV-2 omicron subvariant BA.2.86 and descendant JN.1 in Denmark: a nationwide observational study link
- Dolutegravir plus boosted darunavir versus recommended standard-of-care antiretroviral regimens in people with HIV-1 for whom recommended first-line non-nucleoside reverse transcriptase inhibitor therapy has failed (D2EFT): an open-label, randomised, phase 3b/4 trial link

Lancet Neurology

- B cell-targeting chimeric antigen receptor T cells as an emerging therapy in neuroimmunological diseases link
- Safety and efficacy of active blood-pressure reduction to the recommended thresholds for intravenous thrombolysis in patients with acute ischaemic stroke in the Netherlands (TRUTH): a prospective, observational, cluster-based, parallel-group study <u>link</u>

Lancet Oncology

- Overall survival benefits of cancer drugs initially approved by the US Food and Drug Administration on the basis of immature survival data: a retrospective analysis - link

Lancet Public Health

- The 2024 Europe report of the Lancet Countdown on health and climate change: unprecedented warming demands unprecedented action - <u>link</u>

Lancet Respiratory Medicine

- Effectiveness of preventive treatment among different age groups and Mycobacterium tuberculosis infection status: a systematic review and individual-participant data meta-analysis of contact tracing studies - link

Molecular Diversity Preservation International (MDPI) - Pharmacy Journal

- Evaluation of Steroid-Induced Osteoporosis Prevention Using Tracing Reports in Collaboration between Hospitals and Community Pharmacists link
- Buprenorphine Use for Analgesia in Palliative Care link

Medical Journal of Australia

- Management of patients with diffuse intrinsic pontine glioma in Australia and New Zealand: Australian and New Zealand Children's Haematology/Oncology Group position statement <u>link</u>
- The mental health crisis needs more than increased investment in the mental health system link

Nature Medicine

- Long-term weight loss effects of semaglutide in obesity without diabetes in the SELECT trial - link

New England Journal of Medicine

- Aficamten for Symptomatic Obstructive Hypertrophic Cardiomyopathy link
- Andexanet for Factor Xa Inhibitor–Associated Acute Intracerebral Hemorrhage link
- Intensive Ambulance-Delivered Blood-Pressure Reduction in Hyperacute Stroke link
- Perioperative Nivolumab in Resectable Lung Cancer link
- Early Diagnosis and Treatment of COPD and Asthma A Randomized, Controlled Trial link
- Dupilumab for COPD with Blood Eosinophil Evidence of Type 2 Inflammation link

Pediatrics

- Antimicrobial Stewardship Programs in Neonates: A Meta-Analysis - link - commentary

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au An initiative of NSW clinical pharmacologists & pharmacists

- Maternal Vitamin D Supplementation and Infantile Rickets: Secondary Analysis of a Randomized Trial link
- Incorrect Administration of Adult RSV Vaccines to Young Children link
- Prescribing Patterns of Non-recommended Medications for Children With Acute COVID-19 link

Pharmacotherapy

- The efficacy and safety of sodium-glucose cotransporter-2 inhibitors in solid organ transplant recipients: A scoping review link
- Andexanet alfa versus PCC products for factor Xa inhibitor bleeding: A systematic review with metaanalysis - link
- Management of invasive candidiasis: A focus on rezafungin, ibrexafungerp, and fosmanogepix link

Prescriber UK

- Editorial: Follow the evidence to optimise medicines link
- Reusing medicines to mitigate their environmental impact link

Thrombosis Research

- Oral anticoagulants and cognitive impairment in patients with atrial fibrillation: A systematic review with meta-analysis and trial sequential analysis - link

WEBINARS & PODCASTS

Australian Prescriber Podcasts

- Episode 163 – Managing pre-existing diabetes prior to and during pregnancy

MJA Podcasts

- <u>Episode 17</u>: HIV in Australia – the latest epidemiology, developments in treatment and the path to elimination of HIV transmission - link

Purple Pen Podcast

- PPP 161 - Respiratory Syncytial Virus

UPCOMING EVENTS

Agency for Clinical Innovation, NSW (ACI)

- Mental Health Network Innovation Showcase 2024, Trauma Informed Care Program, Wednesday 29 May 2024 09:00-16:30 - <u>link</u>

Australian Government Department of Health

- Delivering high quality, person-centred palliative care in aged care, webinar, 25 June 2024 14:00-15:00 AEST - link - register

Society of Hospital Pharmacists SHPA

- Medicines Management 2024 MM2024, Adelaide, 14-16 November 2024 – <u>abstract submission</u> closes 15 July 2024

Fortnightly TAG Mail - resources list

9th May 2024

NSW TAG ACTIVITIES

Open email discussions

1. Virtual Pharmacy Service for Patients being discharged from Hospital

Are any NSW healthcare services providing a virtual pharmacy service for patients being discharged from hospital. If so, would you please provide details of how the process works including how S8 medicines supply is managed? (Other jurisdictions don't have the same issues given their uptake of the PBS Reforms.) Closes 15 May 2024.

Recently completed email discussions

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Hospital-funded Shingrix
- Hospital/district approaches to supplying and stocking COVID-19 antiviral medicines
- Handling of medicines by perfusionists
- DTC assessment process for non-GMO phage therapy applications
- DTC pharmacists in NSW

Updated TAG publications

Updated SGLT2 inhibitor medicines for diabetes-Consumer Information Leaflet - link

Contact Sasha Bennett at <u>sasha.bennett@svha.org.au</u> for further information about any email discussions, publications or upcoming meetings.

EDITOR'S PICKS

Ann Int Med: The benefits and risks of receiving investigational solid tumor drugs in randomized trials-link

Ann Int Med: The Safety of Outpatient Health Care: Review of Electronic Health Records - <u>link</u> AJHP: The pharmacist's role in optimizing medication management before, during, and after minimally invasive and bariatric surgery - <u>link</u>

BMJ: Effect of combination treatment with glucagon-like peptide-1 receptor agonists and sodiumglucose cotransporter-2 inhibitors on incidence of cardiovascular and serious renal events BMJ: Use of antipsychotics in adults with dementia - link

BMJ Open:_- Use of GLP1 receptor agonists in early pregnancy and reproductive safety- link
BMJ Open: State of the Art Review: Deprescribing in older adults with polypharmacy - link
BMJ QS: Editorial: 'This time is different': physician knowledge in the age of artificial intelligence - link
BMJ QS Checking all the boxes: a checklist for when and how to use checklists effectively - link
Cochrane: ACE inhibitors and ARBs for preventing the progression of diabetic kidney disease - link

IJCP: Intraclass comparison of inhaled corticosteroids for the risk of pneumonia in chronic obstructive pulmonary airway disorder - link
ISMP: Utilizing Pharmacogenomic Testing Can Improve Medication Safety and Prevent Harm - link
JAMA: - The Women's Health Initiative Randomized Trials and Clinical Practice: A Review - link

JAMA: Harnessing the electronic health record to improve empiric antibiotic prescribing - <u>link</u>
JAMA Network Open: - Concomitant Use of Selective Serotonin Reuptake Inhibitors with Oral Anticoagulants and Risk of Major Bleeding - <u>link</u>

Lancet ID: - Association of nirmatrelvir-ritonavir with post-acute sequelae and mortality in patients admitted to hospital with COVID-19 - link

Lancet PH: Best practices for government agencies to publish data: lessons from COVID-19 - <u>link</u> Lancet RM: Long-term outcomes after treatment of delirium during critical illness with antipsychotics (MIND-USA) - <u>link</u>

MJA: - Measurement of digoxin levels falsely affected by enzalutamide - link

Nature Medicine: New risk score for cardiovascular disease with improved performance - link
Patient Information Forum UK: Balancing the risks and benefits of AI in the production of health information - link

Prescrire: Bad in food but fine in health products? - link

OTHER NEWS

Australian Commission on Safety and Quality in Health Care (ACSQHC)

- Mindful use of psychotropic medicines: new standard a lifeline for people with cognitive disability or impairment link
- Last chance for input on the Aged Care IPC Guide, closes 15 May 2024 link
- Hand washing reduces the spread of germs and saves lives link

REPORTS AND PUBLICATIONS – AUSTRALIA

Agency for Clinical Innovation, NSW (ACI)

The latest weekly Evidence Digest can be found here

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- ICU not wasting <u>link</u>; Triple Zero poster <u>link</u>; Operating theatre efficiency guidelines <u>link</u>; Stay'n Deadly & Stay'n In: Reducing Incomplete Treatment <u>link</u>
- Using virtual care to enhance palliative care experiences link

AHHA

- Unlocking the value: AHHA welcomes recognition of digital technologies in health care - link

Australian Government Department of Health

- Prescribing Pharmaceutical Benefits Scheme medicines what prescribers need to know factsheet
- My QuitBuddy app helps you get, and stay, smoke-free and vape-free link
- Digital Transformation Tech Talk aged care 21 May 2024

Australian Institute for Health and Welfare (AIHW)

- Mental health services Rural and remote health National social housing survey 2023
- Maternal and perinatal outcomes during 2020 and 2021 COVID-19 pandemic link

MIMS monthly updates

- New Products
- -- Nelarabine (<u>Nelarabine-Reach</u>) for the treatment of patients with relapsing/ refractory T-cell acute lymphoblastic leukaemia and T-cell lymphoblastic lymphoma whose disease has not responded to or has relapsed following treatment
- New Indications
- -- Irinotecan (as sucrosofate) (<u>Onivyde</u>) now indicated in combination with oxaliplatin, 5-FU, and leucovorin for the first-line treatment of metastatic pancreatic adenocarcinoma
- -- Trametinib (as dimethyl sulfoxide) (<u>Mekinist</u>) now indicated in combination with dabrafenib for the treatment of paediatric patients 1 year of age and older with BRAF V600E mutation and low-grade glioma who require systemic therapy or high-grade glioma who have progressed following prior treatment and have no satisfactory alternative treatment options
- New Presentation
- -- Trametinib (as dimethyl sulfoxide) (Mekinist) now available as powder for oral solution 0.05 mg/mL

TGA

- <u>Database</u> of section 19A approvals to import and supply medicines to address medicine shortages
 AusPARs:
- -- <u>TECVAYLI</u> (teclistamab) provisional approval for treatment of adults with relapsed or refractory multiple myeloma
- -- <u>AREXVY</u> vaccine approved for the prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) in individuals 60 years and older
- -- OMVOH (mirikizumab) for treatment of moderately to severely active ulcerative colitis in adults
- -- VEOZA (fezolinetant) for treatment of moderate to severe hot flashes associated with menopause

REPORTS AND PUBLICATIONS - INTERNATIONAL

All Wales Medicines Strategy Group

- recommends dabrafenib plus trametinib for the treatment of inoperable anaplastic thyroid cancer with the BRAF V600E variant \underline{link}
- recommends trifarotene (Aklief®) cream for the treatment of acne vulgaris link

British National Formulary

- BNF/BNFC newsletter: April 2024

Canadian Agency for Drugs and Technologies in Health

- Outpatient Nirmatrelvir-Ritonavir and Remdesivir Utilization in Canada link
- Artificial Intelligence for Patient Flow link

Department of Health and Social Care

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- New 5-year plan to combat antimicrobial resistance - link

electronic Medicines Compendium (eMC) (UK)

- New products
- -- Fludrocortisone acetate 0.05mg tablet new, lower strength
- -- Hyrimoz (adalimumab) injection in pre-filled pen (High concentration) new strength (40mg/0.4ml) of adalimumab biosimilar Hyrimoz providing 50% reduction in injection volume
- -- Nephrotrans (sodium hydrogen carbonate) 500 mg gastro-resistant capsules, soft for treatment of metabolic acidosis and for maintenance treatment against recurrence of metabolic acidosis in adults with chronic renal impairment. Dosage depends on the severity of metabolic acidosis.
- -- Rystiggo (rozanolixizumab) add-on to standard therapy for the treatment of generalised myasthenia gravis in adults who are AChR or anti-muscle-specific tyrosine kinase antibody positive
- -- Vafseo (vadadustat) for treatment of symptomatic anaemia associated with chronic kidney disease in adults on chronic maintenance dialysis
- -- Velariq (oxybutynin hydrochloride) 1 mg/mL intravesical solution for the suppression of neurogenic detrusor overactivity in children from 6 years of age and adults, who are managing bladder emptying by clean intermittent catheterisation, not adequately managed with oral anticholinergics
- -- Zilbrysq (zilucoplan sodium) add-on to standard therapy for treatment of generalised myasthenia gravis in adults who are anti-acetylcholine receptor antibody positive

European Medicines Agency (EMA)

- CHMP recommended approvals:
- -- <u>Eribulin Baxter</u>, generic of Halaven, for treatment of adults with locally advanced or metastatic breast cancer and adults with unresectable, advanced or metastatic, liposarcoma
- -- tocilizumab biosimilar (<u>Tofidence</u>; Biogen), highly similar to RoActemra, with data showing it has comparable quality, safety and efficacy, for treatment of rheumatoid arthritis, systemic juvenile idiopathic arthritis, polyarticular juvenile idiopathic arthritis and COVID-19
- -- ustekinumab biosimilar (<u>Wezenla</u>), highly similar to Stelara, with data showing it has comparable quality, safety and efficacy, for treatment of plaque psoriasis, including paediatric plaque psoriasis, psoriatic arthritis and Crohn's disease in adults
- -- aprocitentan (<u>Jeraygo</u>) for treatment of resistant hypertension in adults
- -- capivasertib (<u>Trugap</u>) for locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN alterations
- -- efanesoctocog alfa (<u>Altuvoct</u>) for prevention and treatment of bleeding in patients with haemophilia A caused by factor VIII deficiency
- -- fruquintinib (Fruzagla) for patients with previously treated metastatic colorectal cancer
- -- vibegron (Obgemsa) for the symptomatic treatment of adults with overactive bladder syndrome
- CHMP recommends new contra-indications for Reyataz (atazanavir sulfate)
- ETF recommends updating COVID-19 vaccines to target new JN.1 variant link

Food and Drug Administration (FDA) USA

- New Drug approvals
- -- tisotumab vedotin-tftv for recurrent or metastatic cervical cancer with disease progression on or after chemotherapy link
- Xolremdi (<u>mavorixafor</u>) to treat WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) Pl/label
- hydroxyurea (Xromi) new oral solution for children aged 6 months to 2 years with sickle cell anemia
- methoxy polyethylene glycol/epoetin beta (<u>Mircera</u>) indication for anaemia due to CKD expanded to include children aged 3 months and older
- upadacitinib (<u>Rinvoq, Rinvoq LQ</u>) new indication approved for polyarticular juvenile idiopathic arthritis in children aged 2 years and older
- fidanacogene elaparvovec (Beqvez) gene therapy for moderate-to-severe hemophilia B
- apremilast (Otezla) for plaque psoriasis expanded to include children aged 6 years and older

Medicines and Healthcare products Regulatory Agency (MHRA)

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

- Impact of AI on the regulation of medical products link
- New cabotegravir (Apretude) formulations approved to help prevent HIV-1 infection in adults and adolescents <u>link</u>

MIMS UK

- Medicines shortages: GPs forced to prescribe second-choice drugs while epilepsy patients report switch-induced seizures - <u>link</u>

NHS England

- Culture of care standards for mental health inpatient services - link

NHS Scotland

- Accepted for restricted use: remdesivir (Veklury) for treatment of COVID-19 in adults and children
- Not recommended: tixagevimab and cilgavimab (Evusheld) for treatment of COVID-19 in adults

National Institute for Health and Care Excellence (NICE) UK

- Pembrolizumab for treating relapsed or refractory classical Hodgkin lymphoma in people 3 years and over (TA967)
- Selinexor with dexamethasone for treating relapsed or refractory multiple myeloma after 4 or more treatments (TA970)
- Remdesivir and tixagevimab plus cilgavimab for treating COVID-19 (TA971)

National Institute for Health and Care Research (NIHR)

- NHIR Commentaries: What is the best way to identify people with inherited high cholesterol? - link

Patient Information Forum UK

- Balancing the risks and benefits of AI in the production of health information - link

Specialist Pharmacy Services NHS UK

- PGD templates updated:
- -- Benzylpenicillin injection for suspected meningitis in line with updated NICE guidance NG240 link
- -- Ceftriaxone intramuscular injection for Neisseria gonorrhoeae link
- -- Emtricitabine/tenofovir and raltegravir tablets for HIV Post Exposure Prophylaxis (PEP) link
- -- Fluconazole 150mg capsules for candidiasis link
- -- Nitrofurantoin for Urinary Tract Infection (UTI) link
- -- Podophyllotoxin (topical) for external anogenital warts link
- -- Trimethoprim for Urinary Tract Infection (UTI) link
- -- Copper Intrauterine Device (Cu-IUD) link
- -- Etonogestrel (e.g. Nexplanon®) implant for contraception link
- -- Progestogen only pill (POP) for contraception link
- -- Progestogen-Only Intra-Uterine Device (LNG-IUD) for contraception link
- Choosing a medicine to delay periods link
- Prescribing thiamine in patients at risk of refeeding syndrome link

MEDICATION SAFETY

electronic Medicines Compendium (eMC) (UK)

- Revised SPCs
- -- Brintellix (vortioxetine hydrobromide) sexual dysfunction possible ADR, frequency not known
- -- Cellcept (mycophenolate mofetil) limited data shows mycophenolic acid is excreted in human milk. Potential for serious ADRs in breast-fed infants and remains contraindicated in nursing mothers
- -- Clarithromycin concomitant treatment with ivabradine is now contra-indicated, owing to CYP3A4 inhibition by clarithromycin which can cause elevated levels of ivabradine. Also, caution is now advised with co-administration with edoxaban, particularly in those with a high risk of bleeding
- -- Daktarin Aktiv (miconazole) Cream the excipient benzoic acid may cause irritation to skin, eyes and mucous membranes

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- -- Doptelet (avatrombopag maleate) antiphospholipid syndrome added to list of acquired risk factors in section on potential increased thrombotic risk when administering Doptelet to patients with known risk factors for thromboembolism
- -- Entyvio (vedolizumab) data added from a small prospective observational study reporting the rate of major birth defects was 7.4% in 99 women with ulcerative colitis or Crohn's disease treated with vedolizumab and 5.6% in 76 women treated with other biologic agents (aRR 1.07, 95% CI 0.33-3.52)
- -- Epilim Chrono (valproic acid, sodium valproate) acquired Pelger-Huet anomaly (neutrophils show bilobed arrangement of nuclei) added as ADR (frequency unknown)
- -- Flebogamma (human normal immunoglobulin) DIF info added on use for measles pre-/post exposure prophylaxis for susceptible adults, children and adolescents (2-18 years) in whom active immunisation is contraindicated/not advised, & to note minimum level anti-measles IgG is 4.5 IU/ml
- Galpseud (pseudoephedrine hydrochloride) posterior reversible encephalography syndrome and reversible cerebral vasoconstriction syndrome added as ADRs, and contraindications of severe hypertension or uncontrolled hypertension and severe acute or chronic kidney disease/renal failure
- -- Lumykras (sotorasib) new data suggesting decreased sotorasib exposure when co-administered with omeprazole. Recommend taking acid-reducing agents (e.g. PPI/H2 receptor antagonists) with an acidic beverage (e.g. cola) or taking sotorasib 4 hours before or 10 hours after the antacid
- -- Metalyse (tenecteplase) appropriate presentation should be chosen carefully and in line with the indication. The 40mg and 50mg presentations are only intended for use in acute myocardial infarction. The product name now indicates that 10,000-unit strength is equivalent to 50mg
- -- Opiodur (fentanyl) transdermal patch dysphagia added as an uncommon ADR
- -- Pirfenidone drug reaction with eosinophilia and systemic symptoms (DRESS) has been added as a potential ADR of treatment (unknown frequency). If signs suggestive of DRESS develop, withdraw pirfenidone. If DRESS is confirmed, permanently discontinue treatment.
- -- Ponvory (ponesimod) co-administration of carbamazepine 300 mg twice daily (a strong CYP3A4 and UGT1A1 inducer) at steady-state decreased ponesimod's Cmax by 19.6% and AUC by 25.7%, which is not clinically relevant
- -- Prozep (fluoxetine) warning fluoxetine-pethidine combination risks serotonin syndrome
- -- Rapamune (sirolimus) risk of interaction with cannabidiol updated, with a possible increase in systemic exposure and toxicity, due to inhibition of intestinal P-glycoprotein efflux (observed in a study with another mTOR inhibitor)
- -- Sarclisa (isatuximab) has been studied in children aged 28 days to <18 years of age with relapsed/refractory acute lymphoblastic or myeloid leukaemia, but efficacy has not been established. Data from phase 2 single-arm study (n=67) described.
- -- Selexid (pivmecillinam) severe cutaneous adverse reactions (SCAR) reported in relation to betalactam treatment, including pivmecillinam (unknown frequency). When suspected, discontinue tteatment immediately and take appropriate therapy and/or measures.
- -- Tagrisso (osimertinib) 'skin hyperpigmentation' added as an ADR
- -- VidPrevtyn Beta [COVID-19 Vaccine, recombinant, adjuvanted] dizziness added as rare ADR
- -- ViePax (venlafaxine hydrochloride) hypoglycemia can occur as a result of overdose, which has been reported predominantly in combination with alcohol and/or other medicines. Prompt contact with the National Poisons Information Service recommended in suspected overdose.
- -- Yervoy (ipilimumab) myelitis as a rare potential ADR of ipilimumab and nivolumab combination treatment. If signs & symptoms develop, specialist assessment and treatment is required without delay. Depending on severity, treatment may need to be withheld or discontinued.
- Risk minimisation materials
- -- Cablivi (caplacizumab) 10 mg powder and solvent for solution for injection <u>Patient Alert Card</u> for prescribers and HPs involved in the care of patients treated with caplacizumab provides further information about potential serious risks (major bleeding), including symptoms for which patients should seek immediate medical attention
- -- Caprelsa (vandetanib)- <u>HP guide</u> contains information about risks of QTc prolongation, Torsades de pointes, sudden death, posterior reversible encephalopathy syndrome, teeth & bone abnormalities in children, and also a dosing and monitoring guide for paediatric patients

An initiative of NSW clinical pharmacologists & pharmacists

-- Zometa (Zoledronic Acid) <u>Patient Reminder Card</u> containing important safety information that people need to be aware of before and during treatment with zoledronic acid, in order to reduce the risk of developing osteonecrosis of the jaw

Health Canada - MedEffect Notice

- Health Product InfoWatch, March 2024, April 2024

Institute for Safe Medication Practices (ISMP) USA

- Medication Safety Alert! May 2, 2024
- -- Utilizing Pharmacogenomic Testing Can Improve Medication Safety and Prevent Harm link
- -- Also: Patient received MYXREDLIN instead of CARDENE IV; Errors when converting between salt and elemental dosages; Spike separating from the port of WG Critical Care infusion bags

Medicines and Healthcare products Regulatory Agency (MHRA) UK

- Drug Safety Update April 2024
- -- <u>Finasteride</u>: reminder of the risk psychiatric side effects and of sexual side effects (which may persist after discontinuation of treatment)
- -- Montelukast: reminder of the risk of neuropsychiatric reactions

MIMS monthly updates

- New Contraindications
- -- Atazanavir (<u>Reyataz</u>) is now contraindicated in combination with carbamazepine, phenobarbital, phenytoin, encorafenib, and ivosidenib

Specialist Pharmacy Services NHS UK

- Information resources for managing medicines in liver impairment link
- Anticipated shortage of Orencia (abatacept) medicines link

TGA

- Panadol Children 1 Month 1 Year paracetamol 100mg/mL oral liquid bottle: problem with dosing syringe <u>link</u>
- Shortage of Orencia (abatacept) medicines update
- Vyvanse (lisdexamfetamine dimesilate) capsules shortage resolved link
- Dark Horse capsules link

PAPERS OF INTEREST

American Journal of Health-System Pharmacy (AJHP)

- Targeted and immunotherapy for the management of advanced urothelial carcinoma of the bladder link
- Approaches to medication history taking in different hospital settings: A scoping review link
- The pharmacist's role in optimizing medication management before, during, and after minimally invasive and bariatric surgery <u>link</u>

Annals of Internal Medicine

- The Benefits and Risks of Receiving Investigational Solid Tumor Drugs in Randomized Trials: A Systematic Review and Meta-analysis link
- Sodium–Glucose Cotransporter-2 Inhibitors and the Risk for Dialysis and Cardiovascular Disease in Patients with Stage 5 Chronic Kidney Disease Link
- The Safety of Outpatient Health Care: Review of Electronic Health Records <u>link</u> <u>SPS</u> commentary

Arthritis & Rheumatology

- Risk of gastrointestinal perforation in patients with rheumatic diseases exposed to janus kinase inhibitors versus adalimumab: nationwide cohort study - <u>link</u>

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

British Journal of Clinical Pharmacology

- Development of a therapeutic drug-monitoring algorithm for outpatients receiving voriconazole: A multicentre retrospective study link
- Medication adherence to inflammatory bowel disease medications in Aotearoa New Zealand and correlation with health outcomes: A nationwide database analysis link
- Optimization of vigabatrin dosage in children with epileptic spasms: A population pharmacokinetic approach <u>link</u>

British Medical Journal (BMJ)

- Effect of combination treatment with glucagon-like peptide-1 receptor agonists and sodium-glucose cotransporter-2 inhibitors on incidence of cardiovascular and serious renal events: population based cohort study link
- Prenatal opioid exposure and subsequent risk of neuropsychiatric disorders in children: nationwide birth cohort study in South Korea link
- Health systems and environmental sustainability: updating frameworks for a new era link
- Efficacy of psilocybin for treating symptoms of depression: systematic review and meta-analysis link and Expression of Concern link
- Use of antipsychotics in adults with dementia link

BMJ Open

- Use of GLP1 receptor agonists in early pregnancy and reproductive safety: a multicentre, observational, prospective cohort study based on the databases of six Teratology Information Services link
- Cost-effectiveness of methenamine hippurate compared with antibiotic prophylaxis for the management of recurrent urinary tract infections in secondary care: a multicentre, open-label, randomised, non-inferiority trial <u>link</u>
- State of the Art Review: Deprescribing in older adults with polypharmacy link

BMJ Quality and Safety

- Editorial: 'This time is different': physician knowledge in the age of artificial intelligence link
- Checking all the boxes: a checklist for when and how to use checklists effectively link

Circulation

- The Tricuspid Valve: A Review of Pathology, Imaging, and Current Treatment Options: A Scientific Statement From the American Heart Association link
- Low-Dose Rivaroxaban Plus Aspirin in Patients With Peripheral Artery Disease Undergoing Lower Extremity Revascularization With and Without Concomitant Coronary Artery Disease: Insights From VOYAGER PAD link

Cochrane

- Collaborative care approaches for people with severe mental illness link
- Systemic antibiotics for symptomatic apical periodontitis and acute apical abscess in adults link
- Antiviral medications for preventing cytomegalovirus disease in solid organ transplant recipients link
- Bronchoscopy-guided antimicrobial therapy for cystic fibrosis link
- Daratumumab and antineoplastic therapy versus antineoplastic therapy only for adults with newly diagnosed multiple myeloma ineligible for transplant <u>link</u>
- Dexmedetomidine for analgesia and sedation in newborn infants receiving mechanical ventilation link
- Metformin for endometrial hyperplasia link
- Respiratory syncytial virus vaccination during pregnancy for improving infant outcomes link
- Risk assessment for aggressive behaviour in schizophrenia link
- Angiotensin-converting-enzyme inhibitors and angiotensin receptor blockers for preventing the progression of diabetic kidney disease link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Psychosocial and medication interventions to stop or reduce alcohol consumption during pregnancy

- <u>link</u>

Diabetes Care

- Incretin-Based Weight Loss Pharmacotherapy: Can Resistance Exercise Optimize Changes in Body Composition? link
- Continuous Glucose Monitoring Profiles in Pregnancies with and without Gestational Diabetes Mellitus <u>link</u>
- Increasing Medication Use and Polypharmacy in Type 2 Diabetes: The Danish Experience From 2000 to 2020 link
- Impaired awareness of hypoglycemia in older adults with type 1 diabetes: A post hoc analysis of the WISDM Study <u>link</u>

Drug and Therapeutics Bulletin

- Cytisine for smoking cessation link
- DTB Select: Prenatal use of antiepileptic drugs and childhood psychiatric disorders link
- DTB select: Increasing awareness of the risk of death from a propanolol overdose link
- DTB select: Reducing antibiotic use for acute sinusitis in children link

European Heart Journal

- Aspirin hypersensitivity: a practical guide for cardiologists link
- Embolic strokes of undetermined source: a clinical consensus statement of the ESC Council on Stroke, the European Association of Cardiovascular Imaging and the European Heart Rhythm Association of the ESC link

European Journal of Hospital Pharmacy

- Letter: Assessment of particle contamination in vancomycin syringe pumps following fluid withdrawal using three diverse aseptic reconstitution techniques <u>link</u>
- Comparative analysis of the prevalence 3-HIT concept in people living with HIV and seronegative patients with chronic conditions. Cross-3HIT Project <u>link</u>

International Journal of Clinical Pharmacy

- Prevalence and trends in polypharmacy and excessive polypharmacy: a retrospective national database analysis (2012–2021) link
- Intraclass comparison of inhaled corticosteroids for the risk of pneumonia in chronic obstructive pulmonary airway disorder: a network meta-analysis and meta-regression link

JAMA

- Neurodevelopmental Outcomes After Late Preterm Antenatal Corticosteroids: The ALPS Follow-Up Study link
- APOL1-Mediated Kidney Disease link
- Patient page: What Is Hyperthyroidism? <u>link</u> What Is Autism Spectrum Disorder? <u>link</u> What Is Strep Throat? <u>link</u>
- Aspirin vs Placebo as Adjuvant Therapy for Breast Cancer: The Alliance A011502 Randomized Trial link
- The Women's Health Initiative Randomized Trials and Clinical Practice: A Review link
- Smoking Cessation After Initial Treatment Failure With Varenicline or Nicotine Replacement link
- Three-year outcomes of oral antibiotics vs intravenous and oral antibiotics for uncomplicated acute appendicitis: A secondary analysis of the APPAC II randomized clinical trial <u>link</u>
- Harnessing the Electronic Health Record to Improve Empiric Antibiotic Prescribing link

JAMA Cardiology

- Atrial Fibrillation Ablation in Heart Failure With Reduced vs Preserved Ejection Fraction: A Systematic Review and Meta-Analysis - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

JAMA Dermatology

- Methotrexate Use and Risk of Interstitial Lung Disease in Dermatomyositis - link

JAMA Internal Medicine

- Cytisinicline for Vaping Cessation in Adults Using Nicotine E-Cigarettes: The ORCA-V1 Randomized Clinical Trial - <u>link</u>

JAMA Network Open

- Concomitant Use of Selective Serotonin Reuptake Inhibitors with Oral Anticoagulants and Risk of Major Bleeding - <u>link</u>

JAMA Neurology

- Association of New-Onset Seizures With SARS-CoV-2 Vaccines: A Systematic Review and Meta-Analysis of Randomized Clinical Trials <u>link</u>
- Ghrelin for Neuroprotection in Post-Cardiac Arrest Coma: A Randomized Clinical Trial link

JAMA Psychiatry

- Efficacy and Safety of Xanomeline-Trospium Chloride in Schizophrenia: A Randomized Clinical Trial - link

Journal of the American College of Cardiology

- An "Inclisiran First" Strategy vs Usual Care in Patients with Atherosclerotic Cardiovascular Disease link
- Limb Outcomes With Ticagrelor Plus Aspirin in Patients With Diabetes Mellitus and Atherosclerosis link

Lancet

- Contribution of vaccination to improved survival and health: modelling 50 years of the Expanded Programme on Immunization <a href="https://link.org/link
- Limit packaging size for opioids prescribed at post-surgical discharge link

Lancet Diabetes & Endocrinology

- Comparing advanced hybrid closed loop therapy and standard insulin therapy in pregnant women with type 1 diabetes (CRISTAL): a parallel-group, open-label, randomised controlled trial link
- Sex, race, and BMI in clinical trials of medications for obesity over the past three decades: a systematic review link
- Use of melatonin supplements and risk of type 2 diabetes and cardiovascular diseases in the USA: insights from three prospective cohort studies link

Lancet Haematology

- Diagnosis, treatment, and surveillance of Diamond-Blackfan anaemia syndrome: international consensus statement - link

Lancet Infectious Diseases

- Use of inactivated poliovirus vaccine for poliovirus outbreak response link
- Association of nirmatrelvir-ritonavir with post-acute sequelae and mortality in patients admitted to hospital with COVID-19: a retrospective cohort study <u>link</u>

Lancet Psychiatry

- Long-term persistence of the risk of agranulocytosis with clozapine compared with other antipsychotics: a nationwide cohort and case—control study in Finland - link

Lancet Public Health

- Best practices for government agencies to publish data: lessons from COVID-19 - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Lancet Respiratory Medicine

- Azithromycin therapy for prevention of chronic lung disease of prematurity (AZTEC): a multicentre, double-blind, randomised, placebo-controlled trial link
- Long-term outcomes after treatment of delirium during critical illness with antipsychotics (MIND-USA): a randomised, placebo-controlled, phase 3 trial <u>link</u>

Molecular Diversity Preservation International (MDPI) - Pharmacy Journal

- Development and implementation of an ultraviolet-dye-based qualification procedure for hand washing and disinfection to improve quality assurance of pharmacy preparations and compounding, especially in cleanrooms: a pilot study - link

Medical Journal of Australia

- Measurement of digoxin levels falsely affected by enzalutamide link
- 2023 Australian guideline for assessing and managing cardiovascular disease risk link

Nature Medicine

- New risk score for cardiovascular disease with improved performance - link - SPS commentary

New England Journal of Medicine

- Exagamglogene autotemcel for severe sickle cell disease link
- Exagamglogene autotemcel for transfusion-dependent β-thalassemia link
- Recombinant ADAMTS13 in congenital thrombotic thrombocytopenic purpura link
- Cryptococcal disease in diverse hosts link

Pediatrics (American Academy of Pediatrics)

- Increasing the use of enteral antibiotics in hospitalized children with uncomplicated infections - link

Pharmacotherapy

- Genetic polymorphisms and major bleeding risk during vitamin K antagonists treatment: The BLEEDS case-cohort - link

Prescrire – French Medical Journal

- Editorial: Check before deciding link
- Tezepelumab (Tezspire°) in severe asthma in adults and adolescents link
- Pregabalin during the first trimester of pregnancy: probably a slight increase in major malformations link
- Efgartigimod alfa (Vyvgart°) in generalised myasthenia gravis link
- Bad in food but fine in health products? link

Thorax

- Impact of age at ivacaftor initiation on pulmonary outcomes among people with cystic fibrosis - link

CONSULTATIONS

Australian Commission on Safety and Quality in Health Care (ACSQHC)

- Consultation on the Aged Care Infection Prevention and Control Guide, closing 15 May 2024 - link

TGA

- Proposed amendments to the Poisons Standard - ACMS, ACCS and Joint ACMS-ACCS meetings, June 2024, closes 22 May 2024 - <u>link</u>

WEBINARS & PODCASTS

Australian Prescriber Podcasts

- Episode 162: Management of menopause symptoms

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

MJA Podcasts

- Episode 14: what doctors need to know about gastric and oesophageal cancer
- Episode 15: exercise "vital" for people who have experienced pregnancy loss

UPCOMING EVENTS (New additions listed in TAGMail)

AHHA

- Post-Budget Health Leaders Roundtable, Canberra, 17 May 2024 10:00-16:00 register
- Making the most of technology in healthcare, 23 May 12.30pm 1.30pm AEST register

FDA

- Understanding Current Use of Ketamine for Emerging Areas of Therapeutic Interest, June 27, 2024 9:00 AM - 4:00 PM ET - register

SHPA

- MM2024, 14-16 November 2024, Adelaide BioMed City – <u>call for abstracts</u> - close 11:59pm AEST Monday 15 July 2024

Fortnightly TAG Mail – resources list

25th April 2024

NSW TAG ACTIVITIES

Open email discussions

- **1. Hospital-funded Shingrix**: Are DTCs are receiving requests to approve use and funding of Shingrix in their immunocompromised patient populations that are outside the NIP criteria and what is your approach to these potentially very expensive requests? **Closes 1**st **May 2024**
- 2. Hospital/district approaches to supplying and stocking COVID-19 antiviral medicines: Hospitals are requested to outline any strategies they are considering/implementing concerning supply of COVID-19 antivirals to ED patients and stocking of COVID-19 antivirals for inpatient use. Closes 1st May 2024

Recently completed email discussions

- Handling of medicines by perfusionists
- DTC assessment process for non-GMO phage therapy applications
- DTC pharmacists in NSW
- Patient prioritisation for discharge medication list provision
- Missing medications from wards
- Medication reviews for inpatients in remote Multi-Purpose Services.

Upcoming TAG meetings

NSW TAG Finance Committee Meeting: Friday 3 May 2024 9.00-9.45am NSW TAG Management Committee Meeting: Friday 3 May 2024 9.45-11.00am

Updated TAG publications

Updated SGLT2 inhibitor medicines for diabetes-Consumer InformationLeaflet - link Contact Sasha Bennett at sasha.bennett@svha.org.au for further information about any email discussions, publications or upcoming meetings.

EDITOR'S PICKS

ISMP: Updates List of Error-Prone Abbreviations, Symbols, and Dose Designations - link
SPS NHS UK: Preparation risk assessments for Advanced Therapy Medicinal Products and in-vivo Gene Therapies - link

AP: - Partnered pharmacist medication charting and prescribing in Australian hospitals - link

AP: Cardiovascular disease risk: a practical summary of the 2023 guideline - link

BJCP: Thirst and drugs: A study in the WHO's pharmacovigilance database - link

BJCP: The emergence of psychedelics in the management of pain and opioid use disorder - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

BMJ: Impact of large scale, multicomponent intervention to reduce PPI overuse - link

BMJQS: Paediatric medication incident reporting: a multicentre comparison study of medication errors identified at audit, detected by staff and reported to an incident system - link

Drug Safety: Drug-Drug Interactions and Actual Harm to Hospitalized Patients: A Multicentre Study

Examining the Prevalence Pre- and Post-Electronic Medication System Implementation - <u>link</u>

EHJ: Ten years of direct oral anticoagulants: lessons learned and challenges ahead - link

EJHP: Policy recommendations for medication safety improvement for ICUs - link

HospPediatrics: Decreasing Prescribing Errors in Antimicrobial Stewardship Program - link

IJCP: Delabeling of allergy to beta-lactam antibiotics in hospitalized patients: a prospective study evaluating cost savings - link

JPS: An Analysis of Incident Reports Related to EMM: How They Change Over Time - <u>link</u> JPPR: - Standard of practice in palliative care for pharmacy services - <u>link</u>

LancetGH: - Mechanisms and management of loss of response to anti-TNF therapy for patients with Crohn's disease - link

LancetPH:_Beyond misinformation: developing a public health prevention framework for managing information ecosystems - link

MDPI: Redesigning Medication Management in the Emergency Department: The Impact of Partnered Pharmacist Medication Charting - <u>link</u>

OTHER NEWS

Australian Commission on Safety and Quality in Health Care (ACSQHC)

- Join the first psychotropic medicines standard launch link
- Have your say on the Aged Care Infection Prevention and Control Guide link

NSW Health

- Public health warning: severe opioid overdoses in Penrith area link
- Could it be sepsis? link
- HIV treatment for people in NSW who are not eligible for Medicare (GL2024 003)
- Prenatal Screening and Diagnostic Testing for Fetal Chromosomal Abnormality (PD2024 013)

TGA

- Nitrosamine impurities acceptable intakes update <u>link</u>
- All medicinal cannabis products supplied to Australian patients must meet quality standards link

REPORTS AND PUBLICATIONS - AUSTRALIA

Agency for Clinical Innovation, NSW (ACI)

The latest weekly Evidence Digest can be found here

Australian Government Department of Health

- Japanese encephalitis (JEV) resources - link

Australian Institute for Health and Welfare (AIHW)

- Alcohol and other drug treatment services in Australia: early insights link
- Health of children: Australia's health topic summary update link
- Trends in cannabis availability, use, and treatment in Australia, 2013-14 to 2021-22 link
- People with disability in Australia link
- Alcohol, tobacco and other drugs in Australia link
- Dementia Awareness Survey link

TGA

- Database of section 19A approvals to import and supply medicines to address medicine shortages
- AusPAR: Beyfortus

REPORTS AND PUBLICATIONS - INTERNATIONAL

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Agency for Healthcare Research and Quality (AHRQ) USA

 Rapid Evidence Product: Patient Safety Practices Focused on Sepsis Prediction and Recognition link

British Menopause Society

- Management of unscheduled bleeding on hormone replacement therapy (HRT) - link

Canadian Agency for Drugs and Technologies in Health

- Buprenorphine-Based Formulations for Opioid Use Disorder in Correctional Settings - link

electronic Medicines Compendium (eMC) (UK)

- New products
- -- Mepsevii (vestronidase alfa) recombinant form of human beta-glucuronidase (GUS) for non-neurological manifestations of Mucopolysaccharidosis VII (MPS VII; Sly syndrome), a lyosomal storage disorder characterised by the deficiency of GUS
- -- Erleada (apalutamide) 240 mg new strength reduces tablet load for patients on 240mg daily dose
- -- Oxylan (oxycodone hydrochloride) now available in 15mg, 30mg and 60mg strengths (in addition to 5mg, 10mg, 20mg, 40mg and 80mg) for severe pain given at 12-hourly intervals
- -- Pylera (bismuth subcitrate potassium, metronidazole, tetracycline hydrochloride) for use in combination with omeprazole for the eradication of Helicobacter pylori and prevention of relapse of peptic ulcers in patients with active or a history of H. pylori associated ulcers
- Talzenna (talazoparib tosylate) monotherapy in patients with germline BRCA1/2-mutations, who have HER2-negative locally advanced/metastatic breast cancer, and in combination with enzalutamide for patients with metastatic castration-resistant prostate cancer in whom chemotherapy is not clinically indicated

electronic Medicines Compendium (eMC) (UK)

- New or extended indications
- -- Mavenclad (cladribine) broadening of the therapeutic indication to include treatment of relapsing forms of multiple sclerosis (previously only for highly active multiple sclerosis)
- -- Olumiant (baricitinib) new indications of paediatric atopic dermatitis (in those aged ≥2 years who are candidates for systemic therapy) and juvenile idiopathic arthritis (in those aged ≥2 years who have had an inadequate response or intolerance to DMARDs)
- -- Takhzyro (lanadelumab) indication of routine prevention of recurrent attacks of hereditary angioedema extended to cover use in younger age group from age 2 years, and 150 mg in 1 ml prefilled syringe added as a new strength for paediatric use
- -- Xromi (hydroxycarbamide) for the prevention of vaso-occlusive complications of Sickle Cell Disease in patients over 9 months of age (previously from 2 years). Clinical efficacy and safety data from the BABY HUG trial were added to support this license extension

European Medicines Agency (EMA)

- New recommendations to strengthen supply chains of critical medicines - link

Food and Drug Administration (FDA) USA

- New Drug approvals
- -- Pivya (pivmecillinam), for uncomplicated urinary tract Infections
- -- tovorafenib (Ojemda) for patients with relapsed/refractory BRAF-altered pediatric low-grade glioma
- -- lutetium Lu 177 dotatate for pediatric patients 12 years and older with GEP-NETS
- -- <u>nogapendekin alfa inbakicept-pmln</u> (Anktiva) for BCG-unresponsive non-muscle invasive bladder cancer
- -- alectinib as adjuvant treatment for ALK-positive non-small cell lung cancer
- -- <u>Lumisight</u> pegulicianine to use as an optical imaging agent for the detection of cancerous tissue
- -- Zevtera (<u>ceftobiprole</u> medocaril sodium) to treat certain bloodstream infections, bacterial skin and associated tissue infections, and community-acquired bacterial pneumonia

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

-- ciltacabtagene autoleucel (Carvykti) for multiple myeloma after 1 or more lines of therapy

MIMS UK

- New tool to help clinicians consider the environmental impact of prescribing - link

Medicines and Healthcare products Regulatory Agency (MHRA)

- Fosdenopterin licensed for the treatment of molybdenum cofactor deficiency - link

NHS England

- Psychological therapies for severe mental health problems - implementation guidance 2024 - link

National Institute for Health and Care Excellence (NICE) UK

- Endometriosis: diagnosis and management, updated (NG73)

National Institute for Health and Care Research (NIHR) Commentaries

- Pelvic organ prolapse: self-management of pessaries can be a good option - link

Royal Pharmaceutical Society

- ... updates patient safety professional standards - link

The King's Fund (UK)

- The role of integrated care systems in improving dementia diagnosis - link

MEDICATION SAFETY

electronic Medicines Compendium (eMC) (UK)

- Revised SPCs
- -- Ameluz (5-aminolevulinic acid hydrochloride) artificial daylight added as alternative light source for photodynamic therapy with Ameluz for the treatment of Actinic keratosis on the face and scalp. In section 4.4, new warning added advising intensive lesion preparation might lead to increased pain
- -- Bondronat (ibandronic acid) information updated on atypical fractures of other long bones, such as the ulna and tibia, which have also been reported in patients receiving long-term treatment. As with atypical femoral fractures, these occur after minimal, or no trauma
- -- Cidomycin (gentamicin sulfate) consider alternative treatment options or genetic testing in patients with mitochondrial DNA mutations (particularly nucleotide 1555 A to G substitution in the 12S rRNA gene) or maternal history of these, including when gentamicin serum levels are in range
- -- Cotellic (cobimetinib hemifumarate) stomatitis included as ADR (frequency 'very common')
- -- Denzapine (clozapine) shelf-life for the unopened product has changed from 6 months to 2 years. Patients are advised to take a dose as soon as it is drawn into oral dispenser and not store doses for later use. SPC now advises that the product must be stored below 25°C and shaken prior to each use
- -- Fabrazyme (agalsidase beta) excreted in human milk and a decision must be made whether to discontinue breastfeeding or to discontinue/abstain from therapy. Section 6.6 now recommends prompt dilution after reconstitution, to minimise protein particle formation over time
- -- Inderal (propranolol hydrochloride) depression included as an ADR with unknown frequency
- -- Pradaxa (dabigatran) for VTE treatment and prevention of recurrent VTE in paediatric patients updated to include use from the time the child is able to swallow soft food [previously from birth] to less than 18 years of age
- -- Rifadin (rifampicin) and Rifinah (isoniazid, rifampicin) contraindicated for use with lurasidone as it markedly decreases the exposure of lurasidone. Additionally, cerebellar syndrome is added as an ADR of unknown frequency, with a warning that this has been reported mainly in patients with chronic kidney disease
- -- Sarclisa (isatuximab) interference with indirect Coombs test may persist for ≥6 months after last infusion. Advice that no dose adjustment recommended in patients with mild-severe renal impairment expanded to cover those with end-stage renal disease based on pharmacokinetic analysis

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- -- Semaglutide containing products intestinal obstruction included as an ADR (frequency 'not known'). Section discussing lack of interaction with warfarin updated to include interaction between acenocoumarol and semaglutide-containing products
- -- Tysabri (natalizumab) injections administered by a HP outside a clinical setting (e.g. at home) may be considered for patients who have previously tolerated at least 6 doses of natalizumab well, i.e. who have not experienced hypersensitivity reactions
- -- Vokanamet (metformin hydrochloride, canagliflozin hemihydrate) data describing outcomes following in utero exposure to metformin added. These do not indicate an increased risk of congenital malformations. Manufacturer advises Vokanamet should not be used in pregnancy due to lack of data for use of canagliflozin or Vokanamet in pregnant women
- -- Wegovy (semaglutide) intestinal obstruction added as an ADR (frequency not known). Information in section 4.5 on interaction with warfarin updated to discuss other coumarin derivatives and advise frequent INR monitoring if semaglutide is started in those on such treatment
- Risk minimisation materials
- -- etrasimod (<u>Velsipity</u>) prescriber checklist highlights important potential risks & recommended tests before & during treatment, a patient card raises awareness about embryofoetal toxicity in pregnant females exposed to etrasimod, and a patient/caregiver guide provides important safety information

EMA

- PRAC concludes available evidence does not support causal links between GLP-1RAs (dulaglutide, exenatide, liraglutide, lixisenatide and semaglutide) and suicidal and self-injurious thoughts and actions link
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) <u>8-11 April 2024</u>

Food and Drug Administration (FDA) USA

- FDA requires boxed warning for T cell malignancies following treatment with BCMA-directed or CD19-directed autologous chimeric antigen receptor (CAR) T cell immunotherapies - link

Institute for Safe Medication Practices (ISMP) USA

- ISMP Updates List of Error-Prone Abbreviations, Symbols, and Dose Designations link
- Medication Safety Alert! April 18, 2024
- -- Patient Death After Inadvertent Infusion of PRN Medication Hanging on Bedside IV Pole link

Specialist Pharmacy Services NHS UK

- Medication Safety Update March 2024
- Using folic acid with phenytoin link
- Switching between mesalazine oral tablet preparations link

TGA

- Update: Extension to the shortage of Zactin Tabs (fluoxetine 20mg dispersible tablets) link
- Extension to the shortage of Vyvanse 60mg (lisdexamfetamine dimesilate) capsules link

PAPERS OF INTEREST

American Journal of Health-System Pharmacy (AJHP)

- Approaches to medication history taking in different hospital settings: A scoping review link
- The efficacy and safety of direct oral anticoagulants in the treatment of the acute phase of heparin-induced thrombocytopenia: A systematic review link

Annals of Internal Medicine

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Update Alert: Nonpharmacologic and Pharmacologic Treatments of Adult Patients with Major Depressive Disorder: A Systematic Review and Network Meta-analysis for a Clinical Guideline by the American College of Physicians link
- Newer Pharmacologic Treatments in Adults with Type 2 Diabetes: A Systematic Review and Network Meta-analysis for the American College of Physicians <a href="https://link.com/link.
- Excessive Alcohol Use and Alcohol Use Disorders: A Policy Brief of the American College of Physicians link
- Assessing clinician utilization of next-generation antibiotics against resistant gram-negative infections in U.S. hospitals: A retrospective cohort study <u>link</u>

Australian Prescriber

- Biologic therapies for severe asthma with persistent type 2 inflammation link
- Partnered pharmacist medication charting and prescribing in Australian hospitals link
- Diagnosis and management of obstructive sleep apnoea in adults link
- Assessing, communicating and managing cardiovascular disease risk: a practical summary of the 2023 guideline <u>link</u>
- Letter: Evidence-based management of menopause link
- Letter: Digital health: dashboards, dashboards everywhere link
- New drugs
- -- Andusomeran & raxtozinameran for prevention of COVID-19 disease
- -- Faricimab for neovascular age-related macular degeneration and diabetic macular oedema
- -- Relugolix+estradiol+norethisterone for symptomatic uterine fibroids
- TGA Medicines Safety Update summary: Updated warnings of faricimab (Vabysmo) retinal vasculitis risk link

British Journal of Clinical Pharmacology

- Thirst and drugs: A study in the World Health Organization's pharmacovigilance database link
- From taboo to treatment: The emergence of psychedelics in the management of pain and opioid use disorder <u>link</u>
- A randomized, double-blind study to compare the efficacy and safety of nalbuphine nasal spray and injectable solution in patients after orthopaedic interventions and traumatological procedures <u>link</u>
- Letter: Bleeding in patients on concurrent treatment with serotonin reuptake inhibitor (SRI) and acetylsalicylic acid (ASA) compared with ASA alone: a pharmacovigilance study link
- Administration mode matters for 5-fluorouracil therapy: Physiologically based pharmacokinetic evidence for avoidance of myelotoxicity by continuous infusion but not intravenous bolus <u>link</u>

British Journal of General Practice

- Weight Management with Orlistat in Type 2 Diabetes – An Electronic Healthcare Records Study - link

British Medical Journal (BMJ)

- Efficacy of a single low dose of esketamine after childbirth for mothers with symptoms of prenatal depression: randomised clinical trial <u>link</u>
- Glucagon-like peptide 1 receptor agonist use and risk of thyroid cancer: Scandinavian cohort study link – SPS commentary
- Advances in management of heart failure link
- Impact of large scale, multicomponent intervention to reduce proton pump inhibitor overuse in integrated healthcare system: difference-in-difference study link SPS commentary
- Refocusing the World Health Organization's model list of essential medicines on the needs of low and middle income countries link
- Multiple adverse outcomes associated with antipsychotic use in people with dementia: population based matched cohort study link
- How to communicate about climate change with patients link
- Oxycodone initiation in Australia (2014–2018): Sociodemographic factors and preceding health service use link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

BMJ Open

- Colchicine for the treatment of patients with COVID-19: an updated systematic review and metaanalysis of randomised controlled trials - <u>link</u>

BMJ Quality and Safety

- Paediatric medication incident reporting: a multicentre comparison study of medication errors identified at audit, detected by staff and reported to an incident system - link

Circulation

- Patient-Centered Adult Cardiovascular Care: A Scientific Statement From the American Heart Association <u>link</u>
- Positive Vasoreactivity Testing in Pulmonary Arterial Hypertension: Therapeutic Consequences, Treatment Patterns, and Outcomes in the Modern Management Era <u>link</u>
- Environmental Exposures and Pediatric Cardiology: A Scientific Statement From the American Heart Association link
- Diagnosis and Management of Cardiac Sarcoidosis: A Scientific Statement From the American Heart Association <u>link</u>

Diabetes, Obesity and Metabolism

- Impact of empagliflozin on insulin needs in patients with heart failure and diabetes: An EMPEROR-Pooled analysis - link

Drug Safety

- Drug–Drug Interactions and Actual Harm to Hospitalized Patients: A Multicentre Study Examining the Prevalence Pre- and Post-Electronic Medication System Implementation - <u>link</u>

European Heart Journal

- Ten years of direct oral anticoagulants: lessons learned and challenges ahead - link

European Journal of Allergy and Clinical Immunology

- A randomized double-blinded trial to assess recurrence of systemic allergic reactions following COVID-19 mRNA vaccination - link

European Journal of Hospital Pharmacy

- Development and prioritisation of policy recommendations for medication safety improvement for intensive care units: a European Association of Hospital Pharmacists Special Interest Group Delphi Study link
- Letter: Home antibiotic therapy in elastomeric infusion pumps past, present and future link
- Adverse drug effect in the context of drug shortage: the CIRUPT prospective study from the French pharmacovigilance network <u>link</u>

Heart

- Preconception counselling in women of reproductive age attending cardiology clinics in Scotland link
- Outcomes in patients treated with loop diuretics without a diagnosis of heart failure: a retrospective cohort study link

Hospital Pediatrics

- Decreasing Prescribing Errors in Antimicrobial Stewardship Program-Restricted Medications - link

International Journal of Clinical Pharmacy

- Delabeling of allergy to beta-lactam antibiotics in hospitalized patients: a prospective study evaluating cost savings - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Cost-effectiveness analysis of fruquintinib in Chinese patients with refractory metastatic colorectal cancer link
- Adverse events of nivolumab plus ipilimumab versus nivolumab plus cabozantinib: a real-world pharmacovigilance study <u>link</u>
- Clinical impact of an individualised clinical pharmacy programme into the memory care pathway of older people: an observational study link
- Exploring the impact of anticholinergic burden on urinary independence: insights from a post-stroke cohort of older adults <u>link</u>

International Journal for Quality in Health Care

- Process management program to prevent falls in hospitalized patients with neuropsychiatric disorders: a quality improvement program - link

JAMA

- Using Effect Scores to Characterize Heterogeneity of Treatment Effects link
- Associations Between Surrogate Markers and Clinical Outcomes for Nononcologic Chronic Disease Treatments <a href="https://link.org/lin
- Uterine Fibroids link
- Assessing the Real-World Effectiveness of Immunizations for Respiratory Syncytial Virus link
- Serious Bleeding in Patients With Atrial Fibrillation Using Diltiazem With Apixaban or Rivaroxaban link
- Patient page: What Is Hepatitis D Infection? link
- Stewardship Prompts to Improve Antibiotic Selection for Pneumonia: The INSPIRE Randomized Clinical Trial link
- Stewardship Prompts to Improve Antibiotic Selection for Urinary Tract Infection: The INSPIRE Randomized Clinical Trial <u>link</u>
- Preoperative GLP-1 Receptor Agonist Use and Risk of Postoperative Respiratory Complications link
- Interstitial Lung Disease: A Review link
- Letter: Industry Payments to US Physicians by Specialty and Product Type- link

JAMA Cardiology

- Extended Clopidogrel Monotherapy vs DAPT in Patients With Acute Coronary Syndromes at High Ischemic and Bleeding Risk: The OPT-BIRISK Randomized Clinical Trial - Link

JAMA Internal Medicine

- Acute Cardiac Events in Hospitalized Older Adults with Respiratory Syncytial Virus Infection link
- Sodium-Glucose Cotransporter-2 Inhibitors vs Sulfonylureas for Gout Prevention Among Patients With Type 2 Diabetes Receiving Metformin <u>link</u>
- Antihypertensive Medication and Fracture Risk in Older Veterans Health Administration Nursing Home Residents <u>link</u>
- Inappropriate Diagnosis of Pneumonia Among Hospitalized Adults link

JAMA Network Open

- Shorter Dual Antiplatelet Therapy for Older Adults After Percutaneous Coronary Intervention: A Systematic Review and Network Meta-Analysis link SPS commentary
- SGLT2 Inhibitors, Functional Capacity, and Quality of Life in Patients With Heart Failure: A Systematic Review and Meta-Analysis <u>link</u>

Journal of the American Geriatrics Society

- Proarrhythmic major adverse cardiac events with donepezil: A systematic review with meta-analysis - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Journal of Clinical Oncology

- Impact of Propofol Exposure on Neurocognitive Outcomes in Children With High-Risk B ALL: A Children's Oncology Group Study link
- Use of Sodium Thiosulfate as an Otoprotectant in Patients with Cancer Treated with Platinum Compounds: A Review of the Literature <u>link</u>

Journal of Patient Safety

- An Analysis of Incident Reports Related to Electronic Medication Management: How They Change Over Time - <u>link</u>

Journal of Pharmaceutical Analysis

- Advancing drug safety and mitigating health concerns: High-resolution mass spectrometry in the levothyroxine case study - link

Journal of Pharmacy Practice and Research (JPPR)

- Standard of practice in palliative care for pharmacy services link
- Antibiotics administered as continuous intravenous infusion over 24 hours by elastomeric devices to patients treated at home: a study of infusion efficiency link

Journal of Thrombosis and Haemastasis

- Cyclophosphamide vs rituximab for eradicating inhibitors in acquired hemophilia A: A randomized trial in 108 patients - <u>link</u>

Lancet

- B-cell non-Hodgkin lymphomas link
- Systemic lupus erythematosus link

Lancet Gastroenterology and Hepatology

- Mechanisms and management of loss of response to anti-TNF therapy for patients with Crohn's disease: 3-year data from the prospective, multicentre PANTS cohort study <u>link</u>
- Pathophysiology and therapeutic options for cirrhotic portal hypertension link

Lancet HIV

- Associations between change in BMI and the risk of hypertension and dyslipidaemia in people receiving integrase strand-transfer inhibitors, tenofovir alafenamide, or both compared with other contemporary antiretroviral regimens - link

Lancet Neurology

- Complex regional pain syndrome: advances in epidemiology, pathophysiology, diagnosis, and treatment - link

Lancet Oncology

- Changes in hospital mortality in patients with cancer during the COVID-19 pandemic (ISARIC-CCP-UK): a prospective, multicentre cohort study - link

Lancet Psychiatry

- Prevalence of multimorbidity in people with and without severe mental illness: a systematic review and meta-analysis - link

Lancet Public Health

- Beyond misinformation: developing a public health prevention framework for managing information ecosystems - link

Molecular Diversity Preservation International (MDPI) - Pharmacy Journal

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Predictive Modeling of Factors Influencing Adherence to SGLT-2 Inhibitors in Ambulatory Care: Insights from Prescription Claims Data Analysis <u>link</u>
- Redesigning Medication Management in the Emergency Department: The Impact of Partnered Pharmacist Medication Charting on the Time to Administer Pre-Admission Time-Critical Medicines, Medication Order Completeness, and Venous Thromboembolism Risk Assessment <a href="https://link.gov/link

Medical Journal of Australia

- Perspective: Towards national paediatric health clinical practice guidelines - link

New England Journal of Medicine

- Alectinib in Resected ALK-Positive Non–Small-Cell Lung Cancer link SPS commentary
- Guidance on Energy and Macronutrients across the Life Span link
- Overall Survival with Adjuvant Pembrolizumab in Renal-Cell Carcinoma link
- Retinoblastoma Origins and Destinations link

Pediatrics (American Academy of Pediatrics)

- Antibiotics for Acute Sinusitis in Children: A Meta-Analysis - link - commentary

Pharmacotherapy

- Antiviral influenza treatments and hemorrhage-related adverse events in the United States Food and Drug Administration Adverse Event Reporting System (FAERS) database link
- Warfarin dosage in a postpartum woman while breastfeeding: A case report link

Stroke

- Intravenous Alteplase Versus Best Medical Therapy for Patients with Minor Stroke: A Systematic Review and Meta-Analysis - <a href="https://link.org/link.o

CONSULTATIONS (

Australian Commission on Safety and Quality in Health Care (ACSQHC)

- Consultation on the Aged Care Infection Prevention and Control Guide, closing 15 May 2024 - link

TGA

- Consultation: clarification of how Clinical Decision Support System (CDSS) software is regulated, closes on 6 May 2024 - link

WEBINARS & PODCASTS

Australian Prescriber Podcasts

- Episode 161 - Managing hypercholesterolaemia - link

FDA Division of Drug Information is presenting a series of CE webinars

- Fraudulent Drugs: You're Using What? - May 21, 2024 - register

MJA Podcasts

- <u>Episode 13</u>: Advice for clinicians on salt and nutrients found in Australian yeast extracts and tomato sauces
- Episode 12: developments in treating kidney disease

Purple Pen Podcast

- PPP 160 - Social and Cultural Considerations in Antimicrobial Use - 14 April 2024

UPCOMING EVENTS

AHHA

- Post-Budget Health Leaders Roundtable, Canberra, 17 May 2024 10:00-16:00 - register

SHPA

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Fortnightly TAG Mail – resources list

11th April 2024

Open email discussions

- **1. Hospital-funded Shingrix**: Are DTCs are receiving requests to approve use and funding of Shingrix in their immunocompromised patient populations that are outside the NIP criteria and what is your approach to these potentially very expensive requests? **Closes 24th April 2024**
- **2.** Hospital/district approaches to supplying and stocking COVID-19: Hospitals are requested to outline any strategies they are considering/implementing concerning supply of COVID-19 antivirals to ED patients and stocking of COVID-19 antivirals for inpatient use. **Closes 1st May 2024**

Recently completed email discussions

- Handling of medicines by perfusionists
- DTC assessment process for non-GMO phage therapy applications
- DTC pharmacists in NSW
- Patient prioritisation for discharge medication list provision
- Missing medications from wards
- Medication reviews for inpatients in remote Multi-Purpose Services.

Upcoming TAG meetings

NSW TAG Editorial Committee Meeting: Monday 15th April 2024 11.00-12.30pm

Updated TAG publications

Updated SGLT2 inhibitor Consumer Leaflet - link.

Contact Sasha Bennett at <u>sasha.bennett@svha.org.au</u> for further information about any email discussions, publications or upcoming meetings.

EDITOR'S PICKS

AIM: - Management of Inpatient Elevated Blood Pressures - link

NHS England: Pharmacogenomics tutorial for pharmacists/pharmacy technicians - link

ISMP: Guardians of Grafts: Reducing Medication Errors in Transplant Recipients - link

BJCP: Assessing pain in persons with opioid use disorder: - link

BMJ Open: Implementation of an intervention aimed at deprescribing benzodiazepines in a large US healthcare system using patient education materials- <a href="https://link.google.com/link.go

BMJQS: Estimating the impact on patient safety of enabling the digital transfer of patients' prescription information in the English NHS - <u>link</u>

Drug Safety: Drug-drug interactions and actual harm to hospitalized patients: a multicentre study examining the prevalence pre- and post-electronic medication system implementation - <u>link</u>

EHJ: Low-dose colchicine for atherosclerosis: long-term safety - link

EHJ: Use of new and emerging cancer drugs: what the cardiologist needs to know - link-

EJHP: Appropriateness of antithrombotics in geriatric inpatients with atrial fibrillation - link

HLC: Discharge Information About Adverse Drug Reactions Indicates Lower Self-Reported Adverse

Drug Reactions and Fewer Concerns in Patients After Percutaneous Coronary Intervention - <u>link</u> HTA: Evaluation of venous thromboembolism risk assessment models for hospital inpatients- <u>link</u>

IMJ: The increasing costs of medicines and their implications for patients, physicians and the health system - link

IJCP: Novel opportunities for clinical pharmacy research: development of a machine learning model to identify medication related causes of delirium in different patient groups - <u>link</u>

IJCP: Clinical pharmacy key performance indicators for hospital inpatient setting - link

JAGS: - Melatonin does not reduce delirium severity in hospitalized older adults - link

JAMA Network Open: Drug Efficacy in the Treatment of Antipsychotic-Induced Akathisia - link

JAMA Oncology: Clinical Value of Molecular Targets and FDA-Approved Genome-Targeted Cancer Therapies - <u>link</u>

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988

Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Lancet D&E: Effects of statin therapy on diagnoses of new-onset diabetes and worsening glycaemia in large-scale randomised blinded statin trials— link

MJA: Editorial-Interventions for reducing the prescribing of pharmaceutical opioids in Australia: are they effectively reducing opioid harm? – <u>link</u> – and <u>research article</u>

NEJM: - Nirmatrelvir for Vaccinated or Unvaccinated Adult Outpatients with Covid-19 - <u>link</u> – <u>SPS</u> <u>commentary</u>

PEC: Medication Errors in Pediatric Emergency Departments - <u>link</u> Prescrire International: Prescrire's ratings of new drugs in 2023

OTHER NEWS

Australian Commission on Safety and Quality in Health Care (ACSQHC)

- Launch of clinical care standard for psychotropic medicines - link

CATAG

Medicines Advice Initiative Australia (MAIA) project: Cumulative Medicines toolkit: Practice tool and Teaching tool - link

Collaborating with Consumers project: Understanding medicines access programs - <u>link</u> **NSW Health**

- Measles alert for Western Sydney [31 March 2024] and factsheet
- Maintaining health during and after floods and storms link

TGA

- Update on the rescheduling of bromoxynil products - April 2024 - link

REPORTS AND PUBLICATIONS - AUSTRALIA

Agency for Clinical Innovation, NSW (ACI)

The latest weekly Evidence Digest can be found here

- Digital mental health interventions for young people evidence check - link

Australian Government Department of Health

- Unleashing the Potential of our Health Workforce - Scope of Practice Review - Issues Paper 1 - link

Australian Institute for Health and Welfare (AIHW)

- Australia's disability strategy 2021–2031 - link

MIMS monthly updates April 2024

- New Products
- -- Fezolinetant ($\underline{\text{Veoza}}$) for moderate to severe vasomotor symptoms (VMS) associated with menopause
- -- Prasterone (<u>Intrarosa</u>) for vulvar and vaginal atrophy in postmenopausal women having moderate to severe symptoms
- -- Recombinant respiratory syncytial virus pre-fusion F protein (RSVPreF3) vaccine (<u>Arexvy</u>) for active immunisation of individuals 60 years and older for the prevention of LRTD caused by RSV per official recommendations
- New Presentation
- -- Melatonin (Voquily) is now available as capsules and as an oral solution
- New Indications
- -- Empagliflozin (<u>Jardiance</u>) is now indicated to reduce the risk of kidney disease progression in adults with chronic kidney disease (CKD) stages 2 and 3A with urine albumin to creatinine ratio (UACR) ≥ 30 mg/g, or CKD stages 3B, 4 and 5 irrespective of UACR.
- -- Pembrolizumab (rch) ($\underline{\text{Keytruda}}$) is now indicated as monotherapy for the adjuvant treatment of patients with Stage IB ($\underline{\text{T2a}} \ge 4$ cm), II, or IIIA NSCLC who have undergone complete resection and platinum-based chemotherapy.

TGA

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- <u>Database</u> of section 19A approvals to import and supply medicines to address medicine shortages
 AusPARs:
- -- Tibsovo (ivosidenib) for the treatment of acute myeloid leukaemia that carries a particular mutation

REPORTS AND PUBLICATIONS – INTERNATIONAL

Agency for Healthcare Research and Quality (AHRQ) USA

- Rapid Evidence Product: Prevention in Adults of Transmission of Infection With Multidrug-Resistant Organisms link
- Rapid Research: Failure To Rescue Rapid Response Systems link

Canadian Agency for Drugs and Technologies in Health

- Long-Term Use of Omalizumab for Chronic Idiopathic Urticaria - link

electronic Medicines Compendium (eMC) (UK)

- New products
- -- Ayvakyt (avapritinib) monotherapy for adult patients with unresectable or metastatic gastrointestinal stromal tumours (GIST) harbouring the platelet-derived growth factor receptor alpha (PDGFRA) D842V mutation
- -- Genvoya (elvitegravir, cobicistat, emtricitabine, tenofovir alafenamide fumarate) new (lower) strength licensed for treatment of HIV without any known mutations linked to resistance to integrase inhibitor class, emtricitabine or tenofovir in patients aged from 2 years and with body weight ≥14 kg
- -- Povidone iodine 5% w/v eye drops solution for the pre-operative preparation of the surgical field (eyelids, lashes and cheeks) and irrigation of the ocular surface (cornea, conjunctiva and palpebral fornixes). Each 4ml single use container provides 200 mg of povidone iodine
- -- Rivaroxaban 2.5mg generic version licensed for use in combination with aspirin alone or aspirin + clopidogrel or ticlopidine, for prevention of atherothrombotic events after ACS with elevated cardiac biomarkers, or for CAD or symptomatic PAD at high risk of ischaemic events
- -- Velsipity (etrasimod) for patients aged ≥16 years with moderately to severely active ulcerative colitis who have had inadequate response, lost response, or were intolerant to either conventional therapy or a biological agent
- Revised SPCs
- -- DuoResp Spiromax (budesonide, formoterol) now also licensed for use as a reliever therapy for adults and adolescents (12 years and older) with mild asthma. The shelf-life after first opening has been extended from 6 months to 12 months
- -- Omeprazole new indication of the treatment of Zollinger-Ellison syndrome

Food and Drug Administration (FDA) USA

- FDA Approves First Prescription App for Depression link
- New Drug approvals
- -- Vafseo (vadadustat) to treat anemia due to chronic kidney disease
- -- Voydeya (danicopan) to treat extravascular haemolysis with paroxysmal nocturnal hemoglobinuria
- -- <u>Zevtera</u> (ceftobiprole medocaril sodium) to treat certain bloodstream infections, bacterial skin and associated tissue infections, and community-acquired bacterial pneumonia
- -- idecabtagene vicleucel (<u>Abecma</u>) CAR-T therapy approved for multiple myeloma after 2 or more lines of therapy
- New indications
- -- FDA grants accelerated approval to fam-trastuzumab deruxtecan-nxki (<u>Enhertu</u>) for unresectable or metastatic HER2-positive solid tumors
- -- iloperidone (<u>Fanapt</u>) for acute treatment of manic or mixed episodes associated with bipolar I disorder
- -- dolutegravir/lamivudine (Dovato) indication for HIV expanded to include adolescents
- -- ciltacabtagene autoleucel ($\underline{Carvykti}$) earlier treatment approved for multiple myeloma after 1 or more lines of therapy

Medicines and Healthcare products Regulatory Agency (MHRA)

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- MHRA approves combined antibiotic cefepime/enmetazobactam (Exblifep 2g/0.5 g powder for concentrate for solution for infusion) <a href="https://link.py.ncbi.nlm.
- Fosdenopterin approved to treat adult patients with molybdenum cofactor deficiency (MoCD) Type A
- link

NHS England

- Medicines Learning Portal: Pharmacogenomics tutorial for pharmacists/pharmacy technicians link
- Quality & outcomes framework guidance for 2024/25, including new cholesterol indicator (CHOL004)

NHS Scotland/Scottish Medicines Consortium

- Accepted for use:
- -- <u>dostarlimab</u> (Jemperli) in combination with platinum-containing chemotherapy for patients with mismatch repair deficient/microsatellite instability-high primary advanced or recurrent endometrial cancer
- -- mavacamten (Camzyos) for symptomatic obstructive hypertrophic cardiomyopathy
- -- ritlecitinib (Litfulo) for severe alopecia areata in adults and adolescents 12 years of age and older
- Accepted for restricted use:
- -- <u>daridorexant</u> (Quviviq) for adult insomnia patients with symptoms present for at least 3 months whose daytime functioning is impacted
- -- <u>tirzepatide</u> (Mounjaro) for adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

National Institute for Health and Care Excellence (NICE) UK

- Olaparib for maintenance treatment of BRCA mutation-positive advanced ovarian, fallopian tube or peritoneal cancer after response to first-line platinum-based chemotherapy (TA962)
- Epidermal radiotherapy using rhenium-188 paste for non-melanoma skin cancer (IPG784)
- Dostarlimab with platinum-based chemotherapy for treating advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency (TA963)
- Twin and triplet pregnancy- updated guidance (NG137)
- Cabozantinib with nivolumab for untreated advanced renal cell carcinoma (TA964)

National Institute for Health and Care Research (NIHR)

- Irritable bowel syndrome: low-dose antidepressant improves symptoms link
- Surgery is better than nasal sprays for people with severely blocked airways link

Scottish Intercollegiate Guideline Network (SIGN) UK

- SIGN170 Optimising glycaemic control in people with type 1 diabetes - link - toolkit

Specialist Pharmacy Services NHS UK

- Understanding complementary medicines - link

UK Health Security Agency

- National criteria for prompt intravenous-to-oral switch (IVOS) of antimicrobials in children and young people (including newborns) - $\underline{\text{link}}$ – $\underline{\text{SPS commentary}}$

World Health Organisation (WHO)

- Consolidated guidelines on person-centred viral hepatitis strategic information: using data to support country scale-up of hepatitis prevention, diagnosis and treatment services $\underline{\text{link}}$
- Co-administration of treatment for drug-resistant tuberculosis and hepatitis C: rapid communication link
- WHO publishes new guidelines on hepatitis B link
- WHO launches guidance on conducting reviews of tuberculosis programmes link
- WHO unveils a digital health promoter harnessing generative AI for public health link
- Telehealth quality of care tool link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

MEDICATION SAFETY

All Wales Therapeutics and Toxicology Centre

- The All Wales Policy for Medicines Administration, Recording, Review, Storage & Disposal (Update)

electronic Medicines Compendium (eMC) (UK)

- Revised SPCs
- -- Benlysta (belimumab) frequency of ADRs urticaria and rash from 'uncommon' to 'common', and diarrhoea and nausea from 'very common' to 'common'
- -- Bonviva (ibandronic acid) atypical fractures of long bones other than the femur added as a potential ADR of treatment (frequency unknown). These fractures occur after minimal, or no trauma and some patients experience prodromal pain prior to presenting with a completed fracture
- -- Copaxone (glatiramer) moderate amount of data (300-1000 pregnancy outcomes) indicate no malformative or feto/neonatal toxicity, & animal studies do not indicate reproductive toxicity. Manufacturers advise use may be considered during pregnancy, if necessary
- -- Dalacin (clindamycin) risk of the known possible adverse effect of oesophagitis and oesophageal ulcer is increased if taken in a lying position and/or with a small amount of water
- -- Edronax (Reboxetine) serotonin syndrome included as possible ADR, frequency 'not known'
- -- Elvanse Adult (lisdexamfetamine) epistaxis added as potential ADR of uncommon frequency
- -- Equasym (methylphenidate) contusion added as ADR of unknown frequency
- -- Eylea (aflibercept) unopened vial may be stored outside refrigerator below 25 °C for up to 24 hrs
- -- Gavreto (pralsetinib) male patients with female partners of childbearing potential must use effective contraception, including a barrier method during treatment with pralsetinib and for at least 1 week following the last dose of treatment
- -- Lemsip Cough for Mucus Cough & Catarrh (guaifenesin & cetylpyridinium chloride) contraindicated in children under 6 years. Caution is use is also advised in patients with porphyria
- -- Matrifen (fentanyl) transdermal dysphagia added as uncommon potential ADR
- -- Mektovi (binimetinib) occurrence of tumour lysis syndrome, which may be fatal, has been linked to use of binimetinib in association with encorafenib. Risk factors include high tumour burden, pre-existing chronic renal insufficiency, oliquria, dehydration, hypotension and acidic urine
- -- Neupogen (filgrastim) extramedullary haematopoeisis added as ADR of rare frequency
- -- Ninlaro (ixazomib citrate) rare ADRs added: toxic epidermal necrolysis (TEN), anaphylactic reaction, and angioedema. Further warning and precaution information on TEN is also detailed
- -- Nortriptyline unmasking of Brugada syndrome has been reported with nortriptyline. Nortriptyline should generally be avoided in patients with or suspected of having Brugada syndrome. Risk factors for Brugada syndrome include a family history of cardiac arrest or sudden death
- -- Ontozry (cenobamate) suicidal ideation and behaviour have been reported in patients treated with anti-epileptic medicinal products including cenobamate (uncommon frequency)
- -- Questran and Questran Light (colestyramine) info added on concomitant use with a statin, avoiding use in patients with exudative/bloody diarrhoea, timing of administration in relation to absorption of other drugs, risk of constipation or its aggravation, and drug interactions with digoxin and spironolactone
- -- Remsima (infliximab) the period in which administration of live vaccines to infants exposed to infliximab in utero is not recommended has been extended from 6 months to 12 months, after birth. Additionally, dyslipidaemia has been added as an uncommon ADR
- -- Sodium Oxybate shelf-life for unopened product has been changed from 3 to 5 years, and shelf-life after first opening has been changed from 40 to 90 days
- -- Sutent (sunitinib) hyperammonemic encephalopathy added as a potential ADR of treatment (unknown frequency). In patients who develop unexplained lethargy or changes in mental status, ammonia level should be measured and appropriate clinical management should be initiated
- -- Upstaza (eladocagene exuparvovec) feeding disorders included as a possible 'common' ADR, frequencies of irritability changed from 'very common' to 'common' and decubitus ulcer from 'common' to 'very common', paragraph included about cerebrospinal fluid leaks
- -- Zelboraf (vemurafenib) stomatitis added as a common potential ADR of treatment
- Risk minimisation materials

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

-- Farydak (<u>Panobinostat</u>) - patient cards for cycles 1-8 and 9-16 are intended to help patients keep track of their treatment regimen and maintain compliance

Institute for Safe Medication Practices (ISMP) USA

- Medication Safety Alert! April 4, 2024 including: Look-alike vials of Adrenalin and Retacrit
- -- Guardians of Grafts: Reducing Medication Errors in Transplant Recipients link

Medicines and Healthcare products Regulatory Agency (MHRA) UK

- - National Patient Safety Alert: Reducing risks for transfusion-associated circulatory overload link
- Drug Safety Update March 2024
- -- Pseudoephedrine Risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) link

Medsafe (New Zealand Medicines and Medical Devices Safety Authority)

- Calcium channel blockers and the possible risk of new-onset eczema - link

MIMS monthly updates April 2024

- New Contraindications
- -- Morphine sulfate pentahydrate (<u>DBL Morphine Sulfate Injection</u>) is now contraindicated in respiratory failure; bronchial asthma or other obstructive airways disease (regardless of disease duration, severity); emphysema (any severity); severe depressed level of consciousness; diabetic ketoacidosis; and alcoholism or delirium tremens (regardless of disease duration).
- -- Nirmatrelvir and ritonavir (<u>Paxlovid</u>) is now contraindicated for concomitant use with sildenafil when used for pulmonary hypertension; avanafil and vardenafil when used for erectile dysfunction; and zolpidem.

Specialist Pharmacy Services NHS UK

- Using tetracycline antibiotics during breastfeeding link
- Calculating kidney function link

TGA

- Update on the shortage of Bicillin L-A (benzathine benzylpenicillin tetrahydrate) prefilled syringe for injection <u>link</u>
- Substandard semaglutide vials link

PAPERS OF INTEREST

American Journal of Cardiology

- Atrial Thrombosis Prevalence Before Cardioversion or Catheter Ablation of Atrial Fibrillation: An Updated Systematic Review and Meta-Analysis of Direct Oral Anticoagulants Versus Vitamin K Antagonists <u>link</u>
- Cardiovascular Outcomes with Empagliflozin and Dapagliflozin in Patients Without Diabetes link

American Journal of Gastroenterology

- Comparative Efficacy of P-CAB vs Proton Pump Inhibitors for Grade C/D Esophagitis: A Systematic Review and Network Meta-analysis - <u>link</u>

American Journal of Health-System Pharmacy (AJHP)

- Evaluation of pharmacy-supplied half and quarter tablets at an academic medical center link
- Impact of a calcium replacement protocol during massive transfusion in trauma patients at a level 2 trauma center link
- Integration of electronic project management software in an investigational drug service pharmacy within an academic medical center link
- Implementation of CYP2C19 and CYP2D6 genotyping to guide antidepressant use in a large rural health system $\underline{\text{link}}$

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Annals of Emergency Medicine

- Topical Diclofenac Versus Oral Ibuprofen Versus Diclofenac + Ibuprofen for Emergency Department Patients with Acute Low Back Pain: A Randomized Study - link

Annals of Internal Medicine

- Management of Inpatient Elevated Blood Pressures: A Systematic Review of Clinical Practice Guidelines - link
- Long-Term Effect of Salt Substitution for Cardiovascular Outcomes: A Systematic Review and Meta-Analysis - link

Arthritis & Rheumatology

- Effect of secukinumab versus adalimumab biosimilar on radiographic progression in patients with radiographic axial spondyloarthritis: Results from a head-to-head randomized phase IIIb study - link

British Journal of Clinical Pharmacology

- Assessing pain in persons with opioid use disorder: Approaches, techniques and special considerations - link
- Association between reversal agents (sugammadex vs. neostigmine) for neuromuscular block and postoperative pulmonary complications: A retrospective analysis - link
- OpenSAFELY: The impact of COVID-19 on azathioprine, leflunomide and methotrexate monitoring, and factors associated with change in monitoring rate - link

British Journal of General Practice

- Prednisolone in COPD: the overlooked harm - link

British Medical Journal (BMJ)

- Derivation and external validation of a simple risk score for predicting severe acute kidney injury after intravenous cisplatin: cohort study - link
- Use of progestogens and the risk of intracranial meningioma: national case-control study link
- Practice pointer: Group A beta-haemolytic streptococcal infection in children link
- Quantifying possible bias in clinical and epidemiological studies with quantitative bias analysis: common approaches and limitations - link

BMJ Open

- Implementation of an intervention aimed at deprescribing benzodiazepines in a large US healthcare system using patient education materials: a pre/post-observational study with a control group - link

BMJ Quality and Safety

- Estimating the impact on patient safety of enabling the digital transfer of patients' prescription information in the English NHS - link

Circulation

- Sodium Glucose Co-transporter 2 Inhibitors and Major Adverse Cardiovascular Outcomes: A SMART-C Collaborative Meta-Analysis - link
- Topical Versus Intravenous Tranexamic Acid in Patients Undergoing Cardiac Surgery: The DEPOSITION Randomized Controlled Trial - link
- A Prospective Randomized Trial of Direct Oral Anticoagulant Therapy with A Fully Magnetically Levitated LVAD: The DOT-HM3 Study - link
- Randomized Evaluation of a Remote Management Program to Improve Guideline-directed Medical Therapy: The Diabetes Remote Intervention to Improve Use of Evidence-based Medications (DRIVE) Trial - link

Cochrane

- Etidronate for the primary and secondary prevention of osteoporotic fractures in postmenopausal women - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au An initiative of NSW clinical pharmacologists & pharmacists

- Inhaled bronchodilators for the prevention and treatment of chronic lung disease in preterm infants - link

Diabetes Care

- Association Between Treatment Adherence and Continuous Glucose Monitoring Outcomes in People With Diabetes Using Smart Insulin Pens in a Real-World Setting Link
- Point-of-Care HbA1c in Clinical Practice: Caveats and Considerations for Optimal Use link
- Timing of Moderate to Vigorous Physical Activity, Mortality, Cardiovascular Disease, and Microvascular Disease in Adults With Obesity Link

Drug and Therapeutics Bulletin

- DTB Select: Donanemab in early symptomatic Alzheimer's disease link
- Medicines and global warming: a complex problem link

Drug Safety

- Drug-drug interactions and actual harm to hospitalized patients: a multicentre study examining the prevalence pre- and post-electronic medication system implementation - link

European Heart Journal

- Oral anticoagulation in device-detected atrial fibrillation: effects of age, sex, cardiovascular comorbidities, and kidney function on outcomes in the NOAH-AFNET 6 trial Link
- Low-dose colchicine for atherosclerosis: long-term safety link
- Use of new and emerging cancer drugs: what the cardiologist needs to know link

European Journal of Hospital Pharmacy

- Appropriateness of antithrombotics in geriatric inpatients with atrial fibrillation: a retrospective, cross-sectional study \underline{link}
- Haemodynamic effects of intravenous acetaminophen in critically ill paediatric patients: a retrospective chart review <u>link</u>

Health Technology Assessment

- Evaluation of venous thromboembolism risk assessment models for hospital inpatients: the VTEAM evidence synthesis <u>link</u>
- Bisphosphonate alternative regimens for the prevention of osteoporotic fragility fractures: BLAST-OFF, a mixed-methods study <u>link</u>

Heart, Lung and Circulation

- Discharge Information About Adverse Drug Reactions Indicates Lower Self-Reported Adverse Drug Reactions and Fewer Concerns in Patients After Percutaneous Coronary Intervention - Ink

Hospital Pediatrics

- Decreasing prescribing errors in antimicrobial stewardship program-restricted medications - link

Internal Medicine Journal

- The increasing costs of medicines and their implications for patients, physicians and the health system - $\underline{\text{link}}$

International Journal of Clinical Pharmacy

- Novel opportunities for clinical pharmacy research: development of a machine learning model to identify medication related causes of delirium in different patient groups $\underline{\text{link}}$
- Clinical pharmacy key performance indicators for hospital inpatient setting: a systematic review link

JAMA

- Acetaminophen Use During Pregnancy and Children's Risk of Autism, ADHD, and Intellectual Disability - <u>link</u> – <u>SPS commentary</u>

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Risk Assessment and Prevention of Falls in Older Community-Dwelling Adults: A Review link
- Common Oral Conditions: A Review link
- Reducing Hospitalizations and Multidrug-Resistant Organisms via Regional Decolonization in Hospitals and Nursing Homes <u>link</u> <u>SPS commentary</u>
- Integrated Hepatitis C-Opioid Use Disorder Care Through Facilitated Telemedicine: A Randomized Trial link
- Clinical Benefit and Regulatory Outcomes of Cancer Drugs Receiving Accelerated Approval link
- JAMA Patient Page: I Read Health Information Online—Can I Trust It? link
- Systemic Lupus Erythematosus: A Review link
- Mortality Among Users of Anabolic Steroids link

JAMA Cardiology

- Antibiotic Prophylaxis and Infective Endocarditis Incidence Following Invasive Dental Procedures: A Systematic Review and Meta-Analysis <u>link</u>
- Influenza Vaccine Immune Response in Patients with High-Risk Cardiovascular Disease: A Secondary Analysis of the INVESTED Randomized Clinical Trial Link
- Plozasiran (ARO-APOC3) for Severe Hypertriglyceridemia: The SHASTA-2 Randomized Clinical Trial link

JAMA Dermatology

- Human Leukocyte Antigens and Sulfamethoxazole/Cotrimoxazole-Induced Severe Cutaneous Adverse Reactions: A Systematic Review and Meta-Analysis - <u>link</u> - <u>SPS commentary</u>
- Emergency Contraception for Patients Taking Isotretinoin link

JAMA Internal Medicine

- d-Mannose for Prevention of Recurrent Urinary Tract Infection Among Women: A Randomized Clinical Trial - <u>link</u>

JAMA Network Open

- Estimated Sustainable Cost-Based Prices for Diabetes Medicines link
- Drug Efficacy in the Treatment of Antipsychotic-Induced Akathisia link

JAMA Neurology

- Progress in Pharmacologic Management of Neuropsychiatric Syndromes in Neurodegenerative Disorders <u>link</u>
- Early Seizure Prophylaxis in Mild and Moderate Traumatic Brain Injury: A Systematic Review and Meta-Analysis <u>link</u>

JAMA Oncology

- Patient Page: Cancer Care in the Era of Artificial Intelligence link
- Clinical Value of Molecular Targets and FDA-Approved Genome-Targeted Cancer Therapies link

Journal of the American Geriatrics Society

- Melatonin does not reduce delirium severity in hospitalized older adults: Results of a randomized placebo-controlled trial - link

Journal of the American College of Cardiology

- Angiotensin Receptor-Neprilysin Inhibition in Patients With STEMI vs NSTEMI link
- Association of Antiarrhythmic Drug Therapy With Syncope and Pacemaker Implantation in Patients With Atrial Fibrillation link
- Efficacy and Safety of Dapagliflozin in Patients with Acute Heart Failure link

Journal of Infection

- Within-episode repeat antibiotic prescriptions in patients with respiratory tract infections: A population-based cohort study - $\underline{\text{link}}$

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Journal of the National Cancer Institute

- Association of metformin use and cancer incidence: a systematic review and meta-analysis - link

Journal of Pharmacy Practice and Research (JPPR)

- Risk of Pseudomonas aeruginosa antimicrobial resistance using time series analysis of antibiotic usage - link

Lancet

- Valvular heart disease: from mechanisms to management link
- Pharmacotherapy for adults with overweight and obesity: a systematic review and network metaanalysis of randomised controlled trials - <u>link</u>
- Ticagrelor alone versus ticagrelor plus aspirin from month 1 to month 12 after percutaneous coronary intervention in patients with acute coronary syndromes (ULTIMATE-DAPT): a randomised, placebo-controlled, double-blind clinical trial link

Lancet Diabetes & Endocrinology

- Effects of statin therapy on diagnoses of new-onset diabetes and worsening glycaemia in large-scale randomised blinded statin trials: an individual participant data meta-analysis $\underline{\text{link}}$ $\underline{\text{SPS}}$ $\underline{\text{commentary}}$
- Endocrine health in survivors of adult-onset cancer link

Lancet Respiratory Medicine

- High-dose, short-duration versus standard rifampicin for tuberculosis preventive treatment: a partially blinded, three-arm, non-inferiority, randomised, controlled trial - <u>link</u>

Molecular Diversity Preservation International (MDPI) - Pharmacy Journal

- Association of Average Daily Morphine Milligram Equivalents and Falls in Older Adult Chronic Opioid Users <u>link</u>
- Evolution of Telehealth—Its Impact on Palliative Care and Medication Management link
- Evaluation of Oral Amoxicillin/Clavulanate for Urinary Tract Infections Caused by Ceftriaxone Non-Susceptible Enterobacterales $\underline{\text{link}}$

Medical Journal of Australia

- Australian consensus statement on doxycycline post-exposure prophylaxis (doxy-PEP) for the prevention of syphilis, chlamydia and gonorrhoea among gay, bisexual and other men who have sex with men link and response
- Editorial: Interventions for reducing the prescribing of pharmaceutical opioids in Australia: are they effectively reducing opioid harm? <u>link</u> and <u>research article</u>
- The uptake of long-acting depot buprenorphine for treating opioid dependence in Australia, 2019–2022: longitudinal sales data analysis link

New England Journal of Medicine

- Nirmatrelvir for Vaccinated or Unvaccinated Adult Outpatients with Covid-19 <u>link</u> <u>SPS</u> <u>commentary</u>
- Prevention of Cardiovascular Disease in Type 1 Diabetes link
- Apolipoprotein A1 Infusions and Cardiovascular Outcomes after Acute Myocardial Infarction link
- Beta-Blockers after Myocardial Infarction and Preserved Ejection Fraction link
- Empagliflozin after Acute Myocardial Infarction link SPS commentary
- Olezarsen for Hypertriglyceridemia in Patients at High Cardiovascular Risk link
- Semaglutide in Patients with Obesity-Related Heart Failure and Type 2 Diabetes link

Pediatric Emergency Care

- Medication Errors in Pediatric Emergency Departments: A Systematic Review and Recommendations for Enhancing Medication Safety - <u>link</u>

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

Pharmacotherapy

- Simulated cost-effectiveness of a novel precision-quided dosing strategy in adult patients with Crohn's disease initiating infliximab maintenance therapy - link
- Vancomycin AUC0-24 estimation using first-order pharmacokinetic methods in pediatric patients link

Prescrire International – April 2024 issue including:

- Editorial: Evaluating drugs for today's patients, without neglecting tomorrow's patients link
- GLP-1 agonists: depression, suicidal thoughts or behaviour?
- RSVpreF vaccine (Abrysvo°) during pregnancy to prevent RSV infection in the woman's child after
- Prescrire's ratings of new drugs in 2023

WEBINARS & PODCASTS

Australian Prescriber Podcasts

Episode 161 – Managing hypercholesterolaemia

MJA Podcasts

- Episode 11: Pregnancy supplements how much is too much?
- Episode 10: How GPs can help women improve their self-compassion and reduce depression

Victorian Institute of Forensic Medicine

- Residential Aged Care Communiqué Episode #17: Diabetes mellitus - link

UPCOMING EVENTS

AHHA

- Webinar: Advancing VBHC in Australia: Lessons from the NHS Wales, online, 2 May 2024 12:30-13:30 - <u>register</u>
- Post-Budget Health Leaders Roundtable, Canberra, 17 May 2024 10:00-16:00 register

Fortnightly TAG Mail – resources list

28th March 2024

NSW TAG ACTIVITIES

Open email discussions

- 1.DTC assessment process for non-GMO phage therapy applications: Do NSW TAG members have a process for DTC assessment of these applications and, if so, would they be willing to share it? Closes 3rd April 2024
- 2. Handling of medicines by perfusionists: How are hospitals managing oversight of this type of medicine use? Are other sites using Standing Orders for perfusionists (as suggested by the Medication Handling PD)? Do sites have a perfusionists' imprest list? Has it been expanding and does it include restricted medicines? Is administration documented and if so, where? Closes 3rd April 2024.

Recently completed email discussions

- DTC pharmacists in NSW
- Patient prioritisation for discharge medication list provision
- Missing medications from wards
- Medication reviews for inpatients in remote Multi-Purpose Services.

Upcoming TAG meetings

NSW TAG General Meeting: Thursday 4th April 2024 11.30-1pm NSW TAG Management Committee 3rd May 2024 9.45am-11am

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988

Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au An initiative of NSW clinical pharmacologists & pharmacists

Updated TAG publications

Updated SGLT2 inhibitor Consumer Leaflet; NSW TAG Copyright Statement and Permission Form Contact Sasha Bennett at sasha.bennett@svha.org.au for further information about any email discussions, publications or upcoming meetings.

EDITOR'S PICKS

AJHP: Standardization of key performance indicators and metrics for investigational drug services: Consensus recommendations among IDS specialists - link

AJHP: Evaluating the utility of procalcitonin and a clinical decision support tool to determine duration of antimicrobial therapy for respiratory tract infections - link

BJCP: Assessment and evaluation of prescribing competencies: A SR and recommendations - link

BJCP: The risk of delirium after sedation with propofol or midazolam in ICU patients - link

BJCP: Differences in prescribing errors between electronic prescribing and traditional prescribing among medical students - link

BJCP: Innovations in pharmacovigilance studies of medicines in older people - link

BMJ: Current safeguards, risk mitigation, and transparency measures of large language models against the generation of health disinformation - link

CPC: Smoking cessation patient resources: the perioperative care benefits - link

EJHP: The threatened medicines information pharmacist! - link

Hosp Pharm: Analysis of intervention employability in pharmacy-related medication safety reports at a tertiary medical center - link

JAMA: Management of Outpatients with Diabetes at High Risk of Hypoglycemia - link

JAMA Dermatology: Adjuvant Immunotherapy in Stage II Melanoma - link

JAMA Oncology: Neoadjuvant Chemoimmunotherapy for NSCLC - link

JPPR: Cultivating optimal analgesic prescribing practices in a metropolitan hospital network: evaluating an analgesic stewardship program - link

JPPR: Standard of practice in pharmacy informatics - link

Lancet Neurology: Review: Secondary stroke prevention in people with atrial fibrillation - link

MJA- Perspectives: Contemporary management of advanced colorectal cancer - link

NEJM: Risk of Autism after Prenatal Topiramate, Valproate, or Lamotrigine Exposure - link

SIGN: Optimising glycaemic control in people with type 1 diabetes, a decision-support toolkit - link

SPS: Understanding contamination control in pharmacy aseptic services - link

WHO: Global burden of preventable medication-related harm in health care: a systematic review - link

OTHER NEWS (new additions in bold)

NSW Health

- Stay safe from mosquitoes this Easter long weekend link
- NSW Health consults with staff on updating COVID-19 vaccination requirements link
- Measles alert for western Sydney link
- Hepatitis C Testing and Care in Alcohol and Other Drug Services (IB2024_015)
- Pension Based Fees (IB2024 016)
- Clinical Governance in NSW (PD2024 010)
- The Use of the Emergency Care Assessment and Treatment (ECAT) Protocols (PD2024 011)

REPORTS AND PUBLICATIONS - AUSTRALIA

Agency for Clinical Innovation, NSW (ACI)

The latest weekly Evidence Digest can be found here

- NSW Paediatric PCA or NCA chart (SMR130.026) [presentation]
- NSW Weight Based Paediatric PCA or NCA chart [SMR130031] (presentation)

Australian Institute for Health and Welfare (AIHW)

- Treatment pathways for people hospitalised for acute coronary syndrome link
- Better cardiac care measures for Aboriginal and Torres Strait Islander people: eighth national report 2023 - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Acute rheumatic fever and rheumatic heart disease in Australia, 2022 link
- Dementia in Australia link

PBS Updates- link

- Stocktake of PBS medicines available for endometriosis and related conditions Report
- Updates to the HTA Policy and Methods Review Reference Committee 26 March 2024
- Drug Utilisation Sub-Committee (DUSC) Utilisation Analysis Public Release Documents and Outcome Statement

Pharmacy Council of NSW

- Guidelines on dose administration aids and staged supply of dispensed medicines - link

TGA

- <u>Database</u> of section 19A approvals to import and supply medicines to address medicine shortages
 AusPARs:
- -- MELATONIN-<u>LINK</u>, IMMELA, MELAKSO, VOQUILY for short-term treatment of jet lag in adults aged 18 and over, and for sleep disorders in children and adolescents with neurodevelopmental disorders
- -- Alhemo (<u>concizumab</u>) is approved to prevent or reduce frequency of bleeding in patients who have haemophilia B with FIX inhibitors

REPORTS AND PUBLICATIONS - INTERNATIONAL

Agency for Healthcare Research and Quality (AHRQ) USA

- ADHD Diagnosis and Treatment in Children and Adolescents - link

British National Formulary

- BNF/BNFC newsletter: March 2024

Canadian Agency for Drugs and Technologies in Health

- Utilization Analysis of Tofacitinib and Other Drugs Among Individuals With Ulcerative Colitis: Feasibility Analysis, updated <u>link</u>
- Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors in Type 2 Diabetes Mellitus, Heart Failure, and Chronic Kidney Disease, updated <u>link</u>

Centre for Perioperative Care UK

- Smoking cessation patient resources: the perioperative care benefits - link

electronic Medicines Compendium (eMC) (UK)

- New products
- -- Adacel (diphtheria, tetanus and pertussis vaccine) pre-filled for active immunization in persons from 4 years of age as a booster following primary immunization, and for passive protection against pertussis in early infancy following maternal immunization during pregnancy
- -- Entresto (valsartan, sacubitril) capsules for opening for children and adolescents aged ≥1 year with symptomatic chronic heart failure with left ventricular systolic dysfunction. The capsules should be opened and the granules sprinkled onto a small amount (1-2 teaspoons) of soft food
- -- Sendolor (morphine hydrochloride trihydrate) for severe acute pain, cancer pain and breakthrough cancer pain, for IV, subcutaneous, intramuscular, epidural or intrathecal administration
- -- Tyruko 300 mg (natalizumab biosimilar) for use as a single disease modifying therapy in adults with highly active relapsing remitting multiple sclerosis (RRMS) despite a full and adequate course of treatment with at least one disease modifying therapy, & in those with rapidly evolving severe RRMS
- -- Vanflyta (quizartinib) in combination with cytarabine & anthracycline induction and cytarabine consolidation chemotherapy, followed by quizartinib maintenance monotherapy for adult patients with newly diagnosed FLT3-ITD positive acute myeloid leukaemia
- -- Verorab (rabies vaccine) inactivated rabies vaccine for pre- and post- exposure prophylaxis
- Revised SPCs

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- -- AmBisome (amphotericin) updated with dosing recommendation for Cryptococcal meningitis for people living with HIV; amended dosing recommendations for mycoses and mucormycosis
- -- HyQvia (human normal immunoglobulin) license extension for use as immunomodulatory therapy in adults, children and adolescents (0 to 18 years) in chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy after stabilisation with IV immunoglobulin
- -- Imfinzi (durvalumab) durvalumab + tremelimumab has been studied in children aged 1-17 years with neuroblastoma, solid tumour and sarcoma (outside the authorised indications), however the results did not allow the conclusion that the benefits of such use outweigh the risks

European Medicines Agency (EMA)

- CHMP changes to the terms of the marketing authorisation
- -- enzalutamide (<u>Xtandi</u>) also as monotherapy or in combination with androgen deprivation therapy for treatment of adult men with high risk biochemical recurrent non-metastatic hormone sensitive prostate cancer who are unsuitable for salvage radiotherapy
- -- selpercatinib (<u>Retsevmo</u>) to include its use for the treatment of adults with advanced RET fusion-positive solid tumours, when treatment options not targeting RET provide limited clinical benefit, or have been exhausted
- CHMP approvals
- -- bempedoic acid (Nilemdo) to reduce cardiovascular risk
- -- bimekizumab (Bimzelx) for severe hidradenitis suppurativa
- CHMP marketing authorisations
- -- irinotecan hydrochloride trihydrate (<u>Onivyde</u> pegylated liposomal) for first-line treatment of metastatic adenocarcinoma of the pancreas
- -- aztreonam / avibactam (Emblaveo) for treatment of multi-drug resistant bacterial infection
- -- dantrolene sodium / hemiheptahydrate (Agilus) for treatment of malignant hyperthermia
- -- insulin icodec (Awigli) long-acting basal insulin given subcutaneously once a week
- -- intravitreal bevacizumab gamma (<u>Lytenava</u>) for treatment of neovascular (wet) age-related macular degeneration
- -- iptacopan (Fabhalta) for paroxysmal nocturnal haemoglobinuria
- -- dopamine hydrochloride (Neoatricon) for hypotension
- -- porcine pancreas enzymes (Micrazym) in the EU evidence comparable to Creon

Food and Drug Administration (FDA) USA

- Approvals- link
- -- atidarsagene autotemcel (Lenmeldy) gene therapy approved for metachromatic leukodystrophy
- -- bempedoic acid (Nexletol) new indication approved for CV risk reduction
- -- givinostat (Duvyzat) for Duchenne Muscular Dystrophy in patients aged 6 years an older PI/label
- -- mirvetuximab soravtansine-gynx for FR α positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer
- -- pemivibart (<u>Pemgarda</u>) EUA for monoclonal antibody to prevent COVID-19 in immunosuppressed individuals
- -- <u>ponatinib</u> with chemotherapy for newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia
- -- ravulizumab (<u>Ultomiris</u>) C5 complement inhibitor for neuromyelitis optica spectrum disorder
- -- <u>resmetirom</u> for adults with noncirrhotic non-alcoholic steatohepatitis (NASH) with moderate to advanced fibrosis <u>PI/label</u>
- -- Sotatercept-Csrk (Winrevair) for treatment of adults with pulmonary arterial hypertension
- -- Tevimbra (<u>tislelizumab-jsgr</u>) to treat unresectable or metastatic esophageal squamous cell carcinoma
- -- Tryvio (aprocitentan) to treat hypertension

Medicines and Healthcare products Regulatory Agency (MHRA)

- Ganaxolone (Ztalmy) for epileptic seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder in children - Link

An initiative of NSW clinical pharmacologists & pharmacists

MIMS UK

- Understanding diabetes technologies: free MIMS online supplement - link

NHS England

- Clinical commissioning policy: prescribing of gender affirming hormones (masculinising or feminising hormones) as part of the children and young people's gender service <u>link</u> <u>SPS commentary</u>
- Guidance: Desflurane decommissioning and clinical use link

NHS Scotland - Scottish Medicines Consortium

- Accepted for restricted use:
- -- Nirmatrelvir and ritonavir (Paxlovid®) for the treatment of Covid-19 in adults

National Institute for Health and Care Excellence (NICE) UK

- Meningitis (bacterial) and meningococcal disease: recognition, diagnosis and management (NG240)
- Momelotinib for treating myelofibrosis-related splenomegaly or symptoms (TA957)
- Ovarian cancer: identifying and managing familial and genetic risk (NG241)
- Digital health technologies to help manage symptoms of psychosis and prevent relapse in adults and young people: early value assessment (<u>HTE17</u>)
- Desflurane for maintenance of anaesthesia (ES41)
- Daratumumab in combination for treating newly diagnosed systemic amyloid light-chain amyloidosis (TA959)
- Ritlecitinib for treating severe alopecia areata in people 12 years and over (TA958)

National Institute for Health and Care Research (NIHR)

- NIHR Commentaries
- -- Children in intensive care have better outcomes with lower oxygen targets link
- - Irritable bowel syndrome: low-dose antidepressant improves symptoms link

Parliamentary and Health Service Ombudsman UK

- End of life care: improving DNACPR conversations for everyone - link

Scottish Intercollegiate Guideline Network (SIGN) UK

- Optimising glycaemic control in people with type 1 diabetes, a decision-support toolkit - link

Specialist Pharmacy Services NHS UK

- Understanding contamination control in pharmacy aseptic services - link

UK Health Security Agency

- National measles guidelines - update to measles post exposure prophylaxis section - link

World Health Organisation (WHO)

- Global burden of preventable medication-related harm in health care: a systematic review link
- WHO launches new toolkit empowering health professionals to tackle climate change link

MEDICATION SAFETY

electronic Medicines Compendium (eMC) (UK)

- Revised SPCs
- -- Benlysta (belimumab) updated to advise progressive multifocal leukoencephalopathy (PML) reported with Benlysta for SLE, to watch for cognitive, neurological or psychiatric symptoms/signs, & action to take if they occur. If PML suspected, Benlysta, must be stopped until PML excluded
- -- Braftovi (encorafenib) Tumour Lysis Syndrome added as an ADR with a frequency of 'unknown'
- -- Clomid (clomifene) should not be given if history of significant, medically confirmed vision disorders related to use of Clomid is known. Information on visual disturbances updated to note some cases have been prolonged or irreversible, especially with increased dose or duration

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- -- Cresemba (isavuconazonium) updated with improved guidance for healthcare professionals in relation to how to manage co-administration of cyclophosphamide with isavuconazole
- -- Fenpaed Ibuprofen Fixed drug eruption added as undesirable effect (frequency unknown)
- -- Lioresal (baclofen) hypertonia as a symptom of withdrawal/abrupt discontinuation. Undesirable effects added: face swelling and peripheral oedema, alopecia, hypersensitivity, and sexual dysfunction (frequency not known)
- -- Miprosed (midazolam) Kounis syndrome added as possible ADR, frequency 'unknown'
- -- Spikevax bivalent original/Omicron BA.4-5 (50 micrograms/50 micrograms)/mL, Spikevax XBB.1.5 0.1 mg/mL chronic urticaria as ADR of unknown frequency. It is already noted that urticaria can occur uncommonly with acute or delayed onset (~2 weeks post dose). SPC advises not to give subsequent doses to those with prior severe allergic reactions
- -- Quinoric (hydroxychloroquine sulfate) benefits/risk of continuing treatment should be assessed in those with significant liver function abnormalities, and a heading for azithromycin and macrolide antibiotics has been added to the interactions section
- -- Targinact (oxycodone hydrochloride, naloxone hydrochloride dehydrate) undesirable effects reclassified as frequency not known: drug dependence (previously rare), drug withdrawal syndrome (previously uncommon), and drug tolerance (previously uncommon)
- -- Toradol (ketorolac) may cause oligohydramnios resulting from foetal renal dysfunction from the 20th week of pregnancy. It should not be given during the first and second trimester, unless clearly necessary, and is contra-indicated during the third trimester
- -- Venzip (venlafaxine hydrochloride) XL risk of hypoglycaemia related to overdose. Severe poisoning symptoms may occur in adults after intake of approximately 3grams of venlafaxine
- -- Vibramycin-D (doxycycline) 'Fixed eruption' added as a possible "rare" ADR
- -- VidPrevtyn Beta (covid-19 Vaccine; recombinant, adjuvanted) new safety data from 6236 patients in a Phase 3 study. Booster vaccine given ≥4 months after primary series vaccine, with median duration follow up 58 days (84% completing ≥6 weeks follow up). Safety profile consistent with adverse reactions from previous study
- -- Yescarta (axicabtagene ciloleucel) JC virus reactivation leading to progressive multifocal leukoencephalopathy (PML) in patients also taking other immunosuppressants. Cases with fatal outcome reported & PML should be considered in those with new/worsening neurological symptoms
- -- Viread (tenofovir disoproxil fumarate) 'Bone mineral density decreased' listed as a possible "common" ADR. Warning regarding bone effects amended
- Risk minimisation materials
- -- Tyruko (natalizumab biosimilar) Physician's guidelines discuss the risk and nature of PML, risk factors for its development, its diagnosis and treatment, specific steps to be taken to minimise this risk and the identification and management of possible sequelae. A patient alert card is also available

FDA

- Approves safety labelling changes regarding DPD deficiency for fluorouracil injection products link
- Warns Consumers to Avoid Certain Topical Pain Relief Products Due to Potential for Dangerous Health Effects <u>link</u>

Institute for Safe Medication Practices (ISMP) USA

- Medication Safety Alert! March 21, 2024
- -- Implement Strategies to Prevent Persistent Medication Errors and Hazards: 2024 link
- -- Magnesium sulfate almost administered instead of dexmedeTOMIDine
- -- Fleet enemas, not as benign as they seem

MedEffect, Canada

- Ezetrol (ezetimibe) and the Risks of Drug-Induced Liver Injury and Severe Cutaneous Adverse Reactions - <u>link</u>

Specialist Pharmacy Services NHS UK

- Treating impetigo topically during breastfeeding link
- Using macrolide antibiotics during breastfeeding link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Treating nausea during breastfeeding link
- Medication safety update March 2024

TGA

- Updated warnings of faricimab (Vabysmo) retinal vasculitis risk link
- Metalyse (tenecteplase) 40 mg powder for injection to be discontinued link
- Shortages of Estradot (estradiol) transdermal patches to continue link
- Product Information safety updates March 2024
- Updates to the Prescribing Medicines in Pregnancy database March 2024

PAPERS OF INTEREST

American Journal of Health-System Pharmacy (AJHP)

- Considerations of gender-affirming care for transgender and gender-diverse youth link
- latrogenic hyperchloremia: An overview in hospitalized patients for pharmacists link
- Impact of pharmacist-driven referral to increase specialty pharmacy prescription capture link
- Standardization of key performance indicators and metrics for investigational drug services (IDS): Consensus recommendations among IDS specialists link
- The paradigm to overcome in acute decompensated heart failure link
- Evaluating the utility of procalcitonin and a clinical decision support tool to determine duration of antimicrobial therapy for respiratory tract infections link
- Analysis of appropriateness and safety when discharging patients on triple-antithrombotic therapies link

Arthritis & Rheumatology

- Effect of Recent Antirheumatic Drug on Features of Rheumatoid Arthritis—Associated Lymphoproliferative Disorders link
- Risk of Venous Thromboembolism with Tofacitinib Versus Tumor Necrosis Factor Inhibitors in Cardiovascular Risk-enriched Rheumatoid Arthritis Patients link

British Journal of Clinical Pharmacology

- The risk of delirium after sedation with propofol or midazolam in intensive care unit patients link
- Assessment and evaluation of prescribing competences: A systematic review and recommendations
- Frailty in clinical drug trials: Frailty assessments, subgroup analyses and outcomes link
- Differences in prescribing errors between electronic prescribing and traditional prescribing among medical students: A randomized pilot study <u>link</u>
- Therapeutic drug monitoring, liquid biopsies or pharmacogenomics for prediction of human drug metabolism and response <u>link</u>
- Innovations in pharmacovigilance studies of medicines in older people link

British Journal of General Practice

- Preventive interventions to improve older people's health outcomes: systematic review and meta-analysis $\underline{\mathsf{link}}$ $\underline{\mathsf{SPS}}$ commentary
- Risk of Parkinson's disease in people with New Onset Anxiety over 50 years Incidence and Associated Features <u>link</u> <u>SPS commentary</u>

British Medical Journal (BMJ)

- Impact of chronic oral glucocorticoid treatment on mortality in patients with COVID-19: analysis of a population-based cohort <u>link</u>
- Statins, risk, and personalised care link
- Current safeguards, risk mitigation, and transparency measures of large language models against the generation of health disinformation: repeated cross sectional analysis <u>link</u> <u>SPS commentary</u>
- Community based complex interventions to sustain independence in older people: systematic review and network meta-analysis <u>link</u> <u>SPS commentary</u>

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

- Practice Pointer: Dry eye disease management link
- State of the Art Review: Effectiveness and safety of drugs for obesity link

BMJ Open

- Association between benzodiazepine coprescription and mortality in people on opioid replacement therapy: a population-based cohort study <u>link</u> <u>SPS commentary</u>
- Exploring the pharmacists' role in optimising antithrombotic therapy in primary care: a qualitative study link
- Finerenone cardiovascular and kidney outcomes by age and sex: FIDELITY post hoc analysis of two phase 3, multicentre, double-blind trials link

Cochrane

- Prophylactic corticosteroids for cardiopulmonary bypass in adult cardiac surgery link
- Prebiotics for induction and maintenance of remission in ulcerative colitis link
- Psychological therapies for depression in older adults residing in long-term care settings link

Diabetes Care

- Comparing Continuous Glucose Monitoring and Blood Glucose Monitoring in Adults With Inadequately Controlled, Insulin-Treated Type 2 Diabetes (Steno2tech Study): A 12-Month, Single-Center, Randomized Controlled Trial link
- Individualizing Treatment of Type 2 Diabetes After Metformin: More Insights From GRADE link
- Effects of tirzepatide versus basal insulins in people with type 2 diabetes and different baseline glycemic patterns: post hoc analyses of the SURPASS-3 and SURPASS-4 trials link

Drug and Therapeutics Bulletin

- DTB Select: Does oseltamivir prevent hospitalisation in people with influenza? link
- DTB Select: Effect of topical testosterone on pre-diabetes and diabetes link
- DTB Select: Use of oral penicillin challenge in low-risk penicillin allergy link
- Slynd: does a drospirenone progestogen-only pill offer an advantage? link

European Heart Journal

- Inorganic nitrate benefits contrast-induced nephropathy after coronary angiography for acute coronary syndromes: the NITRATE-CIN trial - link

European Journal of Hospital Pharmacy

- Economic impact of a clinical pharmacist in the orthopaedic sector: a review of the literature link
- The threatened medicines information pharmacist! link

Health Technology Assessment

- A randomised, double blind, placebo-controlled trial of a two-week course of dexamethasone for adult patients with a symptomatic Chronic Subdural Haematoma (Dex-CSDH trial) link
- Early switch from intravenous to oral antibiotic therapy in patients with cancer who have low-risk neutropenic sepsis: the EASI-SWITCH RCT link
- Allopurinol and cardiovascular outcomes in patients with ischaemic heart disease: the ALL-HEART RCT and economic evaluation <u>link</u>

Hosp Pharm

- Analysis of intervention employability in pharmacy-related medication safety reports at a tertiary medical center - link

International Journal of Clinical Pharmacy

- The efficacy of zuranolone versus placebo in postpartum depression and major depressive disorder: a systematic review and meta-analysis - link

JAMA

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au An initiative of NSW clinical pharmacologists & pharmacists

- Management of Outpatients with Diabetes at High Risk of Hypoglycemia link
- Use of Lecanemab for Patients with Cardiovascular Disease The Challenge of Uncertainty link
- Stroke Risk After COVID-19 Bivalent Vaccination Among US Older Adults link SPS commentary
- Patient page: What Is Perinatal Depression? link; What Is Priapism? link
- Eosinophilic Gastrointestinal Disease link
- Selective Androgen Receptor Modulators—Transformative Drugs or Heralds of the Next Drug Epidemic? $\underline{\text{link}}$

JAMA Cardiology

- Ticagrelor or Clopidogrel Monotherapy vs Dual Antiplatelet Therapy After Percutaneous Coronary Intervention: A Systematic Review and Patient-Level Meta-Analysis - link

JAMA Dermatology

- Adjuvant Immunotherapy in Stage II Melanoma—Further Risk Stratification is Needed link
- Expert Recommendations on Use of Topical Therapeutics for Vitiligo in Pediatric, Adolescent, and Young Adult Patients <u>link</u>
- Outcome Measurement Instruments Used to Evaluate Dermatologic Adverse Events in Cancer Trials: A Systematic Review <u>link</u>

JAMA Network Open

- Intensive vs Conventional Blood Pressure Control After Thrombectomy in Acute Ischemic Stroke link
- Habitual Short Sleep Duration, Diet, and Development of Type 2 Diabetes in Adults link

JAMA Neurology

- Risk of Major Congenital Malformations and Exposure to Antiseizure Medication Monotherapy link
- Early Use of Erenumab vs Nonspecific Oral Migraine Preventives: The APPRAISE Randomized Clinical Trial <u>link</u>
- High-Efficacy Therapy Discontinuation vs Continuation in Patients 50 Years and Older with Nonactive MS <u>link</u>

JAMA Oncology

- Neoadjuvant Chemoimmunotherapy for NSCLC: A Systematic Review and Meta-Analysis link
- PARP Inhibitors for Breast Cancer Treatment: A Review link

JAMA Psychiatry

- Bright Light Therapy as Add-On to Inpatient Treatment in Youth With Moderate to Severe Depression: A Randomized Clinical Trial link
- Baseline Antipsychotic Dose and Transition to Psychosis in Individuals at Clinical High Risk: A Systematic Review and Meta-Analysis link

Journal of Infection

- A multicentre observational study to investigate feasibility of a direct oral penicillin challenge in delabelling 'low risk' patients with penicillin allergy by non-allergy healthcare professionals (SPACE study): Implications for healthcare systems - link

Journal of Pharmacy Practice and Research (JPPR)

- Cultivating optimal analgesic prescribing practices in a metropolitan hospital network: evaluating an analgesic stewardship program <a href="https://link.gov/lin
- Standard of practice in pharmacy informatics link
- Reasonable adjustments to application of the Medication Safety Standard for adult patients living with intellectual disability in Australian hospital settings link

Lancet Diabetes & Endocrinology

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

- Tight versus liberal blood-glucose control in the intensive care unit: special considerations for patients with diabetes - link

Lancet Neurology

- Global, regional, and national burden of disorders affecting the nervous system, 1990–2021: a systematic analysis for the Global Burden of Disease Study 2021 link
- Review: Secondary stroke prevention in people with atrial fibrillation: treatments and trials link

Lancet Psychiatry

- Heterogeneity of outcome measures in depression trials and the relevance of the content of outcome measures to patients: a systematic review link
- Establishing a research agenda for the study and assessment of opioid withdrawal link

Lancet Respiratory Medicine

- Efficacy of oral corticosteroids for acute preschool wheeze: a systematic review and individual participant data meta-analysis of randomised clinical trials - Link - SPS commentary

Medical Journal of Australia

- Perpectives: Contemporary management of advanced colorectal cancer: the Australian experience - link

New England Journal of Medicine

- Oral Iptacopan Monotherapy in Paroxysmal Nocturnal Hemoglobinuria link SPS commentary
- Ribociclib plus Endocrine Therapy in Early Breast Cancer link
- Risk of Autism after Prenatal Topiramate, Valproate, or Lamotrigine Exposure link

Pediatrics (American Academy of Pediatrics)

- Treatments for ADHD in Children and Adolescents: A Systematic Review - link

Pharmaceutical Journal

- Fourteen nitazenes made Class A controlled drugs - link

Pharmacotherapy

- Exploring variations in recommended first-choice therapy for complicated urinary tract infections in males: Insights from outpatient settings across age, race, and ethnicity - <u>link</u>

WEBINARS & PODCASTS

Australian Prescriber Podcasts

- Episode 160 - Ongoing challenges of off-label prescribing

MJA Podcasts

- Episode 9: Reducing psychological distress among patients after cardiac surgery

SHPA

- MedsAware: Deprescribing Action Week - available until 21 April 2024

Fortnightly TAG Mail – resources list

14th March 2024

NSW TAG ACTIVITIES

Open email discussions

- 3. Patient prioritisation for discharge medication list provision: A TAG member would like to know how other hospitals prioritise their patients for the creation/supply of pharmacist-generated discharge medication lists. Closes 18th March 2024.
- 4.**DTC pharmacists in NSW:** what FTE is assigned to the DTC pharmacist role; is the DTC pharmacist role district or facility based; is the DTC pharmacist also the secretariat for the DTC; who

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

does the DTC pharmacist report to; do you have a Position Statement, and if so, would you be willing to share; is the DTC Pharmacist role combined with any other Pharmacist role, and if so, what (and FTE is possible); and, does the DTC have additional administrative support? Closes 21st March 2024

- 5. **DTC** assessment process for non-GMO phage therapy applications: do NSW TAG members have a process for DTC assessment of these applications and, if so, would they be willing to share it? Closes 24th March 2024
- 6. **Handling of medicines by perfusionists:** How are hospitals managing oversight of this type of medicine use? Are other sites using Standing Orders for perfusionists (as suggested by the Medication Handling PD)? Do sites have a perfusionists' imprest list? Has it been expanding and does it include restricted medicines? Is administration documented and if so, where? **Closes 28th March 2024.**

Recently completed email discussions

- Missing medications from wards
- Medication reviews for inpatients in remote Multi-Purpose Services.

Upcoming TAG meetings

NSW TAG General Meeting: Thursday 4th April 2024 11.30-1pm NSW TAG Management Committee 3rd May 2024 9.45am-11am

Updated TAG publications

Coming soon: Updated SGLT2 inhibitor Consumer Leaflet; NSW TAG Copyright Statement and Permission Form

Contact Sasha Bennett at <u>sasha.bennett@svha.org.au</u> for further information about any email discussions, publications or upcoming meetings.

EDITOR'S PICKS

AHHA: Climate change disasters impact in human health- link

Deeble Institute: Value-based health care: Lessons from NHS Wales - link

AHRQ: Adverse events essociated With COVID-19 pharmaceutical treatments - link

NHS England: - UK survey report of pharmacy professionals' involvement in research - link

AJHP: Optimized adult epidural infusion preparations to reduce waste and improve operational efficiency - link

BMJ: - Ultra-processed food exposure and adverse health outcomes- link

DOM: - Glycaemic control and macrovascular and microvascular outcomes in type 2 diabetes: Systematic review and meta-analysis of cardiovascular outcome trials of novel glucose-lowering agents - link

Drug Safety: - Exploring the Role of Guidelines in Contributing to Medication Errors- link

EJHP: Development of hospital pharmacy services at transition of care points - link

IJQHC: - How are we handling protein drugs in hospitals? - link

JAMA Network Open: Telemedicine vs telephone consultations and medication prescribing errors among referring physicians – <u>link</u>

Lancet: mRNA-based therapeutics: looking beyond COVID-19 vaccines - link

MDPI: - Influences of software changes on oxycodone prescribing at an Australian ED-link

MJA: Clinical artificial intelligence in Australian hospitals - link

NEJM: Microplastics and nanoplastics in atheromas and aardiovascular events - link

SHTI: Effects of an electronic medication system on medication administration errors - link

OTHER NEWS

NSW Health

- Measles alert for Sydney Domestic Airport and Sydney CBD - link

TGA

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Consultation to remove glucagon-like-peptide-1 (GLP-1) receptor agonist analogues from the pharmacist extemporaneous compounding exemption - <u>link</u>

REPORTS AND PUBLICATIONS - AUSTRALIA

Agency for Clinical Innovation, NSW (ACI)

The latest weekly Evidence Digest can be found here

Australian Healthcare and Hospitals Association (AHHA)

- These three climate disasters will have the biggest impact on human health by 2050 - link

Australian Institute for Health and Welfare (AIHW)

- Spinal injuries in Australia 2020-21 link
- Medicare-subsidised GP, allied health and specialist health care across local areas: 2022-23 link

Deeble Institute

- Perspectives Brief No. 30: Value-based health care: Lessons from NHS Wales link
- Perspectives Brief No.29: Engaging older persons and carers as co-researchers link

MIMS monthly updates

- New Products
- -- Nirsevimab (<u>Beyfortus</u>), a recombinant long-acting monoclonal antibody indicated for the prevention of RSV lower respiratory tract disease in neonates, infants born during or entering their first RSV season and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season in accordance with official recommendations
- New Indications
- -- Brentuximab vedotin (<u>Adcetris</u>) for previously untreated CD30+ stage III or IV Hodgkin lymphoma in combination with doxorubicin, vinblastine, and dacarbazine.
- -- Dostarlimab (<u>Jemperli</u>) in combination with carboplatin and paclitaxel for adults with primary advanced or recurrent mismatch repair deficient/ microsatellite instability-high endometrial cancer
- -- Nivolumab (Opdivo) as monotherapy for the adjuvant treatment of adults and adolescent patients 12 years and older with completely resected Stage IIB, IIC, III or IV melanoma
- -- Pneumococcal 20 valent polysaccharide conjugate vaccine (<u>Prevenar 20</u>) for active immunisation to prevent pneumococcal disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in individuals from 6 weeks of age and older in accordance with official recommendations
- -- Ravulizumab (rch) (<u>Ultomiris</u> 100 mg/mL) for adults with Neuromyelitis Optica Spectrum Disorder (NMOSD) who are anti-aquaporin 4 antibody-positive. Not for acute treatment of an NMOSD relapse.
- -- Relugolix, estradiol and norethisterone acetate (Ryego) for symptomatic endometriosis in adult women of reproductive age with a history of previous medical or surgical treatment for their endometriosis

PBS

- PBS arrangements due to discontinuation of Ordine 10 (morphine hydrochloride trihydrate) oral liquids effective - 1 March 2024 - link

TGA

- Shortage updates for Vyvanse (lisdexamfetamine dimesilate) capsules link
- Substitution approved for gliclazide 30 mg tablet shortages link
- Database of section 19A approvals to import and supply medicines to address medicine shortages
- AusPARs:
- -- <u>Exarane/Exarane Forte</u> (enoxaparin sodium) for prevention of thrombo-embolic disorders/ thrombosis; prophylaxis of venous thromboembolism; treatment of deep vein thrombosis/ unstable angina/ non-Q-wave myocardial infarction/ acute ST-segment elevation myocardial infarction
- -- Nurtec ODT (<u>rimegepant</u>) for acute treatment of migraine and prophylactic treatment of episodic migraine in adults

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

- Australian prescription medicine decision summaries:
- -- Spy Agent Green, an imaging agent (dye)
- -- Onakta (<u>tirbanibulin</u>) for the topical field treatment of non-hyperkeratotic, nonhypertrophic actinic keratosis of the face or scalp in adults
- -- Veoza (<u>fezolinetant</u>) for the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause

REPORTS AND PUBLICATIONS - INTERNATIONAL

Agency for Healthcare Research and Quality (AHRQ) USA

- Rapid Evidence Product: Adverse Events Associated With COVID-19 Pharmaceutical Treatments link

All Wales Medicines Strategy Group

- All Wales protocol for the appropriate prescribing of antipsychotics for people living with dementia - link

Canadian Agency for Drugs and Technologies in Health

- Aerosol Therapy with Inhalers During Mechanical Ventilation link
- Ketamine for Adults with Substance Use Disorders link
- Opioid-Sparing Effects of IV Acetaminophen for Patients Undergoing Surgery link

Department of Health and Social Care UK

- Government's response to the Science, Innovation and Technology Committee's report 'The antimicrobial potential of bacteriophages' $\underline{\text{link}}$
- Safeguarding adults protocol updated: pressure ulcers and raising a safeguarding concern link

electronic Medicines Compendium (eMC) (UK)

- New products
- -- Coagadex (human coagulation factor X) for treatment and prophylaxis of bleeding episodes and for perioperative management in patients with hereditary factor X deficiency. All age groups.
- -- Xgeva (denosumab) prefilled syringe for prevention of skeletal-related events in adults with advanced malignancies involving bone and the treatment of giant cell tumour of bone. For this indication, it has previously only been available as a single use vial.
- Revised SPC
- -- Imbruvica (ibrutinib) data added from Study CLL3011, which provides follow-up data over a median of 52 months showing that overall survival hazard ratio was 0.458 [95% CI (0.257 to 0.818, p=0068) for patients on ibrutinib and venetoclax vs. chlorambucil and obinutuzumab

Food and Drug Administration (FDA) USA

- New Drug approvals
- -- first interchangeable <u>denosumab</u> biosimilars to Prolia and Xgeva in US to treat certain types of osteoporosis and prevent bone events in cancer
- -- tocilizumab (Tyenne), 2nd biosimilar to Actemra
- -- zanubrutinib for relapsed or refractory follicular lymphoma in combination with obinutuzumab
- -- <u>Letybo</u> (letibotulinumtoxinA-wlbg) temporarily improve the appearance of moderate-to-severe glabellar lines
- -- <u>inotuzumab ozogamicin</u> (Besponsa) for CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL) expanded to include children
- -- amivantamab-vmjw for EGFR exon 20 insertion-mutated non-small cell lung cancer indications
- New indication
- -- alirocumab (Praluent) for children aged 8 years and older with HeFH to reduce LDL-C
- -- <u>nivolumab</u> in combination with cisplatin and gemcitabine for unresectable or metastatic urothelial carcinoma
- -- <u>semaglutide</u> (Wegovy) to reduce CV risk in adults with CV disease who are either obese or overweight <u>SPS commentary</u>

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

The Kings Fund

- Thoughts on the NHS's productivity decline - link

Medicines and Healthcare products Regulatory Agency (MHRA)

- MHRA approves
- -- new <u>denosumab</u> formulation via new International Recognition Procedure (IRP) <u>SPS commentary</u>
- piflufolastat as diagnostic tool for adults with prostate cancer link
- rozanolixizumab to treat adults with generalised myasthenia gravis
- ganaxolone for treatment of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)
- etrasimod for treatment of moderately to severely active ulcerative colitis over 16 years
- quizartinib for first-line treatment of acute myeloid leukaemia

NHS England

- Report of a UK survey of pharmacy professionals' involvement in research link
- Antimicrobial resistance and antimicrobial stewardship pharmacy undergraduate competency framework link

NHS Scotland

- Accepted for use:
- -- Ivosidenib (Tibsovo®) for treatment of adults with acute myeloid leukaemia
- -- Olaparib (Lynparza®) for treatment of prostate cancer
- -- <u>Talazoparib</u> (Talzenna®) for treatment of adults with germline BRCA1/2-mutations, who have HER2-negative locally advanced or metastatic breast cancer
- Accepted for restricted use:
- -- Foslevodopa-foscarbidopa (Produodopa®) for treatment of advanced Parkinson's disease
- Not recommended:
- -- Axicabtagene ciloleucel (Yescarta®) for the treatment of relapsed or refractory B-cell lymphomas

National Institute for Health and Care Excellence (NICE) UK

- Epcoritamab for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic treatments (TA954)
- Etrasimod for moderately to severely active ulcerative colitis in people aged 16 and over (TA956)
- Vitamin B12 deficiency in over 16s: diagnosis and management (NG239) SPS commentary
- Digital technologies for delivering multidisciplinary weight-management services: early value assessment health technology evaluation ($\frac{\mathsf{HTE14}}{\mathsf{IE14}}$)
- Digital technologies for managing non-specific low back pain: early value assessment health technology evaluation (HTE16)
- Lung cancer: diagnosis and management, updated (NG122)
- COVID-19 rapid guideline: managing COVID-19, updated (NG191)
- Dupilumab for treating moderate to severe prurigo nodularis (TA955)
- Fluocinolone acetonide intravitreal implant for treating chronic diabetic macular oedema (TA953)
- Nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19 guidance (TA878)

Specialist Pharmacy Services NHS UK

- Occupational health services (OHS) and medicines mechanisms link
- Preparing to use tocilizumab biosimilar link
- Ensuring time-critical use of rasburicase link
- Preparing to use eculizumab biosimilar link SPS commentary

World Health Organisation (WHO)

- HIV drug resistance: Brief report 2024 <u>link</u>; New report documents increase in HIV drug resistance to dolutegravir <u>link</u>
- Guideline on haemoglobin cut-offs to define anaemia in individuals and populations link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- New manual released to support diagnosis of mental, behavioural and neurodevelopmental disorders added in ICD-11 <u>link</u>
- WHO launches Pharmaceutical Quality Assurance guidelines, 10th edition link

MEDICATION SAFETY

Australian and New Zealand College of Anaesthetists (ANZCA) & Faculty of Pain Medicine
- IV paracetamol in short supply - link

electronic Medicines Compendium (eMC) (UK)

- Revised SPCs
- -- Ajovy (fremanezumab) interactions with medications that are substrates, inducers, or inhibitors of cytochrome P450 enzymes are unlikely, and there are no adequate data on developmental risk associated with use in pregnant women, and no data on presence in human milk
- -- Cabazitaxel tillomed (cabazitaxel) due to the genotoxic risk of cabazitaxel, men should use contraceptive measures during and for 4 months after cessation of treatment
- -- Coagadex (human coagulation factor X) most common ADRs were infusion site erythema, infusion site pain, fatigue and back pain
- -- Diflucan (fluconazole) for longer treatment, contraception may be considered, as appropriate, in women of childbearing potential throughout the treatment period and for 1 week after the final dose. Data from a meta-analysis on cardiac malformations have been added SPS commentary
- -- Forxiga (dapagliflozin) cases of phimosis/acquired phimosis reported concurrent with genital infections and in some cases, circumcision was required
- -- Fosavance (alendronic acid/colecalciferol) atypical fractures (FCs) of other bones (ulna,tibia) reported after long-term (LT) treatment; they may occur after minimal/no trauma & there may be prodromal pain prior to experiencing completed FC. Ulna FC may be linked to repetitive stress due to LT use of walking aids
- -- Increlex (mecasermin) pre-prandial glucose monitoring recommended at treatment initiation and until well-tolerated dose established. Monitoring should continue regardless of pre-prandial condition, if possible at time of event, if frequent and/or severe symptoms of hypoglycaemia occur
- -- Kineret (anakinra) isolated cases of injection site amyloid deposits reported in patients with neonatal-onset multisystem inflammatory disease/chronic infantile neurological, cutaneous, articular syndrome who received high doses over prolonged periods. Rotation of injection site advised
- -- Lokelma (sodium zirconium cyclosilicate) updated interaction study data in healthy volunteers showing co-administration of Lokelma 15 g with tacrolimus 5 mg resulted in a decreased tacrolimus AUC and Cmax by 37% and 29% respectively, therefore, tacrolimus should be taken ≥2 hours before or after Lokelma
- -- Oxypro (oxycodone) "Sphincter of Oddi dysfunction" (SoO) added as an ADR (frequency not known). Because it can cause SoO dysfunction, which can raise intrabiliary pressure & increase risk of pancreatitis, it should be used with caution in patients with pancreatitis/ biliary tract disease
- -- Rifampicin products shown to decrease mifepristone (MF) AUC by 6.3-fold and its metabolites 22-hydroxy mifepristone and N-demethyl MF by 20-fold and 5.9-fold, respectively, suggesting reduced efficacy of MF when given concomitantly with potent CYP inducer such as rifampicin
- -- Scheriproct (prednisolone/cinchocaine) Ointment epidemiological studies suggest possible increased risk of oral clefts in newborns of women treated with glucocorticoids (GCs) during 1st trimester. Topical GCs should be avoided in this period. It also notes corticosteroids are excreted in small amounts in breast milk
- -- Spravato (esketamine hydrochloride) respiratory depression is a rare & transient ADR that may occur at high doses after rapid injection when used for anaesthesia. Spravato should only be used in patients with clinically significant cardiovascular or respiratory conditions if potential benefit outweighs harm risk
- -- Tostran (testosterone) instructions on how to prime the canister pump before first use.
- -- Truvada (tenofovir disoproxil fumarate, emtricitabine) decreased bone mineral density is a common ADR, and the warning/precaution on bone effects has been further strengthened
- -- Xgeva (denosumab) single use vial & administration should only be performed by an HP

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

- -- Zavicefta (ceftazidime pentahydrate, avibactam sodium) 'Kounis syndrome' (acute coronary syndrome associated with an allergic reaction) as an adverse effect (frequency unknown). This follows post-marketing reports of hypersensitivity reactions which progressed to Kounis syndrome -- Zyban (bupropion hydrochloride) panic attack is an undesirable effect (frequency unknown)
- Risk minimisation materials
- -- alglucosidase alfa (<u>Myozyme</u>): Safety information packet for HPs containing guidance on risks associated with treatment, their clinical management, and immunological testing which will help to further characterise the potential mechanism of infusion-associated reactions and hypersensitivity reactions
- -- Cerdelga (<u>eliglustat</u>) prescriber guide contains a checklist of actions to be completed before and after treatment initiation, and information on CYP2D6 genotyping assessment (Sanofi Genzyme offers CYP2D6 metaboliser status testing free of charge in the UK). A patient alert card is also available -- Epysqli (eculizumab biosimilar) Physician's Guide contains information on prevention measures.
- detection, careful monitoring &/or proper management of selected safety concerns associated with eculizumab. Also a patient/parent information guide, a patient safety card & certificate of vaccination -- Kevzara (sarilumab) Patient Alert card: contains important safety information for patients to be aware of before, during & after treatment, including symptoms of serious infections & gastrointestinal
- perforation, the need for screening for tuberculosis prior to treatment, & monitoring requirements -- Tasmar (tolcapone) patient diary: contains information on risks of liver injury (rare but potentially fatal) and neuroleptic malignant syndrome associated with use of tolcapone and the monitoring that will take place during treatment, with space to record liver function tests throughout the first year

FΜΔ

- European PRAC concludes available data do not support a causal association between Comirnaty and Spikevax and cases of postmenopausal bleeding - <u>link</u>

Health Canada - MedEffect Notice

- Health Product InfoWatch, February 2024

Institute for Safe Medication Practices (ISMP) USA

- Medication Safety Alert! March 7, 2024
- -- Drug Diversion Prevention Beyond Controlled Substance Medications link
- -- Worth repeating...SUMAtriptan injection wrong route errors continue
- -- Accidental overdoses and adverse effects from compounded GLP-1 agonists
- -- Safe drug administration during fasting

Medsafe (New Zealand Medicines and Medical Devices Safety Authority)

- Recent cases of lead poisoning with Ayurvedic medicines link
- Prescriber Update March 2024

MIMS monthly updates

- New Contraindications
- -- Apomorphine hydrochloride hemihydrate (<u>Movapo</u>, Movapo Pen and Movapo PFS) for concomitant use with 5HT3 antagonists including antiemetics (eg ondansetron, granisetron, palonosetron)
- -- Clomifene citrate (<u>Clomid</u>) in patients with known history of significant, medically confirmed vision disorders related to the use of Clomid (prior or ongoing treatment)
- -- Factor VIII inhibitor bypassing fraction (<u>Feiba NF</u>) in acute myocardial infarction, unless indicated in life-threatening bleeding events
- -- Itraconazole (Lozanoc) for concomitant use with apixaban, rivaroxaban, dabigatran, mobocertinib, finerenone and voclosporin, including 2 weeks after itraconazole treatment, and in chronic lymphocytic leukaemia/ small lymphocytic lymphoma patients during the dose initiation, titration, and ramp-up phases of venetoclax treatment

MIMS, UK

- Propranolol overdose reports: what's happening on the frontline? - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au | An initiative of NSW clinical pharmacologists & pharmacists

- Montelukast neuropsychiatric reactions: How can prescribers adapt their practice? - link

Specialist Pharmacy Services NHS UK

- Treating heartburn and dyspepsia during breastfeeding link
- Treating insomnia during breastfeeding link
- Using gastrointestinal antispasmodics during breastfeeding link

PAPERS OF INTEREST

Age and Ageing

- Effects of rhythm-control and rate-control strategies on cognitive function and dementia in atrial fibrillation: a systematic review and meta-analysis - link

American Journal of Health-System Pharmacy (AJHP)

- Comparative effectiveness of sacubitril/valsartan versus angiotensin receptor blockers in patients with heart failure with preserved ejection fraction: A real-world study - link
- Development of optimized adult epidural infusion preparations to reduce waste and improve operational efficiency - link
- Study to assess the impact of analytics software on operating room controlled substance management and drug diversion - link
- Cost evaluation of continuation of therapy with dalbavancin compared to standard-of-care antibiotics alone in hospitalized persons who inject drugs, with severe gram-positive infections - link
- Characterizing redundancy in pharmacy residency research projects link
- A review of fecal microbiota, live-islm for the prevention of recurrent Clostridioides difficile infection -

Annals of Internal Medicine

- Long-Term Effect of Randomization to Calcium and Vitamin D Supplementation on Health in Older Women: Postintervention Follow-up of a Randomized Clinical Trial - link
- In the clinic: Acute Colonic Diverticulitis link

British Journal of Clinical Pharmacology

- Sodium-glucose cotransporter-2 inhibitors and the risk of lung cancer among patients with type 2 diabetes - link
- Statin use and the risk of Parkinson's disease in persons with diabetes: A nested case-control study - link

British Journal of General Practice

- A systematic review of interventions to improve medication adherence in adults with mental-physical multimorbidity in primary care - link

British Medical Journal (BMJ)

- Ultra-processed food exposure and adverse health outcomes; umbrella review of epidemiological meta-analyses - <u>link</u> - <u>SPS commentary</u>
- Illness trajectories of incurable solid cancers link
- Using illness trajectories to inform person centred, advance care planning link
- Opinion: Let's talk differently about obesity link
- Practice Pointer: Advance and future care planning link
- NHS rolls out dostarlimab (Jemperli) for advanced primary or recurrent endometrial cancer link
- MHRA investigates risks associated with montelukast after concerns over neuropsychiatric reactions - link - SPS commentary
- Suspected acute respiratory infection in over 16s: assessment at first presentation and initial management—summary of NICE guidance

BMJ Open

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au An initiative of NSW clinical pharmacologists & pharmacists

- Comparative effectiveness of baricitinib and alternative biological DMARDs in a Swiss cohort study of patients with RA - <u>link</u>

Circulation

- Are Recommendations That Favour Other Agents Over Angiotensin-Converting Enzyme Inhibitors in Africans With Hypertension Justified? - <u>link</u>

Diabetes Care

- Differential Effects of Type 2 Diabetes Treatment Regimens on Diabetes Distress and Depressive Symptoms in the Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE): A Randomized Clinical Trial link
- Perinatal Outcomes in Early and Late Gestational Diabetes Mellitus After Treatment From 24-28 Weeks' Gestation: A TOBOGM Secondary Analysis link

Diabetes, Obesity and Metabolism

- Does metformin reduce the risk of cancer in obesity and diabetes? A systematic review and metaanalysis - link
- Glycaemic control and macrovascular and microvascular outcomes in type 2 diabetes: Systematic review and meta-analysis of cardiovascular outcome trials of novel glucose-lowering agents link
- Glycaemic control and macrovascular and microvascular outcomes: A systematic review and metaanalysis of trials investigating intensive glucose-lowering strategies in people with type 2 diabetes link

Drug and Therapeutics Bulletin

- DTB select: Safety update: valproate safety and educational materials link
- Do regulatory safety warnings on medicines miss the mark? link

Drug Safety

- Exploring the Role of Guidelines in Contributing to Medication Errors: A Descriptive Analysis of National Patient Safety Incident Data - Link

European Heart Journal

- Pulmonary arterial hypertension treatment: an individual participant data network meta-analysis link
- Semaglutide and cardiovascular outcomes by baseline HbA1c in diabetes: the SUSTAIN 6 and PIONEER 6 trials link
- Intravenous iron for heart failure, iron deficiency definitions, and clinical response: the IRONMAN trial <u>link</u>

European Journal of Hospital Pharmacy

- Development of hospital pharmacy services at transition of care points: a scoping review link
- Extravasation of brentuximab vedotin, an antibody-drug conjugate, in a patient with anaplastic large cell lymphoma <u>link</u>

Gastroenterology

- Standard of Care Versus Octreotide in Angiodysplasia-Related Bleeding (the OCEAN Study): A Multicenter Randomized Controlled Trial - link

Health Technology Assessment

- Thromboprophylaxis during pregnancy and the puerperium: a systematic review and economic evaluation to estimate the value of future research - link

Heart

- The role of COVID-19 vaccines in preventing post-COVID-19 thromboembolic and cardiovascular complications - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

International Journal for Quality in Health Care

- How are we handling protein drugs in hospitals? A Human Factors and Systems Engineering Approach to compare two hospitals and suggest a best practice - <u>Link</u>

JAMA

- GLP-1 Agonists for Obesity- A New Recipe for Success? link
- HIV Preexposure Prophylaxis With Emtricitabine and Tenofovir Disoproxil Fumarate Among Cisgender Women <u>link</u>
- Patient page: What is Cushing Syndrome? link
- A Review: Cardiac Amyloidosis Due to Transthyretin Protein link; Allergic Rhinitis link
- Disease-Modifying Drugs for Adult-Onset Rheumatoid Arthritis link
- Diagnosis and Management of Myotonic Dystrophy Type 1 link
- ADHD Pharmacotherapy and Mortality in Individuals With ADHD link SPS commentary

JAMA Internal Medicine

- Clinical outcomes of rapid respiratory virus testing in emergency departments: A systematic review and meta-analysis link SPS commentary
- Dementia Prevention and Treatment: A Narrative Review link
- Opioid Prescribing and Outcomes in Patients With Sickle Cell Disease Post–2016 CDC Guideline link
- Clinical Decision Support for Hypertension Management in Chronic Kidney Disease: A Randomized Clinical Trial link

JAMA Network Open

- Telemedicine vs telephone consultations and medication prescribing errors among referring physicians: a cluster randomized crossover trial \underline{link}
- Institutional and Regional Variation in Opioid Prescribing for Hospitalized Infants in the US- link

JAMA Neurology

- Batoclimab vs Placebo for Generalized Myasthenia Gravis: A Randomized Clinical Trial link
- LDL-C Levels and Bleeding Risk in Patients Taking DAPT After Minor Ischemic Stroke or TIA link
- Treatment of Refractory Status Epilepticus with Continuous Intravenous Anaesthetic Drugs link
- Clopidogrel Plus Aspirin vs Aspirin Alone in Patients With Acute Mild to Moderate Stroke link

JAMA Pediatrics

- Development and Validation of an Automated Classifier to Diagnose Acute Otitis Media in Children - <a href="https://link.com/li

JAMA Psychiatry

- All-Cause and Cause-Specific Mortality Among Individuals with Hypochondriasis - link

Journal of Clinical Oncology

- Impact of Helicobacter pylori Infection and Treatment on Colorectal Cancer in a Large, Nationwide Cohort - <u>link</u> - <u>SPS commentary</u>

Journal of General Internal Medicine

- Identifying the Best Initial Oral Antibiotics for Adults with Community-Acquired Pneumonia: A Network Meta-Analysis - <u>link</u> – <u>SPS commentary</u>

Journal of Pharmacy Practice and Research (JPPR)

- Factors associated with an increased risk of vitamin B12 deficiency in patients with type 2 diabetes mellitus on metformin - link

Lancet

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Worldwide trends in underweight and obesity from 1990 to 2022: a pooled analysis of 3663 population-representative studies with 222 million children, adolescents, and adults Link
- Seminar: Crohn's disease link
- Updates on the management of inflammatory bowel disease from periconception to pregnancy and lactation $\underline{\text{link}}$
- mRNA-based therapeutics: looking beyond COVID-19 vaccines link

Lancet Diabetes & Endocrinology

- Duration of fracture prevention after zoledronate treatment in women with osteopenia: observational follow-up of a 6-year randomised controlled trial to 10 years <u>link</u> <u>SPS commentary</u>
- Undiagnosed type 2 diabetes: an invisible risk factor link SPS commentary

Lancet HIV

- Uncovering HIV and malaria interactions: the latest evidence and knowledge gaps - link

Lancet Infectious Diseases

- Accelerating antibiotic access and stewardship: a new model to safeguard public health link
- Prevalence of subclinical pulmonary tuberculosis in adults in community settings: an individual participant data meta-analysis link SPS commentary

Lancet Oncology

- Correlations of response rate and progression-free survival with overall survival in immunotherapy trials for metastatic non-small-cell lung cancer: an FDA pooled analysis - link

Molecular Diversity Preservation International (MDPI) - Pharmacy Journal

- A Systematic Review of Naldemedine and Naloxegol for the Treatment of Opioid-Induced Constipation in Cancer Patients <u>link</u>
- Rational Prescribing of Pancreatic Enzymes for Patients with Pancreatic Cancer link
- Influences of Software Changes on Oxycodone Prescribing at an Australian Tertiary Emergency Department: A Retrospective Review link

Medical Journal of Australia

- Why clinical artificial intelligence is (almost) non-existent in Australian hospitals and how to fix it - link

Morbidity and Mortality Weekly Report

- Early Estimate of Nirsevimab Effectiveness for Prevention of Respiratory Syncytial Virus—Associated Hospitalization Among Infants Entering Their First Respiratory Syncytial Virus Season - <u>link</u>

New England Journal of Medicine

- Enfortumab Vedotin and Pembrolizumab in Untreated Advanced Urothelial Cancer link
- Microplastics and Nanoplastics in Atheromas and Cardiovascular Events link
- Health Effects of Fossil Fuel-Derived Endocrine Disruptors link

Pharmacotherapy

- Optimal starting dosing regimen of intravenous oxytocin for labor induction based on the population kinetic-pharmacodynamic model of uterine contraction frequency - <u>link</u>

Studies in Health Technology and Informatics

- Stepped-wedge cluster RCT to assess the effects of an electronic medication system on medication administration errors - link

CONSULTATIONS

TGA

- Consultation: Clarification of how Clinical Decision Support System (CDSS) software is regulated, closes 6 May 2024 - <u>link</u>

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

WEBINARS & PODCASTS

Australian Prescriber Podcasts

- Episode 159 - Therapeutic Guidelines Dermatology

MJA Podcasts

- Episode 7: Australia's national bowel cancer screening program

Purple Pen Podcast

- PPP 159 - Deprescribing psychotropics

UPCOMING EVENTS

(New additions listed in TAGMail)

AHHA

- From Hurting to Healing: Driving Workforce Wellbeing - 26 March 2024 12:30-13:30 - <u>link</u> – <u>register</u> here

FDA

- FDA Drug Topics: Navigating FDA's Drug Information Resources - March 26, 2024 - register here

Fortnightly TAG Mail – resources list 29th February 2024

NSW TAG ACTIVITIES

Open email discussions

- 7. Patient prioritisation for discharge medication list provision: A TAG member would like to know how other hospitals prioritise their patients for the creation/supply of pharmacist-generated discharge medication lists. Closes 8th March 2024.
- 8. **NSW TAG Collaborative to develop medicine-related documents:** See email sent to NSW TAG members 27/2/2024. Closes 15th March 2024.
- 9. **Missing medications from wards:** A member has been experiencing medications going missing in the wards after being dispensed from pharmacy. A recent example concerned Paxlovid where five boxes were sent to the same patient over 2 days because the medication had gone missing. The incidents are being entered into IMS+. Are hospitals experiencing similar issues? Have any strategies been implemented to reduce such occurrences? Extended to 8th March 2024
- 10. Medication reviews for inpatients in remote Multi-Purpose Services. A rural member has been requested to provide inpatient medication reviews for patients in remote Multi-Purpose Services (MPSs) in their local health district. Currently, the hospital accepts virtual pharmacy referrals for new hospital admissions (but not from MPSs). Are other hospitals with oversight of MPSs also being requested to provide inpatient medication reviews/providing a medication review service to MPSsand if so, how are they managing this workload? Extended to 8th March 2024

Recently completed email discussions

- Long-term supply issue with lidocaine 2% + 1:200,000 adrenaline injection
- Storage of medicines in patient's locked drawers and medication transfer between treatment room and bedside

Upcoming TAG meeting dates

NSW TAG General Meeting: Thursday 4th April 2024 11.30-1pm

Updated TAG publications

Coming soon: Updated SGLT2 inhibitor Consumer Leaflet; NSW TAG Copyright Statement and Permission Form

Contact Sasha Bennett at <u>sasha.bennett@svha.org.au</u> for further information about any email discussions, publications or upcoming meetings.

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

EDITOR'S PICKS

AJHSP: Artificial intelligence in pharmacy: A guide for clinicians - link

AJHSP: Recent and anticipated novel drug approvals for 2024 - link

Aust Prescr: Managing hypercholesterolaemia - <u>link;</u> Therapeutic inertia - <u>link;</u> Morphine oral liquid availability - <u>link</u>

BJCP: Quality indicators for appropriate in-hospital pharmacotherapeutic stewardship: An international modified Delphi study - Link - SPS commentary

BJCP: Clinical decision-making in benzodiazepine deprescribing by healthcare providers vs. Alassisted approach - link

BMJ: Effect of exercise for depression: systematic review and network meta-analysis of randomised controlled trials - link-SPS commentary

BMJ QS: Between-hospital variation in indicators of quality of care: a systematic review - <u>link</u> Circulation: RNA Therapeutics for the Cardiovascular System - <u>link</u>

Cochrane: - Evening versus morning dosing regimen drug therapy for hypertension - <u>link</u>

IMJ: COVID-19 vaccination: are more jabs needed or are we now immune? - link

ISMP: Three Additions to 2024-2025 Targeted Medication Safety Best Practices for Hospitals - Link Internal medicine: Age-Related Risk of Serious Fall Events and Opioid Analgesic Use - Link JPPR: Standard of practice in pain management for pharmacy services - Link JPPR: Standard of practice in pain management for pharmacy services - Link JPPR: Standard of practice in pain management for pharmacy services - Link JPPR: Standard of practice in pain management for pharmacy services - Link JPPR: Standard of practice in pain management for pharmacy services - Link JPPR: Standard of practice in pain management for pharmacy services - Link JPPR: Standard of practice in pain management for pharmacy services - Link JPPR: Standard of practice in pain management for pharmacy services - Link JPPR: Standard of practice in pain management for pharmacy services - Link JPPR: <a href

OTHER NEWS

NSW Health

- High-Risk Medicines Management (PD2024 006)
- --includes new standards for anti-cancer drugs and insulin
- NSW Health Procurement (Goods & Services) (PD2024 009)
- Measles alert for western Sydney link Legionnaires' disease alert for Sydney link
- Public health warning: Opioid overdoses after using drugs people believed to be cocaine or methamphetamine <u>link</u> Warning: High-dose MDMA tablets (ecstasy) circulating in NSW <u>link</u>

Pharmacy Board of Australia

- Regulators come together as one million Australians turn to medicinal cannabis treatments - link

REPORTS AND PUBLICATIONS - AUSTRALIA

Agency for Clinical Innovation, NSW (ACI)

The latest weekly Evidence Digest can be found here

- New program to improve patient and staff experience in emergency care $\underline{\text{link}}$ $\underline{\text{ECAT}}$ $\underline{\text{implementation plan}}$
- Management of adults with COVID-19 in the post-acute phase link
- Model of care for the management of low back pain: Summary link
- Using virtual care to enhance palliative care experiences link

Australian Government Department of Health

- Helping young Australians learn about the harms of vaping link
- ATAGI Statement on the Administration of COVID-19 Vaccines in 2024 fact sheet
- Getting vaccinated against influenza Resource collection collection
- ATAGI Statement on the Clinical Use Of Arexvy (RSV PRE-F3) Vaccine for RSV fact sheet
- ATAGI Statement on the Administration of Seasonal Influenza Vaccines in 2024 fact sheet

Australian Institute for Health and Welfare (AIHW)

- National Drug Strategy Household Survey 2022–2023 <u>link</u> with many supplementary reports on specific agents e.g. non-medical use of pharmaceutical stimulants <u>link</u>
- OECD health care quality and outcomes indicators, Australia 2022-23 link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- GEN: Younger people in residential aged care link
- Family, domestic and sexual violence link

PRS

- PBS subsidy arrangements for gliclazide 30 mg tablets SSSI - 29 February 2024 - link

TGA

- <u>Database</u> of section 19A approvals to import and supply medicines to address medicine shortages AusPARs:
- -- <u>Vegzelma</u> (bevacizumab) in combination with fluoropyrimidine-based chemotherapy for treatment of patients with metastatic colorectal cancer
- -- MS-2 Step (composite pack) approval granted to make changes in Product Information (PI) and Risk Management Plan (RMP)
- Australian prescription medicine decision summaries:
- -- <u>Erwinase</u> as a component of a multi-agent chemotherapeutic regimen for acute lymphoblastic leukemia (ALL) patients, who have developed hypersensitivity to pegylated asparaginase obtained from E. coli

REPORTS AND PUBLICATIONS - INTERNATIONAL

The Academy of Medical Sciences UK

- Prioritising early childhood to promote the nation's health, wellbeing and prosperity - link

All Wales Medicines Strategy Group

- All Wales adult asthma management and prescribing guideline, updated

British In Vitro Diagnostics Association

- Calls for CRP testing at POC to tackle threat of AMR - link

British National Formulary

- BNF/BNFC newsletter: February 2024

Canadian Agency for Drugs and Technologies in Health

- Cost-Effectiveness of Respiratory Syncytial Virus Vaccines for Adults link
- Reference list: POC Testing for Acetaminophen link

Department of Health and Social Care UK

- Roadmap for meeting the PrEP needs of those at significant risk of HIV - link - SPS commentary

electronic Medicines Compendium (eMC) (UK)

- New products
- -- Epysqli (eculizumab biosimilar) highly similar to the reference product Soliris
- -- Ivermectin 3mg tablets for GI strongyloidiasis (anguillulosis), suspected or diagnosed microfilaraemia in patients with lymphatic filariasis due to Wuchereria bancrofti, and human sarcoptic scabies. This is the first oral ivermectin product to be licensed in the UK
- New/expanded indications
- -- Libtayo (cemiplimab) use with platinum-based chemotherapy for 1st line treatment of non-small cell lung cancer expressing PD-L1 (in ≥1% of tumour cells), with no EGFR, ALK or ROS1 aberrations, in adults with locally advanced (not candidates for chemoradiation) or metastatic disease

European Centre for Disease Control (ECDC)

- Hypervirulent Resistant K pneumoniae On the Rise in EU - link

European Medicines Agency (EMA)

- Antimicrobial consumption and resistance in bacteria from humans and food-producing animals: Fourth joint inter-agency report on integrated analysis of antimicrobial agent consumption and

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/EEA – <u>link</u> – <u>SPS commentary</u>

- CHMP recommended changes to the terms of the marketing authorisation:
- -- <u>pembrolizumab</u> in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment, for the treatment of resectable non-small cell lung carcinoma at high risk of recurrence in adults
- -- Apremilast Accord a generic of Otezla, for psoriatic arthritis, psoriasis and Behcet's disease
- -- Celldemic (influenza vaccine) for active immunisation against the H5N1 subtype of Influenza A virus in adults and children aged ≥6 months, based on a robust immune response three weeks after two doses of the vaccine given three weeks apart. The most common side-effects include injection site pain, myalgia, and fatigue
- -- Incellipan (influenza vaccine) as above in an officially declared pandemic
- --<u>danicopan</u> (Voydeya) for residual haemolytic anaemia in adults with paroxysmal nocturnal haemoglobinuria (PNH) <u>link</u>
- -- <u>Nintedanib Accord</u> a generic of Ofev, for idiopathic pulmonary fibrosis, other chronic fibrosing interstitial lung diseases with a progressive phenotype, and systemic sclerosis associated interstitial lung disease
- -- retifanlimab (Zynyz) first-line for adult Merkel cell carcinoma not amenable to surgery or radiation
- -- sparsentan (Filspari) for adult primary immunoglobulin A nephropathy (IgAN)
- -- <u>tislelizumab</u> (Tizveni) for locally advanced or metastatic non-small cell lung cancer
- -- tofersen (Qalsody) for amyotrophic lateral sclerosis link
- -- ustekinumab biosimilar (<u>Pyzchiva</u>) highly similar to Stelara, for psoriasis, psoriatic arthritis, ulcerative colitis and Crohn's disease
- CHMP recommended extension to the existing indication:
- -- abrocitinib (Cibinqo) for moderate-to-severe atopic dermatitis in adolescents 12 years and older
- -- <u>ciltacabtagene autoleucel</u> to include adults with relapsed and refractory multiple myeloma who have received ≥1 prior therapy (currently says ≥3 prior therapies) and are refractory to lenalidomide
- -- hydroxycarbamide (Xromi)- to include prevention of vaso-occlusive complications of sickle cell disease in patients from 9 months of age (currently restricted to use in those over 2 years of age)
- -- <u>ivacaftor</u> use in children from 1 month of age who are at least 3kg (currently from 4 months and weighing at least 5kg) and new presentation of Kalydeco granules (13.4 mg granules in sachet)
- -- <u>luspatercept</u> for transfusion-dependent anaemia due to very low, low and intermediate-risk myelodysplastic syndromes (currently restricted to those with ring sideroblasts, who had unsatisfactory response/ are ineligible for erythropoietin-based therapy)

electronic Medicines Compendium (eMC) (UK)

- New or expanded indications
- -- Keytruda (pembrolizumab) 1st line use in locally advanced unresectable or metastatic biliary tract carcinoma in adults, in combination with gemcitabine & cisplatin added.
- -- Libtayo (cemiplimab)- New indication of use with platinum-based chemotherapy for 1st line treatment of non-small cell lung cancer expressing PD-L1 (in ≥1% of tumour cells), with no EGFR, ALK or ROS1 aberrations, in adults with locally advanced (not candidates for chemoradiation) or metastatic disease

Food and Drug Administration (FDA) USA

- New Drug approvals
- -- <u>lifileucel</u> (Amtagvi), first cellular therapy for unresectable or metastatic melanoma
- -- osimertinib with chemotherapy for EGFR-mutated non-small cell lung cancer
- -- $\underline{\text{Exblifep}}$ (cefepime, enmetazobactam), cephalosporin/beta-lactamase inhibitor for complicated urinary tract infections $-\underline{\text{label (PI)}}$ $\underline{\text{letter}}$
- -- Xolair (<u>omalizumab</u>), first medication to help reduce allergic reactions to multiple foods after accidental exposure
- -- adalimumab (Simlandi), new high-concentration, citrate-free biosimilar to Humira
- -- teclistamab (Tecvayli), new biweekly maintenance for multiple myeloma in complete remission
- -- acetylcysteine antidote (Legubeti), new oral dosage form for acetaminophen overdose

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au An initiative of NSW clinical pharmacologists & pharmacists

General Pharmaceutical Council UK

- Statement on the reclassification of codeine linctus to a prescription-only medicine - link

Monthly Index of Medical Specialities MIMS UK

- Practical steps to reduce health inequalities in your practice - link

NHS England

- Martha's rule to be rolled out in English hospitals from April - link - SPS commentary

National Institute for Health and Care Excellence (NICE) UK

- Tuberculosis (NG33) 1.1.3.10 discussing criteria for offering BCG vaccination to selected neonates, final bullet 'have a family history of TB in the past 5 years' removed SPS commentary
- Talazoparib for treating HER2-negative advanced breast cancer with germline BRCA mutations (TA952)
- Etrasimod for treating moderately to severely active ulcerative colitis in people aged 16 and over (TA953)

National Institute for Health and Care Research (NIHR)

- NIHR commentaries: Alcohol dependence: telephone support plus financial incentives helped people take acamprosate - <u>link</u>

Nuffield Trust UK

- Antibiotic prescribing indicators - link

OECD

-Securing Medical Supply Chains in a Post-Pandemic World - link

The King's Fund (UK)

- Mental health 360 - link

UK Health Security Agency

- Tuberculosis in England, 2023 report (data up to end of 2022) link SPS commentary
- Hepatitis A infection: prevention and control guidance update SPS commentary
- Pertussis: guidelines for public health management link

MEDICATION SAFETY

electronic Medicines Compendium (eMC) (UK)

- Revised SPCs
- -- Bavencio (avelumab) in patients with pre-existing autoimmune disease (AID), study data suggests risk of immune-related adverse reactions may be increased compared with the risk in those without AID. Sarcoidosis added as uncommon ADR
- -- Decapeptyl (triptorelin pamoate) idiopathic intracranial hypertension (pseudotumor cerebri) reported in paediatric patients. Patients should be warned for signs and symptoms including severe or recurrent headache, vision disturbances and tinnitus
- -- Hydrea (hydroxycarbamide) potential ADRs include systemic and cutaneous lupus erythematosus (very rare), haemolytic anaemia, interstitial lung disease, pneumonitis, alveolitis, allergic alveolitis and cough (all frequency unknown)
- -- Imbruvica (ibrutinib) treatment should be withheld for any new onset or worsening grade 2 cardiac failure or grade 3 cardiac arrhythmias, and a table of recommended dose modifications for events of cardiac failure or cardiac arrhythmia events added
- -- Imfinzi (durvalumab) immune-mediated arthritis and uveitis added to list of immune-mediated ADRs observed in patients treated with durvalumab alone or in combination with tremelimumab
- -- Imjudo (tremelimumab) uveitis added as rare ADR, and immune-mediated arthritis as uncommon

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- -- Ketalar (ketamine) hepatotoxicity (such as mixed liver injury, cholestatic liver injury and biliary dilation) reported in patients with extended use (>3 days). Hence, not recommended for long-term use
- -- Keytruda (pembrolizumab)- ADRs of leukopenia & dizziness frequency changed from very common to common. Optic neuritis added as rare
- -- Linezolid hyponatraemia and/or SIADH observed in some patients. Serum sodium levels should be monitored regularly in patients at risk of hyponatraemia (e.g. elderly patients; those taking medicines that may lower blood sodium levels)
- -- Trileptal (oxcarbazepine) potential for congenital abnormalities in the offspring of women treated with combination therapies greater than those receiving monotherapy
- -- Rocephin (ceftriaxone) information added about displacement volumes and solvent volume for reconstitution of the vials
- Risk minimisation materials
- -- Aclasta (<u>zoledronic acid monohydrate</u>) Patient Reminder Card regarding osteonecrosis of the jaw risk, reported very rarely in patients receiving this medicine for osteoporosis, the possible need for dental examination prior to treatment, and measures to take to reduce risk whilst receiving treatment -- alemtuzumab (<u>Lemtrada</u>) Health professional guide provides information about potential serious risks and recommendations on risk mitigation through patient counselling, monitoring and management. Patient guide and alert card also available
- -- Cerezyme (<u>imiglucerase</u>) home infusion manual for health professionals. Also, a manual for patients, which discusses Gaucher disease, the treatment, and how it is prepared and administered in the home setting
- -- Enspryng (<u>satralizumab</u>) Patient card with important safety information on increased susceptibility to infection, including a list of signs of infection for which medical attention should be sought, and actions for the treating healthcare professional to take if infection is suspected
- -- Fabrazyme (<u>agalsidase beta</u>) home infusion manual for health professionals. Also a manual for patients, which discusses organisation of treatment and how it is prepared and administered at home, and a log book
- -- <u>Fibrovein</u> (sodium tetradecyl sulphate) key safety concerns associated with this product and measures to be taken before treatment discussed, including consideration of contra-indications, practitioner training, correct preparation and administration, and follow-up

Food and Drug Administration (FDA) USA

- Do Not Use Smartwatches or Smart Rings to Measure Blood Glucose Levels: FDA Safety Communication link
- US FDA withdraws approval of melphalan flufenamide (Pepaxto) in multiple myeloma
- FDA Drug Topics: Tips to Navigating Drug Interaction Information in the US Prescribing Information

Institute for Safe Medication Practices (ISMP) USA

- Medication Safety Alert! February 22, 2024 including:
- -- Three Additions to 2024-2025 Targeted Medication Safety Best Practices for Hospitals link

Medicines and Healthcare products Regulatory Agency (MHRA) UK

- Valproate: important new regulatory measures for oversight of prescribing to new patients and existing female patients <u>link</u>— <u>SPS commentary</u>
- Update on MHRA safety review of medicines containing pseudoephedrine link
- Drug Safety Update February 2024
- -- Codeine linctus (codeine oral solutions): reclassification to prescription-only medicine <u>link</u> <u>SPS</u> commentary
- -- Pseudoephedrine: very rare risk of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) <u>link</u> <u>SPS commentary</u>

Specialist Pharmacy Service

- Using benzodiazepines during breastfeeding link
- Tocilizumab biosimilar: Patient Information Sheet link
- Using penicillin antibiotics during breastfeeding link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

- Medication safety update February 2024

TGA

- Transfer of Ordine (morphine) oral liquid products to Arrotex link
- Product Information safety updates February 2024
- Safety Advisory: Medicines containing Withania somnifera (Withania, Ashwagandha) potential for gastrointestinal symptoms and very rare cases of liver injury Link

PAPERS OF INTEREST

Age and Ageing

- Sodium-glucose cotransporter-2 inhibitors (SGLT2) in frail or older people with type 2 diabetes and heart failure: a systematic review and meta-analysis - <u>link</u>

American Journal of Health-System Pharmacy (AJHP)

- Using name overlap analysis to understand medication name search safety link
- Artificial intelligence in pharmacy: A guide for clinicians link
- Clinical dashboard development and implementation to standardize data capture and reporting across health-system specialty pharmacies link
- Recent and anticipated novel drug approvals for 2024 link
- The need for an emergency planning and preparedness strategic plan for pharmacy leadership link
- Impact of a pharmacy technician on an interprofessional antithrombotic stewardship program at an academic medical center $\underline{\text{link}}$
- Key considerations in navigating ticagrelor's reported effect on heparin-induced thrombocytopenia functional assays in a landscape of limited data Link

Annals of Internal Medicine

- A Risk Profile Using Simple Hematologic Parameters to Assess Benefits from Baricitinib in Patients Hospitalized With COVID-19: A Post Hoc Analysis of the Adaptive COVID-19 Treatment Trial-2 - <u>Link</u>
 - The Management of Posttraumatic Stress Disorder and Acute Stress Disorder: Synopsis of the 2023 U.S. Department of Veterans Affairs and U.S. Department of Defense Clinical Practice Guideline - <u>Link</u>

Arthritis & Rheumatology

- Effect of Intravenous Zoledronic Acid on Total Knee Replacement in Patients with Symptomatic Knee Osteoarthritis and Without Severe Joint Space Narrowing: A Prespecified Secondary Analysis of the ZAP2 Trial link
- Hydroxychloroquine in Lupus Pregnancy and Risk of Preeclampsia link
- Weight Loss for Patients with Gout and Concomitant Obesity: A Proof-of-Concept Randomized Trial

Australian Prescriber February 2024

- Managing pre-existing diabetes prior to and during pregnancy link
- Managing hypercholesterolaemia link
- Therapeutic inertia link
- Diagnosis and management of eosinophilic oesophagitis link
- Severe liver injury following use of RAD-140, a selective androgen receptor modulator, for body building link
- TGA Medicines Safety Update and Australian Prescriber—back to the future (take 2)
- -- Use caution when prescribing baclofen off label link
- -- New warnings of romosozumab (Evenity) cardiovascular risks link
- Morphine oral liquid availability link
- News drugs: Andexanet alfa for reversal of direct factor Xa inhibitor anticoagulation link

British Journal of Clinical Pharmacology

- Maternal exposure to folate antagonists and susceptibility to congenital heart disease in offspring: A systematic review and meta-analysis - link - SPS commentary

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

- Genetic biomarkers of methotrexate response and safety in Crohn's disease: Data from the Spanish ENEIDA registry <u>link</u>
- Quality indicators for appropriate in-hospital pharmacotherapeutic stewardship: An international modified Delphi study <u>link</u> <u>SPS commentary</u>
- Advanced prescription of injectable anticancer drugs: Safety assessment in a European Comprehensive Cancer Centre using the risk matrix approach <u>link</u>
- Prevalence of potentially inappropriate medications among newly treated patients with type 2 diabetes in UK primary care <u>link</u>
- Eculizumab dose tapering should take into account the nonlinearity of its pharmacokinetics link
- The development and evaluation of dose-prediction tools for allopurinol therapy (Easy-Allo tools) link
- Estimation of adherence to urate-lowering therapy in people living with gout using Australia's Pharmaceutical Benefits Scheme and patient-reported dosing link
- Clinical characteristics of acute lacosamide poisoning: Pavia Poison Control Centre experience link
- Clinical decision-making in benzodiazepine deprescribing by healthcare providers vs. Al-assisted approach <u>link</u>
- Older adults' adherence to medications and willingness to deprescribe: A substudy of a randomized clinical trial link
- Call to action: Harmonization of pharmacovigilance regulations for post-marketing pregnancy and breastfeeding safety studies <u>link</u>

British Journal of Obstetrics and Gynaecology

- Fezolinetant impact on health-related quality of life for vasomotor symptoms due to the menopause: Pooled data from SKYLIGHT 1 and SKYLIGHT 2 randomised controlled trials - Link

British Medical Journal (BMJ)

- Effect of exercise for depression: systematic review and network meta-analysis of randomised controlled trials link SPS commentary
- Association of non-alcoholic fatty liver disease with cardiovascular disease and all cause death in patients with type 2 diabetes mellitus: nationwide population based study <u>link</u> <u>SPS commentary</u>
- Advances in diagnosis and treatment of bladder cancer link
- Practice pointer: Challenges in diagnosing asthma in children link
- Infection specialists call for more clarity on prescribing fluoroquinolones link
- US FDA breakthrough therapy designation and consumer drug advertising: a recipe for confusion link
- News: British Generic Manufacturers Association warns of worsening medicine shortages link
- Review: Management of chronic pancreatitis link
- Regression discontinuity design studies: a guide for health researchers link

BMJ Open

- Predictors at diagnosis for start of biologic disease-modifying antirheumatic drugs in patients with early rheumatoid arthritis: a cohort study link
- Impact of immunosuppressive therapy on SARS-CoV-2 mRNA vaccine effectiveness in patients with immune-mediated inflammatory diseases: a Danish nationwide cohort study link
- Mortality and health-related quality of life in older adults with long-term use of opioids, z-hypnotics or benzodiazepines: a prospective observational study at 5 years follow-up <u>link</u>
- Randomised, blinded, cross-over evaluation of the palatability of and preference for different potassium binders in participants with chronic hyperkalaemia in the USA, Canada and Europe: the APPETIZE study link
- What is the quantity, quality and type of systematic review evidence available to inform the optimal prescribing of statins and antihypertensives? A systematic umbrella review and evidence and gap map <u>link</u> <u>SPS commentary</u>

BMJ Quality and Safety

- Between-hospital variation in indicators of quality of care: a systematic review - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au An initiative of NSW clinical pharmacologists & pharmacists

Circulation

- Neurodevelopmental Outcomes for Individuals With Congenital Heart Disease: Updates in Neuroprotection, Risk-Stratification, Evaluation, and Management: A Scientific Statement From the American Heart Association link
- Postprocedural Anticoagulation After Primary Percutaneous Coronary Intervention for ST-Segment–Elevation Myocardial Infarction: A Multicenter, Randomized, Double-Blind Trial <u>link</u>
- Cardiogenic Shock in Older Adults: A Focus on Age-Associated Risks and Approach to Management: A Scientific Statement From the American Heart Association Link
- RNA Therapeutics for the Cardiovascular System link

Cochrane

- Macrolide antibiotics (including azithromycin) for cystic fibrosis link
- Non-clotting factor therapies for preventing bleeds in people with congenital hemophilia A or B link
- Infliximab for maintenance of medically-induced remission in Crohn's disease link
- Evening versus morning dosing regimen drug therapy for hypertension link

Diabetes Care

- Risk of Anaphylaxis Among New Users of GLP-1 Receptor Agonists: A Cohort Study link
- Accuracy and Feasibility of Real-time Continuous Glucose Monitoring in Critically III Patients After Abdominal Surgery and Solid Organ Transplantation <u>link</u>
- Cardiovascular and Kidney Risks in Individuals With Type 2 Diabetes: Contemporary Understanding With Greater Emphasis on Excess Adiposity <a href="https://link.org/link.o

European Heart Journal

- Booster vaccination with SARS-CoV-2 mRNA vaccines and myocarditis in adolescents and young adults: a Nordic cohort study <u>link</u> <u>SPS commentary</u>
- Severe mental illness: cardiovascular risk assessment and management link
- Mechanisms of rosuvastatin-related acute kidney injury following cardiac surgery: the STICS trial link

European Journal of Clinical Pharmacology

- Effects of first-line nucleot(s)ide analogues on lipid profiles in patients with chronic hepatitis B: a network meta-analysis link
- Proton pump inhibitors associated with an increased risk of mortality in elderly: a systematic review and meta-analysis link
- Efficacy and safety of adalimumab in pediatric patients with Crohn's disease: A systematic review and meta-analysis link
- Antidepressant deprescribing: State of the art and recommendations—A literature overview link
- Age of onset for increased dose-adjusted serum concentrations of antidepressants and association with sex and genotype: An observational study of 34,777 individuals $\underline{\text{link}}$
- Drug-drug interaction perpetrators of oxycodone in patients with cancer: frequency and clinical relevance link

European Journal of Hospital Pharmacy

- Effect of a smart temperature logger on correctly storing biological disease-modifying antirheumatic drugs at home: a pre-post study $\underline{\text{link}}$
- Physicochemical stability of pevonedistat at 50, 100 and 200 μ g/mL diluted in 0.9% sodium chloride and at 10 mg/mL in partially used vials link

Front Psychiatry

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

- unDerstandIng the cauSes of mediCation errOrs and adVerse drug evEnts for patients with mental illness in community caRe (DISCOVER): a qualitative study - link

Internal Medicine Journal

- COVID-19 vaccination: are more jabs needed or are we now immune? link
- The impact of coronavirus-19 vaccination on anti-nuclear cytoplasmic antibody vasculitis hospitalisations in a Sydney health network <u>link</u>
- Cushing syndrome and tertiary adrenal insufficiency from prolonged concomitant use of budesonide and Posaconazole link
- Lurbinectedin in small cell lung cancer: real-world experience of a multicentre national early access programme link

International Journal of Clinical Pharmacy

- Antipsychotic prescribing and drug-related readmissions in multimorbid older inpatients: a post-hoc analysis of the OPERAM population - <a href="https://link.google.com/lin

JAMA

- What Is Bipolar Disorder? link
- Diagnosis and Management of Paroxysmal Supraventricular Tachycardia link
- Adverse Events After XBB.1.5-Containing COVID-19 mRNA Vaccines link
- Chronic Thromboembolic Pulmonary Hypertension link

JAMA Cardiology

- Interventions for Optimization of Guideline-Directed Medical Therapy: A Systematic Review link
- Lipoprotein(a), C-Reactive Protein, and Cardiovascular Risk in Primary and Secondary Prevention Populations <u>link</u>

JAMA Internal Medicine

- Age-Related Risk of Serious Fall Events and Opioid Analgesic Use link
- Body Composition in Anti-Obesity Medication Trials—Beyond Scales link
- Management of Resistant Hypertension—An Update link
- Individualizing Care for Older Adults with Diabetes Amid the Revolution in Pharmacotherapy link

JAMA Neurology

- Sublingual Edaravone Dexborneol for the Treatment of Acute Ischemic Stroke, The TASTE-SL Randomized Clinical Trial - link – SPS commentary

Journal of Clinical Oncology

- US Food and Drug Administration Approval Summary: Elacestrant for Estrogen Receptor–Positive, Human Epidermal Growth Factor Receptor 2–Negative, ESR1-Mutated Advanced or Metastatic Breast Cancer link SPS commentary
- Topical Diclofenac for Prevention of Capecitabine-Associated Hand-Foot Syndrome: A Double-Blind Randomized Controlled Trial <u>link</u>
- Long-Term Outcomes of Medical Management vs Bariatric Surgery in Type 2 Diabetes <u>link</u> <u>SPS</u> <u>commentary</u>

Journal of Pharmacy Practice and Research (JPPR)

- Standard of practice in pain management for pharmacy services - link

Lancet

- Heart failure with preserved ejection fraction: everything the clinician needs to know link
- Targeted prophylactic anticoagulation based on the TRiP(cast) score in patients with lower limb immobilisation: a multicentre, stepped wedge, randomised implementation trial $\underline{\text{link}}$ $\underline{\text{SPS}}$ $\underline{\text{commentary}}$
- Diagnosis and management of ANCA-associated vasculitis link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

- Long-term efficacy of a recombinant hepatitis E vaccine in adults: 10-year results from a randomised, double-blind, placebo-controlled, phase 3 trial <u>link</u> <u>SPS commentary</u>
- Reviews: Hyperthyroidism <u>link</u> Behçet's syndrome <u>link</u>

Lancet Diabetes & Endocrinology

- 5-year follow-up of the randomised Diabetes Remission Clinical Trial (DiRECT) of continued support for weight loss maintenance in the UK: an extension study - <u>link</u>

Lancet Digital Health

-Characterisation of digital therapeutic clinical trials: a systematic review with natural language processing - link

Lancet Gastroenterology and Hepatology

- A biomarker-stratified comparison of top-down versus accelerated step-up treatment strategies for patients with newly diagnosed Crohn's disease (PROFILE): a multicentre, open-label randomised controlled trial - link

Lancet Infectious Diseases

- Managing treatment failure in Neisseria gonorrhoeae infection: current guidelines and future directions <u>link</u>
- Effect of BCG vaccination against Mycobacterium tuberculosis infection in adult Brazilian health-care workers: a nested clinical trial link SPS commentary

Lancet Neurology

- Comparative effectiveness of azathioprine and mycophenolate mofetil for myasthenia gravis (PROMISE-MG): a prospective cohort study link
- Clinical trials for progressive multiple sclerosis: progress, new lessons learned, and remaining challenges <u>link</u>
- Potential treatment targets for migraine: emerging options and future prospects link

Lancet Respiratory Medicine

- Reframing sepsis immunobiology for translation: towards informative subtyping and targeted immunomodulatory therapies - Link

Molecular Diversity Preservation International (MDPI) - Pharmacy Journal

- Medication Review: What's in a Name and What Is It about? link
- Development of a Prediction Model to Identify the Risk of Clostridioides difficile Infection in Hospitalized Patients Receiving at Least One Dose of Antibiotics <u>link</u>
- Strategies to Improve Therapeutic Adherence in Polymedicated Patients over 65 Years: A Systematic Review and Meta-Analysis <u>link</u>
- A Review of Olanzapine in the Treatment of Cancer Anorexia-Cachexia Syndrome link

Medical Journal of Australia

- Perspective: Enhanced recovery after surgery: an update for the generalist link
- Perspective: Inflammation: the next target for secondary prevention in coronary artery disease link

Nature Medicine

-To do no harm — and the most good — with AI in health care - link

New England Journal of Medicine

- Cefepime-Taniborbactam in Complicated Urinary Tract Infection link
- Electronic Nicotine-Delivery Systems for Smoking Cessation link SPS commentary
- Behçet's Syndrome <u>link</u>
- Treatment-Resistant Depression in Older Adults link
- A Phase 3 Trial of Seladelpar in Primary Biliary Cholangitis link SPS commentary

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

- Rusfertide, a Hepcidin Mimetic, for Control of Erythrocytosis in Polycythemia Vera link
- Benralizumab versus Mepolizumab for Eosinophilic Granulomatosis with Polyangiitis link
- Omalizumab for the Treatment of Multiple Food Allergies link SPS commentary

Pediatric Quality & Safety

- Antimicrobial Stewardship and Improved Antibiotic Utilization in the Pediatric Cardiac Intensive Care Unit link
- Improving Anticoagulation Care for Pediatric Oncology Patients: A Quality Improvement Initiative link

Pharmaceutical Journal

- Changing the culture of fluoroquinolone prescribing - link

Pharmacotherapy

- International consensus recommendations for the use of prolonged-infusion β -lactams – Comment on - Response to comment on

Prescrire International - March 2024 includes:

- -- Editorial: 40 years without sales representatives link
- -- Pregabalin and gabapentin: sometimes fatal overdoses

Prescriber UK

- NICE recommends belumosudil for graft-versus-host disease - link

Research in Social and Administrative Pharmacy

-Economic evaluations of telepharmacy services in non-cancer settings: A systematic review - link

Thorax

- Greenhouse gas emissions associated with suboptimal asthma care in the UK: the SABINA healthCARe-Based envirONmental cost of treatment (CARBON) study - link

Vaccine

- Acute disseminated encephalomyelitis and transverse myelitis following COVID-19 vaccination – A self-controlled case series analysis – <u>link</u> - <u>SPS commentary</u>

CONSULTATIONS (new additions in bold)

TGA

- Consultation: Adoption of International Scientific Guidelines in Australia R01-2023, closes <u>4 March</u> 2024
- Consultation: Medicine shortages in Australia Challenges and opportunities, closes 12 March 2024

WEBINARS & PODCASTS

Australian Prescriber Podcasts

- Episode 158: National Medicines Policy 2.0

MJA Podcasts

- Episode 6: Raising awareness of heart valve disease
- Episode 5: Cancer and heart health: discussing cardiotoxic cancer medications

Purple Pen Podcast

- PPP 158 Psoriasis
- <u>PPP 157</u> Tinnitus

UPCOMING EVENTS

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

(New additions listed in TAGMail - click here for the running list of other events)

Agency for Clinical Innovation, NSW (ACI)

- What are effective Frailty Strategies? Reflections of the last 5 years of the Frailty Initiative (online) Thursday 21 Mar 2024 14:00-15:00 register here
- Patient Reported Measures Research Symposium (free, online), Friday 17 May 2024 9:00-16:00 register <u>here</u>

Fortnightly TAG Mail – resources list 15th February 2024

CONGRATULATIONS

Adj Assoc Prof Rosemary Burke was awarded a Public Service Medal for outstanding public service in the implementation and running of the COVID-19 vaccination program and Special Health Accommodation pharmacy support for the NSW Department of Health. Rosemary is the Director of Pharmacy and Chief Pharmacy Information Officer, Sydney Local Health District. Rosemary is a long-standing and highly valued member of NSW TAG and has led major national and NSW TAG medication safety and electronic medicines management initiatives.

NSW TAG ACTIVITIES

New open email discussions

1. Missing medications from wards

A member has been experiencing medications going missing in the wards after being dispensed from pharmacy. A recent example concerned Paxlovid where five boxes were sent to the same patient over 2 days because the medication had gone missing. The incidents are being entered into IMS+. Are hospitals experiencing similar issues? Have any strategies been implemented to reduce such occurrences? Presumably, ADCs can mitigate this risk but in the meantime......Closes 28th February

2. Medication reviews for inpatients in remote Multi-Purpose Services

A rural member has been requested to provide inpatient medication reviews for patients in remote Multi-Purpose Services (MPSs) in their local health district. Currently, the hospital accepts virtual pharmacy referrals for new hospital admissions (but not from MPSs).

Are other hospitals with oversight of MPSs also being requested to provide inpatient medication reviews/providing a medication review service to MPSsand if so, how are they managing this workload? Closes **28**th **February**

3. Long-term supply issue with lidocaine 2% + 1:200,000 adrenaline injection

A NSW TAG member has the following query regarding the long-term supply of lidocaine 2% + 1:200,000 adrenaline injection. They are looking to benchmark their practice with other LHDs. How is your hospital/district managing the supply issue:

- compounding or obtaining 3rd party compounded product,
- using an alternative, such as ropivacaine 0.75%,
- supplying drugs separately and anaesthetists mixing as needed in theatres, or
- doing something else? Closes 21st February 2024.

4. Storage of medicines in patient's locked drawers and medication transfer between treatment room and bedside

Following recent DTC accreditation, one of the accreditors questioned strips of medications, rather than original boxes, being in the locked patient bedside drawers and also how medications are transported from the treatment room to the patient bedside, again original packaging vs strips. What are other hospitals doing in terms of keeping strips of medications in patient's drawers? These would be medications that are on ward imprest, kept within their original packaging in the treatment room but a strip may be placed in the patient's locked drawer, e.g. paracetamol. And following on from that, do nursing staff take medications in original packaging from the treatment room to the patient bedside or would they just take strips of medication? The Medication Handling policy mentions supply of medications from pharmacy in original packaging, unless dispensed for specific patients, but not specifically storage on the wards.' Closes **21st February 2024**

Upcoming TAG meeting dates

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

NSW Management Committee 21st February 2024

Members are reminded to respond by **23rd February** to the <u>Doodle poll</u> for their availability regarding the next NSW TAG General Meeting.

Contact Sasha Bennett at <u>sasha.bennett@svha.org.au</u> for further information about any email discussions or upcoming meetings.

EDITOR'S PICKS

AJHP: Phenytoin enzyme induction for management of supratherapeutic tacrolimus levels due to drug-drug interaction with nirmatrelvir/ritonavir: Case series and discussion - <u>link</u>

AJMQ: Prospective study of the multisite spread of a medication safety intervention: factors common to hospitals with improved outcomes - <a href="https://link.com

ACD: Medication errors involving intravenous paracetamol in children: experience from enquiries to the National Poisons Information Service $-\frac{link}{}$ - $\frac{SPS\ commentary}{}$

BMJ QS: Editorial: It is up to healthcare professionals to talk to us in a way that we can understand: informed consent processes in people with an intellectual disability - <u>link</u>

Heart: Colchicine in atherosclerotic cardiovascular disease - link

IJCP: - Financial impact of medication reviews by clinical pharmacists to reduce in-hospital adverse drug events: a return-on-investment analysis - <u>link</u>

IMJ: Variation in approaches to acute ANCA-associated vasculitis in Australia and New Zealand: rituximab, plasma exchange and glucocorticoids - link

ISMP: The Dark Side—Safety Issues When Protecting Medications from Light - link

MDPI: New Adverse Drug Reaction Signals from 2017 to 2021: Genuine Alerts or False Alarms?- <u>link</u> **Parliamentary and Health Service Ombudsman:** Discharge from mental health care: making it safe and patient-centred - <u>link</u>

Pharmaceutical Journal: Everything you need to know about nitazenes - link

OTHER NEWS (new additions in bold) Australian Commission on Safety and Quality in Health Care (ACSQHC)

- Get ready to implement the National Safety and Quality Mental Health Standards for Community Managed Organisations - <u>link</u>

NSW Health

- Measles alert for Sydney $\underline{\text{link}}$; Cryptosporidiosis alert for NSW $\underline{\text{link}}$; Measles alert for northern NSW $\underline{\text{link}}$; New sustainable water technology to be on 'tap' at NSW hospitals $\underline{\text{link}}$; Australia's oldest hospital recognised with Nightingale Award $\underline{\text{link}}$
- Authorised Nurse Immuniser and Authorised Midwife Immunisers (PD2024_004)
- Early Response to High Consequence Infectious Diseases (PD2024 005)

REPORTS AND PUBLICATIONS – AUSTRALIA

Agency for Clinical Innovation, NSW (ACI)

The latest weekly Evidence Digest can be found here

- Clinical practice guide for assessment and management of adults, children and young people with symptoms of long COVID - $\underline{\text{link}}$

AHHA

- Adapting to the digital age of healthcare data - link

Australian Institute for Health and Welfare (AIHW)

- Australia's Health Performance Framework 6 indicators link
- GEN Aged Care Data: Residential Aged Care Quality Indicators July to September 2023 link
- Mental Health Services link
- Specialist paediatric palliative care delivered to children who died in 2021 link

PBS

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- PBS subsidy arrangements for fluoxetine 10 mg capsules following the issuance of Serious Scarcity and Substitutable Medicines Instrument (SSSI) - 1 February 2024 - link - 2 February 2024 - link

TGA

- Database of section 19A approvals to import and supply medicines to address medicine shortages
- AusPARs:
- -- <u>Minjuvi</u> for adults with relapsed or refractory diffuse large B-cell lymphoma who are not eligible for autologous stem cell transplant
- -- Comirnaty Original/Omicron BA.4-5 (<u>tozinameran/famtozinameran</u>) to prevent COVID-19 in individuals 5 years of age and older
- -- <u>Doptelet</u> for thrombocytopenia in adult patients with chronic liver disease and chronic immune thrombocytopenia
- -- Comirnaty Omicron XBB.1.5 (<u>raxtozinameran</u>) COVID-19 VACCINE to prevent COVID-19 in individuals 6 months to 12 years old
- Australian prescription medicine decision summaries:
- -- Onbevzi, biosimilar to Avastin (bevacizumab), for use in several types of cancer

REPORTS AND PUBLICATIONS - INTERNATIONAL

Academy of Medical Royal Colleges

Evidence-based Interventions - Clinical guidance: Release 4 — Urology - link - SPS commentary

Agency for Healthcare Research and Quality (AHRQ) USA

- Rapid Evidence Product:
- -- Feb 09, 2024: Computerized Clinical Decision Support To Prevent Medication Errors and Adverse Drug Events link
- -- Feb 01, 2024: Deprescribing To Reduce Medication Harms in Older Adults link
- New Tool Helps Manage Opioid Use in Older Adults link

The Academy of Medical Sciences UK

- Prioritising early childhood to promote the nation's health, wellbeing and prosperity - link

British National Formulary

- BNF/BNFC newsletter: January 2024

Department of Health and Social Care UK

- Hospital discharge service guidance, updated - link

electronic Medicines Compendium (eMC) (UK)

- New products
- -- Aqumeldi (enalapril) 0.25 mg orodispersible tablets for heart failure in children from birth to < 18
- -- Clarinaze Hayfever Relief (mometasone) 0.05% seasonal allergic rhinitis symptoms
- -- Cardioxane (dexrazoxane) infusion for prevention of chronic cumulative cardiotoxicity caused by anthracycline use in breast cancer patients who have received a prior cumulative dose of 300 mg/m2 of doxorubicin or 540 mg/m2 of epirubicin when further anthracycline treatment is required
- -- Dimethyl fumarate gastro-resistant hard capsules (Celix) generic of Tecfidera® for adult and paediatric patients aged 13 years and older with relapsing remitting multiple sclerosis
- -- Enspryng (satralizumab) pre-filled syringe for monotherapy or in combination with immunosuppressive therapy for neuromyelitis optica spectrum disorders in adults and adolescents from 12 years of age who are anti-aquaporin-4 IgG seropositive
- -- Nuvaxovid XBB.1.5 dispersion for injection (Novovax), COVID-19 Vaccine (recombinant, adjuvanted) for 12 years of age and older. Administer at least 3 months after most recent dose of a COVID-19 vaccine
- -- Mounjaro KwikPen (tirzepatide) for adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise, and for weight management, including weight loss and maintenance

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- -- Omjjara (momelotinib) for disease-related splenomegaly or symptoms in adults with moderatesevere anaemia and primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis & are JAK inhibitor naïve/have tried ruxolitinib
- -- Rezzayo (rezafungin) infusion invasive candidiasis in adults Prescriber link
- -- Vecicom (tapentadol) 100mg 150mg 200mg 250mg Prolonged-release Tabs severe chronic pain
- -- Vyvgart (efgartigimod) new subcutaneous formulation for add-on to standard therapy for adults with generalised Myasthenia Gravis who are anti-acetylcholine receptor antibody positive -New/expanded indications
- -- Brukinsa (zanubrutinib) for adults with refractory/ relapsed follicular lymphoma after >2 prior systemic therapies. Includes dosing information for use in combination with Obinutuzumab
- -- Cuvitru (human normal immunoglobulin) new indication for secondary immunodeficiencies in patients who suffer from severe or recurrent infections, ineffective antimicrobial treatment and either proven specific antibody failure (PSAF) or serum IgG level of <4g/l SPS commentary
- -- Dexamethasone for adult and adolescent patients (aged ≥ 12 years with body weight ≥ 40 kg) with Covid-19 who require supplemental oxygen therapy
- -- Enhertu (trastuzumab deruxtecan) new indication for adult patients with advanced NSCLC whose tumours have an activating HER2 (ERBB2) mutation and who require systemic therapy following platinum-based chemotherapy with or without immunotherapy
- -- Keytruda (pembrolizumab) now also for treatment of gastric or gastro-oesophageal junction (GEJ) adenocarcinoma. Indication for oesophageal carcinoma changed
- -- Plavix (clopidogrel) ST segment elevation acute myocardial infarction indication expanded, in combination with ASA, to patients undergoing percutaneous coronary intervention (including stent placement)
- -- Praluent (alirocumab) extended use for primary hypercholesterolaemia and mixed dyslipidaemia with heterozygous familial hypercholesterolaemia in paediatric patients 8 years and older
- -- Yervoy (ipilimumab) for melanoma in adolescents (aged ≥12 years; already licensed for adults);

European Medicines Agency (EMA)

- European CHMP adopts/recommends:
- -- selpercatinib (<u>Retsevmo</u>) new indication adults & adolescents with RET fusion-positive thyroid cancer that is radioactive iodine-refractory (if radioactive iodine is appropriate)
- -- idecabtagene vicleucel (<u>Abecma</u>) extended indication adult patients with relapsed and refractory multiple myeloma who have received at least two (currently three) prior therapies
- -- pegcetacoplan (<u>Aspaveli</u>) indication extension patients with paroxysmal nocturnal haemoglobinuria who have haemolytic anaemia & have not had previous treatment with a C5 inhibitor
- -- cefepime / enmetazobactam (<u>Exblifep</u>) approval UTIs and pneumonia as effective as piperacillin / tazobactam in complicated UTIs, including pyelonephritis, in a phase 3 RCT
- -- efbemalenograstim alfa (<u>Ryzneuta</u>) approval to reduce the duration of neutropenia and the incidence of febrile neutropenia due to chemotherapy. An immunostimulant/colony stimulating factor that belongs to the class of haematopoietic growth factors (G-CSF), shown to reduce the duration of severe neutropenia during the first cycle of chemotherapy to a similar extent to pegfilgrastim
- ataluren (<u>Translarna</u>) not recommended for renewal as accumulated evidence has not confirmed effectiveness in patients with Duchenne muscular dystrophy caused by a nonsense mutation
- leriglitazone (Nezglyal) authorisation refused to treat male adults and children aged ≥2 years with cerebral adrenoleukodystrophy
- pegcetacoplan (<u>Syfovre</u>) authorisation refused to treat geographic atrophy caused by age-related macular degeneration

Food and Drug Administration (FDA) USA

- New Drug approvals
- -- irinotecan liposome for first-line treatment of metastatic pancreatic adenocarcinoma
- -- budesonide (<u>Eohilia</u>) new oral suspension dosage form approved for eosinophilic esophagitis in patients aged 11 years and older <u>Pl/label</u>

Medicines and Healthcare products Regulatory Agency (MHRA)

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Paclitaxel coated devices (PCD) used in the treatment of peripheral arterial disease: update to previous MHRA guidance on use (<u>DSI/2024/001</u>)
- MHRA approvals for Comirnaty (Pfizer/BioNTech) and Nuvaxovid (Novavax) COVID-19 vaccines will enable thawing and re-labelling of the vaccine outside of the NHS link
- - Yellow Card Biobank to investigate how a patient's genetic makeup can impact the safety of Direct Oral Anticoagulants (DOACs) <u>link</u>

NHS England

- NHS Type 2 Diabetes Path to Remission Programme service specification (2023) - link

NHS Scotland

- Accepted for use:
- -- <u>dupilumab</u> (Dupixent®) for adults with moderate-to-severe prurigo nodularis who are candidates for systemic therapy
- -- secukinumab (Cosentyx®) for active moderate-severe hidradenitis suppurativa (HS) in adults with an inadequate response to conventional systemic therapy
- Accepted for restricted use:
- -- <u>difelikefalin</u> (Kapruvia®) for moderate-to-severe pruritus associated with chronic kidney disease in patients on haemodialysis
- -- <u>loncastuximab tesirine</u> (Zynlonta®) for relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL)
- Not recommended:
- -- <u>cabozantinib</u> (Cabometyx®) for locally advanced or metastatic differentiated thyroid carcinoma, refractory or not eligible for radioactive iodine

NHS Improvement

- Transition to NRFit™ connectors for intrathecal and epidural procedures, and delivery of regional blocks - link

National Institute for Health and Care Excellence (NICE) UK

- Belumosudil for treating chronic graft-versus-host disease after 2 or more systemic treatments in people 12 years and over (TA949)
- Nivolumab-relatlimab for untreated unresectable or metastatic melanoma in people 12 years and over (TA950)
- Olaparib with abiraterone for untreated hormone-relapsed metastatic prostate cancer (TA951)
- Suspected sepsis: recognition, diagnosis and early management, updated (NG51)
- Caesarean birth, updated (NG192)

National Institute for Health and Care Research (NIHR)

- NIHR Alert: Even short periods of diabetes remission are linked to lower risk of heart attack & stroke
- Abrocitinib, tralokinumab and upadacitinib for treating moderate-to-severe atopic dermatitis link
- NIHR <u>alert</u>: How common are side-effects of treatment to prevent gout flares when starting allopurinol?

Parliamentary and Health Service Ombudsman

- Discharge from mental health care: making it safe and patient-centred - link

Patient Safety Commissioner UK

- The Hughes Report: Options for redress for those harmed by valproate and pelvic mesh - link

Royal Pharmaceutical Society

- Refreshes professional standards for Homecare Services - link

Specialist Pharmacy Services NHS UK

- Using St Mark's electrolyte solution - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- The licence and supporting evidence for natalizumab biosimilar link SPS commentary
- Preparing to use natalizumab biosimilar link SPS commentary
- Requirements for Governance and Preparation of Gene Therapy link
- Introduction to PGDs link

STAMMA UK

- Stammering & patient contact - link

UK Health Security Agency

- National measles guidelines updated

World Health Organisation (WHO)

- Tuberculosis preventive treatment: rapid communication link
- Clinical management of diphtheria: guideline, 2 February 2024
- WHO publishes the WHO Medically Important Antimicrobials List for Human Medicine link
- European Medicines Agency (EMA) adopts a positive scientific opinion on arPraziquantel link

MEDICATION SAFETY

electronic Medicines Compendium (eMC) (UK)

- Revised SPCs
- -- Affenid XL (methylphenidate) more information about possible effects of methylphenidate on ability to drive and operate machines included
- -- Brufen (ibuprofen) Kounis syndrome reported, defined as CV symptoms secondary to an allergic or hypersensitive reaction associated with coronary artery constriction and potential MI
- -- Brukinsa (zanubrutinib). Advises avoidance/dose modification when co-administered with moderate CYP3A enzyme inducers
- -- Cipralex (citalopram) hyperprolactinaemia added as an undesirable effect of unknown frequency
- -- Distaclor (cefaclor) neurotoxicity including encephalopathy, myoclonus & seizures. If cefaclor-associated neurotoxicity is suspected, discontinuation should be considered
- -- Depo-Medrone (methylprednisolone acetate) "Post injection pain flare (following intra-articular, periarticular, and tendon sheath injections)"
- -- Eucreas (vildagliptin/metformin) cutaneous vasculitis as an ADR (frequency unknown)
- -- Entocort CR (budesonide) hypersensitivity reactions such as angioedema added as known possible ADR of unknown frequency
- -- Finasteride oral tablets suicidal ideation added as a potential ADR (frequency unknown)
- -- Froben (flurbiprofen) can mask symptoms of infection with advice for caution if a patient currently has an infection. It also includes updated information use during pregnancy SPS commentary
- -- Imodium (loperamide) Instants and Instant Melts contain maltodextrin which contains glucose and should thus be avoided by patients with rare glucose-galactose malabsorption
- -- Keytruda (pembrolizumab) Frequency of ADR myositis changed from "very common" to "common"
- -- Koselugo (selumetinib hydrogen sulfate) administration with or without food. Additional pharmacokinetic study data added to support this
- -- Lenvima (lenvatinib) gastrointestinal perforation included as a common ADR of monotherapy and in combination with pembrolizumab
- -- Lopinavir/Ritonavir Mylan interaction with DOACs added. Clinical monitoring and/or dose reduction of the DOAC should be considered when a DOAC transported by P-gp but not metabolised by CYP3A4, including dabigatran and edoxaban, is co-administered with lopinavir/ritonavir
- -- Mavenclad (cladribine) interaction studies show cladribine has no effects on the plasma levels of ethinylestradiol and levonorgestrel. The requirement to add a barrier method of contraception for women using systemic contraceptives has been removed
- -- Maxtrex (methotrexate) photosensitivity observed in some patients. Exposure to intense sunlight or UV rays should be avoided and use a sun-protection product with a high protection factor

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- -- MST Continus, MXL, Sevredol (morphine sulfate) generalised exanthematous pustulosis, central sleep apnoea syndrome, pancreatitis and spasm of the sphincter of Oddi added as ADRs of unknown frequency. Also interaction with gabapentin/pregabalin which increases risk of respiratory depression
- -- Naprosyn EC (naproxen) from 20th week of pregnancy onward, naproxen use may cause oligohydramnios resulting from foetal renal dysfunction. In addition, there have been reports of ductus arteriosus constriction following treatment in the second trimester
- -- Naseptin (neomycin, chlorhexidine) contains cetostearyl alcohol which may cause local skin reactions (e.g., contact dermatitis)
- -- Neupro (rotigotine) occasional reports of dystonic reactions including dystonia, abnormal posture, torticollis & pleurothotonus (Pisa Syndrome) in patients with Parkinson's disease after initiation/incremental dose increase. Regimen should be reviewed & dose adjustment considered
- -- Nexviadyme (avalglucosidase alfa) updated dosing information for patients with Infantile Onset Pompe disease with insufficient response on 20 mg/kg. Dose increase to 40 mg/kg every other week should now be considered if no safety concerns. Updates of extension study data also included
- -- Opdivo (nivolumab) cytokine release syndrome as possible "common" ADR
- -- Paracetamol and Codeine Extra updated to note that alcohol and drugs which induce hepatic microsomal enzymes e.g. antiepileptic drugs, may increase the hepatotoxicity of paracetamol, particularly after overdose
- -- Produodopa (foscarbidopa and foslevodopa) information about how to determine the hourly infusion rate of Produodopa included. Phase 3 clinical data added to pharmacodynamics section
- -- Ropinirole hiccups (frequency uncommon), spontaneous penile erection (frequency not known)
- -- Rydapt (midostaurin) no dose adjustment required in patients aged over 65 years. In patients aged ≥60 years, it should be used only in patients eligible to receive intensive induction chemotherapy with adequate performance status and without significant comorbidities
- -- Telfast (fexofenadine) blurred vision as ADR of unknown frequency; concomitant use with P-gp inhibitors or inducers can affect exposure to fexofenadine, a P-gp substrate
- -- Tysabri (natalizumab) shelf life of the diluted solution has changed from 8 to 24 hours. The diluted product should be used as soon as possible and within 24 hours if stored at 2°C to 8°C. It should be allowed to warm to room temperature prior to infusion
- -- Ventolin (salbutamol) Evohaler overuse of short-acting beta-agonists may mask the progression of the underlying disease and contribute to deteriorating asthma control and increased risk of severe asthma exacerbations and mortality. Patients who take more than twice a week "as needed" salbutamol should be re-evaluated for proper treatment adjustment
- -- Vyvgart (efgartigimod alfa) live or live-attenuated vaccines generally not recommended for patients being treated with efgartigimod alfa. If required, they should be administered at least 4 weeks before treatment and at least 2 weeks after the last dose of efgartigimod alfa
- -- Yervoy (ipilimumab) Cytokine Release Syndrome added as an ADR occurring at a frequency of <1%. It has been reported as an infusion reaction (possibly resulting from a rapid injection rate)
- -- Zithromax (azithromycin) following use of azithromycin in neonates (treatment up to 42 days of life), infantile hypertrophic pyloric stenosis has been reported. Parents/caregivers should be informed to contact a physician if vomiting or irritability with feeding occurs
- -- Zomorph (morphine sulfate) dosing information in children aged over 6, with a recommended starting dose in the range of 0.2 to 0.8 mg morphine per kg bodyweight 12 hourly. Use in children under six years of age is contra-indicated
- Risk minimisation materials
- -- Elfabrio (<u>pegunigalsidase alfa</u>) information for HPs, patients & caregivers, and an infusion diary booklet to help minimise the risk of hypersensitivity reactions and medication errors for patients in the home infusion setting

EMA

- EMA's safety committee (PRAC) reminds healthcare professionals of risk of serious and potentially fatal adverse reactions with Paxlovid (nirmatrelvir, ritonavir) when used in combination with certain immunosuppressants - link

Institute for Safe Medication Practices (ISMP) USA

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Medication Safety Alert! February 8, 2024 includes
- -- The Dark Side—Safety Issues When Protecting Medications from Light link
- -- Worth repeating... Respiratory Syncytial Virus (RSV) vaccines are not approved for children; AREXVY is not approved during pregnancy!
- -- Limit ketorolac therapy to 5 days

Specialist Pharmacy Service

- Medication Safety Update January 2024
- Using NSAIDS during breastfeeding link
- Using nitrofurantoin during breastfeeding link

TGA

- Safety advisory Spiriya Respimat® Solution for Inhalation 2.5ug link: Products tested that contain undeclared substances - sildenafil, tadalafil and vardenafil - link
- Recall: Henry Blooms Herb-a-lax link

PAPERS OF INTEREST

American Journal of Cardiology

- Cardiovascular Safety of Azithromycin in Patients Hospitalized With COVID-19: A Prespecified Pooled Analysis of the COALITION I and COALITION II Randomized Clinical Trials - link

American Journal of Health-System Pharmacy (AJHP)

- Phenytoin enzyme induction for management of supratherapeutic tacrolimus levels due to drug-drug interaction with nirmatrelvir/ritonavir: Case series and discussion - link
- Physical compatibility of colistin with analgesics during simulated Y-site administration link
- Optimal follow-up schedule for patients taking PCSK9 monoclonal antibodies in a health system: Analysis of specialty pharmacy clinical interventions - link
- Minimization of preventable drug waste through use of a vial combination calculator tool link
- Loncastuximab tesirine: Risk for dose variance link
- Implementation and evaluation of an EHR-integrated perpetual inventory system in a large tertiary hospital oncology pharmacy - link

Am J Med Qual

- Prospective study of the multisite spread of a medication safety intervention: factors common to hospitals with improved outcomes - link

Annals of Internal Medicine

- Immune-Related Adverse Events of Immune Checkpoint Inhibitors - link

Archives of Disease in Childhood

- Medication errors involving intravenous paracetamol in children: experience from enquiries to the National Poisons Information Service – link – SPS commentary

British Journal of Clinical Pharmacology

- -Breast milk oxycodone concentrations in mothers given oxycodone for post-Caesarean delivery pain management - <u>link</u> - <u>SPS commentary</u> - Appropriateness of direct oral anticoagulant prescribing in older subjects with atrial fibrillation
- discharged from acute medical wards link
- Bleeding in patients on concurrent treatment with a selective serotonin reuptake inhibitor (SSRI) and low-dose acetylsalicylic acid (ASA) compared with SSRI or low-dose ASA alone—A systematic review and meta-analysis - link
- Economic evaluation of personalized vs. standard dosing of 5-fluorouracil in first-line chemotherapy for metastatic colorectal cancer in Australia - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Population pharmacokinetics and dose optimization of levofloxacin in elderly patients with pneumonia - link

British Journal of General Practice

- Familial hypercholesterolaemia in UK primary care: a Clinical Practice Research Datalink study of an under-recognised condition - <u>link</u>

British Medical Journal (BMJ)

- Comparative effectiveness of GLP-1 receptor agonists on glycaemic control, body weight, and lipid profile for type 2 diabetes: systematic review and network meta-analysis link
- Intrapartum care-updated summary of NICE guidance link
- Biogen abandons aducanumab (Aduhelm) after controversial approval left it unfunded by Medicare link
- Practical Prescribing: Thiazide diuretics link
- Attention deficit/hyperactivity disorder (ADHD) in children: more focus on care and support, less on diagnosis <u>link</u>
- Medical misinformation on social media—are the platforms equipped to be the judge? link
- Pulmonary embolism link

BMJ Open

- Treatment pathways, economic burden and clinical outcomes in new users of inhaled corticosteroid/long-acting B2-agonist dual therapy with chronic obstructive pulmonary disease in a primary care setting in England: a retrospective cohort study link
- Comparative effectiveness of biologics in patients with rheumatoid arthritis stratified by body mass index: a cohort study in a Swiss registry <u>link</u>
- Use of drugs for hyperlipidaemia and diabetes and risk of primary and secondary brain tumours: nested case—control studies using the UK Clinical Practice Research Datalink (CPRD) link

BMJ Quality & Safety

- Editorial: It is up to healthcare professionals to talk to us in a way that we can understand: informed consent processes in people with an intellectual disability - link

Circulation

- Pharmacological Management of Cardiac Arrhythmias in the Fetal and Neonatal Periods: A Scientific Statement from the American Heart Association Link
- Estimated Lifetime Cardiovascular, Kidney, and Mortality Benefits of Combination Treatment With SGLT2 Inhibitors, GLP-1 Receptor Agonists, and Nonsteroidal MRA Compared With Conventional Care in Patients With Type 2 Diabetes and Albuminuria Link
- Cardiovascular Outcomes in GRADE (Glycemia Reduction Approaches in Type 2 Diabetes: A Comparative Effectiveness Study) <u>link</u> <u>SPS commentary</u>
- Opportunities in the Postpartum Period to Reduce Cardiovascular Disease Risk After Adverse Pregnancy Outcomes: A Scientific Statement from the American Heart Association <u>link</u>

Cochrane

- Erector spinae plane block for postoperative pain link
- Methotrexate for juvenile idiopathic arthritis link
- Favipiravir for treating COVID-19 link
- Non-immunosuppressive treatment for IgA nephropathy link
- Pharmacological interventions for pruritus in adult palliative care patients link

Diabetes Care

- Association of Baseline Factors With Glycaemic Outcomes in GRADE: A Comparative Effectiveness Randomized Clinical Trial link
- Atypical Diabetes: What Have We Learned and What Does the Future Hold? link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Drug and Therapeutics Bulletin

- Republished Case report: Delirium secondary to anticholinergics link
- Republished Case report: Intravenous acetaminophen associated with acute liver failure link
- DTB Select: Tramadol-warfarin interaction <u>link</u> <u>SPS commentary</u>
- Republished Case report: Drug-induced haemolysis: another reason to be cautious with nitrofurantoin link
- Republished Case report: Severe azathioprine-induced liver injury 22 months after initiation of treatment link
- Republished case report: Hydrocortisone-induced symptomatic sinus bradycardia link
- DTB Select: Do COX-inhibitors improve emergency contraception efficacy? link SPS commentary
- Safety update: omega-3-acid ethyl esters and atrial fibrillation link
- Very low calorie diets and total diet replacement in type 2 diabetes: where are we now? link

European Heart Journal

- Legacy benefits of blood pressure treatment on cardiovascular events are primarily mediated by improved blood pressure variability: the ASCOT trial <u>link</u>
- Viewpoint: Icosapent ethyl for hypertriglyceridaemia and atherosclerosis: greater RESPECT for increased therapeutic use <u>link</u>
- Ischaemic heart disease in patients with cancer link

European Journal of Hospital Pharmacy

- Analysis of the use of antibiotics by AWaRe categories during the COVID-19 pandemic in hospitals across Scotland: a national population-based study <u>link</u> <u>SPS commentary</u>
- RETRACTION—Specific features of rational pharmacotherapy in elderly patients link
- Combination of a propofol emulsion with alpha-2 adrenergic receptor agonists used for multimodal analgesia or sedation in intensive care units: a physicochemical stability study link

Heart

- Percutaneous coronary intervention versus medical therapy in stable angina: a matched cohort study <u>link</u>
- Colchicine in atherosclerotic cardiovascular disease link

Internal Medicine Journal

- Variation in approaches to acute ANCA-associated vasculitis in Australia and New Zealand: rituximab, plasma exchange and glucocorticoids <u>link</u>
- Development of a list of Australian potentially inappropriate medicines using the Delphi technique link
- Quality use of publicly subsidised tapentadol in Australia: a population-based analysis link

International Journal of Clinical Pharmacy

- Whole blood thiamine, intravenous thiamine supplementation and delirium occurrence in the intensive care unit: retrospective cohort analyses link
- First generation antipsychotic-associated serious adverse events in women: a retrospective analysis of a pharmacovigilance database link
- Effects of inpatient creatinine testing frequency on acute kidney injury identification and staging: a historical cohort study link
- Financial impact of medication reviews by clinical pharmacists to reduce in-hospital adverse drug events: a return-on-investment analysis $\underline{\text{link}}$

JAMA

- Delivering Effective Messages in the Patient-Clinician Encounter link
- What Is Ulcerative Colitis? link
- Time to Treatment With Intravenous Thrombolysis Before Thrombectomy and Functional Outcomes in Acute Ischemic Stroke: A Meta-Analysis link SPS commentary

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Apixaban to Prevent Recurrence After Cryptogenic Stroke in Patients With Atrial Cardiopathy: The ARCADIA Randomized Clinical Trial <u>link</u> <u>SPS commentary</u>
- Methylprednisolone as Adjunct to Endovascular Thrombectomy for Large-Vessel Occlusion Stroke: The MARVEL Randomized Clinical Trial <u>link</u> <u>SPS commentary</u>
- What Is Childhood Leukaemia? link

JAMA Internal Medicine

- Sodium-Glucose Cotransporter 2 Inhibitors and Nephrolithiasis Risk in Patients with Type 2 Diabetes link
- Effect of Testosterone on Progression From Prediabetes to Diabetes in Men With Hypogonadism: A Substudy of the TRAVERSE Randomized Clinical Trial link SPS commentary
- Outcomes of Various Classes of Oral Antidiabetic Drugs on Nonalcoholic Fatty Liver Disease link

JAMA Network Open

- Ketamine Compared with Morphine for Out-of-Hospital Analgesia for Patients with Traumatic Pain link
- Efficacy and Safety of 5-Day Oral Ensitrelvir for Patients with Mild to Moderate COVID-19: The SCORPIO-SR Randomized Clinical Trial <u>link</u>

JAMA Neurology

- Risk of Stroke and Myocardial Infarction among Initiators of Triptans link SPS commentary
- Highly Effective Therapies as First-Line Treatment for Pediatric-Onset Multiple Sclerosis link
- Time to Anticoagulation Reversal and Outcomes After Intracerebral Hemorrhage link

JAMA Psychiatry

- Associations of the Gut Microbiome with Treatment Resistance in Schizophrenia - link

Journal of the American College of Cardiology

- Randomized Trial of Macitentan/Tadalafil Single-Tablet Combination Therapy for Pulmonary Arterial Hypertension - link

Journal of Pharmacy Practice and Research (JPPR)

- Ageing well with human immunodeficiency virus link
- Effectiveness of pharmaceutical care for improving medication-related quality of life and adherence to treatment among people living with schizophrenia: a randomised controlled trial link
- Improving the antibiotic duration of therapy with the implementation of antimicrobial lanyard cards and education in a regional hospital link

Lancet

- Oral gepotidacin versus nitrofurantoin in patients with uncomplicated urinary tract infection (EAGLE-2 and EAGLE-3): two randomised, controlled, double-blind, double-dummy, phase 3, non-inferiority trials link SPS commentary
- Viral gastroenteritis link

Lancet Diabetes & Endocrinology

- Air pollution exposure and cardiometabolic risk - link

Lancet Gastroenterology and Hepatology

- Safety and efficacy of autologous haematopoietic stem-cell transplantation with low-dose cyclophosphamide mobilisation and reduced intensity conditioning versus standard of care in refractory Crohn's disease (ASTIClite): an open-label, multicentre, randomised controlled trial Link
- Acute severe ulcerative colitis management: unanswered questions and latest insights link

Lancet Haematology

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Diagnosis and management of pyruvate kinase deficiency: international expert guidelines - link

Lancet Infectious Diseases

- Mucormycosis after CD19 chimeric antigen receptor T-cell therapy: results of a US Food and Drug Administration adverse events reporting system analysis and a review of the literature <u>link</u>
- Global guideline for the diagnosis and management of cryptococcosis: an initiative of the ECMM and ISHAM in cooperation with the ASM link

Lancet Psychiatry

- Pharmacological treatments for psychotic depression: a systematic review and network meta-analysis – \underline{link} – \underline{SPS} $\underline{commentary}$

Lancet Respiratory Medicine

- Hydrocortisone plus fludrocortisone for community acquired pneumonia-related septic shock: a subgroup analysis of the APROCHSS phase 3 randomised trial - <u>link</u> – <u>SPS commentary</u>

Molecular Diversity Preservation International (MDPI) - Pharmacy Journal

- New Adverse Drug Reaction Signals from 2017 to 2021—Genuine Alerts or False Alarms? link
- Enteral Delivery of Pravastatin Sodium Tablets: Effect of Compounding into a Liquid Form and Co-Administration of Enteral Nutrition <u>link</u>

New England Journal of Medicine

- Skin Antisepsis before Surgical Fixation of Extremity Fractures link
- Trial of N-Acetyl-I-Leucine in Niemann-Pick Disease Type C link SPS commentary
- A Phase 3, Randomized, Controlled Trial of Resmetirom in NASH with Liver Fibrosis link
- Coccidioidomycosis and Histoplasmosis in Immunocompetent Persons link
- Tenecteplase for Stroke at 4.5 to 24 Hours with Perfusion-Imaging Selection link

Neurology

- Phosphodiesterase Type 5 Inhibitors in Men with Erectile Dysfunction and the Risk of Alzheimer Disease: A Cohort Study - <u>link</u> – <u>SPS commentary</u>

Obstetrics and Gynecology

- Naltrexone compared with Buprenorphine or Methadone in Pregnancy: A Systematic Review link
- Efficacy and Safety of Fezolinetant for the Treatment of Menopause-Associated Vasomotor Symptoms: A Meta-analysis $\underline{\sf link}$

Pharmaceutical Journal

- Everything you need to know about nitazenes - link

Pharmacotherapy

- Use of bivalirudin after initial heparin management among adult patients on long-term venovenous extracorporeal support as a bridge to lung transplant: A case series - link

CONSULTATIONS

Australian Commission on Safety and Quality in Health Care (ACSQHC)

- Updating the National Guidelines for On-Screen Presentation of Discharge Summaries - Closing 20 February 2024 - $\underline{\text{link}}$

WEBINARS & PODCASTS

Australian Prescriber Podcasts

- Episode 157 - Top 10 drugs 2021-22 and 2022-23 - link

MJA Podcasts

- Episode 4: The health and wellbeing of children and young people

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

UPCOMING EVENTS

(New additions – see cumulative listing for older events)

FDA Division of Drug Information is presenting a series of CE webinars

- FDA Drug Topics: Tips to Navigating Drug Interaction Information in the US Prescribing Information - February 27, 2024 - <u>link</u>

Fortnightly TAG Mail – resources list 1 February 2024

We're piloting a new feature in TAGMail 2024- Editor's Picks- for those short on time!

NSW TAG ACTIVITIES

Current open email discussions

1. Long-term supply issue with lidocaine 2% + 1:200,000 adrenaline injection

A NSW TAG member has the following query regarding the long-term supply of lidocaine 2% + 1:200,000 adrenaline injection. They are looking to benchmark their practice with other LHDs. How is your hospital/district managing the supply issue:

- compounding or obtaining 3rd party compounded product,
- using an alternative, such as ropivacaine 0.75%,
- supplying drugs separately and anaesthetists mixing as needed in theatres, or
- doing something else? Closes 15th February 2024.

2. Storage of medicines in patient's locked drawers and medication transfer between treatment room and bedside

Following recent DTC accreditation, one of the accreditors questioned strips of medications, rather than original boxes, being in the locked patient bedside drawers and also how medications are transported from the treatment room to the patient bedside, again original packaging vs strips.

What are other hospitals doing in terms of keeping strips of medications in patient's drawers? These would be medications that are on ward imprest, kept within their original packaging in the treatment room but a strip may be placed in the patient's locked drawer, e.g. paracetamol. And following on from that, do nursing staff take medications in original packaging from the treatment room to the patient bedside or would they just take strips of medication? The Medication Handling policy mentions supply of medications from pharmacy in original packaging, unless dispensed for specific patients, but not specifically storage on the wards.' Closes **15**th **February 2024**

Upcoming TAG meeting dates

NSW Management Committee 21st February 2024

Contact Sasha Bennett at <u>sasha.bennett@svha.org.au</u> for further information about any email discussions or upcoming meetings.

EDITOR'S PICKS

British Medical Journal (BMJ): Reducing patient and planetary harms from high anticholinergic burden medication – <u>link</u> – <u>SPS commentary</u>

BMJ Open: Availability of evidence and comparative effectiveness for surgical versus drug interventions: an overview of systematic reviews and meta-analyses - link

Diabetes Care: The Specialist Treatment of Inpatients: Caring for Diabetes in Surgery (STOIC-D Surgery) Trial: A Randomized Controlled Trial of Early Intervention With an Electronic Specialist-Led Model of Diabetes Care – link – SPS commentary

European Heart Journal: The '10 commandments' for the 2023 ESC Guidelines for the management of cardiovascular disease in patients with diabetes - <u>link</u>

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988

Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Heart: - Cardiogeriatrics: the current state of the art - link

International Journal for Quality in Health Care: Monitoring for adverse drug events of high-risk medications with a computerized clinical decision support system: a prospective cohort study - link Journal of the American College of Cardiology: When Direct Oral Anticoagulants Should Not Be Standard Treatment: JACC State-of-the-Art Review - link

UK Clinical Pharmacy Association: Joint Position Statement between UK Clinical Pharmacy Association and the Royal College of Emergency Medicine regarding Pharmacists & Pharmacy Services in Emergency Departments - <u>Link</u>

OTHER NEWS (new additions in bold)

NSW Health

- Measles alert for Sydney International Airport [24 January 2024]
- Public health warning: tablets sold as MDMA (Ecstasy) found to contain a potent opioid [29 January 2024]
- Public Health Emergency Response Preparedness (PD2024_002) [23 January 2024]

REPORTS AND PUBLICATIONS - AUSTRALIA

Agency for Clinical Innovation, NSW (ACI)

The latest weekly Evidence Digest can be found here

Australian Government Department of Health

- Shield yourself from shingles - Resources collection - link

Australian Institute for Health and Welfare (AIHW)

- Australia's disability strategy update & annual report link
- Specialist paediatric palliative care delivered to children who died in 2021 link
- Aboriginal and Torres Strait Islander specific primary health care: results from the OSR and nKPI collections link
- Medicare Benefits Scheme funded services: monthly data link

MIMS monthly updates - February 2024

- New Products
- -- Tebentafusp (Kimmtrak) is a bispecific fusion protein, comprised of a T cell receptor (TCR) fused to an antibody fragment with specificity for the CD3 (cluster of differentiation 3) receptor, found on polyclonal T cells. The TCR has specificity for a gp100 peptide (expressed preferentially in melanoma cells) presented by human leukocyte antigen-A*02:01 (HLA-A*02:01). In vitro, tebentafusp bound to HLA-A*02:01-positive uveal melanoma cells and activated polyclonal T cells to release inflammatory cytokines and cytolytic proteins, which results in direct lysis of uveal melanoma tumour cells. Kimmtrak is indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma. Kimmtrak concentrate for intravenous infusion contains tebentafusp 0.1 mg per 0.5 mL and is available in packs of 1 vial
- New indications
- -- <u>Raxtozinameran</u> (Comirnaty Omicron XBB.1.5) is now indicated for active immunisation to prevent COVID-19 in individuals 6 months of age and older in accordance with official recommendations
- -- Tozinameran and famtozinameran (<u>Comirnaty Original/Omicron BA.4-5</u>) is now indicated (with provisional approval) for active immunisation to prevent COVID-19 in individuals 5 years of age and older in accordance with official recommendations
- -- Vosoritide (<u>Voxzogo</u>) is now indicated for the treatment of achondroplasia in all paediatric patients whose epiphyses are not closed

PBS

- PBS Website Update - 1 February 2024

TGA

- <u>Database</u> of section 19A approvals to import and supply medicines to address medicine shortages

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- -- lomustine 10mg 40mg; lisdexamfetamine dimesylate 50mg 60mg; midodrine 50mg
- AusPARs:
- -- Sunlenca (<u>Lenacapavir sodium</u>) for the treatment of adults with multidrug resistant HIV 1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen
- -- Retevmo (<u>selpercatinib</u>) is provisionally approved for treatment of adults with locally advanced or metastatic RET fusion positive non-small cell lung cancer
- Australian prescription medicine decision summaries:
- -- <u>Arexvy</u> (recombinant respiratory syncytial virus pre-fusion F protein) is approved for individuals 60 years and older for prevention of lower respiratory tract disease caused by respiratory syncytial virus
- -- Wezlana (ustekinumab) for plaque psoriasis, psoriatic arthritis, Crohn's, ulcerative colitis

REPORTS AND PUBLICATIONS - INTERNATIONAL

Canadian Agency for Drugs and Technologies in Health

- Health Technology Review Updates: Biologic Drugs for Severe Asthma - <u>link</u>; Buprenorphine Formulations for Opioid Use Disorder – <u>link</u>; The Safety of Niraparib in Ovarian Cancer – <u>link</u>; Ketamine for Adults With Treatment-Resistant Depression or Posttraumatic Stress Disorder: A 2023 Update – <u>link</u>; Ketorolac for Renal Colic - <u>link</u>

Department of Health and Social Care UK

- Improving the mental health of babies, children and young people (BCYP) link
- Expanding access to naloxone: Final outcome link SPS commentary

electronic Medicines Compendium (eMC) (UK)

- New products
- -- BCG-medac Powder and solvent for intravesical suspension for carcinoma-in-situ of the urinary bladder, prevention of recurrence of high-risk non-muscle invasive urothelial bladder carcinoma after resection, and treatment/ prevention of recurrence of aggressive variants of urothelial carcinoma
- -- Bekemv (eculizumab)- biosimilar to Soliris for use in adults and children for paroxysmal nocturnal haemoglobinuria and atypical haemolytic uraemic syndrome <u>SPS commentary</u>
- -- Camzyos (mavacamten)- selective, allosteric, and reversible cardiac myosin inhibitor for symptomatic adult obstructive hypertrophic cardiomyopathy
- -- Ebglyss (lebrikizumab) immunoglobulin (IgG4) monoclonal antibody that binds with high affinity to interleukin-13, licensed for moderate-to-severe atopic dermatitis in adults and adolescents ≥12 years of age of at least 40 kg who are candidates for systemic therapy
- -- Elrexfio (elranatamab)- bi-specific T-cell engaging antibody licensed as monotherapy in adults with relapsed & refractory multiple myeloma, who have received ≥3 prior therapies, including immunomodulatory agent, proteasome inhibitor & anti-CD38 antibody, with disease progression on last therapy
- -- Evkeeza (evinacumab), a recombinant human monoclonal antibody, which specifically binds to and inhibits ANGPTL3, for use as an adjunct to diet and other LDL-C lowering therapies for the treatment of adults and adolescents aged ≥12 years with homozygous familial hypercholesterolaemia
- -- Eylea (aflibercept) for wet age-related macular degeneration (AMD) and visual impairment due to diabetic macular oedema (DMO). Each vial contains 0.263ml, providing an 8mg dose to be given monthly for 3 doses for AMD and DMO. Dosing interval may be extended for up to 4 months
- -- Korserdu (elacestrant)- oral oestrogen receptor-α antagonist & degrader for use in postmenopausal women/men with ER+ve, HER2-ve locally advanced/metastatic breast cancer with an activating ESR1 mutation & disease progression after first line endocrine therapy including CDK 4/6 inhibitor
- -- Levorol (levomepromazine maleate) psychiatric conditions, e.g. schizophrenia, as alternative to chlorpromazine particularly to reduce psychomotor activity. Also, as an adjunct in terminal illness for the relief of pain, distress and refractory (non-chemotherapy related) nausea
- -- Loargys (pegzilarginase) a cobalt substituted recombinant human arginase 1 enzyme conjugated with a mPEG carrier for arginase 1 deficiency (hyperargininemia) in adults, adolescents and children aged 2 years and older

An initiative of NSW clinical pharmacologists & pharmacists

- -- Opdualag (nivolumab, relatlimab)- fixed dose combination of nivolumab (anti-PD-1) and relatlimab (anti-LAG-3) for the first line treatment of advanced (unresectable or metastatic) melanoma in adults & adolescents 12 years of age and older
- -- Quviviq (daridorexant) licensed for adult insomnia characterised by symptoms present for at least 3 months & considerable impact on daytime functioning <u>SPS commentary</u>
- -- Sildenafil KRKA 100mg orodispersible tablets for the treatment of adult men with erectile dysfunction, are an alternative option for patients who have difficulty swallowing film-coated tablets.
- -- Strigol (macrogol 3350) Paediatric 6.86 g powder for oral solution Lemon each sachet contains macrogol 3350, sodium chloride, sodium bicarbonate and potassium chloride for chronic constipation and prevent re-impaction after successful disimpaction in children 2-11 years old and to treat faecal impaction in children aged ≥ 5 years
- -New indications/extensions
- -- Keytruda (pembrolizumab) as monotherapy for the adjuvant treatment of adults with non-small cell lung carcinoma who are at high risk of recurrence following complete resection and platinum based chemotherapy
- -- Mircera (methoxy polyethylene glycol-epoetin beta) extension to cover treatment of symptomatic anaemia linked to chronic kidney disease in paediatric patients from 3 months to <18 years of age who are converting from another erythropoiesis stimulating agent (ESA) after haemoglobin stabilised with previous ESA
- -- Mirena (levonorgestrel) duration of use extended to 8 years for contraception, and 5 years in induction of idiopathic menorrhagia.
- -- Opdivo (nivolumab) adolescent melanoma indication (from age 12 years), and its related dosing

European Medicines Agency (EMA)

- EMA Human medicines highlights 2023 link
- EMA confirms recommendation for non-renewal of authorisation of Duchenne muscular dystrophy medicine Translarna link

Food and Drug Administration (FDA) USA

- FDA revises letter of authorization for the emergency use authorization for Paxlovid link
- New Drug approvals
- -- erdafitinib for locally advanced or metastatic urothelial carcinoma link
- -- ceftazidime/avibactam (<u>Avycaz</u>) all indications approved for newborns of at least 31 weeks destational age
- pembrolizumab (Keytruda) for hepatocellular carcinoma secondary to hepatitis B
- -- immune globulin IV (Gammagard Liquid) for chronic inflammatory demyelinating polyneuropathy
- -- dupilumab (<u>Dupixent</u>) for eosinophilic esophagitis expanded to include children aged 1 y and older who weigh at least 15 kg
- -- bupivacaine/meloxicam (Zynrelef) for soft tissue and orthopedic surgical procedures including foot and ankle expanded
- -- immune globulin SC (HyQvia) for chronic inflammatory demyelinating polyneuropathy

General Pharmaceutical Council

- Joint statement on meeting regulatory standards during periods of global or national shortage of medicines – an update - link

House of Commons Science and Technology Committee

- The antimicrobial potential of bacteriophages - link

Medicines and Healthcare products Regulatory Agency (MHRA)

- Regulatory Roadmap published for new measures to support safe access to medical technology including AI and diagnostics link
- Omjjara licensed for anaemic myelofibrosis patients to treat the symptoms of their disease link
- Rezzavo approved to treat adult patients with invasive candidiasis link
- MHRA approves four-dose Mounjaro (tirzepatide) KwikPen for diabetes and weight management

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Monthly Index of Medical Specialities MIMS UK

- Mirena levonorgestrel-releasing intrauterine system (IUS) licensed for longer use - link

NHS England

- Improving the physical health of people living with severe mental illness $\underline{\text{link}}$ $\underline{\text{SPS commentary}}$
- Five key elements for discharge supporting people with a learning disability and autistic people to leave hospital <u>link</u>
- Guidance for risk assessment and infection prevention and control measures for measles in healthcare settings <u>link</u> <u>SPS commentary</u>
- Direct-to-consumer point-of-care in vitro diagnostic devices for group A streptococcal infections link
- Blood matching genetic test to be made available on the NHS for patients with sickle cell disorder and thalassaemia to reduce transfusion side effects link

NHS Scotland (Scottish Medicines Consortium)

- Accepted for use:
- -- Burosumab (Crysvita®) for X-linked hypophosphataemia
- -- <u>Pembrolizumab</u> (Keytruda®) for microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) tumours
- Not recommended:
- -- Belantamab mafodotin (Blenrep®) for multiple myeloma

National Institute for Health and Care Excellence (NICE) UK

- Olaparib with bevacizumab for maintenance treatment of advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer (TA946)
- Loncastuximab tesirine for treating relapsed or refractory diffuse large B-cell lymphoma and high-grade B-cell lymphoma after 2 or more systemic treatments (TA947)
- Ivosidenib for treating advanced cholangiocarcinoma with an IDH1 R132 mutation after 1 or more systemic treatments (TA948)
- Updated NICE guidance recommends more targeting of antibiotics to those at the highest risk of suspected sepsis link
- Other updates: Neonatal infection (QS75); Skin cancer (QS130)

National Institute for Health and Care Research (NIHR)

- NIHR Alert: How to improve investigations of medical harm - link

Obesity Action Coalition

- Joint statement calls on the US FDA to stipulate that people with obesity must be included in drug trials - <u>link</u>

Royal Pharmaceutical Society

- Royal Pharmaceutical Society revises position on prescribing and dispensing by same healthcare professional – <u>link</u> – <u>SPS commentary</u> – <u>position statement</u> – <u>SPS commentary</u>

Specialist Pharmacy Services NHS UK

- Use of nefopam for chronic pain link
- Natalizumab biosimilar: Patient Information Sheet link
- Treating herpes virus infections during breastfeeding link

The Queen's Nursing Institute

- 70 years of end of life care in the community - link

UK Clinical Pharmacy Association

- Joint Position Statement between UK Clinical Pharmacy Association and the Royal College of Emergency Medicine regarding Pharmacists & Pharmacy Services in Emergency Departments - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

World Health Organisation (WHO)

- Guidelines on the Clinical Management of Sepsis link
- World Health Organisation (WHO) warns of alarming 45-fold rise in measles in Europe <u>link</u> <u>SPS</u> <u>commentary</u>
- WHO awards countries for progress in eliminating industrially produced trans fats for first time link
- Shortages impacting access to glucagon-like peptide 1 receptor agonist products; increasing the potential for falsified versions link

MEDICATION SAFETY

British National Formulary

- Pharmacodynamic effects tables now in digital formats - link

electronic Medicines Compendium (eMC) (UK)

- Revised SPCs
- -- Avelox (moxifloxacin), Ciproxin (ciprofloxacin) possible risk of prolonged, disabling and potentially irreversible serious ADRs highlighted
- -- Buccolam (midazolam) anaphylactic reaction (unknown frequency) added as ADR
- -- Cabometyx (cabozantinib) pneumonia added as one of the most common serious ADRs in both renal cell carcinoma and differentiated thyroid carcinoma
- -- Cetirizine hydrochloride products- contraindication in patients with end-stage renal disease (GFR < 15 ml/min) and dosing information in renal impairment. Breast-feeding risk information and myalgia ADR of unknown frequency added
- -- CitraFleet (light magnesium oxide, sodium picosulfate, citric acid) may induce aphtoid ulcers of the colonic mucosa, with reports of serious cases of colitis (including ischaemic colitis). Colitis should be considered in cases of severe and/or persistent abdominal pain, with/without rectal bleeding, after the ingestion of CitraFleet
- -- Doxorubicin Baxter interstitial lung disease, which may have an acute onset, observed in patients receiving pegylated liposomal doxorubicin, including fatal cases
- -- Eliquis (apixaban) anticoagulant-related nephropathy (ARN) added as ADR (frequency unknown). In patients with kidney disease, it may occur, possibly in relation to episodes of excessive anticoagulation and haematuria. Consider possibility of haemorrhage if evaluating the condition
- -- Elvanse (lisdexamfetamine) Hard Capsules adult indication (use as part of a comprehensive treatment programme for ADHD in adults with pre-existing symptoms of ADHD in childhood), has been incorporated into the Elvanse SmPCs which previously only included paediatric indication
- -- Epilim (sodium valproate) products new safety measures to reduce the known harms of valproate, including risk of birth defects and neurodevelopmental disorders following use in pregnancy, and the risk of impaired fertility in males SPS commentary
- -- Epistatus (midazolam) anaphylactic reaction added as possible ADR of unknown frequency (SPC notes added because this has been reported to occur when midazolam is injected in children and/or adults, which may be of relevance to oromucosal administration)
- -- Erleada (apalutamide) risk of interstitial lung disease, including fatalities. Should be interrupted if there is acute onset &/or unexplained worsening of pulmonary symptoms, & if confirmed, it should be discontinued. Restless leg syndrome added as uncommon ADR
- -- Esmeron (rocuronium bromide) mydriasis and fixed pupils as ADRs, in the context of a potential increased permeability or compromise of the integrity of the blood-brain barrier
- -- Eumovate (clobetasone butyrate) long term topical steroids use can result in the development of rebound eczema and dermatitis flares after stopping treatment (topical steroid withdrawal syndrome)
- -- Hydrocortisone creams & ointment hydrocortisone 1% is classed as a mild corticosteroid <u>SPS</u> commentary
- -- Kivexa (lamivudine, abacavir sulfate) increased risk of cardiovascular events (notably myocardial infarction). It advises that action be taken to minimise modifiable risk factors (e.g. smoking) and to consider alternative treatment options for those with high cardiovascular risk
- -- Inovelon (rufinamide) change in excipients, including information about sorbitol, benzoic acid and sodium content

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- -- Kisplyx Lenvima (lenvatinib mesilate) adrenal insufficiency added as possible ADR, frequency 'uncommon' for monotherapy and in combination with everolimus, and 'common' in combination with pembrolizumab
- -- Lokelma (sodium zirconium cyclosilicate) constipation added as a common ADR
- -- Lorviqua (lorlatinib) proteinuria added as a common ADR. The frequency is 3.4% for all grades and 0.4% for grade 3-4, which represents a more serious adverse effect
- -- Lyrica (pregabalin) suicidal ideation added as a rare ADR
- -- Lyxumia (lixisenatide) cholelithiasis and cholecystitis added as uncommon ADRs. The word "before" added to line in interaction section on administration of oral contraceptive "1 hour" before or 4 hours after lixisenatide did not affect AUC & t1/2 of ethinylestradiol and levonorgestrel
- -- Mirapexin (Pramipexole) restless legs augmentation syndrome (earlier onset of symptoms in the evening/afternoon, increase in symptoms, and involvement of other extremities) added as very common ADR. If suspected, use lowest effective dose, or consider stopping treatment
- -- Mirena (levonorgestrel) Updated information on risk in post-menopausal women, adverse reactions, and bleeding patterns also added
- -- Movicol (macrogol 3350) warning that medicines in solid dose form taken within1 hour of large volumes of Movicol may be flushed from the gastrointestinal tract and not absorbed
- -- Nortriptyline high doses in late pregnancy may cause lethargy in the newborn and urinary retention in pregnant women. Serotonin syndrome has been added as an ADR of unknown frequency. Additionally, several years of treatment may needed be for recurrent depression
- -- Norvir (ritonavir) piroxicam removed from the contraindications and interactions sections
- -- Otrivine (xylometazoline) use with caution in patients taking tri or tetra-cyclic antidepressant treatment, as concomitant use may cause an increase in blood pressure due to the cardiovascular effects of these substances
- -- Premarin (conjugated oestrogens) interaction of oestrogens with lamotrigine. Contraceptives containing oestrogens have been shown to reduce lamotrigine plasma concentrations due to induction of lamotrigine glucuronidation. It is expected that a similar interaction exists with HRT
- -- Paxlovid (nirmatrelvir, ritonavir) Stevens-Johnson syndrome, toxic epidermal necrolysis & anaphylaxis added as rare ADR; hypertension as an uncommon ADR. Potential for increased verapamil, calcineurin inhibitor & mTOR inhibitor levels with concomitant Paxlovid noted, and related monitoring advice included
- -- Prezista (darunavir) crystal nephropathy as a rare ADR identified in the post-marketing setting
- -- Resonium A (sodium polystyrene sulfonate) risk of severe gastrointestinal disorders (such as bowel obstruction, ischaemia, necrosis or perforation) so use of polystyrene sulfonate is not recommended in patients with compromised gastrointestinal motility
- -- Rinvoq (upadacitinib hemihydrate)- hypoglycaemia in patients treated for diabetes added as a precaution. Dose adjustment of anti-diabetic medication may be necessary if hypoglycaemia occurs
- -- Rivastigmine Dr. Reddys risk of electrocardiogram QT prolongation warning. Caution is advised in patients with pre-existing/family history of QTc prolongation or at higher risk of developing torsade de pointes. ECG monitoring may be required for some people
- -- Rybelsus (semaglutide) dizziness added as a new common ADR
- -- Salofalk (mesalazine) treatment should be stopped if renal function deteriorates, warnings on serious blood dyscrasias and cardiac hypersensitivity reactions (myocarditis and pericarditis), rash and pruritis added as common ADRs
- -- Sancuso (granisetron) patch may mask progressive ileus and gastric distension. Serotonin syndrome and skin reactions added as ADRs of unknown frequency. Buprenorphine and opioids now listed as medicines that may lead to serotonin syndrome, when used with granisetron
- -- Sandrena (estradiol hemihydrate) oestrogen containing contraceptives significantly decrease concentrations of lamotrigine when used together. Although this interaction with HRT and lamotrigine not studied, similar effects expected, leading to reduced seizure control
- -- Sevoflurane Baxter delirium has been added as ADR of unknown frequency
- -- Shingrix Herpes zoster vaccine (recombinant, adjuvanted) can be given concomitantly with any authorised or approved COVID-19 mRNA vaccine. This is based on data from the ZOSTER-091 study

An initiative of NSW clinical pharmacologists & pharmacists

- -- Spikevax (formerly COVID-19 Vaccine Moderna) XBB.1.5 vaccine warning about use in immunocompromised individuals removed, safety data in organ transplant recipients and immunogenicity data in organ transplant recipients included
- -- Tecentriq (atezolizumab) data from phase 3 IMvigor130 trial of atezolizumab as monotherapy and in combination with platinum-based chemotherapy in patients with untreated locally advanced or metastatic urothelial carcinoma added
- -- Tecvayli (teclistamab) recommendation to reduce the dosing frequency to 1.5 mg/kg by subcutaneous injection every two weeks for patients who have a complete response or better for a minimum of 6 months
- -- Tegretol (carbamazepine) hypersensitivity reaction information added to advise class I (immediate) reactions including rash, pruritus, urticaria, angioedema & anaphylaxis have been reported, and treatment must be discontinued if they occur. Loratadine removed from list of interacting medicines
- -- Tobramycin increased risk of ototoxicity in mitochondrial DNA mutations (particularly nucleotide 1555 A to G substitution in 12S rRNA gene), even if serum levels are within the recommended range during treatment. Alternative options should be considered in such patients
- -- Vabysmo (faricimab) injection rare cases of retinal vasculitis and/or retinal occlusive vasculitis spontaneously reported in post-marketing and in patients treated with intravitreal therapies
- -- Varivax (varicella-zoster virus [live] vaccine) syncope as post-marketing surveillance ADR
- -- Verzenios (abemaciclib) potential increased risk for serious arterial thromboembolic events (ATEs), including ischaemic stroke and MI when administered with endocrine therapies. Benefits and risks of continuing abemaciclib in those who experience serious ATE should be considered
- -- Veyvondi (vonicog alfa) co-administration of von Willebrand factor and factor VIII, (including premixing these in a single syringe) information removed. Dosing information for long-term prophylaxis against bleeds in von Willebrand disease added
- -- Vfend (voriconazole) newly calculated frequencies for following ADRs: squamous cell carcinoma (SCC) of skin (including cutaneous SCC in situ or Bowen's disease) from "not known" to "common", phototoxicity from "uncommon" to "common", and periostitis from "not known" to "uncommon."
- -- Xifaxanta (rifaximin) severe cutaneous adverse reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis reported in association with use of rifaximin in patients with cirrhosis
- -- Yasmin (ethinylestradiol, drospirenone) exogenous oestrogens may induce or exacerbate symptoms of acquired (as well as hereditary) angioedema. This ADR has an unknown frequency
- -- Zavesca (miglustat) Crohn's disease diagnosed in patients with Niemann-Pick type C disease who are taking miglustat. In patients with chronic diarrhoea and/or abdominal pain that worsen or do not respond to treatment, the possibility of Crohn's disease should be considered
- -- Zejula (niraparib tosylate monohydrate) myelodysplastic syndrome (MDS) and acute myeloid leukaemia (AML) added as common ADRs. Patients with suspected AML/MDS should be referred to a haematologist. Contraceptive advice in women of childbearing age has changed from use for 1 month to 6 months after the last dose
- -- Ziagen (abacavir sulfate) increased risk of cardiovascular events (notably myocardial infarction). Action should be taken to minimise modifiable risk factors (e.g. smoking) and to consider alternative treatment options for those with high cardiovascular risk
- Risk minimisation materials
- -- Abstral (fentanyl citrate) sublingual tablets. The prescriber's guide contains information on breakthrough pain, administration, titration, side-effects, switching and stopping treatment, breastfeeding, and provision of guidance to patients/carers. A patient/carer guide is also available
- -- Casgevy (exagamglogene autotemcel) Patient/carer guide contains information on the possibility of neutrophil engraftment failure (with associated increased risk of infections) and longer time to platelet engraftment (increased risk of bleeding). A patient alert card and administration guide also available
- -- eculizumab (Bekemv) Materials include a Physician's Guide, discussing risk of severe infection and sepsis, especially meningococcal infection, signs and symptoms of severe infection, how to minimise this risk (vaccination requirements; antibiotic prophylaxis) and other serious ADRs SPS commentary
- -- Elrexfio (elranatamab) patient alert card. This patient card, which should be carried at all times, includes information on symptoms of cytokine release syndrome and neurological toxicity, including immune effector cell associated neurotoxicity syndrome, which may be fatal or life-threatening

An initiative of NSW clinical pharmacologists & pharmacists

- -- etranacogene dezaparvovec (Hemgenix) Materials include a healthcare professional guide discussing important risks related to this treatment (hepatotoxicity; thromboembolism; malignancy; germline and horizontal transmission; development of factor IX inhibitors) and how to minimise these SPS commentary
- -- Litfulo (ritlecitinib) Prescriber guide provides a checklist for assessments prior to prescribing, management, monitoring and safety considerations related to the Risk Management Plan for ritlecitinib. A Patient Card containing information on important side-effects is also available
- -- Opdualag (nivolumab and relatlimab) patient card. This medicine can cause serious immune-mediated side-effects that can affect different parts of the body. This card, which must be carried with the person being treated at all times, lists the side effects that can be life threatening and need to be addressed immediately
- -- PecFent (fentanyl citrate) nasal spray. A prescribers guide containing important information on its safe prescribing and use discusses dosing and titration, overdose, opioid use disorder, and includes a prescribers checklist. There is also a pharmacist's guide to dispensing and a patient/carer guide -- Zynlonta (loncastuximab tesirine) Patient Card with important safety information, including risk of
- photosensitivity reactions, such as sunburn-like reactions following exposure to light, itchy rash, skin blistering, darker skin patches, irritation, swelling & pain

EMA

- Precautionary measures to address potential risk of neurodevelopmental disorders in children born to men treated with valproate medicines <u>link</u>
- EMA confirms measures to minimise the risk of serious side effects with medicines containing pseudoephedrine \underline{link}

Food and Drug Administration (FDA) USA

- FDA adds Boxed Warning for increased risk of severe hypocalcaemia in patients with advanced chronic kidney disease taking denosumab (Prolia) – $\underline{\text{link}}$ – $\underline{\text{SPS commentary}}$

Health Canada - MedEffect Notice

- Health Product InfoWatch, January 2024

Institute for Safe Medication Practices (ISMP) USA

- Medication Safety Alert! January 25, 2024
- -- Be Wary of Controlled and Non-Controlled Medication Replicas Sold Online link

Medicines and Healthcare products Regulatory Agency (MHRA) UK

- Drug Safety Update, January 2024
- -- Omega-3-acid ethyl ester medicines (Omacor/Teromeg 1000mg capsules): dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors link
- -- Valproate (Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell ▼): new safety and educational materials to support regulatory measures in men and women under 55 years of age link SPS commentary
- New valproate safety measures apply from 31 January link

Medsafe (New Zealand Medicines and Medical Devices Safety Authority)

- Medsafe successfully prosecutes seller of fake "Miracle Cure" - link

MIMS monthly updates - February 2024

- New contraindications
- -- lopromide (Ultravist 300 and 370) now contraindicated for intrathecal use
- -- Metoclopramide hydrochloride (Maxolon) tablets now contraindicated in children below 15 years

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

-- Rifabutin (<u>Mycobutin</u>) is now contraindicated for concomitant use with rilpivirine prolonged-release suspension for injection

Specialist Pharmacy Service

- Understanding drug interactions link
- Using heparins during breastfeeding link

TGA

- Product Information safety updates January 2024
- Nitrosamine impurities acceptable intakes update link
- The following pose a serious risk to health and should not be taken: <u>Artri King tablets</u>; <u>Commander Stamina Time tablets</u>; <u>Throb Herbal supplement tablets</u>; <u>Kamasutra herbal jelly for him bottle</u>; <u>Excite for her tablets</u>; <u>Kamasutra Herbal Jelly for him oral jelly sachets</u>

PAPERS OF INTEREST

American Journal of Cardiology

- Early Initiation of PCSK9 Inhibitor Therapy Versus Placebo in Patients With Acute Coronary Syndrome: A Systematic Review and Meta-Analysis - link

American Journal of Gastroenterology

- Antibiotics with or without rifaximin for acute hepatic encephalopathy (HE) in critically ill patients With cirrhosis: A double-blind, randomized controlled (ARiE) trial - link

American Journal of Health-System Pharmacy (AJHP)

- Tenecteplase-associated orolingual angioedema: A case report and literature review link
- Risk of bleeding with concomitant use of oral anticoagulants and aspirin: A systematic review and meta-analysis link
- Implementation of clopidogrel pharmacogenetic clinical decision support for a preemptive return of results program link
- Implementation of vancomycin AUC/MIC dosing vs traditional trough dosing and incidence of acute kidney injury at a rural community hospital <u>link</u>

Annals of Internal Medicine

- Effectiveness of Recombinant Zoster Vaccine Against Herpes Zoster in a Real-World Setting <u>link</u> <u>SPS commentary</u>
- Effectiveness of Existing Insomnia Therapies for Patients Undergoing Hemodialysis: A Randomized Clinical Trial link
- Gabapentinoids and Risk for Severe Exacerbation in Chronic Obstructive Pulmonary Disease: A Population-Based Cohort Study link
- Talking With Patients About the New Anti-amyloid Alzheimer Disease Medications link

Arthritis & Rheumatology

- Clinical characteristics of cryopyrin-associated periodic syndrome and long-term real-world efficacy and tolerability of canakinumab in Japan: results of a nationwide survey - link

British Journal of Clinical Pharmacology

- Gabapentinoids in Ireland 2010 to 2020: An observational study of trends in gabapentinoid prescribing, law enforcement drug seizures and post-mortem toxicology <u>link</u>
- Observational studies to emulate randomized trials: Some real-world barriers link
- A physiological approach to renal clearance: From premature neonates to adults link

British Journal of General Practice

- Cost-utility analysis of molnupiravir plus usual care versus usual care alone as early treatment for community-based adults with COVID-19 and increased risk of adverse outcomes in the UK PANORAMIC trial - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

British Journal of Psychiatry

- Sensitivity to light in bipolar disorder: implications for research and clinical practice - link

British Medical Journal (BMJ)

- Combining high quality data with rigorous methods: emulation of a target trial using electronic health records and a nested case-control design <u>link</u>
- Efficacy and safety of tranexamic acid in acute haemorrhage link
- Improving the transparency and reliability of observational studies through registration link
- Why learning how to swallow pills is good for patients, parents, and the planet link
- Effect of Risk Mitigation Guidance opioid and stimulant dispensations on mortality and acute care visits during dual public health emergencies: retrospective cohort study <u>link</u> <u>SPS commentary</u>
- Undisclosed financial conflicts of interest in DSM-5-TR: cross sectional analysis <u>link</u> <u>SPS</u> commentary
- Perinatal depression and its health impact link SPS commentary
- Inclisiran: the test case drug for the Government's life sciences strategy link
- Anaemia Management in Chronic Kidney Disease link
- Reducing patient and planetary harms from high anticholinergic burden medication <u>link</u> <u>SPS</u> <u>commentary</u>
- Therapeutic advances in rheumatoid arthritis link

BMJ Open

- Cannabis for medical use versus opioids for chronic non-cancer pain: a systematic review and network meta-analysis of randomised clinical trials link
- NSAID prescribing and adverse outcomes in common infections: a population-based cohort study link
- Availability of evidence and comparative effectiveness for surgical versus drug interventions: an overview of systematic reviews and meta-analyses <a href="https://link.org/link.o
- Role of vitamin D supplementation in modifying outcomes after surgery: a systematic review of randomised controlled trials link
- Association between antidepressant use during pregnancy and miscarriage: a systematic review and meta-analysis link SPS commentary

Circulation

- Efficacy and Safety of Non–Vitamin-K Antagonist Oral Anticoagulants Versus Warfarin Across the Spectrum of Body Mass Index and Body Weight: An Individual Patient Data Meta-Analysis of Four Randomized Clinical Trials of 58 464 Patients With Atrial Fibrillation - link

Cochrane

- Deep neuromuscular blockade in adults undergoing an abdominal laparoscopic procedure link
- Early versus late administration of amino acids in preterm infants receiving parenteral nutrition link
- Non-vitamin-K-antagonist oral anticoagulants (NOACs) after acute myocardial infarction: a network meta-analysis <u>link</u>
- Probiotics for the postoperative management of term neonates after gastrointestinal surgery link

Diabetes Care

- Impact of Glucose-Lowering Medications on Health-Related Quality of Life in Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE) <u>link</u>
- Comparative Effects of Randomized Second-line Therapy for Type 2 Diabetes on a Composite Outcome Incorporating Glycemic Control, Body Weight, and Hypoglycemia: An Analysis of Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE) link
- The Specialist Treatment of Inpatients: Caring for Diabetes in Surgery (STOIC-D Surgery) Trial: A Randomized Controlled Trial of Early Intervention With an Electronic Specialist-Led Model of Diabetes Care Link SPS commentary

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Optimal Dose and Type of Physical Activity to Improve Glycemic Control in People Diagnosed With Type 2 Diabetes: A Systematic Review and Meta-analysis <u>link</u> <u>SPS commentary</u>
- A Methodological Framework for Meta-analysis and Clinical Interpretation of Subgroup Data: The Case of Major Adverse Cardiovascular Events With GLP-1 Receptor Agonists and SGLT2 Inhibitors in Type 2 Diabetes <a href="https://link.org

Drug and Therapeutics Bulletin

- Low-dose aspirin and anaemia in older people link
- Can antidepressants worsen COPD? link
- Effect of semaglutide on major cardiovascular events link
- ADHD medication shortages: more than just a supply issue link

European Heart Journal

- Green cardiovascular care: a call for sustainable transformation of cardiovascular practices link
- Seeking synergy for novel weight and glucose-lowering pharmacotherapy and exercise training in heart failure patients with preserved ejection fraction (HFpEF) link
- How to diagnose and treat venous congestion in heart failure link
- The '10 commandments' for the 2023 ESC Guidelines for the management of cardiovascular disease in patients with diabetes $\underline{\text{link}}$
- Cannabis for chronic pain: cardiovascular safety in a nationwide Danish study <u>link</u> <u>SPS</u> commentary
- Aspirin-free antiplatelet strategies after percutaneous coronary interventions link
- Cardiovascular disease risk communication and prevention: a meta-analysis link
- Icosapent ethyl following acute coronary syndrome: the REDUCE-IT trial link

European Journal of Hospital Pharmacy

- Evaluation of the impact of pharmacist-led educational intervention on knowledge and skills of cancer patients with totally implantable venous access port: a single-centre, non-randomised controlled study link
- Switching anti-CGRP monoclonal antibodies in chronic migraine: real-world observations of erenumab, fremanezumab and galcanezumab link
- Enhancing pharmaceutical decision support system: evaluating antithrombotic-focused algorithms for addressing drug-related problems link
- Physicochemical and biological stability of diluted vedolizumab in intravenous infusion bags link
- Management of heparin-induced thrombocytopenia during extracorporeal membrane oxygenation support: a case of neutropenia caused by argatroban anticoagulation $\underline{\text{link}}$
- Combination of a propofol emulsion with alpha-2 adrenergic receptor agonists used for multimodal analgesia or sedation in intensive care units: a physicochemical stability study link

Heart

- Postdischarge major bleeding, myocardial infarction, and mortality risk after coronary artery bypass grafting link SPS commentary
- Generalisability of trials on antithrombotic treatment intensification in patients with cardiovascular disease link
- Review of the National Institute for Health and Care Excellence guidelines on chronic heart failure link
- Cardiogeriatrics: the current state of the art link
- Management of pregnancy-related disorders to prevent future risk of coronary artery disease link
- Efficacy and safety of colchicine for the treatment of myopericarditis link

International Journal of Clinical Pharmacy

- Psychiatric adverse events associated with semaglutide, liraglutide and tirzepatide: a pharmacovigilance analysis of individual case safety reports submitted to the EudraVigilance database - <u>link</u>

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Exploring the safety profile of tremelimumab: an analysis of the FDA adverse event reporting system link
- Data mining and analysis of adverse event signals associated with teprotumumab using the Food and Drug Administration adverse event reporting system database <u>link</u>
- A comparison between the adverse event profiles of patients receiving palbociclib and abemaciclib: analysis of two real-world databases <u>link</u>
- Comparison of the sensitivities of pharmacotherapy-related and disease-specific quality of life measures in response to pharmacist-led pharmaceutical care for cancer outpatients: a randomised controlled trial <u>link</u>

International Journal for Quality in Health Care

- Monitoring for adverse drug events of high-risk medications with a computerized clinical decision support system: a prospective cohort study - link

JAMA

- T-Cell Lymphoma From CAR T-Cell Therapy—A New Safety Notice link
- Perioperative toripalimab plus chemotherapy for patients with resectable Non–Small Cell Lung Cancer (NSCLC): The Neotorch randomized clinical trial link
- Intranasal naloxone for opioid overdose link
- International Consensus Criteria for Pediatric Sepsis and Septic Shock link SPS commentary
- Management of Candida auris link

JAMA Cardiology

- Impact of Bempedoic Acid on Total Cardiovascular Events: A Prespecified Analysis of the CLEAR Outcomes Randomized Clinical Trial <a href="https://link.org/link.com/link.c
- Dapagliflozin and Mode of Death in Heart Failure with Improved Ejection Fraction- A Post Hoc Analysis of the DELIVER Trial $\underline{\text{link}}$

JAMA Dermatology

- Causes and Clinical Presentation of Drug-Induced Dermatomyositis: A Systematic Review link
- Sustained Remission Without Corticosteroids Among Patients with Pemphigus Who Had Rituximab as First-Line Therapy link

JAMA Internal Medicine

- Early Tecovirimat Treatment for Mpox Disease Among People With HIV link SPS commentary
- First Trimester Use of Buprenorphine or Methadone and the Risk of Congenital Malformations link
- SPS commentary

JAMA Network Open

- Cumulative update of a systematic overview evaluating interventions addressing polypharmacy - link

JAMA Neurology

- Argatroban in Patients With Acute Ischemic Stroke With Early Neurological Deterioration <u>link</u> SPS commentary
- SARS-CoV-2 Vaccination and Neuroimmunological Disease: A Review link
- Concomitant Medications for Progressive Supranuclear Palsy: A Secondary Analysis of a Randomized Clinical Trial <u>link</u>

JAMA Oncology

- Rapid Advances in Resectable Non-Small Cell Lung Cancer: A Narrative Review link
- Mirtazapine as Appetite Stimulant in Patients with Non–Small Cell Lung Cancer and Anorexia: A Randomized Clinical Trial <a href="https://link.google.com/l

JAMA Psychiatry

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

- Prescription Stimulant Use During Pregnancy and Risk of Neurodevelopmental Disorders in Children

- <u>link</u>

Journal of the American College of Cardiology

- When Direct Oral Anticoagulants Should Not Be Standard Treatment: JACC State-of-the-Art Review

- <u>link</u>

Journal of Clinical Oncology

- Health Care Transitions Among Adolescents and Young Adults with Cancer link
- Cancer-Associated Thrombosis: Management of a Patient with an Isolated Calf Deep Vein Thrombosis <u>link</u>

Journal of Clinical Pharmacology

- Inclusion of Obese Participants in Drug Development: Reflections on the Current Landscape and a Call for Action - <u>link</u>

Lancet

- Indomethacin with or without prophylactic pancreatic stent placement to prevent pancreatitis after ERCP: a randomised non-inferiority trial $-\frac{link}{link} \frac{SPS\ commentary}{link}$
- Lancet series on Parkinson's disease link SPS commentary

Lancet Diabetes & Endocrinology

- Association of glycaemic index and glycaemic load with type 2 diabetes, cardiovascular disease, cancer, and all-cause mortality: a meta-analysis of mega cohorts of more than 100 000 participants - link

Lancet Haematology

- Prophylaxis and management of graft-versus-host disease after stem-cell transplantation for haematological malignancies: updated consensus recommendations of the European Society for Blood and Marrow Transplantation - link

Lancet HIV

- Changes in incidence of hepatitis C virus reinfection and access to direct-acting antiviral therapies in people with HIV from six countries, 2010–19: an analysis of data from a consortium of prospective cohort studies link
- Longitudinal trends in causes of death among adults with HIV on antiretroviral therapy in Europe and North America from 1996 to 2020: a collaboration of cohort studies link SPS commentary

Lancet Infectious Diseases

- Oral linezolid compared with benzathine penicillin G for treatment of early syphilis in adults (Trep-AB Study) in Spain: a prospective, open-label, non-inferiority, randomised controlled trial link SPS commentary
- Efficacy and safety of a structured de-escalation from antipseudomonal β -lactams in bloodstream infections due to Enterobacterales (SIMPLIFY): an open-label, multicentre, randomised trial \underline{link} SPS commentary
- Novel strain of multidrug non-susceptible Neisseria gonorrhoeae in the USA link
- Efficacy and safety of an early oral switch in low-risk Staphylococcus aureus bloodstream infection (SABATO): an international, open-label, parallel-group, randomised, controlled, non-inferiority trial link SPS commentary

Lancet Oncology

- Low-dose versus standard-dose olanzapine with triple antiemetic therapy for prevention of highly emetogenic chemotherapy-induced nausea and vomiting in patients with solid tumours: a single-centre, open-label, non-inferiority, randomised, controlled, phase 3 trial - <u>link</u>

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Lancet Psychiatry

- Efficacy and effectiveness of antipsychotics in schizophrenia: network meta-analyses combining evidence from randomised controlled trials and real-world data – link – SPS commentary

Lancet Public Health

- Nitazenes—heralding a second wave for the UK drug-related death crisis? - link

Lancet Respiratory Medicine

- Profiling the dysregulated immune response in sepsis: overcoming challenges to achieve the goal of precision medicine <u>link</u>
- Clarithromycin for early anti-inflammatory responses in community-acquired pneumonia in Greece (ACCESS): a randomised, double-blind, placebo-controlled trial <u>link</u> <u>SPS commentary</u>
- Risk factors for COVID-19-associated pulmonary aspergillosis: a systematic review and meta-analysis link SPS commentary
- Morphine for treatment of cough in idiopathic pulmonary fibrosis (PACIFY COUGH): a prospective, multicentre, randomised, double-blind, placebo-controlled, two-way crossover trial <u>link</u>

New England Journal of Medicine

- Navigating and Communicating about Serious Illness and End of Life link
- Efficacy and Safety of Acoramidis in Transthyretin Amyloid Cardiomyopathy link
- Oral Simnotrelvir for Adult Patients with Mild-to-Moderate Covid-19 link
- Testosterone Treatment and Fractures in Men with Hypogonadism <u>link</u> <u>SPS commentary</u>
- Syphilis Complicating Pregnancy and Congenital Syphilis link
- Daratumumab, Bortezomib, Lenalidomide, and Dexamethasone for Multiple Myeloma <u>link</u> <u>SPS</u> <u>commentary</u>
- Perspective: Secondary Cancers after Chimeric Antigen Receptor T-Cell Therapy <u>link</u> <u>SPS</u> <u>commentary</u>
- Responding to medical errors implementing the modern ethical paradigm link

Pain Physician

- Comprehensive, Evidence-Based, Consensus Guidelines for Prescription of Opioids for Chronic Non-Cancer Pain from the American Society of Interventional Pain Physicians - link

Pediatrics (American Academy of Pediatrics)

- 2023 American Heart Association and American Academy of Pediatrics Focused Update on Neonatal Resuscitation: An Update to the American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care - <u>link</u>

Pharmaceutical Journal

- Inclisiran: the 'extremely unusual' political influence behind the novel drug's approval - link

Prescrire International - February 2024 includes

- Olaparib (Lynparza°) as "maintenance" therapy for certain advanced ovarian cancers after first-line chemotherapy; Clomifene: serious, sometimes irreversible, vision disorders; Drugs that interfere with the placenta and affect the fetus – with editorial

Rheumatic & Musculoskeletal Diseases

- Hormonal and reproductive factors in relation to the risk of rheumatoid arthritis in women: a prospective cohort study with 223 526 participants – <u>link</u> – <u>SPS commentary</u>

Thorax

- Genetic and T2 biomarkers linked to the efficacy of HDM sublingual immunotherapy in asthma <u>link</u> <u>SPS commentary</u>
- Use of inhaled corticosteroids and the risk of hospitalisation for pneumonia in children with asthma: a nationwide cohort study link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

CONSULTATIONS (new additions in bold)

Australian Commission on Safety and Quality in Health Care (ACSQHC)

- NPAAC Standards Tier 3B and 4, Closing 23 February 2024 link
- Updating the National Guidelines for On-Screen Presentation of Discharge Summaries, Closing 20 February 2024 <u>link</u>

TGA

- Proposed amendments to the Poisons Standard – ACMS, ACCS and Joint ACMS-ACCS meetings, March 2024, Closes on 5 February 2024 - <u>link</u>

WEBINARS & PODCASTS

Australian Prescriber Podcasts

- Episode 156 - Physical health monitoring for people with schizophrenia

MJA Podcasts

- Episode 1: chronic cough in children and adults
- Episode 2: the economics of Australia's health system

UPCOMING EVENTS

(New additions listed in TAGMail - click here for the running list of other events)

Kids Research, Sydney Children's Hospitals Network

- How to get 'grant ready' – free workshop, Friday, 9 February, 9:30am-12:30pm, Teams and Royal Hospital for Women Lecture Theatre – register <u>here</u>

Fortnightly TAG Mail – resources list

18th January 2024



NSW TAG wishes all TAGMail readers a happy, healthy and productive 2024

NSW TAG ACTIVITIES

Upcoming TAG meetings

Meeting for NSW TAG's feedback re Dept of Health's proposed Repurposing Medicines Program 12-1pm Thursday 25th January. Contact Sasha Bennett sasha.bennett@svha.org.au if wish to provide input.

OTHER NEWS (new additions in bold)

NSW Health

- Measles alert for western Sydney link
- Legionnaires' disease alert for Sydney CBD link
- NSW community urged to stay COVID-safe this summer link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Pharmacy Board of Australia

- New accreditation standards for pharmacist prescriber education programs link
- Pharmacist prescribing position statement update link

TGA

- Repeal of Therapeutic Goods (Restricted and Prohibited Representations—Nicotine) Permission (No. 2) 2021 – advertising permission for nicotine repealed as part of the vaping regulation reforms

REPORTS AND PUBLICATIONS - AUSTRALIA

Agency for Clinical Innovation, NSW (ACI)

- The latest weekly Evidence Digests can be found here
- Diagnosis and management of adults with acute ureteric colic link patient fact sheet

Australian Commission on Safety and Quality in Health Care (ACSQHC)

- National Safety and Quality Cosmetic Surgery Standards link
- National Consensus Statement: Essential elements for safe and high-quality end-of-life care link

Australian Government Department of Health

- Launch of the National Immunisation Program Vaccinations in Pharmacy (NIPVIP) Program link
- Hospital data resources link

Australian Institute for Health and Welfare (AIHW)

- Australian facts: Heart, stroke and vascular disease, Diabetes, Chronic kidney disease

CEC

- Fall Prevention in NSW. White Paper 2023 - link

MIMS monthly updates - January 2024

- New Products
- -- <u>Raxtozinameran</u> (Comirnaty Omicron XBB.1.5). Indicated for active immunisation to prevent COVID-19 in those 5 years of age and older as per official recommendations.
- New Indications
- -- Incobotulinumtoxin A (Xeomin) for adult chronic sialorrhoea due to neurological disorders; and in children and adolescents aged 2 to 17 years for the symptomatic treatment of chronic sialorrhoea due to neurological/neurodevelopmental disorders and for spasticity of the lower and/or upper limbs
- -- Olaparib (Lynparza) expanded indications in breast cancer and prostate cancer.

TGA

- <u>Database</u> of section 19A approvals to import and supply medicines to address medicine shortages AusPARs:
- -- Andexxa (<u>andexanet alfa</u>) is provisionally approved for adult patients treated with a direct factor Xa inhibitor when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding
- -- Imjudo (tremelimumab) for the treatment of unresectable hepatocellular carcinoma
- -- Imfinzi (durvalumab) for the treatment of unresectable hepatocellular carcinoma
- -- Opdualag (nivolumab and relatlimab), which is approved for the treatment of patients with unresectable or metastatic melanoma who are at least 12 years old
- Australian prescription medicine decision summaries:
- -- Raniviz (ranibizumab) is approved to treat visual impairment issues
- -- Aquipta (atogepant) is approved for prophylaxis of migraine in adults
- -- Givlaari (givosiran) is approved to treat acute hepatic porphyria
- -- Sohonos (palovarotene) is approved to reduce the formation of heterotopic ossification
- -- Beyfortus (<u>nirsevimab</u>) is approved for the prevention of respiratory syncytial virus (RSV) in neonates, infants and vulnerable children up to the age of 24 months

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- -- Spevigo (<u>spesolimab</u>) is approved for the treatment of flares in adult patients with generalised pustular psoriasis
- -- Heparin Interpharma (<u>heparin sodium</u>) is approved for prophylaxis and treatment of deep vein thrombosis in patients 18 years and older

Victorian Institute of Forensic Medicine

- Clinical Communiqué Volume 10 Issue 4 December 2023 - link

REPORTS AND PUBLICATIONS - INTERNATIONAL

Canadian Agency for Drugs and Technologies in Health

- Leucovorin Dosing for Gastrointestinal Cancer link
- Ketamine for Chronic Non-Cancer Pain: A 2023 Update link
- Horizon scan: Emerging Drugs for Relapsed or Refractory Peripheral T-Cell Lymphoma link
- Reference list: Screening for Thyroid Dysfunction Using Thyroid Stimulating Hormone Testing link

electronic Medicines Compendium (eMC) (UK)

- New products
- -- Colextra-D3 (Colecalciferol) 20,000 IU Soft Capsules for prevention and treatment of vitamin D deficiency in adults and adolescents with an identified risk. It may be used as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency
- -- Kalydeco (ivacaftor) granules in sachet monotherapy for cystic fibrosis (CF) in children ≥1 month, weighing 3-25kg with specific CFTR mutations. Also licensed as part of ivacaftor/tezacaftor/elexacaftor regimen for CF in children aged 2-5yrs who have ≥1 F508del mutation
- -- Hydrocortisone 10mg/5ml and 5mg/5ml oral solutions licensed for replacement therapy in adrenal insufficiency in infants, children and adolescents (from 1 month to <18 years old)
- -- Veoza (<u>fezolinetant</u>) tablets non-hormonal selective neurokinin 3 receptor antagonist licensed for the treatment of moderate to severe vasomotor symptoms associated with menopause -New indications/expanded access
- -- Biktarvy (bictegravir, emtricitabine, and tenofovir alafenamide fumarate) extension for use in paediatric patients from age 2 years, weighing at least 14kg for the treatment of HIV 1, without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir
- -- Evrysdi (risdiplam) for all age groups (previously for use from age 2 months and older). It now includes data from the RAINBOWFISH trial in 18 patients with pre-symptomatic spinal muscular atrophy between 16 and 40 days of age
- -- Nuvaxovid dispersion for injection, COVID-19 Vaccine (recombinant, adjuvanted) extension as a booster dose in the adolescent population from 12 to 18 years, including as a heterologous booster -- Zerbaxa (tazobactam and ceftolozane) extension for Zerbaxa for complicated intra-abdominal infection, acute pyelonephritis and complicated urinary tract infections in paediatric patients

European Medicines Agency (EMA)

- Human medicines: highlights of 2023 and of 2024
- CHMP approved new indications
- -- <u>HyQvia</u> (human normal immunoglobulin) for use in adults, children and adolescents with chronic inflammatory demyelinating polyneuropathy, as maintenance immunomodulatory therapy after stabilization with IVIq
- -- Tenecteplase (Metalyse) for thrombolytic treatment of acute ischaemic stroke in adults, within 4.5 hours from last known well and after exclusion of intracranial haemorrhage also new formulation/strength of 5000 units (25 mg) powder for solution for injection CHMP approved extensions of use
- -- bezlotoxumab (Zinplava) for prevention/recurrence of CDI in all patients aged 1 year and older
- -- <u>VeraSeal</u> (human fibrinogen/human thrombin) for improvement of haemostasis and as suture support in vascular surgery for all age groups
- CHMP marketing authorisation
- -- <u>Dabigatran Etexilate Leon Farma</u> generic to Pradaxa <u>SPS commentary</u>

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au An initiative of NSW clinical pharmacologists & pharmacists

- -- eribulin (Mevlyq) generic to Halaven for the treatment of breast cancer and liposarcoma
- -- etrasimod (Velsipity) for treatment of ulcerative colitis
- -- <u>Ibuprofen Gen.Orph</u> generic to Pedea for the treatment of a haemodynamically significant patent ductus arteriosus in preterm newborn infants
- -- omaveloxolone (Skyclarys) for the treatment of Friedreich's ataxia
- -- Pomalidomide Viatris generic to Imnovid for the treatment of multiple myeloma

Food and Drug Administration (FDA) USA

- New Drug approvals
- -- Two gene therapies (Casgevy and Lyfgenia) to treat sickle cell disease link
- -- pembrolizumab with chemoradiotherapy for FIGO 2014 Stage III-IVA cervical cancer
- -- Filsuvez (birch triterpenes) to treat wounds associated with dystrophic and junctional epidermolysis bullosa
- -- Wainua (eplontersen) to treat polyneuropathy of hereditary transthyretin-mediated amyloidosis
- -- Berdazimer topical (<u>Zelsuvmi</u>) topical nitric oxide—releasing agent for molluscum contagiosum in patients aged 1 year and older
- -- Roflumilast topical (<u>Zoryve</u>) new foam dosage form and new indication approved for seborrheic dermatitis in patients aged 9 years and older
- -- Immune globulin IV (<u>Bivigam</u>) indication for primary immunodeficiency expanded to include children aged 2 years and older
- Enfortumab Vedotin Plus Pembro for Urothelial Cancer link
- Tralokinumab for Treating Eczema in Adolescents link
- Antiparasitic for High-Risk Neuroblastoma link
- Iptacopan to Treat Paroxysmal Nocturnal Hemoglobinuria link
- Idacio (Adalimumab-Aacf), tumor necrosis factor (TNF) blocker

Health Canada

- Handbook for healthcare professionals on biosimilar biologic drugs - link

Health Services Safety Investigation Body

- Electronic patient record systems: recurring themes arising from safety investigations - link

Medicines and Healthcare products Regulatory Agency (MHRA)

- Opdualag licensed for patients with advanced melanoma - link

NHS Scotland - Scottish Medicines Consortium

- Accepted for use:
- -- Bimekizumab (Bimzelx®) for axial spondyloarthritis
- -- Cemiplimab (Libtayo®) for cutaneous squamous cell carcinoma
- -- Cipaglucosidase alfa (Pombiliti®) for Pompe disease SPS commentary
- -- Degarelix (Firmagon®) for prostate cancer
- -- Deucravacitinib (Sotyktu®) for plaque psoriasis
- -- Nivolumab (Opdivo®) for non-small cell lung cancer
- -- Trastuzumab deruxtecan (Enhertu®) for unresectable or metastatic HER2-low breast cancer

National Institute for Health and Care Excellence (NICE) UK

- Pembrolizumab plus chemotherapy with or without bevacizumab for persistent, recurrent or metastatic cervical cancer (TA939)
- Risdiplam for treating spinal muscular atrophy, updated (TA755)
- Empagliflozin for treating chronic kidney disease (TA942) SPS commentary
- Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes (TA943)
- Targeted-release budesonide for treating primary IgA nephropathy (TA937)
- Durvalumab with gemcitabine and cisplatin for treating unresectable or advanced biliary tract cancer (TA944)
- Velmanase alfa for treating alpha-mannosidosis Highly specialised technologies guidance (HST29)

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Sebelipase alfa for treating Wolman disease (HST30)
- Cardiovascular disease: risk assessment & reduction, including lipid modification, updated (NG238)
- SPS commentary
- Acne vulgaris: management (NG198)
- NICE publishes additional resources to support implementation of guidance on digitally enabled therapies for adults with anxiety disorders (<u>HTE9</u>) or depression (<u>HTE8</u>) <u>SPS commentary</u>
- Epilepsies in children, young people and adults (QS211)
- Transition from children's to adults' services (QS140)
- Bipolar disorder: assessment and management, updated (CG185)

National Institute for Health and Care Research (NIHR)

- NIHR alert: Women need support to improve their health before pregnancy link
- NIHR Alert: Tool could reduce blood test monitoring for most people on methotrexate link
- The potential impact of policies and structural interventions in reducing cardiovascular disease and mortality: a systematic review of simulation based studies link

Neonatal & Paediatric Pharmacists Group

- Guideline for peripheral use of adrenaline and noradrenaline in paediatric patients without central access - <u>link</u>

Scottish Intercollegiate Guideline Network (SIGN) UK

- Perinatal mental health conditions: SIGN 169

Specialist Pharmacy Services NHS UK

- Supporting adherence: Complex medication regimens (SPS commentary), Defining and understanding medication adherence (SPS commentary), Explaining how to use or take medicines (SPS commentary), Manual dexterity (SPS commentary), Reminding to take medicines (SPS commentary), Swallowing difficulties (SPS commentary)
- Natalizumab biosimilar: patient information sheet link
- Use of nefopam for chronic pain link
- SPS spotlight monthly digest December 2023

MEDICATION SAFETY

All Wales Therapeutics and Toxicology Centre

- Withdrawal of national desflurane contract in Wales - link

British National Formulary

- BNF/BNFC Newsletter: December 2023
- -- includes: MHRA advice on reports of myasthenia gravis with statins, updated guidance for prevention of secondary cases of diphtheria, and updated safety information to highlight difference between benzylpenicillin sodium and benzathine benzylpenicillin

electronic Medicines Compendium (eMC) (UK)

- Revised SPCs
- -- Avelox (moxifloxacin) possible risk of prolonged, disabling & potentially irreversible serious ADRs highlighted SPS commentary
- -- Azacitidine Seacross cutaneous vasculitis added as undesirable ADR (unknown frequency)
- -- Beovu (brolucizumab) dosing for wet age-related macular degeneration and the treatment timelines for the diabetic macular oedema indication updated
- Brintellix (vortioxetine hydrobromide) dyspepsia, akathisia, bruxism, trismus, restless leg syndrome, tremor, discontinuation syndrome, vision blurred, and galactorrhoea included as ADRs
- -- Brukinsa (zanubrutinib) updated information on interactions between zanubrutinib and moderate (fluconazole and diltiazem) and strong (voriconazole and clarithromycin) CYP3A inhibitors, which resulted in increased zanubrutinib exposures

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- -- Ciproxin (ciprofloxacin) possible risk of prolonged, disabling and potentially irreversible serious ADRs highlighted <u>SPS commentary</u>
- -- EpiPen Adrenaline (epinephrine) additional side effects under cardiac, respiratory & administration site disorders and to state "adrenaline excreted in breast milk would not have effect on nursing infant"
- -- Erythromycin ethyl succinate contraindication with lomitapide due to markedly increased transaminase levels with concomitant use, a warning to use with caution with corticosteroids and information on risk of congenital malformations after use during pregnancy SPS commentary
- -- Enbrel (etanercept) glomerulonephritis is now listed as a potential ADR (frequency unknown)
- -- Femoston-conti estradiol hemihydrate/dydrogesterone) contraceptives containing oestrogens shown to significantly decrease plasma concentrations of lamotrigine, potentially lowering seizure control, and although interaction between HRT & lamotrigine not been studied, it is expected that similar interaction exists
- -- Furosemide lichenoid reactions as a rare ADR
- -- Kalydeco concomitant use of CYP3A inhibitors updated to advise dose reduction is based on dose recommended for the age and weight and to refer to Table 2 for the recommended dose
- -- Mayzent (siponimod fumaric acid) information added on squamous cell carcinoma, herpes viral infection, cryptococcal meningitis and monitoring of treatment effect on lymphocytes
- -- Moxifloxacin risk of disabling and potentially long-lasting or irreversible ADRs, sometimes affecting multiple systems, with fluoroquinolone antibiotics use only when other antibiotics are inappropriate SPS commentary
- -- Nivestim (filgrastim) in post-marketing setting, myelodysplastic syndrome and acute myeloid leukaemia have been associated with the use of pegfilgrastim, an alternative G-CSF medicine, in conjunction with chemotherapy and/or radiotherapy in breast and lung cancer patients
- -- Octasa (mesalazine) eosinophilia and systemic symptoms (DRESS) as an ADR and to note mesalazine may produce red-brown discolouration after contact with sodium hypochlorite bleach
- -- Protium (pantoprazole) severe cutaneous ADRs, reports of false-positive results in some urine screening tests for tetrahydrocannabinol, and updated information on undesirable effects
- -- Rozlytrek (entrectinib) use in patients with congestive heart failure (CHF) updated to note CHF reported in less than 5% of patients with/without a history of cardiac disease in clinical trials with entrectinib. Reactions resolved in 70% of those patients after appropriate management
- -- Suboxone Tablets (naloxone/buprenorphine) recommended starting dose in adults and adolescents >15 years is 4 mg/1 mg and can be repeated up to a maximum dose of 12 mg/3 mg on day 1 to minimise undue withdrawal symptoms and retain the patient in treatment
- -- Targinact (oxycodone/naloxone) more added on treatment goals and discontinuation. Central sleep apnoea syndrome (unknown frequency) and drug dependence (rare) added as ADRs, and toxic leukoencephalopathy after an oxycodone overdose <u>SPS commentary</u>
- -- Tecfidera (dimethyl fumarate) Tecfidera pregnancy registry study results included, in which 289 prospectively collected pregnancy outcomes were documented in patients with MS who were exposed to dimethyl fumarate
- -- Tezspire (tezepelumab) anaphylactic reaction a possible ADR (unknown frequency)
- -- Tixylix Cough Syrup pharmacodynamic properties now mentions that glycerol has demulcent properties and may possibly block sensory cough receptors in the respiratory tract
- -- Zamadol (tramadol hydrochloride) risk of dependence and addiction with opioids SPS commentary
- Risk minimisation materials
- -- Casgevy (exagamglogene autotemcel): Patient Alert Card for patients to carry with them at all times, & notifies healthcare professionals the patient has received this treatment. Patients are at increased risk of bleeding due to possibility of a prolonged period of thrombocytopenia prior to platelet engraftment
- -- <u>Tresiba</u>® (insulin degludec) safety information for healthcare professionals regarding two product strengths, 100units/mL & 200units/mL, and potential risk of dosing error. Both pens have dose display set in the dial in UNITS so no dose conversion is required if transferring patients between strengths <u>SPS commentary</u> and <u>poster</u> <u>SPS commentary</u>

EMA

An initiative of NSW clinical pharmacologists & pharmacists

- First version of the European Union (EU) list of critical medicines agreed to help avoid potential shortages in the EU $\underline{\text{link}}$ $\underline{\text{SPS commentary}}$
- PRAC meeting <u>highlights</u>: New safety information for healthcare professionals: new precautionary measures for valproate-containing medicines; Start of safety review of CAR T-cell medicines
- Potential risk of neurodevelopmental disorders in children born to men treated with valproate medicines: PRAC recommends precautionary measures <u>link</u>

Food and Drug Administration (FDA) USA

- Update on FDA's ongoing evaluation of reports of suicidal thoughts or actions in patients taking a certain type of medicines approved for type 2 diabetes and obesity link
- Updates to labelling for promethazine hydrochloride injection products link
- Updates to labelling for Two Cholesterol-Lowering Agents link

Institute for Safe Medication Practices (ISMP) USA

- Medication Safety Alert! January 11, 2024
- -- High-Alert Medication List for acute care settings updated for 2024 link
- Medication Safety Alert! December 14, 2023
- -- ISMP 26th Annual Cheers Awards: Hitting the Safety High Notes link

MedEffect, Canada

- Health Product InfoWatch, December 2023

Medicines and Healthcare products Regulatory Agency (MHRA) UK

- MHRA update on new study on risk in children born to men taking valproate link
- Drug Safety Update December 2023
- -- Aripiprazole (Abilify and generic brands): risk of pathological gambling link
- -- Vitamin B12 (hydroxocobalamin, cyanocobalamin): advise patients with known cobalt allergy to be vigilant for sensitivity reactions <u>link</u> <u>SPS commentary</u>

Medsafe (New Zealand Medicines and Medical Devices Safety Authority)

- Prescriber Update <u>December 2023</u> includes
- -- Spotlight on dulaglutide link
- -- Discuss possible effects on uterine bleeding in people taking oral anticoagulant therapy link
- DPP-4 inhibitors and the possible risk of ileus link
- Sodium valproate (Epilim) use in people who can father children: important new safety information

MIMS monthly updates - <u>January 2024</u>

- New Contraindications
- -- Romosozumab (Evenity) in patients with a history of myocardial infarction or stroke
- -- Trimethoprim and sulfamethoxazole (<u>Septrin</u> Sugar Free Oral Liquid) in patients with documented megaloblastic anaemia due to folate deficiency, evidence of marked parenchymal damage or blood dyscrasia; in pregnancy (any stage) and in nursing mothers

Specialist Pharmacy Services NHS UK

- Using vitamin D during breastfeeding link
- Managing interactions with methotrexate link
- Using metronidazole during breastfeeding link
- Medication safety update: December 2023
- Managing interactions with direct oral anticoagulants (DOACs) link SPS commentary
- Understanding direct oral anticoagulant (DOAC) interactions link SPS commentary

TGA

- Shortages: <u>Vyvanse</u> (lisdexamfetamine dimesilate) capsules and <u>update</u>, <u>Bicillin L-A</u> (benzathine benzylpenicillin tetrahydrate) prefilled syringe for injection, Substitution approved for <u>fluoxetine 20 mg</u> <u>dispersible</u> tablets (Zactin Tabs)

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Product Information safety updates December 2023
- Romosozumab (Evenity) new warnings about the risk of heart attack and stroke link
- Compounding safety information: semaglutide-like products link
- Products containing undeclared sildenafil: <u>BAIWEI Maximum Powerful</u> tablets, <u>Bigger Longer More Time More Sperms</u> capsules, <u>Ying Da Wang</u> tablets blood pressure may be lowered to dangerous levels
- Product containing undeclared sibutramine: <u>Li Da Daidaihua</u> capsules increased risk of cardiac events and stroke
- Safety alert and product recalls: updated advice following Ralstonia pickettii contamination of some saline products <u>link</u>

UK Health Security Agency

- Vaccine update: issue 344, November 2023, pregnancy special - link

PAPERS OF INTEREST

Annals of Emergency Medicine

- Tranexamic acid for traumatic injury in the emergency setting: A systematic review and biasadjusted meta-analysis of randomized controlled trials - <u>link</u>

Annals of Internal Medicine

- Cumulative Incidence of Thiazide-Induced Hyponatremia: A Population-Based Cohort Study - <u>link</u> – SPS commentary

Arthritis & Rheumatology

- Poly-refractory Rheumatoid Arthritis: An Uncommon Subset of Difficult to Treat Disease with Distinct Inflammatory and Non-inflammatory Phenotypes <u>link</u>
- The incidence of uveitis in patients with axial spondylarthritis treated with biologics or targeted synthetics: a systematic review and network meta-analysis <u>link</u>

Australian Prescriber

- Physical health monitoring for people with schizophrenia link
- Editorial: National Medicines Policy 2.0—what's changed and what's next? link
- Gabapentinoids: a therapeutic review link
- Ongoing challenges of off-label prescribing link
- Top 10 drugs <u>2021–22</u>; Top 10 drugs <u>2022–23</u>
- Herpes zoster (shingles) vaccination update link
- New drugs: <u>Pneumococcal 15-valent and 20-valent conjugate vaccines</u> for prevention of pneumococcal disease; <u>Tirzepatide</u> for type 2 diabetes; <u>Vericiguat</u> for chronic heart failure

BMC Med

- Development of prescribing indicators related to opioid-related harm in patients with chronic pain in primary care- a modified e-Delphi study - link

British Journal of Clinical Pharmacology

- Pharmacokinetics of ceftazidime-avibactam in a critically ill patient under high-volume continuous venovenous haemodiafiltration: A first paediatric case report link
- Plasma 6β -hydroxycortisol to cortisol ratio as a less invasive cytochrome P450 3A phenotyping method link
- The correlation between 4 adherence measurements methods in patients with rheumatoid arthritis using methotrexate link
- Enteral Administration of Crushed Rilpivirine in a Patient with HIV: A Case Report link
- Effect of changes in metabolic enzymes and transporters on drug metabolism in the context of liver disease: impact on pharmacokinetics and drug-drug interactions link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

British Journal of Psychiatry

- Features of immunometabolic depression as predictors of antidepressant treatment outcomes: pooled analysis of four clinical trials - link

British Medical Journal (BMJ)

- Europe suspends hundreds of generic drugs over serious data concerns link
- Advances in the management of pancreatic cancer link
- Management of chronic pain secondary to temporomandibular disorders: a systematic review and network meta-analysis of randomised trials <u>link</u> <u>SPS commentary</u>

BMJ Open

- Clinical impacts of an integrated electronic health record-based smoking cessation intervention during hospitalisation link
- Adverse drug events associated with nortriptyline compared with paroxetine and alternative medications in an older adult population: a retrospective cohort study in Southern California link

BMJ Quality & Safety

- Initial opioid prescription characteristics and risk of opioid misuse, poisoning and dependence: retrospective cohort study - link

Circulation

- Dapagliflozin and Apparent Treatment-Resistant Hypertension in Heart Failure with Mildly Reduced or Preserved Ejection Fraction: The DELIVER Trial link
- Current Status and Principles for the Treatment and Prevention of Diabetic Foot Ulcers in the Cardiovascular Patient Population: A Scientific Statement From the American Heart Association Link
- Flecainide is associated with a lower incidence of arrhythmic events in a large cohort of patients with catecholaminergic polymorphic ventricular tachycardia <u>link</u>

Circ Heart Fail

- Effect of Dapagliflozin Versus Placebo on Symptoms and 6-Minute Walk Distance in Patients with Heart Failure: The DETERMINE Randomized Clinical Trials - link

Cochrane

- Pharmacological interventions for the prevention of bleeding in people undergoing elective hip or knee surgery: a systematic review and network meta-analysis link
- Anticoagulation for people receiving long-term haemodialysis link
- Vitamin B12 supplementation during pregnancy for maternal and child health outcomes link
- Ibuprofen for acute postoperative pain in children link
- Population-based interventions for preventing falls and fall-related injuries in older people link
- Immunomodulators and immunosuppressants for relapsing-remitting multiple sclerosis: a network meta-analysis link
- Maintenance therapy for chronic lymphocytic leukaemia link
- Pharmacological interventions for pruritus in adult palliative care patients link
- Diclofenac for acute postoperative pain in children link
- Lamotrigine add-on therapy for drug-resistant focal epilepsy link
- Anticholinergic deprescribing interventions for reducing risk of cognitive decline or dementia in older adults with and without prior cognitive impairment link
- Corticosteroids for preventing postherpetic neuralgia link

Diabetes Care

- Diabetes Care Standards of Care in Diabetes 2024 link SPS commentary
- Fetal Overgrowth and Preterm Delivery in Women With Type 1 Diabetes Using Insulin Pumps or Multiple Daily Injections: A Post Hoc Analysis of the EVOLVE Study Cohort <u>link</u>
- Outcomes With Finerenone in Patients With Chronic Kidney Disease and Type 2 Diabetes by Baseline Insulin Resistance link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au
An initiative of NSW clinical pharmacologists & pharmacists

Diabetes, Obesity and Metabolism

- Glucagon-like peptide-1 receptor agonists and risk of thyroid cancer: A systematic review and metaanalysis of randomised controlled trials - <u>link</u>
- Efficacy and safety of semaglutide 2.4 mg for weight loss in overweight or obese adults without diabetes: An updated systematic review and meta-analysis including the 2-year STEP 5 trial <u>link</u>
- Effect of sodium-glucose cotransporter-2 inhibitors on myocardial infarction incidence: A systematic review and meta-analysis of randomized controlled trials and cohort studies Link

European Heart Journal

- Oral anticoagulation after atrial fibrillation catheter ablation: benefits and risks link
- Oral strategies to target proprotein convertase subtilisin/kexin type 9 and lipoprotein(a): the new frontier of lipid lowering <u>link</u>

European Journal of Hospital Pharmacy

- Physicochemical and biological stability of diluted vedolizumab in intravenous infusion bags link
- Therapeutic drug monitoring of vancomycin in the case of augmented renal clearance: a case report of a paediatric patient <a href="https://link.google.com
- No effects of nirmatrelvir/ritonavir on darunavir plasma trough concentrations: a case report link
- Switching anti-CGRP monoclonal antibodies in chronic migraine: real-world observations of erenumab, fremanezumab and galcanezumab link
- Inhaled aztreonam lysine in the management of Pseudomonas aeruginosa in patients with cystic fibrosis: real-life effectiveness link
- Evaluation of the stability of aciclovir in elastomeric infusion devices used for outpatient parenteral antimicrobial therapy <u>link</u>

Heart

- Cardiovascular sequelae of trastuzumab and anthracycline in long-term survivors of breast cancer link – SPS commentary
- Diagnosis and management of resistant hypertension link

Internal Medicine Journal

- Transitioning patients from intravenous to subcutaneous infliximab and vedolizumab for inflammatory bowel disease: what is the opportunity cost of improving access to healthcare? - link

International Journal of Clinical Pharmacy

- The prevalence of hepatic and thyroid toxicity associated with imatinib treatment of chronic myeloid leukaemia: a systematic review Iink
- Assessing safety concerns of interstitial lung disease associated with antibody-drug conjugates: a real-world pharmacovigilance evaluation of the FDA adverse event reporting system link
- Valproic acid for agitation in the intensive care unit: an observational study of psychiatric consults link

JAMA

- Metformin Plus Insulin for Preexisting Diabetes or Gestational Diabetes in Early Pregnancy: The MOMPOD Randomized Clinical Trial $\frac{\text{link}}{\text{PS}}$ commentary
- Dementia in Women Using Estrogen-Only Therapy link

JAMA Cardiology

- Dual Antiplatelet Therapy De-Escalation in Stabilized Myocardial Infarction With High Ischemic Risk: Post Hoc Analysis of the TALOS-AMI Randomized Clinical Trial <u>link</u>
- Optimization of Evidence-Based Heart Failure Medications After an Acute Heart Failure Admission: A Secondary Analysis of the STRONG-HF Randomized Clinical Trial Link SPS commentary

JAMA Dermatology

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

- Risk of Paradoxical Eczema in Patients Receiving Biologics for Psoriasis - link

JAMA Internal Medicine

- Safety of GLP-1 Receptor Agonists and Other Second-Line Antidiabetics in Early Pregnancy - link

JAMA Network Open

- Mortality and Morbidity Among Individuals with Hypertension Receiving a Diuretic, ACE Inhibitor, or Calcium Channel Blocker - link

JAMA Neurology

- Brexpiprazole for the Treatment of Agitation in Alzheimer Dementia: A Randomized Clinical Trial – link – SPS commentary

JAMA Oncology

- Research letter: GLP-1 Receptor Agonists and Colorectal Cancer Risk in Drug-Naive Patients With Type 2 Diabetes, With and Without Overweight/Obesity - link

JAMA Psychiatry

- Pharmacologic Treatment of Schizophrenia Beyond Dopamine Receptor Blockade—Has Its Time Come Yet? link
- Benzodiazepine Use During Pregnancy and Risk of Miscarriage link

Journal of the American College of Cardiology

- Safety and Tolerability of Inclisiran for Treatment of Hypercholesterolemia in 7 Clinical Trials - link

Journal of Pharmacy Practice and Research (JPPR)

- Editorial: The challenge of drug prescribing for older people link
- Multidisciplinary care of older adults in the emergency department to influence deprescribing in older adults: a cohort study link
- Vitamin B12 deficiency in older people: a practical approach to recognition and management link

Lancet Haematology

- Indication and management of allogeneic haematopoietic stem-cell transplantation in myelofibrosis: updated recommendations by the EBMT/ELN International Working Group - link

Lancet Infectious Diseases

- Guidelines for the management of Toxoplasma gondii infection and disease in patients with haematological malignancies and after haematopoietic stem-cell transplantation: guidelines from the 9th European Conference on Infections in Leukaemia, 2022 - link

Lancet Neurology

- Corticosteroids versus clobazam for treatment of children with epileptic encephalopathy with spikewave activation in sleep (RESCUE ESES): a multicentre randomised controlled trial - <u>link</u>
- Blood-brain barrier dysfunction in multiple sclerosis: causes, consequences, and potential effects of therapies link
- Neurological adverse events of immune checkpoint inhibitors and the development of paraneoplastic neurological syndromes <u>link</u>

Lancet Psychiatry

- Psychopharmacology in children and adolescents: unmet needs and opportunities link
- Clozapine: past, present, and future link

Lancet Oncology

- Effect of baseline oestradiol serum concentration on the efficacy of anastrozole for preventing breast cancer in postmenopausal women at high risk: a case-control study of the IBIS-II prevention trial - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

Medical Journal of Australia

- Chronic suppurative lung disease and bronchiectasis in children, adolescents and adults in Australia and New Zealand: TSANZ position statement summary <u>link</u>
- Considerations of delayed gastric emptying with peri-operative use of glucagon-like peptide-1 receptor agonists link
- Cough in Children and Adults: Diagnosis, Assessment and Management (CICADA). Summary of an updated position statement on chronic cough in Australia link

New England Journal of Medicine

- Mirvetuximab Soravtansine in FRα-Positive, Platinum-Resistant Ovarian Cancer link
- Chronic Lymphocytic Leukemia Therapy Guided by Measurable Residual Disease <u>link</u> <u>SPS</u> commentary
- Daratumumab, Bortezomib, Lenalidomide, and Dexamethasone (D-VRd) for Multiple Myeloma link
- Efficacy and Safety of an mRNA-Based RSV PreF Vaccine in Older Adults link SPS commentary
- Cannabis-Related Disorders and Toxic Effects link

Pediatrics

- Vaccine Effectiveness Against Long COVID in Children link
- Case report: Neonatal Opioid Withdrawal Syndrome Following Prenatal Use of Supplements Containing Tianeptine <a href="https://link.org
- Advances in the Care of Infants With Prenatal Opioid Exposure and Neonatal Opioid Withdrawal Syndrome Iink

Pharmaceutical Journal

- Coroner advises NHS England to take action to raise awareness about interaction between tramadol and warfarin following death of a patient <a href="https://link.org/link.
- Pharmaceutical journal develops new series of articles mapped to Royal Pharmaceutical Society's 'competency framework for all prescribers' <u>link</u>

Pharmacotherapy

- Multicenter study evaluating target attainment of anti-Factor Xa levels using various enoxaparin prophylactic dosing practices in adult trauma patients <a href="https://link.google.com/l
- Real world study on elexacaftor-tezacaftor-ivacaftor impact on cholesterol levels in adults with cystic fibrosis link
- Is reversal of anticoagulants necessary in neurologically intact traumatic intracranial hemorrhage? link
- Identification of risk factors associated with acute kidney injury in patients taking sodium-glucose cotransporter-2 inhibitors link
- Clinical outcomes associated with anti-Xa-monitored enoxaparin for venous thromboembolism prophylaxis link

Prescrire International - <u>January 2024</u> includes

- Editorial "<u>Safety signals: why bother</u>?"; Abemaciclib (Verzenios°), palbociclib (Ibrance°) & ribociclib (Kisqali°) added to an aromatase inhibitor in certain breast cancers; When the cause of a disorder is not immediately obvious: could a drug be responsible?; Prescribing cascades: recognise them and take corrective action; Defending the right to compensation for the victims of drug-induced harms

Stroke

- Management of Poststroke Hyperglycemia: Results of the TEXAIS Randomized Clinical Trial - link

Thorax

- Influence of age on clinical characteristics, pharmacological management and exacerbations in children with asthma - link

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists

WEBINARS & PODCASTS

Australian Prescriber Podcasts

- Episode 153 Blood glucose monitoring devices
- Episode 154 An update on wound management
 Episode 155 Digital health and prescribing

MJA Podcasts

- The importance of medical record management - link

Purple Pen Podcast

- PPP156 - Cholesterol Update - link

UPCOMING EVENTS

AHHA

- A Discussion of the National Health Reform Agreement, member-only virtual roundtable, Tuesday 20th February 12pm to 1:30pm AEDT - link

FIP

- Advancing future pharmacy and pharmaceutical sciences: Launch of the FIP AIM academic capacity assessment tool, webinar, 24 January 2024, 14:00 - 15:30 CET - register
- Climate change and vector-borne neglected tropical diseases: Positioning pharmacy practice to drive awareness, prevention and management, webinar, 30 January 2024, 15:00 - 16:30 CET register
- Optimising cancer care: community pharmacy strategies to support patients on oral treatment, webinar, 1 February 2024, 15:00 - 16:30 CET - register

Advancing quality use of medicines in NSW public hospitals and the wider community since 1988 Ph: 0407418 072 | Email: nswtag@stvincents.com.au | www.nswtag.org.au

An initiative of NSW clinical pharmacologists & pharmacists