Please click this [link](#) for the cumulative listing of COVID-19 resources in past TAG Mails.

**AUSTRALIAN**

**AHPRA Pharmacy Board**
- Joint statement: Registered health practitioners and students: What you need to know about the COVID-19 vaccine rollout - [link](#)

**Australian Government Department of Health**
- ATAGI Advice on the relative timing of administering influenza & COVID-19 vaccines in 2021 [V2](#)
- COVID-19 Australia: Epidemiology Report 36: Reporting period ending 28 February 2021 - [link](#)
- Webinar: COVID-19 vaccine update for vaccination providers – 17/3/2021 - [link](#)

**National COVID-19 Clinical Evidence Taskforce**
- Guidelines Update [11 March 2021](#)

**NSW Health**
- Information on COVID-19 Vaccine AstraZeneca (ChAdOx1-S) in NSW (updated 12/3/21) - [link](#)
- Management of COVID-19 vaccine: [AstraZeneca (ChAdOx1-S)](#) from refrigerator to administration (updated 12/3/21);
- [Pfizer (COMIRNATY™)](#) from refrigerator to administration (updated 12/3/21)

**NSW Health Critical Intelligence Unit**
- 10 March 2021 - Risk Monitoring Dashboard - [link](#)
- Living Evidence:
  -- COVID-19 vaccines – last updated 16 Mar 2021 - [link](#)
  -- SARS-CoV-2 variants – last updated 12 Mar 2021 - [link](#)
  -- COVID-19 transmission – last updated 16 Mar 2021 - [link](#)
- Evidence Check: Evidence on AstraZeneca vaccine rollout - [link](#)

**TGA**
- Approval of updated storage conditions for the Pfizer COVID-19 vaccine - [link](#)
- AstraZeneca ChAdOx1-S COVID-19 vaccine – 16/03/21 response to overseas precautionary measures - [link](#); 17/03/21 Reports of anaphylaxis (severe allergic reaction) - [link](#)
- COVID-19 vaccines - safety and effectiveness in older adults - [link](#)

**INTERNATIONAL**

**International Society on Thrombosis and Haemostasis**
- ISTH statement on AstraZeneca Covid-19 vaccine and thrombosis - [link](#)

**WHO**
- Methods for the detection and identification of SARS-CoV-2 variants, March 2021 - [link](#)
- COVID-19 strategic preparedness and response plan: 1 February 2021 to 31 January 2022 - [link](#); Operational Planning guideline - [link](#)
Europe
EMA
- Investigation of COVID-19 Vaccine AstraZeneca and thromboembolic events continues - link
- EMA starts rolling review of bamlanivimab and etesevimab for COVID-19 - link
- Highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 8-11 Mar 2021 include safety signal of anaphylaxis with COVID-19 Vaccine AstraZeneca, signal of low levels of blood platelets with COVID-19 vaccines, and signal of localised swelling related to dermal fillers with Comirnaty - link

UK
- King’s College London
  -- Delaying second vaccine dose leaves cancer patients vulnerable to virus; Preliminary data from SOAP trial suggests low response to first dose of Pfizer-BioNTech Covid-19 vaccine in patients with cancer - link
- MHRA
  -- MHRA response to the precautionary suspensions of COVID-19 Vaccine AstraZeneca - link
  -- MHRA response to Danish, Norwegian and Icelandic authorities’ action to temporarily suspend the AstraZeneca COVID-19 vaccine - link
  -- Coronavirus (COVID-19) vaccine adverse reactions – last updated 11 March 2021 - link
  -- COVID-19 Therapeutic Alert from the Chief Medical Officer 17th March 2021: now recommended that convalescent plasma is NOT used in the management of hospitalised patients with confirmed or suspected SARS-CoV-2 infection
- Public Health England
  -- Investigation and management of suspected SARS-CoV-2 reinfections: a guide for clinicians and infection specialists - link
- Scottish Intercollegiate Guideline Network
  -- Managing the long-term effects of COVID-19 SIGN161 with patient booklet

USA
- Centers for Disease Control and Prevention (CDC)
  -- Building Confidence in COVID-19 Vaccines - link
- FDA
  -- Emergency Use Authorization (EUA) for Propofol-Lipuro 1% to maintain sedation via continuous infusion in patients >16 years old who require mechanical ventilation in an ICU setting during the COVID-19 public health emergency – link
  -- The FDA has posted translations of the Janssen COVID-19 Vaccine fact sheet for recipients and caregivers in languages including: Burmese, Chinese, French, Hindi and Russian – link
  -- The Joint Commission
  -- COVID-19 Q&A Webinar for Behavioral Health Care link, slides link

JOURNAL ARTICLES
Ann Intern Med
- What Is the Antibody Response and Role in Conferring Natural Immunity After SARS-CoV-2 Infection? Rapid, Living Practice Points from the American College of Physicians (Version 1) - link with summary for patients
- Antibody Response after SARS-CoV-2 Infection and Implications for Immunity. A Rapid Living Review - link

Anaesthesia
- Timing of surgery following SARS-CoV-2 infection: an international prospective cohort study - link

BMJ
- Update to living systematic review on covid-19 in pregnancy - link
- Webinar: Is Zero Covid possible? - link
- Clinical Review: Severe covid-19 pneumonia: pathogenesis and clinical management - link
- Practice: What is my covid risk? (Supporting patients’ assessment of risk to COVID-19) - link

BMJ Archives of Disease in Childhood
- Short Report: Bronchiolitis and SARS-CoV-2 - link
Bulletin of the World Health Organization
- Infection fatality rate of COVID-19 inferred from seroprevalence data - link

Clinical Infectious Diseases
- Impact of the COVID-19 Vaccine on Asymptomatic Infection among Patients Undergoing Pre-Procedural COVID-19 Molecular Screening - link

Cochrane
- COVID-19 and its cardiovascular effects: a systematic review of prevalence studies - link

Frontiers in Public Health
- How Australian Health Care Services Adapted to Telehealth during the COVID-19 Pandemic: A Survey of Telehealth Professionals - link

Lancet
- Patients with gout: an under-recognised group at high risk of COVID-19 - link
Lancet Gastroenterology and Hepatology
- Gastrointestinal sequelae 90 days after discharge for COVID-19 - link

JAMA
- Viewpoint: Incentivizing Vaccination Uptake. The “Green Pass” Proposal in Israel - link
- Assessment of Acute Kidney Injury and Longitudinal Kidney Function after Hospital Discharge among Patients With and Without COVID-19 - link
- Immunogenicity of the Ad26.COV2.S Vaccine for COVID-19 - link
- Viewpoint: CDC Interim Recommendations for Fully Vaccinated People. An Important First Step - link

JAMIA
- Utilizing health information technology in the treatment and management of patients during the COVID-19 pandemic: lessons from international case study sites – link

Journal of Crohn’s and Colitis
- SARS-CoV-2 vaccination in IBD: past lessons, current evidence and future challenges - link

Journal of General Internal Medicine
- Severity Scores in COVID-19 Pneumonia: a Multicenter, Retrospective, Cohort Study - link

Journal of Geriatric Oncology
- Letter: The SIOG COVID-19 working group recommendations on the rollout of COVID-19 vaccines among older adults with cancer - link

Journal of Investigative Medicine
- Effect of bromhexine in hospitalized patients with COVID-19 - link

Journal of Medical Internet Research
- Virtual Health Care for Community Management of Patients with COVID-19 in Australia: Observational Cohort Study - link

Lancet
- Commentary: Correcting COVID-19 vaccine misinformation - link

Nature
- Sensitivity of SARS-CoV-2 B.1.1.7 to mRNA vaccine-elicited antibodies - link
- Comparison of clinical characteristics and disease outcome of COVID-19 and seasonal influenza - link
- Increased mortality in community-tested cases of SARS-CoV-2 lineage B.1.1.7 - link
- Genetic mechanisms of critical illness in COVID-19 - link
Nature Reviews Immunology
- Perspective: The first 12 months of COVID-19: a timeline of immunological insights - link

Nature Reviews Gastroenterology & Hepatology
- COVID-19 and liver disease: mechanistic and clinical perspectives - link

NEJM
- Efficacy of the ChAdOx1 nCoV-19 Covid-19 Vaccine against the B.1.351 Variant - link
- A Neutralizing Monoclonal Antibody for Hospitalized Patients with Covid-19 - link

PLOS One
- Interventions for treatment of COVID-19: Second edition of a living systematic review with meta-analyses and trial sequential analyses (The LIVING Project) - link

Public Health Research and Practice
- Communicating COVID-19 health information to culturally and linguistically diverse communities: insights from a participatory research collaboration - link
- Perspectives: The vital role of meaningful community engagement in responding to the COVID-19 pandemic - link

Science
- Perspective: Immunity to SARS-CoV-2 variants of concern - link

Scientific Reports
- Comparison of clinical severity and epidemiological spectrum between coronavirus disease 2019 and influenza in children - link

REPORTS AND PUBLICATIONS – AUSTRALIA

Australian Commission on Safety and Quality in Health Care (ACSQHC)
- Staphylococcus aureus bloodstream infection data analysis information sheet - link
- Multi-Purpose Services Aged Care Module - link
- NSQHS Standards Checklist for assessors - link

Australian Government Department of Health
- National Standard Operating Procedures for Clinical Trials - link
- National Principles for Teletrials in Australia - link
- Advanced Nursing Practice - Guidelines for the Australian Context (updated 12/3/21) - link

Australian Institute for Health and Welfare (AIHW)
- GEN: Annual Report 2019-2020: Residential Aged Care Quality Indicators - link

NSW Health
- Admitted Patient Election Processes for NSW Public Hospitals - link

PSA
- Medicine safety: rural and remote care - link

Safer Care Victoria
- Syringe driver compatibility: Guidance document - link
- Opioid conversion ratios: Guidance document - link

TGA
- Advice for health procurement teams about therapeutic goods and medical devices - link
- AusPARs:
  --Nintedanib (as esilate) (Ofev/Vargatef®) indication extended to treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.
- Australian prescription medicine decision summaries:
-- **Esketamine hydrochloride** (Spravato) for the treatment of treatment resistant depression
-- **Cabotegravir** (as sodium) (Vocabria) in combination with rilpivirine tablets for the short-term treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) and have no known or suspected resistance to either cabotegravir or rilpivirine
-- **ChAdOx1-S** (Provisional Australian Biological Name) (COVID-19 Vaccine AstraZeneca)
- Registration of new or extended uses of registered medicine February 2021:
  -- avelumab (Bavencio), cabotegravir; rilpivirine (Cabenuva), nivolumab (Opdivo), perampanel hemisesquihydrate (Fycompa), baricitinib (Olumiant), brigatinib (Alunbrig)

### REPORTS AND PUBLICATIONS – INTERNATIONAL

**Canadian Agency for Drugs and Technologies in Health**
- Interventions to influence the use of antibiotics for acute upper respiratory tract infections - [link](#)
- Basal Insulin Formulations for the Management of Type 2 Diabetes - [link](#)
- Onabotulinum Toxin A for Spasticity Associated with Multiple Sclerosis - [link](#)

**electronic Medicines Compendium (eMC) (UK)**
- New products
  -- Belkyra (deoxycholic acid) for moderate to severe convexity or fullness associated with submental fat (double chin) in adults when the presence has an important psychological impact for the patient.
  -- Retsevmo (selpercatinib) for advanced RET fusion-+ve non-small cell lung cancer and advanced RET fusion-+ve thyroid cancer in adults following prior treatments, and advanced RET-mutant medullary thyroid cancer in patients from 12 years of age following prior treatments.
  -- Palforzia (Peanut (Arachis hypogaea) Allergen Powder-dnfp) indicated for patients aged 4 to 17 years with a confirmed diagnosis of peanut allergy, in conjunction with a peanut-avoidant diet. It may be continued in patients 18 years of age and older.

**Food and Drug Administration (FDA) USA**
- New Drug approvals
  -- tivozanib (Fotivda) for renal cell carcinoma
  -- axicabtagene ciloleucel (Yescarta) CAR T-cell therapy for follicular lymphoma
  -- lorlatinib (Lorbrena) expanded approval as first-line treatment of ALK-positive non-small cell lung cancer
  -- Pepaxto (melphalan flufenamide) new alkylating agent for relapsed/refractory multiple myeloma

**NHS England**
- Clinical commissioning policy statement: Use of adalimumab for refractory chronic non-bacterial osteomyelitis/ostitis (CNO) (all ages) - [link](#)

**National Institute for Health and Clinical Excellence (NICE) UK**
- Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease [TA684]
- Erenumab for preventing migraine [TA682]
- Pembrolizumab with pemetrexed and platinum chemotherapy for untreated, metastatic, non-squamous non-small-cell lung cancer [TA683]

### MEDICATION SAFETY

**electronic Medicines Compendium (eMC) (UK)**
- Revised SPCs
  -- Nytol (diphenhydramine) - hypoesthesia and restless leg syndrome added as potential adverse effects.
  -- Clarelux (clobetasol propionate) cutaneous foam - prolonged use may result in serious undesirable effects; if treatment with local corticosteroid (CS) is clinically justified beyond 2weeks, a less potent CS should be considered. Repeated but short courses may be used to control exacerbations.
  -- Elvanse (lisexamfetamine dimesylate) - syncope added as an uncommon adverse effect.
-- Omnitrope (somatropin) SurePal - although rare, pancreatitis should be considered in somatropin-treated patients who develop abdominal pain, especially in children. Also gynaecomastia (uncommon frequency) reported in post-marketing studies.
-- NutropinAq (somatropin) 10mg/2mL - in patients with endocrine disorders, including growth hormone deficiency, slipped epiphyses of the hip may occur more frequently than in the general population. A patient who develops a limp or complains of hip or knee pain should be evaluated.
-- Sabril (vigabatrin) – intramyelinic oedema (IME), reversible following drug discontinuation, has been reported, particularly in infants treated for infantile spasms (frequency unknown).
-- Klaricid XL Klaricid IV (clarithromycin) - potential interaction with methadone added.
-- Molipaxin (trazodone hydrochloride) risk of serotonin syndrome when co-administered with buprenorphine/opioids.
-- Venlaflex (venlafaxine) - in relation to discontinuing treatment, severe effects may include suicide/suicidal thoughts and aggression; SSRIs/SNRIs may increase the risk of postpartum haemorrhage.
-- Risk minimisation materials
-- Injector’s guide for the safe use of Belkyra (deoxycholic acid)

EMA
- highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 8-11 Mar 2021:
-- Review of thalassaemia medicine Zynteglo commenced
-- Benefits of ifosfamide solutions continue to outweigh risks
-- New safety information for healthcare professionals:
  --- tofacitinib (Xeljanz): initial clinical trial results on increased risk of major cardiovascular events & cancer.
  --- aflibercept (Eylea): recommendations to mitigate risk of intraocular pressure increase.

FDA
- approved revisions to the TRIUMEQ (abacavir/dolutegravir/lamivudine) and DOVATO (dolutegravir/lamivudine) labels - link

Medsafe (New Zealand Medicines and Medical Devices Safety Authority)
- Update to original Communication - reports of lack of efficacy with rocuronium bromide solution for injection 10mg/mL, Hameln - link

TGA
- Various medicines containing Artemisia annua and Artemisia absinthium - recalls due to unacceptable risk in pregnancy - link

PAPERS OF INTEREST

American Journal of Health-System Pharmacy (AJHP)
- Expanding nonclinical roles in specialty pharmacy: How to grow a high-performance specialty pharmacy team - link
- Turning differentiation into value: How health-system specialty pharmacies can align to an outcomes-focused mission - link
- Precision medicine: Opportunities for health-system pharmacists - link
- A framework for graduate and postgraduate specialty pharmacy training - link

Annals of Emergency Medicine
- Adverse events among emergency department patients with cardiovascular conditions: a multicenter study - link

Annals of Internal Medicine
- Weight and Metabolic Changes after Switching from Tenofovir Disoproxil Fumarate to Tenofovir Alafenamide in People Living With HIV - link with summary for patients
- Risk for Non–AIDS-Defining and AIDS-Defining Cancer of Early Versus Delayed Initiation of Antiretroviral Therapy - link

British Journal of Clinical Pharmacology
- A safety signal of somnambulism with the use of antipsychotics and lithium: a pharmacovigilance disproportionality analysis - link
- Approvals of type 2 diabetes drugs tested in cardiovascular outcome trials: a tripartite comparison - link
- Editorial: Nonmedical use of prescription drugs - link
- External evaluation of the predictive performance of seven population pharmacokinetic models for phenobarbital in neonates - link

BMJ Open
- Risk factors for new chronic opioid use after hip fracture surgery: a Danish nationwide cohort study from 2005 to 2016 using the Danish multidisciplinary hip fracture registry - link

BMJ Quality and Safety
- Effectiveness of a multifaceted intervention to improve emergency department care of low back pain: a stepped-wedge, cluster-randomised trial - link
- Smart agent system for insulin infusion protocol management: a simulation-based human factors evaluation study - link

Cochrane
- Different antibiotic treatments for group A streptococcal pharyngitis - link
- Hospital at home: home-based end-of-life care - link
- Zinc supplementation for improving pregnancy and infant outcome – link
- Interventions for preventing thrombosis in solid organ transplant recipients - link
- Topical microbicides for preventing sexually transmitted infections - link
- Biologics for chronic rhinosinusitis – link
- Enteral zinc supplementation for prevention of morbidity and mortality in preterm neonates - link

Diabetes Care
- Meta-analyses of Results from Randomized Outcome Trials Comparing Cardiovascular Effects of SGLT2is and GLP-1RAs in Asian Versus White Patients With and Without Type 2 Diabetes - link

Diabetes Research and Clinical Practice
- All-cause mortality and cardiovascular safety of basal insulin treatment in patients with type 2 diabetes mellitus: A systematic review with meta-analysis and trial sequential analysis - link

Heart
- Prasugrel versus ticagrelor in patients with myocardial infarction undergoing percutaneous coronary intervention - link
- Cardiotoxicities of novel cancer immunotherapies - link

International Journal of Clinical Pharmacy
- A multifaceted clinical decision support intervention to improve adherence to thromboprophylaxis guidelines - link

JAMA
- Effect of Marine Omega-3 Fatty Acid and Vitamin D Supplementation on Incident Atrial Fibrillation. A Randomized Clinical Trial - link

JAMA Dermatology
- Subcutaneous Fat Necrosis during Nivolumab Therapy for Metastatic Melanoma - link

JAMA Facial Plastic Surgery
- Tranexamic Acid in Craniomaxillofacial Surgery: A Meta-Analysis and Systematic Review - link

JAMA Neurology
- Progressive Multifocal Leukoencephalopathy in a Patient with Progressive Multiple Sclerosis Treated with Ocrelizumab Monotherapy - link
- Viewpoint: Administering Thrombolysis for Acute Ischemic Stroke in Patients Taking Direct Oral Anticoagulants. To Treat or How to Treat - link
- Encephalitis Induced by Immune Checkpoint Inhibitors: A Systematic Review - link
JAMA Pediatrics

JAMA Surgery
- DDIWAS: High-throughput electronic health record-based screening of drug-drug interactions - [link]

Journal of the American College of Cardiology
- 10-Year Follow-Up of Patients with Everolimus-Eluting Versus Bare-Metal Stents After ST-Segment Elevation Myocardial Infarction - [link]

J Clin Gastroenterol
- Oral Fecal Microbiota Transplant Capsules Are Safe and Effective for Recurrent Clostridioides difficile Infection: A Systematic Review and Meta-Analysis - [link]

J Gen Intern Med
- Care coordination strategies and barriers during medication safety incidents: a qualitative, cognitive task analysis - [link]

Journal of Palliative Medicine
- Evidence-Based Management of Depression in Palliative Care: A Systematic Review - [link]

Journal of Patient Safety
- The burden of opioid-related adverse drug events on hospitalized previously opioid-free surgical patients - [link]

Lancet
- New dimensions for hospital services and early detection of disease: a Review from the Lancet Commission into liver disease in the UK - [link]

Lancet Psychiatry
- Combining behavioral harm-reduction treatment and extended-release naltrexone for people experiencing homelessness and alcohol use disorder in the USA: a randomised clinical trial - [link]

Medical Journal of Australia
- Research letter: Residential medication management reviews in Australian residential aged care facilities - [link]
- Australian recommendations for the management of hepatocellular carcinoma: a consensus statement - [link]
- Editorial: The general practitioner and the pharmacist: a policy enigma? - [link]

National Institute for Health Research (NIHR)
- The effect of statins on muscle symptoms in primary care: the StatinWISE series of 200 N-of-1 RCTs - [link]

NEJM
- Review article: Extrahepatic Manifestations of Chronic HCV Infection - [link]

Public Library of Science (PLOS)
- Medicines prescribed for asthma, discontinuation and perinatal outcomes, including breastfeeding: A population cohort analysis - [link]

Res Social and Adm Pharm
- Medication errors related to computerized provider order entry systems in hospitals and how they change over time: A narrative review - [link]
## COVID-19 RESOURCES & ARTICLES OF INTEREST

Please click this [link](#) for the cumulative listing of COVID-19 resources in past TAG Mails.

### AUSTRALIAN

**Australian Commission on Safety and Quality in Health Care**
- Australian Guidelines for the Prevention and Control of Infection in Healthcare - [link](#)

**Australian Government Department of Health**
- COVID-19 vaccines hub - [link](#)

**Australian Healthcare and Hospitals Association (AHHA)**
- Deeble Institute Perspective Brief No 15: Victoria’s response to COVID-19 laboratory testing: A public pathology perspective - [link](#)

**AusVax Safety**
- COVID-19 vaccine safety surveillance - [link](#)

**NSW Health**
- COVID-19 vaccination: information for [health providers](#) in NSW webpage - [link](#)
- COVID-19 vaccination: information for [NSW healthcare workers](#) webpage - [link](#)

**NSW Health Critical Intelligence Unit**
- Evidence Check - COVID-19 pre-peer review articles - [link](#)
- Risk Monitoring Dashboard 5/3/2021 - [link](#)
- Living Evidence:
  - COVID-19 vaccines - updated 8/3/2021 - [link](#)
  - SARS-CoV-2 variants - updated 5/3/2021 - [link](#)
  - COVID-19 transmission - updated 4/3/2021 - [link](#)

**TGA**
- TGA COVID-19 vaccines hub - [link](#)
- TGA adopts Access Consortium guidance for fast-tracking authorisations of modified COVID-19 vaccines for variants - [link](#)
- COVID-19 vaccines - safety and effectiveness in older adults - [link](#)

### INTERNATIONAL

**WHO**
- Science in 5: Evolution of the SARS-CoV-2 virus - [link](#)
- The effects of virus variants on COVID-19 vaccines - [link](#)
- Monitoring COVID-19 vaccination: considerations for the collection and use of vaccination data: interim guidance, 3 March 2021 - [link](#)

**Infectious Diseases Data Observatory (IDDO)**
Medical Product Quality Reports about substandard and falsified (SF) COVID-19 medical products, which include data from scientific literature, public alerts and warnings, and lay press from across the world. Medical Product Quality Report - COVID-19 Issues. [Issue 8: January 2021](#)

**UK**
- RECOVERY trial
  -- Trial closes recruitment to colchicine treatment for patients hospitalised with COVID-19 – [link](#)
- NICE
  -- COVID-19 vaccine hesitancy – debunking the myths using a community engagement approach underpinned by NICE guidance - [link](#)

**USA**
- Centers for Disease Control and Prevention (CDC)
-- Science Brief: Background Rationale and Evidence for Public Health Recommendations for Fully Vaccinated People (updated 8/3/2021) - link
-- Conversation Guide to Improve COVID-19 Vaccine Uptake - link
-- The Joint Commission
-- Quick Safety 58: Keeping patients on track with preventative care during pandemic - link

JOurnal articles
American Journal of Health-System Pharmacy
- Pharmacy students play crucial role in COVID-19 mass vaccinations - link
- Transforming pharmacy enterprises for future success in tumultuous times - link
Annals of Internal Medicine
- Clinical and Economic Effects of Widespread Rapid Testing to Decrease SARS-CoV-2 Transmission - link
- Update Alert 5: Masks for Prevention of Respiratory Virus Infections, Including SARS-CoV-2, in Health Care and Community Settings - link
Annals of the Rheumatic Diseases
- Immunomodulatory therapies for SARS-CoV-2 infection: a systematic literature review to inform EULAR points to consider - link
Australian Prescriber
- ChAdOx1-S vaccine for prevention of COVID-19 - link
British Medical Journal
- Editorial: Vitamin D and covid-19 - link
- Risk of mortality in patients infected with SARS-CoV-2 variant of concern 202012/1: matched cohort study - link
European Journal of Nuclear Medicine and Molecular Imaging
- Oxford-AstraZeneca COVID-19 vaccination induced lymphadenopathy on [18F]Choline PET/CT—not only an FDG finding - link
International Journal of Clinical Pharmacy
- Sodium-glucose co-transporter 2 inhibitors in COVID-19: meeting at the crossroads between heart, diabetes and infectious diseases - link
JAMA
- Effect of Ivermectin on Time to Resolution of Symptoms among Adults with Mild COVID-19. A Randomized Clinical Trial - link
- Approaches for Optimal Use of Different COVID-19 Vaccines. Issues of Viral Variants and Vaccine Efficacy - link
- Viewpoint: COVID-19 in 2021—Continuing Uncertainty - link
- Letter: Acute Allergic Reactions to mRNA COVID-19 Vaccines - link
Lancet
- Azithromycin for community treatment of suspected COVID-19 in people at increased risk of an adverse clinical course in the UK (PRINCIPLE): a randomised, controlled, open-label, adaptive platform trial - link
- Letter: Long-haul COVID: heed the lessons from other infection-triggered illnesses - link
- Urgent lessons from COVID 19: why the world needs a standing, coordinated system and sustainable financing for global research and development - link
- Fluorodeoxyglucose PET/CT findings in a systemic inflammatory response syndrome after COVID-19 vaccine - link
Lancet Respiratory Medicine
- Sarilumab in patients admitted to hospital with severe or critical COVID-19: a randomised, double-blind, placebo-controlled, phase 3 trial - link
- COVID-19 and inhaled corticosteroids—another piece in an expanding puzzle - link
- IL-6 blockade for COVID-19: a global scientific call to arms - link

EClinicalMedicine
- Enoxaparin is associated with lower rates of mortality than unfractionated Heparin in hospitalized COVID-19 patients - link

Lancet Rheumatology
- Interleukin-1 and interleukin-6 inhibition in patients with COVID-19 and hyperinflammation, letter; reply

Medical Journal of Australia
- Seroprevalence of SARS-CoV-2-specific antibodies in Sydney after the first epidemic wave of 2020 - link

medRxiv
- Pre-print: Vaccine effectiveness after 1st and 2nd dose of the BNT162b2 mRNA Covid-19 Vaccine in long-term care facility residents and healthcare workers – a Danish cohort study

New England Journal of Medicine
- Baricitinib plus Remdesivir for Hospitalized Adults with Covid-19 - link
- Letter: Delayed Large Local Reactions to mRNA-1273 (Moderna) Vaccine against SARS-CoV-2 - link

PLOS ONE
- Development and validation of a prediction model for tocilizumab failure in hospitalized patients with SARS-CoV-2 infection - link

QJM
- The potential risks of delaying the second vaccine dose during the SARS-CoV-2 pandemic - link

Science
- Epidemiological and evolutionary considerations of SARS-CoV-2 vaccine dosing regimes - link

REPORTS AND PUBLICATIONS – AUSTRALIA

Australian Commission on Safety and Quality in Health Care (ACSQHC)
- Antimicrobial prescribing practice in Australian Hospitals: Results of the 2019 Hospital National Antimicrobial Prescribing Survey - link
- The Australian Group on Antimicrobial Resistance (AGAR) Sepsis Outcome Programs 2019 Report - link

Australian Institute for Health and Welfare (AIHW)
- Hospitalised injury in children and young people, 2017–18 - link

NSW Health
- Safety Notice 003/21: Breast implant associated-anaplastic large cell lymphoma (BIA-ALCL) - link

PBS
- PBAC Public Summary Documents – November 2020 meeting - link

Safer Care Victoria
- Guidance: Acute behavioural disturbance - link

TGA
- Australian prescription medicine decision summaries:
  -- Adalimumab (Abrilada) – new biosimilar medicine
-- **Onasemnogene abeparvovec** (Zolgensma) - approved to treat patients less than 9 months old with symptomatic/pre-symptomatic spinal muscular atrophy (SMA).
-- **Rituximab** (Ruxience) approved to treat non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, GPA and MPA.

### REPORTS AND PUBLICATIONS – INTERNATIONAL

**Agency for Healthcare Research and Quality (AHRQ) USA**
- Automated-Entry Patient-Generated Health Data for Chronic Conditions: The Evidence on Health Outcomes - [link](#)
- Disparities and Barriers to Pediatric Cancer Survivorship Care - [link](#)

**Canadian Agency for Drugs and Technologies in Health**
- Rapid Responses:
  -- Pharmacological Interventions for Weight Loss in Children with Overweight or Obesity - [link](#)
  -- Codeine for Pain Related to Caesarean Section: A Review of Clinical Effectiveness - [link](#)
  -- Codeine for Acute Dental Pain and Acute Pain Related to Dental Procedures - [link](#)
  -- Stellate Ganglion Block for the Treatment of Post-Traumatic Stress Disorder, Depression, and Anxiety - [link](#)

**Food and Drug Administration (FDA) USA**
- Tocilizumab Scores FDA Approval for Systemic Sclerosis–Associated Interstitial Lung Disease - [link](#)
- Adalimumab Earns FDA Approval for Ulcerative Colitis in Children - [link](#)
- New Drug approvals
  -- **Azstarys** (serdexmethylphenidate and dexmethylphenidate) – for Attention Deficit Hyperactivity

**Health Canada**
- Summary Safety Review - Cefuroxime-containing products. Reviewed potential risk of Kounis syndrome after becoming aware of cases reported in the published literature - [link](#)

**National Infusion and Vascular Access Society**
- Intravenous Administration of Medicines to Adults: Guidance on “line flushing” -Version 3 2021 - [link](#)

**National Institute for Health and Clinical Excellence (NICE) UK**
- **Alpha-Stim AID** for anxiety disorders (MTG56)
- **Atopic eczema in under 12s**: diagnosis and management (CG57)

**Royal Pharmaceutical Society**
- Online exhibition: Celebrating Women in Pharmacy - [link](#)

### MEDICATION SAFETY

**electronic Medicines Compendium (eMC) (UK)**
- Revised SPCs
  -- **Feldene** (piroxicam) Gel - eosinophilia and systemic symptoms (DRESS syndrome) included with use of systemic (and possibly topical) piroxicam
  -- Betamethasone dipropionate and calcipotriol (Enstilar) foam - deletion of warning regarding UV exposure and statement regarding photocarcinogenicity studies

**Institute for Safe Medication Practices (ISMP)**
- Medication Safety Alert! [March 11, 2021](#)
-- Analysis of Transdermal Medication Patch Errors Uncovers a “Patchwork” of Safety Challenges
-- Cisatracurium barcode is not scannable
-- SIRVA (shoulder injury related to vaccine administration) persists
-- Praxbind label information needs repositioning
-- ASPEN-ISMP error-reporting project
-- Your Reports at Work: Updated label for NovoLOG Mix 70/30 generic equivalent
Medicines and Healthcare products Regulatory Agency (MHRA) UK
- Early Access Medicines Scheme (EAMS) scientific opinion: Avalglucosidase alfa in the treatment of Pompe disease - link

Medsafe (New Zealand Medicines and Medical Devices Safety Authority)
- Prescriber Update – March 2021: some articles include:
  -- New reporting form for adverse events following immunisation with COVID-19 vaccines
  -- Spotlight on gabapentin and pregabalin for neuropathic pain
  -- Vildagliptin and ACE inhibitors – increased risk of angioedema
  -- Green breast milk – related to propofol?
  -- Administering goserelin implants

TGA
- New legislation to support medicine substitutions when the patient's usual medicine is in 'serious scarcity' - link

PAPERS OF INTEREST

American Journal of Health-System Pharmacy (AJHP)
- Development, implementation, and evaluation of a health outcomes and research program at an integrated health-system specialty pharmacy - link
- Analyzing the costs of developing and operating an integrated health-system specialty pharmacy: The case of a centralized insurance navigation process for specialty clinic patients - link
- Evaluation of a specialty hepatitis C virus telephone pharmacy service - link

Archives of Disease in Childhood
- First do no harm: practitioners’ ability to ‘diagnose’ system weaknesses and improve safety is a critical initial step in improving care quality - link

British Journal of Clinical Pharmacology
- Pregnancy outcomes following gestational exposure to papaverine: an observational comparative study - link
- Initial cardiovascular treatment patterns during the first 90 days following an incident cardiovascular event - link

British Medical Journal (BMJ)
- Aspirin to prevent pre-eclampsia - link – SPS comment
- Vitamin D supplementation and testing in the UK: costly but ineffective? - link

BMJ Open Quality
- Reaching the summit of discharge summaries: a quality improvement project - link

BMJ Quality and Safety
- Use of patient complaints to identify diagnosis-related safety concerns: a mixed-method evaluation - link

Circulation
- Opioid-Associated Out-of-Hospital Cardiac Arrest: Distinctive Clinical Features and Implications for Health Care and Public Responses: A Scientific Statement from the American Heart Association - link
- Letter: Risk of Coronary Artery Disease Conferred by Low-Density Lipoprotein Cholesterol Depends on Polygenic Background - link

Cochrane
- Interventions for cutaneous disease in systemic lupus erythematosus - link
- Timing of domase alfa inhalation for cystic fibrosis - link
- (Ultra-)long-acting insulin analogues for people with type 1 diabetes mellitus - link
- Different classes of antibiotics given to women routinely for preventing infection at caesarean section - link
- Second-generation antidepressants for treatment of seasonal affective disorder - link
- Vascular endothelial growth factor (VEGF) targeting therapy for persistent, recurrent, or metastatic cervical cancer - link

Digital Health
- The use of social media as a tool for stakeholder engagement in health service design and quality improvement: A scoping review - link

European Journal of Hospital Pharmacy
- Cost-saving effect of early less invasive surfactant administration versus continuous positive airway pressure therapy alone for preterm infants with respiratory distress syndrome - link

International Journal of Clinical Pharmacy
- Short and long term impact of combining restrictive and enabling interventions to reduce aztreonam consumption in a community hospital - link
- Factors associated with the frequency of antihypertensive drug adjustments in chronic kidney disease patients: a multicentre, 2-year retrospective study - link

JAMA
- Prevalence of Central Nervous System–Active Polypharmacy among Older Adults with Dementia in the US - link
- Effect of Blinatumomab vs Chemotherapy on Event-Free Survival among Children with High-risk First-Relapse B-Cell Acute Lymphoblastic Leukemia. A Randomized Clinical Trial - link

JAMA Internal Medicine
- Invited Commentary: Adverse Drug Events After Hospitalization—Are We Missing the Mark? - link

JAMA Pediatrics
- Short-Course Antimicrobial Therapy for Pediatric Community-Acquired Pneumonia. The SAFER Randomized Clinical Trial - link

Journal of Clinical Oncology
- Nivolumab and Ipilimumab as Maintenance Therapy in Extensive-Disease Small-Cell Lung Cancer: CheckMate 451 - link

Journal of Patient Safety
- Effects of an Intensive Discharge Intervention on Medication Adherence, Glycemic Control, and Readmission Rates in Patients with Type 2 Diabetes - link
- Review: Toward the Development of the Perfect Medical Team: Critical Components for Adaptation
- Identification of Design Criteria to Improve Patient Care in Electronic Health Record Downtime - link
- Give Intravenous Bolus Overdose a Brake: User Experience and Perception of Safety Device - link
- The Burden of Opioid-Related Adverse Drug Events on Hospitalized Previously Opioid-Free Surgical Patients - link
- Building an Ambulatory Safety Program at an Academic Health System - link
- National and Institutional Trends in Adverse Events Over Time: A Systematic Review and Meta-analysis of Longitudinal Retrospective Patient Record Review Studies - link

Journal of Pharmaceutical Policy and Practice
- Avoiding a Med-Wreck: a structured medication reconciliation framework and standardized auditing tool utilized to optimize patient safety and reallocate hospital resources - link

JMIR Human Factors
- Perceptual Gaps between Clinicians and Technologists on Health Information Technology-Related Errors in Hospitals: Observational Study - link

Molecular Diversity Preservation International (MDPI) – Pharmacy Journal
- A Longitudinal Assessment of the Quality of Insulin Prescribing with Different Prescribing Systems - link

Medical Journal of Australia
- Pharmacovigilance for chlorhexidine anaphylaxis: a preventable adverse reaction - link
National Institute for Health Research (NIHR)
- NIHR Signals
- New sub-groups of diabetes could lead to more targeted treatment for people in India - link

New England Journal of Medicine
- Terlipressin plus Albumin for the Treatment of Type 1 Hepatorenal Syndrome - link
- Nivolumab plus Cabozantinib versus Sunitinib for Advanced Renal-Cell Carcinoma - link
- Clinical Practice: Epistaxis - link

OTO open
- Intraoperative Sentinel Events in the Era of Surgical Safety Checklists: Results of a National Survey

Pediatrics
- Quality Improvement Efforts to Reduce Opioid Prescribing from a Pediatric Emergency Department - link
- Reducing Opioid Doses Prescribed From a Pediatric Emergency Department - link

Pharmacotherapy
- Lack of Drug Interaction between Levetiracetam and High-Dose Methotrexate in Patients with Lymphoma - link

Research in Social and Administrative Pharmacy
- Evaluating the impact of a pharmacist-led prescribing feedback intervention on prescribing errors in a hospital setting - link

TAG Mail – 4 Mar 2021

**COVID-19 RESOURCES & ARTICLES OF INTEREST**

**AUSTRALIAN**
- **AHPRA**
  - Webinar: How a pandemic affects eye health - link

- **Australian Government Department of Health**
  - Webinar: COVID-19 response update for General Practitioners (and allied health) – 4 March 2021 11:30-12:30 AEDT - link
  - PHLN statement on use of saliva as an alternative specimen for the diagnosis of SARS-COV-2 - link
  - COVID-19 Allied Health Package Information for allied health professionals - link

- **Australian Prescriber**
  - Podcast **Episode 100**: COVID-19 vaccination in Australia, infectious diseases physician Kristine Macartney
  - BNT162b2 vaccine for prevention of COVID-19 - link

- **TGA**
  - TGA collecting COVID-19 vaccine side effect reports – link
  - COVID-19 vaccine weekly safety report #1 - 03-03-2021 - link

**INTERNATIONAL**

- **WHO**
  - Background document on the AZD1222 vaccine against COVID-19 developed by Oxford University and AstraZeneca - link
  - Roadmap to improve and ensure good indoor ventilation in the context of COVID-19 - link
  - COVID-19 weekly epidemiological update as of 21/2/21 – link
  -- Special edition: Proposed working definitions of SARS-CoV-2 Variants of Interest and Variants of Concern - link
- Preparedness, prevention and control of COVID-19 in prisons and other places of detention: interim guidance, 08/02/21 - link
- In the wake of the pandemic - Preparing for Long COVID - link
- Science in 5: Vaccines, variants and herd immunity - link
- Living guideline: drugs to prevent COVID-19: interim guidance, 2 March 2021

Europe

EMA
- EMA starts rolling review of Celltrion antibody regdanvimab for COVID-19 - link
- International cooperation to align approaches for regulation of COVID-19 vaccines & medicines - link
- EMA issues advice on use of REGN-COV2 antibody combination (casirivimab / imdevimab) - link
- Regulatory requirements for vaccines intended to provide protection against variant strain(s) of SARS-CoV-2 - link

UK
- Care Quality Commission
  -- Briefing: COVID-19 INSIGHT – February 2021
- GOV.UK Department of Health and Social care
  -- Latest findings from antibody surveillance study published - link
- King Guide Publications
  -- COVID vaccine (Pfizer) updated storage, thawing, dilution information - link
- NHS England
  -- National Diabetes Inpatient COVID-19 Response Team clinical guidance - link
- NICE
  -- COVID-19 rapid evidence summary: Tocilizumab for COVID-19 (update)
- SIGN
  -- Assessment of COVID-19 in primary care - link
- Specialist Pharmacy Service (SPS)
  -- Safety alert: Handling multiple COVID-19 Vaccines. COVID-19 vaccines have different handling and dosing requirements. Sites need to plan to reduce the risk of errors where multiple vaccines are available. Amongst other points, it is advised to use only one vaccine per session.
  - The Centre for Evidence-Based Medicine
  -- Rapid Review: Risks of and from SARS-COV-2 (COVID-19) infection in people with asthma - link
  - The King’s Fund
  -- Covid-19 recovery and resilience: what can health and care learn from other disasters? - link

USA
- American Journal of Medical Toxicology
  -- Webinar: Monoclonal Antibodies; Frontline Update: Anaphylaxis from COVID-19 Vaccine - link
- Centers for Disease Control and Prevention (CDC)
- FDA
  -- Emergency Use Authorization for Third COVID-19 Vaccine - link
  -- FDA Allows More Flexible Storage, Transportation Conditions for Pfizer-BioNTech COVID-19 Vaccine - link

JOURNAL ARTICLES
American Journal of Health-System Pharmacy
- Emergency preparation and mitigation for COVID-19 response in an integrated pharmacy practice model - link
- Advancing ambulatory pharmacy practice through a crisis: Objectives and strategies used in an ambulatory care action team’s response to the COVID-19 pandemic - link
- Multicenter point prevalence evaluation of the utilization and safety of drug therapies for COVID-19 at the onset of the pandemic timeline in the United States - link

ANZ Journal of Surgery
- Utilization of telehealth by surgeons during the COVID 19 pandemic in Australia: lessons learnt - link
- Prevalence of asymptomatic SARS-CoV-2 infection in elective surgical patients in Australia: a prospective surveillance study - link
PNAS
- Influence of a COVID-19 vaccine’s effectiveness and safety profile on vaccination acceptance - link

Thorax
- Development and validation of a prediction model for 30-day mortality in hospitalised patients with COVID-19: the COVID-19 SEIMC score - link

REPORTS AND PUBLICATIONS – AUSTRALIA

Australian Government Department of Health
- Electronic Prescriptions: Data Usage Policy; Privacy Policy; Security and Access Policy

Australian Institute for Health and Welfare (AIHW)
- Hospital safety and quality - link
- Childhood overweight and obesity—the impact of the home environment - link
- Youth detention population in Australia 2020 - link
- Venomous bites and stings 2017–18 - link

NSW Health
- NSW Suicide Monitoring System - Report 4 - January 2021 - link
- Area of Need Program (PD2021_007)
- Reporting of Maternal Deaths to the NSW Clinical Excellence Commission (PD2021_006)
- Forensic Drug and Alcohol Sampling in Emergency Departments (PD2021_005)

Pharmaceutical Benefits Scheme (PBS)
- New and amended listings relating to the following health conditions from 1 March 2021.
  -- Pulmonary Arterial Hypertension (PAH)
  -- Atopic Dematitis
  -- Complex Gastroesophageal Reflux Disease (GORD)
  -- Relapsing-remitting multiple sclerosis (RRMS)
  -- Type 2 Diabetes Mellitus (T2DM)
  -- Asthma
  -- Chronic obstructive pulmonary disease (COPD)

Royal Commission into Aged Care Quality and Safety
- Final Report: Care, Dignity and Respect - link

Safer Care Victoria
- Supporting patient safety: learning from sentinel events. Annual report 2019–20: focus on the three most frequently reported sentinel events issues: pregnancy, labour and the post-natal period; patient falls; medication errors - link

TGA
- Update to listed medicine ingredients in March 2021 - link
- AusPARGS:
  -- Etanercept (Rymti/Etera) - new biosimilar medicine

REPORTS AND PUBLICATIONS – INTERNATIONAL

All Wales Medicines Strategy Group
- Shared Care Prescribing and Monitoring Guidance - link

British National Formulary (BNF)
- Newsletter – February 2021
  -- New monographs (BNF and/or BNF for Children): caplacizumab, COVID-19 vaccine, treprostini
  -- MHRA advice on: andexanet alfa, dimethyl fumarate, erythromycin, fingolimod, methylprednisolone and quinolones.
European Medicines Agency (EMA)
- First oral treatment for spinal muscular atrophy (SMA) recommended for approval - [link](#)
- European CHMP recommends approval of
  - berotralstat (Orladeyo) for prevention of recurrent attacks of hereditary angioedema (HAE) - [link](#)
  - dostarlimab (Jemperli) for recurrent or advanced endometrial cancer - [link](#)
  - isatuximab (Sarclisa) license extension- in combination with carfilzomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy - [link](#)
  - two bevacizumab biosmilars (Abevmy and Lextemy) - for indications as per Avastin - [link](#)
  - cabozantinib (Cabometyx) license extension-as first-line treatment for advanced renal cell carcinoma - [link](#)
  - cannabidiol (Epidyolex) license extension-as adjunctive therapy of seizures associated with tuberous sclerosis complex for patients 2 years of age and older – [link](#)
  - delafloxacin (Quofenix) license extension-for community- acquired pneumonia in adults when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the initial treatment of these infections – [link](#)
  - nivolumab (Opdivo) license extension-as first-line treatment for advanced renal cell carcinoma - [link](#)

Food and Drug Administration (FDA) USA
- FDA Approves Targeted Treatment for Rare Duchenne Muscular Dystrophy Mutation - [link](#)
- FDA Approves First Treatment for Molybdenum Cofactor Deficiency Type A - [link](#)

National Institute for Health and Clinical Excellence (NICE) UK
- Safeguarding adults in care homes [NG189](#)
- Secondary bacterial infection of eczema and other common skin conditions: antimicrobial prescribing [NG190](#)
- Chemotherapy dose standardisation [KTT22](#)
- Suicide prevention: optimising medicines and reducing access to medicines as a means of suicide [KTT24](#)
- Shared decision making [KTT23](#)
- Baricitinib for treating moderate to severe atopic dermatitis – guidance [TA681](#)
- Lenalidomide maintenance treatment after an autologous stem cell transplant for newly diagnosed multiple myeloma – guidance [TA680](#)
- Remsima (infliximab biosimilar) for subcutaneous injection for managing Crohn’s disease and ulcerative colitis – evidence summary [ED35](#)

Specialist Pharmacy Services NHS UK
- Guidance on issuing the Steroid Emergency Card - [link](#)

The National Academies Press
- Medications in Single Dose Vials; Implications of Discarded Drugs - [link](#)
- Meeting the Challenge of Caring for Persons Living with Dementia and Their Care Partners and Caregivers: A Way Forward - [link](#)

MEDICATION SAFETY

**electronic Medicines Compendium (eMC) (UK)**
- Revised SPCs:
  - Somavert (pegvisomant) - patients be carefully monitored for tumour expansion causing serious complications eg visual field defects
  - Velcade (bortezomib) - Guillain-Barré syndrome and demyelinating polyneuropathy added as adverse events (frequency rare)
  - Nimenrix (meningococcal groups A, C, W-135 and Y conjugate vaccine) - Lymphadenopathy added as an adverse effect of unknown frequency
  - Klaricid (clarithromycin) preparations - SPC now notes potential interaction with methadone, a CYP3A4 substrate, whose concentration may be elevated, when given concomitantly with clarithromycin. Close monitoring is advised.
  - Testogel (testosterone) gel - updated in line with PRAC recommendation to highlight caution in use in those with risk factors for VTE owing to reports of thrombotic events with treatment.
-- Vermox (mebendazole) tablets - updated to recommend that owing to limited data, treatment should not be given to those <1 year, and that in those aged 1-2 years mebendazole should only be given if the potential benefit justifies the potential risk.

CEC
- Communication re supply disruption to: Prednefrin Forte eye drops 10mL (3 March 2021) - link

Health Canada – MedEffect Notice
- Safety Brief: Tecentriq (atezolizumab) - link

MIMS monthly updates – March
New Products
-- ChAdOx1-S COVID-19 Vaccine (AstraZeneca) is a monovalent vaccine composed of a single recombinant, replication-deficient chimpanzee adenovirus (ChAdOx1) vector encoding the S-glycoprotein of SARS-CoV-2
-- Comirnaty BNT162b2 [mRNA] COVID-19 Vaccine (Pfizer) contains nucleoside-modified messenger RNA (mRNA) formulated in lipid nanoparticles, which enable the delivery of the non-replicating RNA into host cells to direct transient expression of the SARS-CoV-2 spike (S) antigen
-- Indacaterol (acetate)/mometasone furoate (Alectura Breezhaler) combines indacaterol, a long-acting B2-agonist (LABA), which acts locally on airways to produce bronchodilation, and mometasone furoate, an inhaled corticosteroid (ICS), which reduces pulmonary inflammation
-- Ozanimod (Zeposia) a sphingosine 1-phosphate (S-1-P) receptor modulator, binds with a high affinity to S-1-P receptor subtypes 1 & 5. Ozanimod causes lymphocyte retention in lymphoid tissues
-- Trientine dihydrochloride (Trientine Waymade) has a structure similar to polyamines and chelates copper by forming a stable complex with the four constituent nitrogens in a planar ring
- New Contraindications
-- Cyproterone acetate/ethinylestradiol (Diane-35) now contraindicated in patients with meningioma or a history of meningioma.
-- Fluticasone propionate (Axotide, Flixotide Accuhaler) now contraindicated in patients with severe milk-protein allergy.
-- Mercaptopurine monohydrate (Allmercap) now contraindicated with concomitant yellow fever vaccine.
-- Selegiline hydrochloride (Eldepryl) should not be used in combination with serotonin noradrenaline reuptake inhibitors (e.g. venlafaxine), tricyclic antidepressants, sympathomimetics, monoamine oxidase inhibitors; nor in patients with active duodenal or gastric ulcer

NSW Health
- Identification of Post-Injection Syndrome Olanzapine Pamoate Long Acting Injection 004/21 - link

TGA
- New legislation to support medicine substitutions: allow pharmacists to substitute a different medicine when a patient's usual medicine has been declared to be in 'serious scarcity'.

PAPERS OF INTEREST

American Journal of Health-System Pharmacy (AJHP)
- Guidance on the treatment of antipsychotic-induced hyperprolactinemia when switching the antipsychotic is not an option - link
- Tools and tactics for post-discharge medication management interventions - link

American Journal of Cardiology
- Meta-Analysis Comparing the Safety and Efficacy of Single vs Dual Antiplatelet Therapy in Post Transcatheter Aortic Valve Implantation Patients - link

British Journal of Clinical Pharmacology
- Short report: The potential of individualized dosing of ravulizumab to improve patient-friendliness of paroxysmal nocturnal haemoglobinuria treatment at reduced costs - link
- Tacrolimus dose, blood concentrations and acute nephrotoxicity, but not CYP3A5/ABCB1 genetics, are associated with allograft tacrolimus concentrations in renal transplant recipients - link
- Short report: Characteristics of arsenic species in cerebrospinal fluid (CSF) of acute promyelocytic leukemia (APL) patients treated with arsenic trioxide plus mannitol - link
- Epidemiology of drug-related deaths in European hospitals: a systematic review and meta-analysis of observational studies - link
- Review: Machine Learning in Pharmacometrics: Opportunities and Challenges - link
- External evaluation of the predictive performance of seven population pharmacokinetic models for phenobarbital in neonates - link
- Pharmacist-led intervention on chronic pain management: A systematic review and meta-analysis - link
- Beta-blocker-associated hypoglycaemia: New insights from a real-world pharmacovigilance study - link
- Measuring and reporting treatment adherence: What can we learn by comparing two respiratory conditions? - link
- Pharmacokinetic and pharmacodynamic evidence of adrenaline administered via auto-injector for anaphylactic reactions: A review of literature - link
- Treating the whole glaucoma spectrum: A new treatment approach is required - link

British Journal of General Practice
- Associations with antibiotic prescribing for acute exacerbation of COPD in primary care - link

British Medical Journal (BMJ)
- Statin treatment and muscle symptoms: series of randomised, placebo controlled n-of-1 trials - link
- Effect of reductions in amyloid levels on cognitive change in randomized trials: instrumental variable meta-analysis - link

BMJ Drug and Therapeutics Bulletin
- DTB select: Risk of DKA with SGLT2 inhibitors - link

BMJ Open Infectious Diseases
- Systematic review of prediction models for pulmonary tuberculosis treatment outcomes in adults - link

BMJ Open Qual
- Preventable adverse drug events causing hospitalisation: identifying root causes and developing a surveillance and learning system at an urban community hospital, a cross-sectional observational study - link

BMJ Quality and Safety
- Timeout procedure in paediatric surgery: effective tool or lip service? A randomised prospective observational study - link

Circulation
- How Should We Sequence the Treatments for Heart Failure and a Reduced Ejection Fraction? - link
- Inhibition of Cholesteryl Ester Transfer Protein Preserves High-Density Lipoprotein Cholesterol and Improves Survival in Sepsis - link
- Effects of n-3 Fatty Acid Supplements in Elderly Patients after Myocardial Infarction: A Randomized, Controlled Trial - link

Cochrane
- Adult patient access to electronic health records - link
- Interventions for bacterial folliculitis and boils (furuncles and carbuncles) - link
- Interventions for preventing type 2 diabetes in adults with mental disorders in low- and middle-income countries - link
- Belimumab for systemic lupus erythematosus - link
- Paravertebral anaesthesia with or without sedation versus general anaesthesia for women undergoing breast cancer surgery - link
- Antibiotics to prevent complications following tooth extractions - link
- Silicone gel sheeting for treating keloid scars - link
- Coenzyme Q10 for heart failure - link
- Pharmacological interventions for self-harm in adults - link
- Long-term effects of weight-reducing drugs in people with hypertension - link
- Withdrawal or continuation of cholinesterase inhibitors or memantine or both, in people with dementia - link

**Diabetes Care**
- Cardiovascular, Renal, and Metabolic Outcomes of Dapagliflozin Versus Placebo in a Primary Cardiovascular Prevention Cohort: Analyses from DECLARE-TIMI 58 - link
- Case report: Interferent Effect of Hydroxyurea on Continuous Glucose Monitoring - link

**European Journal of Hospital Pharmacy**
- Drug-related bradycardia precipitating hospital admission in older adults: an ongoing problem - link
- Impact and acceptance of pharmacist-led interventions during HIV care in a third-level hospital in Spain using the Capacity-Motivation-Opportunity pharmaceutical care model: the IRAFE study - link

**Health Expectations**
- Evaluation of patient engagement in medicine development: A multi-stakeholder framework with metrics - link

**Heart**
- Sodium-glucose co-transporter 2 inhibitor therapy: mechanisms of action in heart failure - link

**International Medicine Journal**
- Psychological flexibility is associated with less diabetes distress and lower glycated haemoglobin in adults with type 1 diabetes - link
- Invasive versus Conservative Management in Patients ≥85 years presenting with Non-ST Elevation Myocardial Infarction - link
- Current issues in the prevalence, diagnosis and management of hepatocellular carcinoma in Australia - link

**International Journal of Clinical Pharmacy**
- Evaluation of pharmacists’ interventions on drug-related problems and drug costs in patients with cancer pain - link

**International Journal of Geriatric Psychiatry**
- Intraoperative dexmedetomidine for prevention of postoperative delirium in elderly patients with mild cognitive impairment - link

**International Journal for Quality in Health Care**
- The Effect of Computerized Clinical Decision Support on Adherence to VTE Prophylaxis Clinical Practice Guidelines among Hospitalized Patients - link
- Fall Prevention Education for People with Multiple Sclerosis: A Randomized Clinical Trial - link
- Reengineer healthcare: a human factors and ergonomics framework to improve the socio-technical system - link
- Is the ‘never event’ concept a useful safety management strategy in complex primary healthcare systems? - link
- Innovating health care: key characteristics of human-centered design - link

**JAMA**
- Effect of Subcutaneous Semaglutide vs Placebo as an Adjunct to Intensive Behavioral Therapy on Body Weight in Adults With Overweight or Obesity: The STEP 3 Randomized Clinical Trial - link
- Viewpoint: Medications in Single-Dose Vials and Implications of Discarded Injectable Drugs: A National Academies Report - link
- Diagnosis and Treatment of Irritable Bowel Syndrome - a Review

**JAMA Internal Medicine**
- Severe Hypoglycemia Risk With Long-Acting Insulin Analogs vs Neutral Protamine Hagedorn Insulin - link
- Research Letter: Glycemic Control and Use of High-risk Antihyperglycemic Agents among Nursing Home Residents with Diabetes in Ontario, Canada - link
- Effect of a Multifaceted Clinical Pharmacist Intervention on Medication Safety after Hospitalization in Persons Prescribed High-risk Medications: A Randomized Clinical Trial - link

**JAMA Network Open**
- Association of Anti–Tumor Necrosis Factor Therapy with Mortality among Veterans With Inflammatory Bowel Disease - link
- Association of a Safety Program for Improving Antibiotic Use with Antibiotic Use and Hospital-Onset Clostridioides difficile Infection Rates among US Hospitals - link

**JAMA Neurology**
- Reperfusion Treatment and Stroke Outcomes in Hospitals with Telestroke Capacity - link

**JAMA Oncology**
- Review: Current Treatment Strategies and Future Directions for Extrapulmonary Neuroendocrine Carcinomas - link

**JAMA Ophthalmology**
- Early Experience With Brolucizumab Treatment of Neovascular Age-Related Macular Degeneration - link

**JAMA Psychiatry**
- Association of Attention-Deficit/Hyperactivity Disorder in Childhood and Adolescence with the Risk of Subsequent Psychotic Disorder: A Systematic Review and Meta-analysis - link

**JAMIA (Journal of the American Medical Informatics Association)**
- Exploring the relationship between electronic health records and provider burnout: A systematic review - link
- Digital phenotyping and sensitive health data: Implications for data governance - link
- Extracting postmarketing adverse events from safety reports in the vaccine adverse event reporting system (VAERS) using deep learning - link

**Journal of the American Geriatrics Society**
- Medication review interventions to reduce hospital readmissions in older people - link
- Automated Frailty Screening At-Scale for Pre-Operative Risk Stratification Using the Electronic Frailty Index - link

**Journal of Clinical Oncology**
- Impact of Risk-Adapted Therapy for Pediatric Hodgkin Lymphoma on Risk of Long-Term Morbidity: A Report from the Childhood Cancer Survivor Study - link

**Journal of Palliative Medicine**
- Multicentered Evaluation of Palliative Care Pharmacists’ Interventions and Outcomes in California - link
- Use of a Novel Trigger Tool to Identify Palliative Care Needs in Surgical Patients at a National Referral Hospital in Kenya: A Pilot Study - link

**Lancet**
- Anti-interleukin-21 antibody and liraglutide for the preservation of β-cell function in adults with recent-onset type 1 diabetes: a randomised, double-blind, placebo-controlled, phase 2 trial - link
- Decentralisation, integration, and task-shifting in hepatitis C virus infection testing and treatment: a global systematic review and meta-analysis - link
- Risk predictors of progression to severe disease during the febrile phase of dengue: a systematic review and meta-analysis - link
- Safety and efficacy of intensive blood pressure lowering after successful endovascular therapy in acute ischaemic stroke (BP-TARGET): a multicentre, open-label, randomised controlled trial - link
- Modelling the intervention effect of opioid agonist treatment on multiple mortality outcomes in people who inject drugs: a three-setting analysis - link
- Semaglutide 2.4 mg once a week in adults with overweight or obesity, and type 2 diabetes (STEP 2): a randomised, double-blind, double-dummy, placebo-controlled, phase 3 trial - link
- Alzheimer's disease - Seminar paper highlights the main developments in the field of Alzheimer's disease - link

**Lancet Haematology**
- Rituximab plus high-dose chemotherapy (MegaCHOEP) or conventional chemotherapy (CHOEP-14) in young, high-risk patients with aggressive B-cell lymphoma: 10-year follow-up of a randomised, open-label, phase 3 trial - link

**Lancet Infectious Diseases**
- Standard dose raltegravir or efavirenz-based antiretroviral treatment for patients co-infected with HIV and tuberculosis (ANRS 12 300 Reflate TB 2): an open-label, non-inferiority, randomised, phase 3 trial - link

**Lancet Oncology**
- Treatment of relapsed and refractory multiple myeloma: recommendations from the International Myeloma Working Group - link

**Molecular Diversity Preservation International (MDPI) – Pharmacy Journal**
- Evaluating the Effect a of Handout on Community Pharmacists’ Opioid Safety Counseling - link

**Medical Journal of Australia**
- Guideline Summary: Otitis media guidelines for Australian Aboriginal and Torres Strait Islander children: summary of recommendations - link
- Perspective: Technologies in the management of type 1 diabetes - link

**National Institute for Health Research (NIHR)**
- Reduced exposure to vasopressors through permissive hypotension to reduce mortality in critically ill people aged 65 and over: the 65 RCT - link
- NIHR Signals
  -- People with anaemia may not benefit from iron therapy ahead of major abdominal surgery, research finds - link
  -- Short term palliative care reduced costs without compromising quality for people with neurological conditions - link

**New England Journal of Medicine**
- Glycemic Index, Glycemic Load, and Cardiovascular Disease and Mortality - link
- Muscarinic Cholinergic Receptor Agonist and Peripheral Antagonist for Schizophrenia - link visual abstract - link
- Review: β-Thalassemias - link

**Pediatrics (American Academy of Pediatrics)**
- Current Prescription Opioid Misuse and Suicide Risk Behaviors among High School Students - link

**Pharmaceutical Journal**
- Paracetamol use in infants and young children - link

**Pharmacotherapy**
- Comparative treatment effectiveness of oral fingolimod and conventional injectable disease modifying agents in multiple sclerosis - link
- Enoxaparin versus Unfractionated Heparin for Venous Thromboembolism Prophylaxis in Renally Impaired ICU Patients - link

**Prescrire – French Medical Journal**
- Prescrire International, Issue Number 224 March 2021 - link
  -- Polatuzumab vedotin (Polivy®) and large B-cell lymphoma - link
  -- Review: Covid-19: a recap of treatment options - from Prescribe's comprehensive year-end review - link
Public Library of Science (PLOS)
- Vitamin D levels and risk of type 1 diabetes: A Mendelian randomization study - [link](#)
- Global burden of influenza-associated lower respiratory tract infections and hospitalizations among adults: A systematic review and meta-analysis - [link](#)

TAG Mail – 25 Feb 2021

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<tr>
<th>COVID-19 RESOURCES &amp; ARTICLES OF INTEREST</th>
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<td>Please click this <a href="#">link</a> for the cumulative listing of COVID-19 resources in past TAG Mails.</td>
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<td><strong>Australian Government Department of Health</strong></td>
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<td>- COVID-19 vaccination decision guide for women who are pregnant, breastfeeding, or planning pregnancy - <a href="#">link</a></td>
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<tr>
<td>- Epidemiology Report 35: Reporting period ending 14 February 2021</td>
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| **Australian Institute of Health and Welfare** |
| - Antenatal care during COVID–19, 2020 - [link](#) |

| **CEC** |
| - COVID-19 Infection Prevention and Control - Response and Escalation Framework V2.3 - [link](#) |

| **Health Literacy Hub** |
| - Health Literacy Seminar 1: Applying lessons in covid communication to emerging vaccination issue, 2/3/21 2-3pm - [link](#) |

| **National COVID-19 Clinical Evidence Taskforce** |
| - Updates to the Australian guidelines for the clinical care of people with COVID-19 V34.1 - [link](#) |

| **NSW Health** |
| - Statewide Protocol for the Supply or Administration of COVID-19 Vaccine ([PD2021_004](#)) |
| - Standard operating procedure for administration of COVID-19 vaccines in NSW vaccination clinics ([PD2021_003](#)) |
| - COVID-19 Vaccine Administration by Authorised Registered Nurse and Midwife Immunisers ([IB2021_007](#)) |

| **NSW Health Critical Intelligence Unit** |
| - 24 Feb 2021 - Risk Monitoring Dashboard - [link](#) |
| - Living Evidence - COVID-19 vaccines – last updated 24/2/21 - [link](#) |

| **NPS MedicineWise** |
| - Episode 23: Update on COVID-19 vaccines- 22 February 2021 |

| **Sax Institute** |
| - The impact of COVID-19: new insights from the 45 and Up Study - [link](#) |

| **TGA** |
| - Advertising COVID-19 vaccines to the Australian public - [link](#) |
| - Reporting suspected side effects associated with a COVID-19 vaccine - [link](#) |

<table>
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<tr>
<th>INTERNATIONAL</th>
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<tr>
<td><strong>WHO</strong></td>
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<tr>
<td>- No-fault compensation programme for COVID-19 vaccines is a world first - <a href="#">link</a></td>
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<td>- World Waking Up To Vaccine Equity - <a href="#">link</a></td>
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<tr>
<td>- Science in 5: Vaccine dosage - <a href="#">link</a></td>
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<tr>
<td>- Two additional vaccines listed for emergency use - <a href="#">link</a></td>
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</tbody>
</table>
COVID-19 vaccine introduction and deployment costing tool (CVIC tool), 20 Feb 2021, version 2 pre-release - link

UK
- Association of Reproductive & Clinical Scientists and British Fertility Society
  - Covid-19 vaccines and fertility – FAQs - link
- GOV.UK
  - Regulatory approval of COVID-19 Vaccine AstraZeneca - link
- MHRA
  - Interleukin-6 inhibitors (tocilizumab or sarilumab) for hospitalised patients with COVID-19 pneumonia (adults) – updated interim policy - link
- NICE
  - COVID-19 rapid guideline updates:
    --- Haematopoietic stem cell transplantation (NG164)
    --- Critical care in adults (NG159)
- Public Health England
  - PHE monitoring of the effectiveness of COVID-19 vaccination - data on the real-world efficacy of the COVID-19 vaccines - link
  - The green book, chapter 14a – updated to include information on the Moderna vaccine
- Specialist Pharmacy Services NHS UK
  - Planning access to end of life care medicines out-of-hospital during a pandemic - link

USA
- ASHP discussion forum (Sign up for free) recent topics of discussion include: allocation process for monoclonal antibodies, vaccine handling, bamlanivimab/etesevimab compounding, tocilizumab, timing of vaccine with renal dialysis
- FDA
  - Development of Monoclonal Antibody Products Targeting SARS-CoV-2, Including Addressing the Impact of Emerging Variants, During the COVID 19 Public Health Emergency - link
  - BioSpace article - Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) submission for a proposed label update to the U.S. EUA Prescribing Information which would enable the vaccine to be stored at -25°C to -15°C (-13°F to 5°F), standard freezer temperature, for a total of two weeks - link

JOURNAL ARTICLES
American Journal of Health-System Pharmacy (AJHP)
- Mitigating the risk of COVID-19 exposure by transitioning from clinic-based to home-based immune globulin infusion - link
- Lessons learned from pharmacy learner and educator experiences during early stages of COVID-19 pandemic - link
- Developing statewide remdesivir use criteria - link
- Assessment of narcotic, sedative, and neuromuscular blocker needs of patients with COVID-19 requiring invasive mechanical ventilation - link
- Impact of hydroxychloroquine on disease progression and ICU admissions in patients with SARS-CoV-2 infection - link
- Health-system implementation of a collaborative core curriculum for advanced pharmacy experiential education during the COVID-19 pandemic – link

Annals of Internal Medicine
- Update Alert 7: Risks and Impact of Angiotensin-Converting Enzyme Inhibitors or Angiotensin-Receptor Blockers on SARS-CoV-2 Infection in Adults - link

Australian and New Zealand Journal of Public Health
- A multiple site community outbreak of COVID-19 in Sydney, Australia - link

British Journal of Clinical Pharmacology
- Model-informed drug repurposing: A pharmacometric approach to novel pathogen preparedness, response and retrospection – link
- No association between use of angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers prior to hospital admission and clinical course of COVID-19 in the COvid MEdication (COMET) study - [link]
- Dexamethasone use and Mortality in Hospitalized Patients with Coronavirus Disease 2019: a Multicenter Retrospective Observational Study - [link]
- Repurposing of thalidomide and its derivatives for the treatment of SARS-coV-2 infections: Hints on molecular action - [link]

BMJ
- Editorial: Prophylactic anticoagulation for patients in hospital with covid-19 - [link]
- Clinical review: Vaccines for older adults - [link]
- Feature: Behind the scenes of the Pfizer BioNTech covid-19 vaccine trial - [link]

Cochrane
- Signs and symptoms to determine if a patient presenting in primary care or hospital outpatient settings has COVID-19 - [link]

European Journal of Hospital Pharmacy
- The European COVID-19 drugs calculation tool: an aid for the estimation of the drugs needed during the SARS-CoV 2 pandemic - [link]

Global Child Health
- Clinical characteristics, treatment and outcomes of paediatric COVID-19: a systematic review and meta-analysis - [link]

International Journal for Quality in Health Care
- Impact of a Prolonged COVID-19 Lockdown on Patterns of Admission, Mortality and Performance Indicators in a Cardiovascular Intensive Care Unit - [link]

JAMA
- The Price of Success—How to Evaluate COVID-19 Vaccines When They’re Available Outside of Clinical Trials - [link] – with Editorial

Lancet
- Single-dose administration and the influence of the timing of the booster dose on immunogenicity and efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine: a pooled analysis of 4 randomised trials - [link]
- Correspondence: Delayed second dose of the BNT162b2 vaccine: innovation or misguided conjecture? - [link]

Lancet Digital Health
- Indirect acute effects of the COVID-19 pandemic on physical and mental health in the UK: a population-based study – [link]

medRxiv
- Pre-print: Circulating SARS-CoV-2 variants escape neutralization by vaccine-induced humoral immunity - [link]

Nature
- COVID vaccines and safety: what the research says - [link]

NEJM
- Dexamethasone in Hospitalized Patients with Covid-19 – The RECOVERY Collaborative Group
- Early High-Titer Plasma Therapy to Prevent Severe Covid-19 in Older Adults - [link]
- A Randomized Trial of Convalescent Plasma in Covid-19 Severe Pneumonia - [link]
- Editorial: (A Little) Clarity on Convalescent Plasma for Covid-19 - [link]
- BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting - [link]

Pediatrics
- Enrolling Minors in COVID-19 Vaccine Trials – [link]
Signal Transduction and Targeted Therapy
- Efficacy and safety of systematic corticosteroids among severe COVID-19 patients: a systematic review and meta-analysis of randomized controlled trials - link

REPORTS AND PUBLICATIONS – AUSTRALIA

Australian Commission on Safety and Quality in Health Care (ACSQHC)
- How to analyse Staphylococcus aureus bloodstream infection (SABSI) data for quality improvement

Australian Institute for Health and Welfare (AIHW)
- Queensland’s Deadly Ears Program—Indigenous children receiving services for ear disease and hearing loss - link
- Exploring the definition of chronic conditions for collective monitoring in Australia 2021 - link
- Childhood overweight and obesity—the impact of the home environment - link

Agency for Clinical Innovation (ACI) NSW
- Aged health services in NSW - link
Purpose of the document: to develop an ideal model for NSW Health to deliver aged health services, with the aim of improving the care of older people.

NPS MedicineWise
- MedicineInsight report on chronic kidney disease management - link

Palliative Care Tasmania
- Advance Care Yarning Guide: Decision Making for End of Life For Aboriginal People in lutruwita/Tasmania - link

Royal Commission into Aged Care Quality and Safety
- Research Paper 20 – The quality of care experience and community expectations - link

Stroke Foundation Australia
- Clinical Guidelines for Stroke Management - Living guidelines recent updates

TGA
- The TGA's risk management approach to the regulation of therapeutic goods - link
- AusPAR:
  -- Opicapone (Ongentys) - adjunctive therapy to preparations of levodopa/ DOPA decarboxylase inhibitors (DDCI) in adult patients with Parkinson’s disease and end-of-dose motor fluctuations who cannot be stabilised on those combinations.

REPORTS AND PUBLICATIONS – INTERNATIONAL

Canadian Agency for Drugs and Technologies in Health
- Rapid Responses
  -- Switching from Reference to Biosimilar Adalimumab for Patients with Various Inflammatory Conditions- link
  -- Incentives and Support Programs to Improve Adherence to Tuberculosis Treatment - link
  -- Switching From Reference to Biosimilar Etanercept for Patients with Plaque Psoriasis- link
  -- Rapid Testing for the Diagnosis of Pulmonary Tuberculosis and Rifampicin Resistance: A Review of Cost-Effectiveness - link

Electronic Medicines Compendium (eMC) (UK)
- Revised SPC:
  --Imfinzi (durvalumab)- added alternative dosing regimen of 1500 mg every 4 weeks for locally advanced NSCLC.
  - Licence extensions
-- Plavix (clopidogrel) 300 mg- for use in combination with aspirin in adult patients with moderate to high-risk transient ischaemic attack (ABCD2-[1] score ≥4) or minor ischaemic stroke (NIHSS-[2] ≤3) within 24 hours of an event.
-- Spravato (esketamine) 28 mg nasal spray– extended for treatment of adults with moderate to severe episode of major depressive disorder, as acute short-term treatment in conjunction with oral antidepressants, for the rapid reduction of depressive symptoms, which constitute a psychiatric emergency.
- New products
-- Arikayce (amikacin) Liposomal 590 mg Nebuliser Dispersion - for the treatment of non-tuberculous mycobacterial lung infections caused by Mycobacterium avium Complex in adults with limited treatment options who do not have cystic fibrosis.

**Food and Drug Administration (FDA) USA**
- Entresto® (sacubitril and valsartan) tablets – updated indication: to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure - [link]
- New Drug approvals
-- Osela (trilaciclib) approved to reduce the frequency of chemotherapy-induced bone marrow suppression in adults receiving certain types of chemotherapy for extensive-stage (when the cancer has spread beyond the lungs) small cell lung cancer.

**Health Canada**
- Summary Safety Reviews
-- Ceftriaxone-containing products - Assessing the Potential Risk of Encephalopathy - [link]
-- Tecentriq (atezolizumab) - Assessing the Potential Risk of Autoimmune Hemolytic Anemia - [link]

**International Pharmaceutical Federation (FIP)**
- Medicines reconciliation: A toolkit for pharmacists - [link]

**Medicines and Healthcare products Regulatory Agency (MHRA)**
- Medicines in pregnancy and breastfeeding: new initiative for consistent guidance; report on optimising data for medicines used during pregnancy - [link]
- Paclitaxel drug-coated balloons (DCBs) or drug-eluting stents (DESs): Reconfirmed position on use in patients with intermittent claudication and critical limb ischaemia - [link]

**National Institute for Health and Clinical Excellence (NICE) UK**
- Filgotinib for treating moderate to severe rheumatoid arthritis guidance (TA676)
- Autologous anti-CD19-transduced CD3+ cells for treating relapsed or refractory mantle cell lymphoma guidance (TA677)
- Dapagliflozin for treating chronic heart failure with reduced ejection fraction guidance (TA679)
- Niraparib for maintenance treatment of advanced ovarian, fallopian tube and peritoneal cancer after response to first-line platinum-based chemotherapy guidance (TA673)
- Remsima (infliximab biosimilar) subcutaneous injection for managing Crohn’s disease and ulcerative colitis evidence summary (ES35)
- Metreleptin for treating lipodystrophy (HST14)

**Partnership for Health IT Patient Safety (a national collaborative)**
- Report: Optimizing Health IT for Safe Integration of Behavioral Health and Primary Care - [link]

**Public Health England**

**Specialist Pharmacy Services NHS UK**
- Updated national Patient Group Direction: Pre-Exposure Prophylaxis (PrEP) for the prevention of HIV infection - [link]
- PGD template: Aciclovir for treatment of genital herpes simplex infection - [link]
- PGD template: Imiquimod for treatment of anogenital warts - [link]
- PGD template: Podophyllotoxin for treatment of anogenital warts - [link]
electronic Medicines Compendium (eMC) (UK)
- Revised SPCs
  -- Asmanex (mometasone furoate) Twisthaler Inhalation Powder - now advises that after each dose, patients should rinse their mouth with water and spit out the contents without swallowing.
  -- Esmya (ulipristal acetate) - updated with more restricted licence of intermittent treatment of moderate/severe symptoms of uterine fibroids in pre-menopausal adults of reproductive age not eligible for surgery when uterine fibroid embolisation and/or surgical treatments are not suitable/have failed.
  -- Xromi (hydroxycarbamide)- frequency of monitoring full blood cell count and target absolute neutrophil count changed. Additional information on overdose added.
  -- Solu-Medrone (methylprednisolone)– Updated to include information on hypertrophic cardiomyopathy, which may develop after administration of methylprednisolone to prematurely born infants. Perform appropriate diagnostic evaluation and monitoring of cardiac function and structure.
  -- Bydureon (exenatide) products - addition of delayed gastric emptying as an uncommon side effect. Also added to Byetta (exenatide) SPCs.
  -- Episenta (sodium valproate)- Update includes undesirable effects in the paediatric population, mainly severe liver damage under the age of 3 years. Pharmacokinetic data shows systemic clearance varies with age below 10 years. Ages up to 2 months have decreased clearance compared to adults.
  -- Vibramycin-D (doxycycline) - updated with added warning regarding risk of exacerbating systemic lupus erythematosus and undesirable effects of visual disturbances and link to cranial hypertension.

Institute for Safe Medication Practices (ISMP) USA
- Medication Safety Alert! February 25, 2021
  -- A Recurring Call to Action: Every Healthcare Organization Needs a Medication Safety Officer!
  -- Error-prone concentrations of ibuprofen suspensions
  -- Dispense unit dose syringes using the most appropriate concentration
  -- Silicone-free syringes required

Medicines and Healthcare products Regulatory Agency (MHRA) UK
- Medicines in pregnancy and breastfeeding: new initiative for consistent guidance; report on optimising data for medicines used during pregnancy - link
- Drug Safety Updates:
  -- Ulipristal acetate 5mg (Esmya): further restrictions due to risk of serious liver injury - link
  -- Pregabalin (Lyrica): reports of severe respiratory depression - link
  -- Alkindi (hydrocortisone granules): risk of acute adrenal insufficiency in children when switching from hydrocortisone tablet formulations to granules - link
  -- Letters to Healthcare Professionals
  -- Esmya (ulipristal acetate) 5mg: indications for uterine fibroids restricted due to concerns of severe liver injury - link
  -- Accord Thalidomide 50mg hard capsules: Pregnancy Prevention Programme to minimise the risk of teratogenicity - link
  -- E-cigarettes and vaping: policy, regulation and guidance (updated) - link – with evidence update
  -- Vaping better than nicotine replacement therapy for stopping smoking, evidence suggests - link

MIMS monthly updates - February
- New Products
  -- Ripretinib (Qinlock) is a switch-control tyrosine kinase inhibitor that binds to both the switch pocket and the activation loop to lock the kinase in the inactive state, preventing downstream signalling and cell proliferation
  -- New Contraindications
    -- Measles, mumps and rubella live virus vaccine (M-M-R II) should not be given to pregnant females. If vaccination of post-pubertal females is undertaken for protection against rubella, pregnancy should be avoided for one month following vaccination.
    -- Metronidazole: now contraindicated in patients who have taken disulfiram within the previous two weeks; and with concomitant consumption of alcohol or products containing propylene glycol (or within three days after therapy with metronidazole).
Monobasic sodium phosphate/dibasic sodium phosphate (Phospho-Soda): now contraindicated in children under 18 years of age, and should not be used in combination with other laxative products containing sodium phosphate.

**Specialist Pharmacy Service (SPS) UK**
- BD syringes - Field Safety Notice (FSN) and intraocular injections - [link](#)

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**PAPERS OF INTEREST**

**American Journal of Health-System Pharmacy (AJHP)**
- Acute and severe ribavirin-associated hyperuricemia and acute kidney injury: An underrecognized adverse effect - [link](#)
- Network meta-analysis of infliximab biosimilars for the treatment of rheumatoid arthritis - [link](#)
- Tackling the challenges of nanomedicines: are we ready? – [link](#)
- Update on methylphenidate and dexamethylphenidate formulations for children with attention-deficit/hyperactivity disorder - [link](#)
- Basic surface electrocardiogram interpretation for the pharmacist - [link](#)
- Description of a pharmacist-managed/administered penicillin allergy skin testing service at a community hospital – [link](#)
- Stability of 10-mg/mL and 50-mg/mL ketamine oral solutions - [link](#)

**Anaesthesia**
- Incidence of accidental awareness during general anaesthesia in obstetrics: a multicentre, prospective cohort study - [link](#)

**Annals of Internal Medicine**
- Comparative Effectiveness and Harms of Antibiotics for Outpatient Diverticulitis. Two Nationwide Cohort Studies

**Arthritis & Rheumatology**
- A randomized, phase 2 study evaluating the efficacy and safety of anakinra in the treatment of gout flares - [link](#)

**British Journal of Clinical Pharmacology**
- Change in the regulatory framework for zolpidem: What is the impact on the landscape of the prescription of sedative medications? The French national ZORRO study - [link](#)
- Cardiovascular safety of the tyrosine kinase inhibitor nintedanib - [link](#)
- Bisphosphonate nephropathy: a case series and review of the literature - [link](#)
- Adalimumab-induced platelet antibodies resulting in severe thrombocytopenia - [link](#)
- Deprivation, dementia prevalence and regional demography on prescribing of anti-dementia drugs in England: a time trend analysis - [link](#)
- The Association between Cigarette Smoking and Efavirenz Plasma Concentration using the Population Pharmacokinetic Approach - [link](#)
- The Oxford Catalogue of Opioids: a systematic synthesis of opioid drug names and their pharmacology – [link](#)
- Measuring Prescription Opioid Misuse and Its Consequences - [link](#)
- The Effect of Aging on Infliximab Exposure and Response in Patients with Inflammatory Bowel Diseases - [link](#)
- Inter-rater reliability of assessments regarding the quality of drug treatment, and drug-related hospital admissions - [link](#)
- Ethionamide population pharmacokinetics/pharmacodynamics and therapeutic implications in South African adult patients with drug-resistant tuberculosis – [link](#)
- Monitoring of gene expression in tacrolimus-treated de novo renal allograft recipients facilitates individualized immunosuppression – results of the IMAGEN study - [link](#)
- Drug-induced peripheral oedema: An aetiology-based review - [link](#)

**British Journal of General Practice**
- Prevalence and Predictors of Potentially Inappropriate Prescribing in Middle-Aged Adults: Repeated Cross-Sectional Study - [link](#)
- Guidance impact on primary care prescribing rates of simple analgesia: an interrupted time series analysis in England - link

BMC Medicine
- Preventable medication harm across health care settings: systematic review and meta-analysis - link

BMJ Drug and Therapeutics Bulletin
- Bisphosphonate holidays - link
- Review: What is the significance of nitrosamine contamination in medicines? – link
- Republished: Symptomatic digoxin toxicity in a patient on haemodialysis – link

BMJ Heart
- Review: Postmenopausal hormone therapy for cardiovascular health: the evolving data - link

BMJ Open
- Changes in prescribing rates of sodium-containing medications in the UK from 2009 to 2018: a cross-sectional study with interrupted time series analysis - link

BMJ Quality and Safety
- Medication-related harm in older adults following hospital discharge: development and validation of a prediction tool - link

Circulation
- Commentary: Mending Broken Hearts: A New Treatment Paradigm for Immune Checkpoint Inhibitor–Induced Myocarditis - link

Cochrane
- Antibiotics for secondary prevention of coronary heart disease - link
- Cholinesterase inhibitors for vascular dementia and other vascular cognitive impairments: a network meta-analysis - link
- Caffeine dosing regimens in preterm infants with or at risk for apnea of prematurity - link
- Rituximab for people with multiple sclerosis - link
- Primary prophylaxis for venous thromboembolism in ambulatory cancer patients receiving chemotherapy – link

European Heart Journal
- Commentary: Antiplatelet and direct oral anticoagulation management after coronary artery bypass graft surgery: the Cinderella of current cardiovascular trials, please show me (some) evidence - link

European Journal of Hospital Pharmacy
- Formulation and stability of an extemporaneously compounded propafenone hydrochloride oral suspension for children with arrhythmia - link

JAMA
- Effect of High-Dose Baclofen on Agitation-Related Events Among Patients With Unhealthy Alcohol Use Receiving Mechanical Ventilation. A Randomized Clinical Trial – link – with Editorial
- Effect of Vitamin C, Thiamine, and Hydrocortisone on Ventilator- and Vasopressor-Free Days in Patients with Sepsis. The VICTAS Randomized Clinical Trial - link – with Editorial
- Review: Diagnosis and Treatment of Multiple Sclerosis - link

JAMA Oncology
- Comment: Caution With Routine Use of Daratumumab for Newly Diagnosed High-Risk Multiple Myeloma – link - reply

JAMA Pediatrics
- Rituximab vs Low-Dose Mycophenolate Mofetil in Recurrence of Steroid-Dependent Nephrotic Syndrome in Children and Young Adults. A Randomized Clinical Trial - link
JAMIA (Journal of the American Medical Informatics Association)
- Toolkits for implementing and evaluating digital health: A systematic review of rigor and reporting - [link]
- Improving the delivery of palliative care through predictive modeling and healthcare informatics - [link]

Journal of General Internal Medicine
- Association between In-Clinic Opioid Administration and Discharge Opioid Prescription in Urgent Care: a Retrospective Cohort Study - [link]

Journal of Patient Safety
- Implementing patient and family involvement interventions for promoting patient safety: a systematic review and meta-analysis - [link]

Lancet Respiratory Medicine
- Neutrophil extracellular traps, disease severity, and antibiotic response in bronchiectasis: an international, observational, multicohort study - [link]

Molecular Diversity Preservation International (MDPI) – Pharmacy Journal
- Challenges Faced by Health Professionals in Obtaining Correct Medication Information in the Absence of a Shared Digital Medication List - [link]

Medical Journal of Australia
- Reducing Medical Admissions and Presentations into Hospital through Optimising Medicines (REMAIN HOME): a stepped wedge, cluster randomised controlled trial - [link]

New England Journal of Medicine
- Avacopan for the Treatment of ANCA-Associated Vasculitis - [link]
- Review: β-Thalassemias - [link]

Pediatrics (American Academy of Pediatrics)
- Efficacy and Safety of Metformin for Obesity: A Systematic Review - [link] - with comment

Pharmacotherapy
- Analysis of Fentanyl Pharmacokinetics, and its Sedative Effects and Tolerance in Critically-Ill Children - [link]

Public Library of Science (PLOS)
- Dose-dependent oral glucocorticoid cardiovascular risks in people with immune-mediated inflammatory diseases: A population-based cohort study - [link]

Therapeutics and Clinical Risk Management
- Potentially Inappropriate Prescriptions to Older Patients in Emergency Departments in South Korea: A Retrospective Study - [link]

TAG Mail – 18 Feb 2021

COVID-19 RESOURCES & ARTICLES OF INTEREST
Please click this [link] for the cumulative listing of COVID-19 resources in past TAG Mails.

AUSTRALIAN

Australian Government Department of Health
- ATAGI clinical guidance on COVID-19 Vaccine in Australia in 2021 - [link]
- ATAGI immunisation provider guide to obtaining informed consent for COVID-19 vaccine - [link]
- Stakeholder pack for multicultural audiences with information on COVID-19 vaccines - [link]

National COVID-19 Clinical Evidence Taskforce
- New and Updated recommendations as at 11/02/2021
-- New: Oestrogen-containing therapies (combination of two existing recommendations)
-- Updated: Bamlanivimab, Colchicine, Ivermectin, Tocilizumab

**NSW Health Critical Intelligence Unit**
- Mental health models to support children and young people 10/02/2021 - [link](#)

**TGA**
- TGA provisionally approves AstraZeneca’s COVID-19 vaccine - [link](#)
- Testing of face masks and respirators - [link](#)

**INTERNATIONAL**

**Organisation for Economic Co-operation and Development (OECD)**
- Strengthening the frontline: How primary health care helps health systems adapt during the COVID 19 pandemic - [link](#)

**International Medication Safety Network (ISMN)**
- 2021 – The IMSN Covid-19 Vaccine Safety initiative - [link](#)

**WHO**
- COVID-19 vaccination: supply and logistics guidance: interim guidance, 12 February 2021 - [link](#)
- The Oxford/AstraZeneca COVID-19 vaccine: what you need to know - [link](#)
- Interim recommendations for use of the AZD1222 (ChAdOx1-S (recombinant)) vaccine against COVID-19 developed by Oxford University and AstraZeneca - [link](#), supporting background paper- [link](#)
- COVID-19 Weekly Epidemiological Update as of 7/2/2021 - [link](#)
- Sustaining lives and livelihoods: a decision framework for calibrating social and movement measures during the COVID-19 pandemic - [link](#)

**Europe**

**EMA**
- Highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 8-11 Feb 2021 - [link](#)
  -- Use of remdesivir is not associated with kidney problems
  -- New safety signal procedure with Remdesivir
- EMA starts rolling review of CureVac’s COVID-19 vaccine (CVnCoV) - [link](#)
- Application received for conditional marketing authorisation of COVID-19 Vaccine Janssen - [link](#)

**UK**

**MHRA**
- Coronavirus vaccine - weekly summary of Yellow Card reporting. Updated 11 February 2021- [link](#)
**NICE**
- Updated COVID-19 rapid guidelines:
  --- Critical care in adults ([NG159](#))
  --- Delivery of systemic anticancer treatments ([NG161](#))
  --- Delivery of radiotherapy ([NG162](#))
  --- Haematopoietic stem cell transplantation ([NG164](#))
**Public Health England**
- The Green Book: COVID-19 vaccination information for public health professionals chapter update
- Specialist Pharmacy Services NHS UK
- Preparing and administering COVID-19 Vaccines guidance - [link](#)
- Planning access to end of life care medicines out-of-hospital during a pandemic - [link](#)

**USA**

**American Society of Health-System Pharmacists (ASHP)**
- ASHP discussion forum ([Sign up](#) for free) recent topics of discussion include: Timing of vaccine with renal dialysis; Vaccine Drive-Through Clinic; and others
- Centers for Disease Control and Prevention (CDC)
- COVID-19 Vaccination Intent, Perceptions, and Reasons for Not Vaccinating among Groups Prioritized for Early Vaccination - United States, September and December 2020 - [link](#)
- Interim Infection Prevention and Control Recommendations for Healthcare Personnel during the Coronavirus Disease 2019 (COVID-19) Pandemic (updated) - [link](#)
-- Interim Guidance on Duration of Isolation and Precautions for Adults with COVID-19 (updated) - link
-- Essential Workers COVID-19 Vaccine Toolkit (updated) - link
-- Vaccination Considerations for People who are Pregnant or Breastfeeding (updated) - link

JOURNAL ARTICLES

American Journal of Health-System Pharmacy (AJHP)
- Leveraging pharmacists to maintain and extend buprenorphine supply for opioid use disorder amid COVID-19 pandemic - link
- The usefulness of an ambulatory care pharmacy performance dashboard during the COVID-19 pandemic in a complex tertiary care system - link
- Adapting ambulatory care learning environments in response to the COVID-19 pandemic - link

Arthritis & Rheumatology
- American College of Rheumatology Clinical Guidance for Multisystem Inflammatory Syndrome in Children Associated With SARS-CoV-2 and Hyperinflammation in Pediatric COVID-19: Version 2

Australasian Psychiatry
- Burnout and psychological distress amongst Australian healthcare workers during the COVID-19 pandemic - link

Australian Health Review
- Use of telehealth mental health services during the COVID-19 pandemic - link
- Virtual models of chronic disease management: lessons from the experiences of virtual care during the COVID-19 response - link

BMJ
- Early initiation of prophylactic anticoagulation for prevention of coronavirus disease 2019 mortality in patients admitted to hospital in the United States: cohort study - link

BMJ ADC Fetal & Neonatal edition
- SARS-CoV-2 genome and antibodies in breastmilk: a systematic review and meta-analysis - link

BMJ Archive of Disease in Childhood
- Clinical characteristics, treatment and outcomes of paediatric COVID-19: a systematic review and meta-analysis - link

BMJ Medical Ethics
- Vaccine ethics: an ethical framework for global distribution of COVID-19 vaccines - link

BMJ Quality and Safety
- Viewpoint: Rethinking standardised infection rates and risk adjustment in the COVID-19 era - link
- Mortality and pulmonary complications in patients undergoing upper extremity surgery at the peak of the SARS-CoV-2 pandemic in the UK: a national cohort study - link

Clinical Orthopaedics and Related Research
- How Satisfied Are Patients and Surgeons with Telemedicine in Orthopaedic Care During the COVID-19 Pandemic? A Systematic Review and Meta-analysis - link

Cochrane
- Chloroquine or hydroxychloroquine for prevention and treatment of COVID-19 - link

Eurosurveillance
- Impact of age, ethnicity, sex and prior infection status on immunogenicity following a single dose of the BNT162b2 mRNA COVID-19 vaccine: real-world evidence from healthcare workers, Israel, December 2020 to January 2021 - link

International Journal of Environmental Research and Public Health
- Hospital-Acquired SARS-Cov-2 Infections in Patients: Inevitable Conditions or Medical Malpractice? - link
International Journal of Nursing Studies
- Estimating the burden of COVID-19 on the Australian healthcare workers and health system during the first six months of the pandemic - [link]

JAMA
- Viewpoint: Involving Pregnant Individuals in Clinical Research on COVID-19 Vaccines - [link]
- Effect of High-Dose Zinc and Ascorbic Acid Supplementation vs Usual Care on Symptom Length and Reduction among Ambulatory Patients with SARS-CoV-2 Infection. The COVID A to Z Randomized Clinical Trial - [link]
- Insights: Reports of Anaphylaxis after Receipt of mRNA COVID-19 Vaccines in the US- 14/12/20- to 18/1/21 - [link]
- Perspectives: Researchers Investigate What COVID-19 Does to the Heart - [link]
- Effect of a Single High Dose of Vitamin D3 on Hospital Length of Stay in Patients With Moderate to Severe COVID-19 - A Randomized Clinical Trial; Editorial

JAMIA (Journal of the American Medical Informatics Association)
- Biomedical and health informatics approaches remain essential for addressing the COVID-19 pandemic - [link]

Journal of Hepatology
- EASL position paper on the use of COVID-19 vaccines in patients with chronic liver diseases, hepatobiliary cancer and liver transplant recipients - [link]

Kidney International Reports
- Systematic review of safety and efficacy of COVID-19 vaccines in patients with kidney disease

Lancet
- Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment - [link]
- Association between Clinical Frailty Scale score and hospital mortality in adult patients with COVID-19 (COMET): an international, multicentre, retrospective, observational cohort study - [link]

medRxiv
- Pre-print: Estimating real-world COVID-19 vaccine effectiveness in Israel - [link]
- Pre-print: Tocilizumab in patients admitted to hospital with COVID-19 (RECOVERY): preliminary results of a randomised, controlled, open-label, platform trial

Molecular Therapy
- Allergic Reactions and Anaphylaxis to LNP-Based COVID-19 Vaccines - [link]

Nature
- mRNA vaccine-elicited antibodies to SARS-CoV-2 and circulating variants - [link]
- Letter: COVID vaccines and safety: what the research says - [link]

Nature Communications
- Methodological quality of COVID-19 clinical research - [link]
- Potential health & economic impacts of dexamethasone treatment for patients with COVID-19 - [link]

New England Journal of Medicine
- Antibody Status and Incidence of SARS-CoV-2 Infection in Health Care Workers - [link]
- Repurposed Antiviral Drugs for Covid-19 - Interim WHO Solidarity Trial Results - [link]
- Case vignette: Delayed Second Dose versus Standard Regimen for Covid-19 Vaccination - [link]

Pediatrics
- Case Report: Remestemcel-L Therapy for COVID-19-Associated Multisystem Inflammatory Syndrome in Children - [link]
- Factors Associated With Severe SARS-CoV-2 Infection - [link]

PROSPERO - International prospective register of systematic reviews
REPORTS AND PUBLICATIONS – AUSTRALIA

AHHA
- The Health Advocate – February 2021
-- This issue focuses on closing the gap and features the following: Rapid Service design and Cultural Safety, Ask the Specialists: a Cultural Education Podcast, Co-design in Oral Health, Learning through healing

Australian Commission on Safety and Quality in Health Care (ACSQHC)
- Commission eNews (Summer Edition) – link
-- This issue includes: Safer naming, labelling, selection and storage of medicines, Making every colonoscopy count, New Antimicrobial Stewardship Clinical Care Standard, Antimicrobial stewardship for children, Reducing the rates – venous thromboembolism, Cognitive impairment consumer rights in 10 languages, National Clinical Trials Governance Framework

Australian Institute for Health and Welfare (AIHW)
- Eye health- link

PBS
- Public consultation on the post-market review of medicines for smoking cessation - link

TGA
- AusPARs:
  -- Inqovi 35/100 (Decitabine and cedazuridine) - for adult patients with myelodysplastic syndromes intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups, and patients with chronic myelomonocytic leukaemia.
  -- Australian prescription medicine decision summaries:
  -- Poteligeo (Mogamulizumab) - adult patients (≥ 18 years of age) with mycosis fungoides or Sézary syndrome who have received at least one prior systemic therapy.

REPORTS AND PUBLICATIONS – INTERNATIONAL

Agency for Healthcare Research and Quality (AHRQ) USA
- Evidence on Use of Clinical Reasoning Checklists for Diagnostic Error Reduction - link
- Telediagnosis for Acute Care: Implications for the Quality and Safety of Diagnosis - link
- Health Information Technology for Engaging Patients in Diagnostic Decision Making in Emergency Departments - link
- Integrating Palliative Care in Ambulatory Care of Noncancer Serious Chronic Illness: A Systematic Review - link

ECRI
“2021 Top 10 Health Technology Hazards,” focusing on potential risk areas and problems that can be avoided - link

Food and Drug Administration (FDA) USA
- Botox (Onabotulinum toxin A) – additional indication: for neurogenic detrusor overactivity in pediatric patients ≥ 5 years of age with inadequate response to or intolerant of anticholinergic medication
- Entresto (sacubitril/valsartan) granted expanded indication in chronic heart failure
- New Drug approvals:
  -- Cosela (trilaciclib) - to reduce bone marrow suppression caused by chemotherapy.
  -- Regeneron (Evkeeza) - for homozygous familial hypercholesterolemia.
  -- Cemiplimab (Libtayo) - for locally advanced and metastatic Basal Cell Carcinoma.

**Medicines and Healthcare products Regulatory Agency (MHRA)**
- Guidance on applying human factors to medical devices - [link]
- Valproate use by women and girls (updated) - [link]
- New partnership pledges clear and consistent evidence-based guidance on medicines for pregnant and breastfeeding women - [link]
- Medicines in Pregnancy Registry: Valproate use in females aged 0 to 54 in England (April 2018 to September 2020) [link]

**Public Health England**
- Ultrasound gel: good infection prevention practice guidance - [link]
- Patient group direction templates for: MenB risk groups - [link], MenB vaccine (Bexsero®) - [link]

**Specialist Pharmacy Services NHS UK**
- Updated national Patient Group Direction: Pre-Exposure Prophylaxis (PrEP) for the prevention of HIV infection - [link]

**The National Academies Press**
- Diagnosing and Treating Adult Cancers and Associated Impairments - [link]

**World Health Organisation (WHO)**
- Guidelines on the management of chronic pain in children - [link]

**MEDICATION SAFETY**

**Electronic Medicines Compendium (eMC) (UK)**
- Revised SPCs
  -- Aubagio (teriflunomide) - updated with further information on cases of drug-induced liver injury (frequency unknown), drug reaction with eosinophilia and systemic symptoms (frequency uncommon) and updated liver monitoring with concomitant potentially hepatotoxic drugs.
  -- Keytruda (pembrolizumab) - now licensed as monotherapy for the first line treatment of metastatic microsatellite instability high or mismatch repair deficient colorectal cancer in adults.
  -- Tivicay (dolutegravir) dispersible tablets - new formulation available for HIV in patients aged ≥ 24 weeks and weighing ≥ 3 kg, or for those in whom film-coated (FC) tablets are not appropriate. The bioavailability of dispersible tablets and FC tablets is not comparable.
  -- Depefex (venlafaxine hydrochloride) – all strengths - updated to include risk of serotonin syndrome especially if taken with other serotonergic agents; and that suicide/suicidal thoughts & aggression have been observed during changes in venlafaxine dosing regimen, including during discontinuation.
  -- Eldepryl (selegiline hydrochloride) - all strengths - updated to include risk of serotonin syndrome with concomitant administration of selegiline hydrochloride and buprenorphine/opioids, which may result in a potentially life-threatening condition.
- Risk minimisation materials:
  -- Imnovid (pomalidomide) capsules - various materials to support the safe prescribing and dispensing of pomalidomide, including information about the Pregnancy Prevention Programme
  -- Pro-Epanutin (fosphenytoin) - two dosing aids with equations and a dosing table available to determine the appropriate loading dose in adults and children.
- Bendamustine - updated with information on cases of progressive multifocal leukoencephalopathy following use mainly in combination with rituximab or obinutuzumab. Increased risk for non-melanoma skin cancers also added - periodic skin examination recommended for all patients

**EMA**
- Highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 8-11 Feb 2021 -[link]
-- Includes new Safety Information for Healthcare Professionals:
--- Strimvelis (autologous CD34+ enriched cell fraction): Long-term follow-up due to risk of cancer
--- Venclyxto (venetoclax): New measures for minimising the risk of tumour lysis syndrome
--- Zolgensma (onasemnogene abeparvovec): recommendations to manage risk of thrombotic microangiopathy.

NSW Health
- Safety Notice 002/21 - Variability in oxygen delivery with bag valve masks Absence of a valve to prevent air entrainment during spontaneous ventilation - link

TGA
- Ergometrine maleate injection (500 microgram/mL) ampoule - Alternative product approved for expected shortage. Advice for health professionals of important differences between the alternative product and the Australian registered product e.g. the alternative product uses a different name to identify the active ingredient and is a different concentration to the Australian registered product.
- Recall: Various medicines containing Artemisia annua and Artemisia absinthium. Recalls due to unacceptable risk in pregnancy.
- Sertraline shortage: shortages of multiple brands of sertraline 50 mg and 100 mg tablets; expected to last until late February and possibly April 2021. Serious Shortage Medicine Substitution Notice.

PAPERS OF INTEREST

American Journal of Health-System Pharmacy (AJHP)
- A strategic approach to improving pharmacy enterprise automation: Development and initial application of the Autonomous Pharmacy Framework - link
- Imipenem/cilastatin/relebactam: A new carbapenem β-lactamase inhibitor combination - link
- Tools and tactics for post discharge medication management interventions - link
- A clinical focus on the use of extended-duration thromboprophylaxis in medically ill patients - link
- Accuracy and safety of medication histories obtained at the time of intensive care unit admission of delirious or mechanically ventilated patients - link

Annals of Internal Medicine
- Safety and Efficacy of Checkpoint Inhibition in Patients with Melanoma and Preexisting Autoimmune Disease. A Cohort Study - link
- Annals for Hospitalists Inpatient Notes - Identifying High-Risk Patients with Syncope - What Hospitalists Need to Know - link

Australian Health Review
- Australia’s persistently high rate of early-term prelabour Caesarean delivery - link

British Journal of Clinical Pharmacology
- Review: Improving anticoagulation in sub-Saharan Africa – what are the challenges, and how can we overcome them? - link
- Population Pharmacokinetics and Pharmacodynamics of Tranexamic Acid in Women Undergoing Cesarean Delivery - link
- Pilot drug and therapeutic committee programme in Sierra Leone: A descriptive mixed method study - link
- Inhibition of interleukin 6 signalling and renal function: A Mendelian randomization study - link
- Nitrous oxide induced neurotoxicity: a case report and literature review - link

British Journal of General Practice
- Nortriptyline for pain in knee osteoarthritis in general practice: a double blind randomised controlled trial - link

British Medical Journal (BMJ)
- Association between antihypertensive treatment and adverse events: systematic review and meta-analysis - link
- Association between use of macrolides in pregnancy and risk of major birth defects: nationwide, register based cohort study - link
- Association of first trimester prescription opioid use with congenital malformations in the offspring: population based cohort study - [link]  

**BMJ Heart**  
- Preventing cardiovascular disease among sexual and gender minority persons - [link]  
- Review: Aortitis: recent advances, current concepts and future possibilities - [link]  
- Comparative effectiveness of oral anticoagulants in everyday practice - [link]  
- Cardiac channelopathies: diagnosis and contemporary management - [link]  

**BMJ Open**  
- Insufficient iodine nutrition status and the risk of pre-eclampsia: a systemic review and meta-analysis - [link]  
- Different doses of prucalopride in treating chronic idiopathic constipation: a meta-analysis and Bayesian analysis - [link]  
- Sepsis in patients with haematological versus solid cancer: a retrospective cohort study - [link]  
- Direct oral anticoagulants in treatment of cerebral venous thrombosis: a systematic review - [link]  

**BMJ Quality and Safety**  
- Systematic review and meta-analysis of interventions for operating room to intensive care unit handoffs - [link]  

**Circulation**  
- Effect of empagliflozin on left ventricular volumes in patients with type 2 diabetes, or prediabetes, and heart failure with reduced ejection fraction (SUGAR-DM-HF) - [link]  
- Blood Pressure Effects of Sodium Reduction: Dose-Response Meta-Analysis of Experimental Studies - [link]  
- Comparison of the Efficacy and Safety Outcomes of Edoxaban in 8040 Women Versus 13 065 Men with Atrial Fibrillation in the ENGAGE AF-TIMI 48 Trial - [link]  

**Cochrane**  
- Antidepressants for functional abdominal pain disorders in children and adolescents - [link]  
- Topical versus systemic antibiotics for chronic suppurative otitis media - [link]  
- Anticholinergics combined with alpha-blockers for treating lower urinary tract symptoms related to benign prostatic obstruction - [link]  
- Antidepressant treatment for postnatal depression - [link]  
- The effectiveness and adverse effects of D-cycloserine compared with placebo on social and communication skills in individuals with autism spectrum disorder - [link]  
- Aldosterone antagonists for people with chronic kidney disease requiring dialysis - [link]  

**EClinical Medicine**  
- Intramuscular midazolam, olanzapine, or haloperidol for the management of acute agitation: A multi-centre, double-blind, randomised clinical trial - [link]  

**European Journal of Hospital Pharmacy**  
- Outcomes of Clostridioides difficile infection in adult cancer and non-cancer patients hospitalised in a tertiary hospital: a prospective cohort study - [link]  

**Expert Opinion on Pharmacotherapy**  
- Review: Wrong administration route of medications in the domestic setting: a review of an underestimated public health topic - [link]  

**Health Research Policy and Systems**  
- Exploring the theory, barriers and enablers for patient and public involvement across health, social care and patient safety: a systematic review of reviews - [link]  

**Heart**  
- Review: Chronic kidney disease detection, staging and treatment in cardiovascular disease prevention - [link]  
- Review: Vaping and cardiac disease - [link]
- Recreational substance use among patients with premature atherosclerotic cardiovascular disease - [link]

**International Journal of Clinical Pharmacy**
- Reducing corticosteroid phobia in pharmacy staff and parents of children with atopic dermatitis - [link]
- Uptake of biosimilars for TNF-α inhibitors adalimumab and etanercept following the best-value biological medicine initiative in Ireland - [link]

**JAMA**
- Viewpoint: Continued increases in overdose deaths related to synthetic opioids; Implications for clinical practice - [link]

**JAMA Cardiology**
- Time to clinical benefit of dapagliflozin and significance of prior heart failure hospitalization in patients with heart failure with reduced ejection fraction - [link]

**JAMA Network Open**
- Clinical characteristics and outcomes associated with oral anticoagulant use among patients hospitalized with intracerebral hemorrhage - [link]
- Projected estimates of opioid mortality after community-level interventions - [link]
- Effect of a coordinated community and chronic care model team intervention vs usual care on systolic blood pressure in patients with stroke or transient ischemic attack - The SUCCEED Randomized Clinical Trial - [link]
- Effects of tai chi or exercise on sleep in older adults with insomnia - A Randomized Clinical Trial - [link]
- Trends over time in use of non-recommended tests and treatments since publication of the American Academy of Pediatrics Bronchiolitis Guideline - [link]
- Assessment of interprofessional collaborative practices and outcomes in adults with diabetes and hypertension in primary care. a systematic review and meta-analysis - [link]
- Systematic evaluation of state policy interventions targeting the US opioid epidemic, 2007-2018 - [link]
- Assessment of Food and Drug Administration– and European Medicines Agency–Approved systemic oncology therapies and clinically meaningful improvements in quality of life. A systematic review - [link]
- Effect of levothyroxine therapy on the development of depressive symptoms in older adults with subclinical hypothyroidism - an ancillary study of a randomized clinical trial - [link]

**JAMA Neurology**
- Association of Glycolysis-Enhancing α-1 Blockers with Risk of Developing Parkinson Disease - [link]
- Viewpoint: Possible Consequences of the Approval of a Disease-Modifying Therapy for Alzheimer Disease - [link]

**JAMA Psychiatry**
- Individual Differences in Response to Antidepressants. A Meta-analysis of Placebo-Controlled Randomized Clinical Trials - [link]

**JAMIA (Journal of the American Medical Informatics Association)**
- Machine learning–based outcome prediction and novel hypotheses generation for substance use disorder treatment - [link]
- Association between evidence-based training and clinician proficiency in electronic health record use - [link]

**Journal of Patient Safety**
- Knowledge, attitudes, and expectations of Medical Staff toward Medical Error Management Policies in Humanitarian Medicine. A Qualitative Study - [link]

**Journal of Palliative Medicine**
- Low-dose trazodone for delirium in patients with cancer who received specialist palliative care: A multicenter prospective study - [link]

**Lancet**
- QT effects of bedaquiline, delamanid, or both in patients with rifampicin-resistant tuberculosis: a phase 2, open-label, randomised, controlled trial - link
- Long-term safety and efficacy of tezacaftor–ivacaftor in individuals with cystic fibrosis aged 12 years or older who are homozygous or heterozygous for Phe508del CFTR (EXTEND): an open-label extension study - link
- Prevalence and risk factors for cisplatin-induced hearing loss in children, adolescents, and young adults: a multi-institutional North American cohort study - link
- Global guideline for the diagnosis and management of rare mould infections: an initiative of the European Confederation of Medical Mycology in cooperation with the International Society for Human and Animal Mycology and the American Society for Microbiology - link
- Review: Menstrual migraine: a distinct disorder needing greater recognition - link

**Molecular Diversity Preservation International (MDPI) – Pharmacy Journal**
- The contribution of pharmacists and pharmacy technicians to person-centred care within a medicine’s optimisation in care homes service: a qualitative evaluation - link
- Implementation of a teaching electronic medical record within didactic instruction using a drug information question assignment - link
- Using technology-supported transfer of care systems: informing good practice recommendations - link

**National Institute for Health Research (NIHR) Signals**
-- Physiotherapist-led exercise eases shoulder pain but ultrasound guidance for injections makes no difference, study finds - link
-- An innovative swallowable sponge detects Barrett’s oesophagus in people with heartburn, study shows - link
-- Men who have sex with men are less likely to use drugs to prevent HIV if they are young, unemployed or have a low disposable income, research finds - link

**New England Journal of Medicine**
- Once-weekly semaglutide in adults with overweight or obesity - link
- Randomized trial of a vaccine regimen to prevent chronic hcv infection - link
- Lenvatinib plus pembrolizumab or everolimus for advanced renal cell Carcinoma – link
- Enfortumab vedotin in previously treated advanced urothelial carcinoma – link
- Avacopan for the treatment of ANCA-associated vasculitis – link

**Pain**
- Assessing reasons for decreased primary care access for individuals on prescribed opioids. An audit study - link

**Pediatric Quality and Safety**
- A quality improvement learning collaborative for human papillomavirus vaccination - link
- Improving preventive care for children with sickle cell anemia: a quality improvement initiative - link
- delayed antibiotic prescription for children with respiratory infections: A randomized trial - link

**Pharmacotherapy**
- Food effects on the formulation, dosing, and administration of cannabidiol (cbd) in humans: a systematic review of clinical studies - link
- Prophylactic norepinephrine infusion for postspinal anesthesia hypotension in patients undergoing cesarean section: a randomized, controlled, dose-finding trial - link
- Use of psychiatric medication by college students: A decade of data - link

**Public Library of Science (PLOS)**
- Comparative effect of physical exercise versus statins on improving arterial stiffness in patients with high cardiometabolic risk: A network meta-analysis - link

**PLOS ONE**
- Heat-stability study of various insulin types in tropical temperature conditions: New insights towards improving diabetes care - link

**Thrombosis Research**
- Prediction models for recurrence and bleeding in patients with venous thromboembolism: A systematic review and critical appraisal - [link](#)

## TAG Mail – 11 Feb 2021

### COVID-19 RESOURCES & ARTICLES OF INTEREST

Please click this [link](#) for the cumulative listing of COVID-19 resources in past TAG Mails.

#### AUSTRALIAN

**Australian Government Department of Health**
- Australian Health Protection Principal Committee (AHPPC) updated statement on minimising the potential risk of COVID-19 transmission in schools - [link](#)
- Australia’s vaccination strategy - [link](#)
- Minimising the risk of infectious respiratory disease transmission in the context of COVID-19: the hierarchy of controls - [link](#)
- COVID-19 National Incident Room Surveillance Team:
  - Epidemic Report 34 - reporting period [ending 31 January 2021](#); technical [supplement](#)

**Australasian Society of Clinical Immunology and Allergy (ASCIA)**
- Allergy, Immunodeficiency, Autoimmunity and COVID-19 Vaccination Position Statement - [link](#), FAQ - [link](#)

**NSW Health Critical Intelligence Unit**
- Emerging evidence about COVID-19 vaccines evidence check (update 5/2/21) - [link](#)
- SARS-CoV-2 variants evidence check (update 5/2/21) - [link](#)
- Self-collected and saliva test evidence check 8/2/21 - [link](#)
- 10 Feb 2021 - Risk Monitoring [Dashboard](#)

**Royal Australian College of General Practitioners**
- COVID-19 vaccine information for GPs - [link](#)

**Society of Hospital Pharmacists of Australia (SHPA)**
- Webinar: Global challenges with COVID-19 vaccines - 7pm AEDT, Thurs 25 February - [link](#)

**TGA**
- COVID-19 vaccine safety monitoring and reporting - [link](#)

#### INTERNATIONAL

**Organisation for Economic Co-operation and Development (OECD)**
- Policy Responses to Coronavirus (COVID-19) vaccines for developing countries: An equal shot at recovery - [link](#)

**WHO**
- Definition and categorization of the timing of mother-to-child transmission of SARS-CoV-2: scientific brief, 8 February 2021 - [link](#)
- Community needs, perceptions and demand: community assessment tool: a module from the suite of health service capacity assessments in the context of the COVID-19 pandemic: interim guidance, 5 February 2021 - [link](#)
- Operational guidance: legal and regulatory framework facilitating vaccine deployment - [link](#)
- WHO's Science in 5 on COVID-19: [Vaccine myths vs science](#) 5 February 2021.
- Different types of COVID-19 vaccines - [link](#)
- WHO launches pilot [social listening tool for COVID-19](#) - platform analyses people's questions and concerns in 20 countries to help ensure they receive accurate and understandable health information
- Online vaccination training for health workers - free 3-hour course to ensure safe and efficient COVID-19 vaccine administration - [link](#)
- 10 steps to community readiness: what countries should do to prepare communities for a COVID-19 vaccine, treatment or new test, 8 February 2021 - [link](#)
- Data for action: achieving high uptake of COVID-19 vaccines: gathering and using data on the behavioural and social drivers of vaccination: a guidebook for immunization programmes and implementing partners: interim guidance, 3 February 2021 - link
- Conducting community engagement for COVID-19 vaccines: interim guidance, 31 January 2021

Canada
Health Canada – MedEffect Notice
- Pfizer-BioNTech COVID-19 Vaccine: Updated Dosage and Administration and Post-Market Adverse Reaction Information - link

Europe
EMA
- EMA reviewing data on monoclonal antibody use for COVID-19 - link
- EMA starts rolling review of Novavax’s COVID-19 vaccine (NVX-CoV2373) - link

UK
- Department of Health and Social Care
-- World-first COVID-19 alternating dose vaccine study launches in UK - link
- NHS England SPS
-- Suitability for COVID-19 vaccination based on prior allergy or current dietary practices - link
- MHRA
-- Latest monitoring data confirms safety of COVID-19 vaccines - link
-- Report: Coronavirus (COVID-19) vaccine adverse reactions - link
-- Interleukin-6 inhibitors (tocilizumab and sarilumab) for critically ill patients with COVID-19 pneumonia (adults) - link
- Public Health England
-- COVID-19 vaccination programme: Information for healthcare practitioners (updated) - link
- Scottish Intercollegiate Guideline Network (SIGN) UK
-- Evidence Review: Assessment of COVID-19 in primary care: the identification of symptoms, signs, characteristics, comorbidities and clinical signs in adults, children and young people, which may indicate a higher risk of progression to severe disease - link
- Specialist Pharmacy Services NHS UK
-- Summary of COVID-19 medicines guidance (updated): Respiratory disorders
- The Kings Fund
-- Covid-19 recovery and resilience: what can health and care learn from other disasters? - link
-- Resources: Leading through Covid-19: supporting health & care leaders in unprecedented times

USA
- American Society of Health-System Pharmacists (ASHP)
-- ASHP discussion forum (Sign up for free) recent topics of discussion include: sharing of different suspect vaccines ADR; vaccination cards;
-- Optimizing the Preparation and Administration of COVID-19 Vaccines (2/4/2021) – link
- Centers for Disease Control and Prevention (CDC)
-- Decline in COVID-19 Hospitalization Growth Rates Associated with Statewide Mask Mandates - 10 States, March-October 2020 - link
-- Demographic Characteristics of Persons Vaccinated during the First Month of the COVID-19 Vaccination Program - United States, December 14, 2020-January 14, 2021 - link
-- Toolkit for Pregnant People and New Parents - link
-- COVID-19 Frequently Asked Questions (updated) - link
-- COVID-19 Vaccine Information for Specific Groups - link
- FDA
-- FDA alerts health care professionals and compounders of potential risks associated with the compounding of remdesivir drug products - link
-- FDA Updates Emergency Use Authorization for COVID-19 Convalescent Plasma to Reflect New Data - link
-- Emergency use authorization (EUA) issued for bamlanivimab and etesevimab administered together for the treatment of mild to moderate COVID-19 in adults and pediatric patients
- ISMP
- COVID-19 Medication Safety Resource Page - link
-The Joint Commission
-- Quick Safety 57: Supporting safe, equitable care during the COVID-19 pandemic - link

JOURNAL ARTICLES
American Journal of Health-System Pharmacy (AJHP)
- Antimicrobial stewardship perspectives from a New York City hospital during the COVID-19 pandemic: Challenges and opportunities - link
- Multicenter point prevalence evaluation of the utilization and safety of drug therapies for COVID-19 at the onset of the pandemic timeline in the United States - link

Annals of Internal Medicine
- Major Update: Remdesivir for Adults with COVID-19: A Living Systematic Review and Meta-analysis for the American College of Physicians Practice Points - link

BMJ
- Why aren't covid-19 vaccines being manufactured in standard prefilled syringes? - link
- Analysis: Put to the test: use of rapid testing technologies for covid-19 - link

Emerging Infectious Diseases
- COVID-19–Associated Pulmonary Aspergillosis, March–August 2020 - link

Environmental Research
- Evaluation of SARS-COV-2 transmission through indoor air in hospitals and prevention methods: A systematic review - link

European Journal of Clinical Pharmacology
- The effect of tocilizumab on mortality in hospitalized patients with COVID-19: a meta-analysis of randomized controlled trials - link

Health Affairs
- Variation In Telemedicine Use And Outpatient Care During The COVID-19 Pandemic In The United States - link

Infection Control & Hospital Epidemiology
- Air contamination of households versus hospital inpatient rooms occupied by SARS-CoV-2 positive patients - link

International Journal of Infectious Diseases
- Incubation period of COVID-19: a meta-analysis - link

JAMA
- Viewpoint: A Viral Pandemic, Vaccine Safety, and Compensation for Adverse Events - link
- Viewpoint: COVID-19 Vaccination in Pregnant and Lactating Women - link
- Research letter: Comparison of Demand for Drugs Used for COVID-19 Treatment and Other Drugs during the Early Phase of the COVID-19 Pandemic in Italy - link
- Assessment of Seroprevalence of SARS-CoV-2 and Risk Factors Associated with COVID-19 Infection among Outpatients in Virginia - link
- Susceptibility to SARS-CoV-2 Infection among Children and Adolescents Compared With Adults A Systematic Review and Meta-analysis - link
- Research letter: Povidone Iodine Mouthwash, Gargle, and Nasal Spray to Reduce Nasopharyngeal Viral Load in Patients with COVID-19. A Randomized Clinical Trial - link

JAMA Health Forum
- Experts Offer Advice to Shore Up Confidence in COVID-19 Vaccines - link

Lancet
- Safety, tolerability, and immunogenicity of an inactivated SARS-CoV-2 vaccine (CoronaVac) in healthy adults aged 60 years and older: a randomised, double-blind, placebo-controlled, phase 1/2 clinical trial - link
- Peginterferon lambda for the treatment of outpatients with COVID-19: a phase 2, placebo-controlled randomised trial - link
- Interleukin-1 and interleukin-6 inhibition compared with standard management in patients with COVID-19 and hyperinflammation: a cohort study - link
- Report: Understanding variants of SARS-CoV-2 - link
- A simple nomogram for predicting failure of non-invasive respiratory strategies in adults with COVID-19: a retrospective multicentre study - link
- COVID-19 vaccine hesitancy in a representative working-age population in France: a survey experiment based on vaccine characteristics - link
- Correspondence: CovMT: an interactive SARS-CoV-2 mutation tracker, with a focus on critical variants - link

Nature Communications
- Rapid decline of neutralizing antibodies against SARS-CoV-2 among infected healthcare workers - link

Nature Podcast
- Coronapod: Variants – what you need to know - link

New England Journal of Medicine
- Covid-19 Vaccine Training: Explore the virology of SARS-CoV-2, mechanism of action of Covid-19 vaccines, the efficacy and safety of currently available Covid-19 vaccines, and the practicalities involved in vaccine administration – Free online course - link
- Commentary: Opportunities for Artificial Intelligence–Enabled Social Media Analysis of Public Attitudes toward Covid-19 Vaccines - link
- Comment: SARS-CoV-2 vaccination and phase 1 cancer clinical trials - link

medRxiv
- Pre-print: Decreased SARS-CoV-2 viral load following vaccination - link
- Pre-print: Poor antigen-specific responses to the second BNT162b2 mRNA vaccine dose in SARS-CoV-2-experienced individuals - link

Postgraduate Medical Journal
- Statin use and clinical outcomes in patients with COVID-19: An updated systematic review and meta-analysis - link

PROSPERO - International prospective register of systematic reviews
- The use of janus kinase inhibitors in hospitalized patients with COVID-19: systematic review and meta-analysis - link

Thorax
- Current smoking and COVID-19 risk: results from a population symptom app in over 2.4 million people - link

REPORTS AND PUBLICATIONS – AUSTRALIA

AHHA
- Evidence Brief No. 22 - Supporting school aged children with Developmental Language Disorder (DLD) - link

Australian Commission on Safety and Quality in Health Care (ACSQHC)
- Active Ingredient Prescribing - link, fact sheet link, prescriber user guide link,
-- List of Medicines for Brand Consideration (LMBC) – link
-- List of Excluded Medicinal Items (LEMI) - link

Australian Institute for Health and Welfare (AIHW)
- Eye health - link

TGA
- AusPARs
  -- Decitabine and cedazuridine (Inqovi 35/100) is indicated for the treatment of adult ps with myelodysplastic syndromes (MDS) intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups, and patients with chronic myelomonocytic leukaemia (CMML)
  - Registration of new or extended uses of registered medicine
  -- Tremfya (guselkumab) for treatment of adult patients with active psoriatic arthritis, who have had an inadequate response to, or are intolerant to prior DMARD therapy.

REPORTS AND PUBLICATIONS – INTERNATIONAL

Agency for Healthcare Research and Quality (AHRQ) USA
- Research Protocol: Management of Infantile Epilepsy - link

Canadian Agency for Drugs and Technologies in Health
- Rapid Response: Hypertonic Saline for the Treatment of Diabetic Ketoacidosis in Children - link

Care Quality Commission (UK)
- Enabling innovation and adoption in health and social care: Developing a shared view - link

electronic Medicines Compendium (UK)
- Licence extensions
  -- Nplate (romiplostim) - for chronic primary immune thrombocytopenia in paediatric patients’ > 1 year of age refractory to other treatments (e.g. corticosteroids, immunoglobulins)
  -- Tivicay (dolutegravir) - paediatric extension. Use in combination with other antiretrovirals, for HIV in children from 6 years old, weighing at least 14kg. New dispersible tablets for children aged ≥ 4 weeks and weighing > 3 kg now available. Elevated bilirubin levels added as rare side-effect.
  -- Doptelet (avatrombopag maleate) - for primary chronic immune thrombocytopenia in adults who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).

European Medicines Agency (EMA)
- Nitrosamine impurities - link

Food and Drug Administration (FDA) USA
- New Drug approvals
  -- Breyanzi (lisocabtagene maraleucel) - for adults with relapsed or refractory Large-B-Cell Lymphoma
  -- Tepmetko (tepotinib) – for non-small cell lung cancer
  -- Ukoniq (umbralisib) – for relapsed or refractory marginal zone lymphoma and relapsed or refractory follicular lymphoma

NHS England
- Managing a healthy weight in adult secure services – practice guidance - link

National Institute for Health and Clinical Excellence (NICE) UK
- Trabectedin for the treatment of advanced soft tissue sarcoma (TA185)
- Leukomed Sorbact for preventing surgical site infection (MTG55)

MEDICATION SAFETY

electronic Medicines Compendium (eMC) (UK)
- Revised SPCs
  -- Indivina (medroxyprogesterone acetate/estradiol valerate) – Large meta-analysis showed that after stopping treatment, excess risk of breast cancer will decrease with time and time needed to return to baseline depends on duration of prior HRT use.
  -- Salofalk (mesalazine) - Stevens-Johnson syndrome and toxic epidermal necrolysis added as adverse effects (unknown frequency).
-- Triumeq (lamivudine/abacavir sulfate/dolutegravir sodium) 50 mg/600 mg/300 mg film-coated tablets - In vitro study found concomitant administration of single dose riociguat (0.5 mg) led to 3-fold higher riociguat levels. Elevated bilirubin levels added as a rare adverse effect.
-- Enbrel (etanercept) - Headache added as an ADR (very common frequency).
-- Ozempic (semaglutide)- updated to incorporate information from a study of semaglutide as add-on to SGLT2 inhibitor treatment (SUSTAIN 9), including efficacy results and safety (rates of hypoglycaemia and gastrointestinal adverse events).
-- Rydapt (midostaurin) – do not use in combination with intensive paediatric AML combination chemotherapy regimens including anthracyclines, fludarabine and cytarabine because of risk of prolonged haematological recovery (e.g. prolonged severe neutropenia and thrombocytopenia).
-- Lamotrigine- added information on photosensitivity reactions. In several cases, the reaction occurred with a high dose (> 400mg), upon dose escalation or rapid up-titration.
-- Sertraline-updated to include information on the risk of developing Serotonin Syndrome or Neuroleptic Malignant Syndrome, including increased risk with concomitant use of other serotonergic medicines.
-- Duloxetine updated to include caution in the elderly, risk of serotonin syndrome when using concomitantly with serotonergic agents. Also details new potential adverse effect of postpartum haemorrhage (unknown frequency)
-- Venlafaxine - a new potential adverse effect of postpartum haemorrhage (unknown frequency).

EMA
- Sorafenib product-specific bioequivalence guidance (update) - link

Food and Drug Administration (FDA) USA
- Tofacitinib (Xeljanz, Xeljanz XR):
  -- Initial safety trial results find increased risk of serious heart-related problems and cancer - link
  -- FDA approves Boxed Warning about increased risk of blood clots and death with higher dose of arthritis and ulcerative colitis medicine tofacitinib - link
  - Product Information (Labelling) safety-related changes:
    -- Lamotrigine –Updated warnings and precautions – In vitro testing showed that lamotrigine exhibits Class IB antiarrhythmic activity at therapeutically relevant concentration. Lamotrigine could slow ventricular conduction (widen QRS) and induce proarrhythmia, including sudden death, in patients with structural heart disease or myocardial ischemia. Recommend avoiding use in patients with cardiac conduction disorders (e.g., second- or third-degree heart block), ventricular arrhythmias, or cardiac disease or abnormality (e.g., myocardial ischemia, heart failure, structural heart disease, Brugada syndrome or other sodium channelopathies). Concomitant use of other sodium channel blockers may increase the risk of proarrhythmia - link; ILAE/AES Task Force Advisory document - link

Institute for Safe Medication Practices (ISMP) USA
- ISMP Identifies Errors with Extended-Release Opioids, Infusion Pumps as among Top Medication Safety Issues in 2020 - link
- Medication Safety Alert! February 11, 2021
  -- Updated Guidance Needed for Longstanding Large Volume Parenteral (LVP) Labeling and Packaging Problems
  -- Cisatracurium mislabeling incident calls for more efficient ways to alert the field
  -- Dosing errors with ENTRESTO
  -- Syringe with trailing zeros

TGA
- Safety information: Resurrection Male Sexual Enhancement capsules pose a serious risk to your health and should not be taken - link

PAPERS OF INTEREST

American Journal of Health-System Pharmacy (AJHP)
- Iodine allergy: Common misperceptions - link
- Fostemsavir: The first oral attachment inhibitor for treatment of HIV-1 infection - link
- Drug information: Atoltivimab, Maftivimab, and Odesivimab-ebgn - link
- The high-value pharmacy enterprise framework: Advancing pharmacy practice in health systems through a consensus-based, strategic approach - link
- Assessment of the impact of an opioid-specific education series on rates of medication-assisted treatment for opioid use disorder in veterans - link
- Brief intervention medication therapy management: Establishment of an opioid misuse intervention model delivered in a community pharmacy - link
- The substance use intervention team: A hospital-based intervention and outpatient clinic to improve care for patients with substance use disorders - link
- Point-of-care naloxone distribution in the emergency department: A pilot study - link

**Annals of Internal Medicine**
- Acute Pancreatitis - link
- Should You Recommend Cannabinoids for This Patient With Painful Neuropathy? Grand Rounds Discussion From Beth Israel Deaconess Medical Center - link

**Arthritis & Rheumatology**
- Review: New Therapeutic Targets in Antineutrophil Cytoplasm Antibody–Associated Vasculitis - link
- Long-Term Outcomes in Patients with Connective Tissue Disease-Associated Pulmonary Arterial Hypertension in the Modern Treatment Era: Meta-Analyses of Randomized, Controlled Trials and Observational Registries - link
- ACR, AAD, RDS, and AAO 2020 Joint Statement on Hydroxychloroquine Use with Respect to Retinal Toxicity - link
- Efficacy and Safety of Tocilizumab for Polyarticular-Course Juvenile Idiopathic Arthritis in the Open-Label Two-Year Extension of a Phase III Trial - link

**Australian Health Review, Journal of the Australian Healthcare & Hospitals Association**
- Developing and piloting an adaptable oxycodone quality improvement strategy: steps towards opioid stewardship - link

**British Journal of Clinical Pharmacology**
- Proton pump inhibitors and risk of all-cause and cause-specific mortality: A cohort study - link
- Comprehensive evaluation of microneedle-based intradermal adalimumab delivery vs. subcutaneous administration: results of a randomized controlled clinical trial - link
- Impact Of Anticoagulant Exposure Misclassification On The Bleeding Risk Of DOACs - link
- A pharmacovigilance study of pharmacokinetic drug interactions using a translational informatics discovery approach - link
- Developing a physiologically based pharmacokinetic model of apixaban to predict scenarios of drug-drug interactions, renal impairment and pediatric populations - link

**British Journal of Psychiatry**
- Effectiveness of exercise-based interventions in reducing depressive symptoms in people without clinical depression: systematic review and meta-analysis of randomised controlled trials - link

**BMC Health Services Research**
- Delivering exceptionally safe transitions of care to older people: a qualitative study of multidisciplinary staff perspectives - link
- Acting between guidelines and reality- an interview study exploring the strategies of first line managers in patient safety work - link

**British Medical Journal (BMJ)**
- Clinical Review: Uveitis for the non-ophthalmologist - link
- Absolute cardiovascular disease risk score and pharmacotherapy at the time of admission in patients presenting with acute coronary syndrome due to coronary artery disease in a single Australian tertiary centre: a cross-sectional study - link
- Use of high dose cyproterone acetate and risk of intracranial meningioma in women: cohort study

**BMJ DTB**
- Republished: Denosumab-induced severe hypocalcaemia in a patient with vitamin D deficiency - link

**BMJ Quality and Safety**
- Adherence to guideline-recommended HbA1c testing frequency and better outcomes in patients with type 2 diabetes: a 5-year retrospective cohort study in Australian general practice - link

Circulation
- Empagliflozin Effects on Pulmonary Artery Pressure in Patients with Heart Failure: Results from EMpagliflozin Evaluation By MeasuRing ImpAct on HemodynamIcs in PatiEnts with Heart Failure (EMBRACE-HF) Trial - link
- Blood Pressure Effects of Canagliflozin and Clinical Outcomes in Type 2 Diabetes and Chronic Kidney Disease: Insights from the CREDENCE Trial - link
- Ablation Versus Drug Therapy for Atrial Fibrillation in Heart Failure: Results from the CABANA Trial - link

Cochrane
- Chemotherapy versus surgery for initial treatment in advanced ovarian epithelial cancer - link
- Salbutamol for transient tachypnea of the newborn - link
- Skin care interventions in infants for preventing eczema and food allergy - link
- Brexipiprazole versus placebo or other antidepressive agents for treating depression - link
- Ozanimod for relapsing-remitting multiple sclerosis - link

Diabetes Care
- Glucose Control, Sulfonylureas, and Insulin Treatment in Elderly People with Type 2 Diabetes and Risk of Severe Hypoglycemia and Death: An Observational Study - link
- Rapid Changes in Serum Testosterone in Men with Newly Diagnosed Type 2 Diabetes with Intensive Insulin and Metformin - link

European Journal of Hospital Pharmacy
- Case Report: An unusual case of piperacillin-tazobactam-induced fever, eosinophilia, thrombocytopenia and liver damage - link

Health Expectations
- How different health literacy dimensions influences health and well-being among men and women: The mediating role of health behaviours - link
- Knowledge sharing to support long-term condition self-management—Patient and health-care professional perspectives - link

Health Technology Assessment
- Enzyme-linked immunosorbent assays for monitoring TNF-alpha inhibitors and antibody levels in people with rheumatoid arthritis: a systematic review and economic evaluation - link

Internal Medicine Journal
- Patterns of azithromycin use in obstructive airway diseases: a real-world observational study - link

International Journal of Clinical Pharmacy
- Potentially inappropriate prescriptions and therapeutic complexity in older HIV patients with comorbidities - link
- Impact of clinical pharmacist services on quality adjusted life years in head and neck cancer patients - link

International Journal for Quality in Health Care
- Time and Predictors of Treatment for Aneurysmal Subarachnoid Haemorrhage (ASA): A Systematic Review - link
- Mitigating Imperfect Data Validity in Administrative Data PSIs: a Method for Estimating True Adverse Event Rates - link

JAMA
- Review: Diagnosis and Treatment of Hip and Knee Osteoarthritis - link

JAMA Internal Medicine
- Risk of Progression to Diabetes among Older Adults with Prediabetes - link
- Teachable moment: The Toxic Effects of an Incomplete Medication History - link
JAMA Network Open
- Association of Rituximab Use with Adverse Events in Children, Adolescents, and Young Adults - link
- Comparison between Non–vitamin K Antagonist Oral Anticoagulants and Low-Molecular-Weight Heparin in Asian Individuals With Cancer-Associated Venous Thromboembolism - link
- Association between Statin use at the Time of Intra-abdominal Surgery and Postoperative Adhesion-Related Complications and Small-Bowel Obstruction - link

JAMA Neurology
- Comparison of Corticosteroid Tapering Regimens in Myasthenia Gravis. A Randomized Clinical Trial - link

JAMA Oncology
- Efficacy of Endocrine Therapy for the Treatment of Breast Cancer in Men. Results from the MALE Phase 2 Randomized Clinical Trial - link

JAMA Pediatrics
- Association between Proton Pump Inhibitor use and risk of Asthma in Children - link

JAMA Surgery
- Early Corticosteroid Cessation vs Long-term Corticosteroid Therapy in Kidney Transplant Recipients. Long-term Outcomes of a Randomized Clinical Trial - link

JAMIA (Journal of the American Medical Informatics Association)
- Advancement in predicting interactions between drugs used to treat psoriasis and its comorbidities by integrating molecular and clinical resources - link
- Moving toward a sociotechnical systems approach to continuous health information technology design: the path forward for improving electronic health record usability and reducing clinician burnout - link

Journal of Clinical Oncology
- Adjuvant Pertuzumab and Trastuzumab in Early HER2-Positive Breast Cancer in the APHINITY Trial: 6 Years' Follow-Up - link

Journal of Patient Safety
- The Association between Health Care Staff Engagement and Patient Safety Outcomes. A Systematic Review and Meta-Analysis - link

Journal of Palliative Medicine
- An Assessment of Emergency Department-Based Interventions for Patients with Advanced or End-Stage Illness: A Systematic Review - link

Journal of Pharmacy Practice and Research (JPPR)
- Interventions to decrease the incidence of dispensing errors in hospital pharmacy: a systematic review and meta-analysis - link
- Review: Pharmacological management of stroke in older people - link
- Review: Carbamazepine, oxcarbazepine, and lacosamide as adjunctive analgesics: a review of the literature - link

Lancet
- Review: Established and novel therapeutic options for autoimmune hepatitis - link
- Posaconazole versus voriconazole for primary treatment of invasive aspergillosis: a phase 3, randomised, controlled, non-inferiority trial - link

Molecular Diversity Preservation International (MDPI) – Pharmacy Journal
- Pharmaceutical Discharge Management: Implementation in Swiss Hospitals Compared to International Guidelines - link
- Application of Standardized Antimicrobial Administration Ratio as a Motivational Tool within a Multi-Hospital Healthcare System - link
- What Is Known about Community Pharmacy-Based Take-Home Naloxone Programs and Program Interventions? A Scoping Review - link
- The Association between Medication Experiences and Beliefs and Low Medication Adherence in Patients with Chronic Disease from Two Different Societies: The USA and the Sultanate of Oman - link

Medical Journal of Australia
- High prevalence of Crohn disease and ulcerative colitis among older people in Sydney - link
- Research Letter: Residential medication management reviews in Australian residential aged care facilities - link

National Institute for Health Research (NIHR) Signals
- Active monitoring in early prostate cancer prevents as many deaths as surgery or radiotherapy, new research shows - link
- A simple checklist reliably identified paranoia in adolescents with mental health problems, research shows - link

New England Journal of Medicine
- Review: Management of Antithrombotic Therapy after Acute Coronary Syndromes - link

Pediatrics
- Improving Influenza Vaccination in Children with Comorbidities: A Systematic Review - link
- Marijuana Use to Address Symptoms and Side Effects by Youth with Chronic Medical Conditions - link

Pediatric Anesthesia
- Outcomes from wake up safe, the pediatric anesthesia quality improvement initiative - link

Pharmacotherapy
- Factors Influencing Antibiotic Duration in Culture-Negative Neonatal Early-Onset Sepsis - link
- Clinical and economic evaluation of a surveillance protocol to manage hepatitis B virus (HBV) reactivation among lymphoma patients with resolved HBV infection receiving rituximab - link
- Association between the timing of asthma diagnosis and medication use during pregnancy - link
- Comparative Effectiveness and Safety of High-Dose Rivaroxaban and Apixaban for Atrial Fibrillation: A Propensity Score-Matched Cohort Study - link
- Influence of Digoxin on Mortality in Patients with Atrial Fibrillation: Overview of Systematic Reviews - link

TAG Mail – 4 Feb 2021

COVID-19 RESOURCES & ARTICLES OF INTEREST
Please click this link for the cumulative listing of COVID-19 resources in past TAG Mails.

AUSTRALIAN
Australian Government Department of Health
- Expression of Interest for primary care participation in Phase 1b COVID-19 vaccine rollout – link
- Community pharmacy COVID-19 vaccine rollout from Phase 2A - link

Australian Prescriber
- COVID-19 vaccines – are we there yet? - link

CEC
- Medication Safety updates (last updated 27 Jan 2021) - link

National COVID-19 Clinical Evidence Taskforce
- New and Updated recommendations as at 29/01/2021
-- New Recommendations: Baricitinib, REGN-COV2, Sarilumab
-- Updated Recommendations: Azithromycin, Tocilizumab, Convalescent plasma (new remark)
-- Taskforce recommendation for tocilizumab unchanged
-- Azithromycin recommendation updated to ‘Do Not Use’

**NSW Health Critical Intelligence Unit**
- 3 Feb 2021 - Risk Monitoring Dashboard - [link]
- Living Evidence - COVID-19 vaccines - [link]
- Living Evidence - SARS-CoV-2 variants - [link]

**TGA**
- Investigation reveals no specific risk of harm from vaccination with the Pfizer-BioNTech COVID-19 vaccine in elderly patients - [link]
- Advice on face masks and gowns during COVID-19 - [link]
- Reuse of face masks and gowns during the COVID-19 pandemic - [link]
- Guidance on medical/surgical face masks and respirator standards – [link]

**INTERNATIONAL**
- International Pharmaceutical Federation (FIP)
  - COVID-19 vaccines: Frequently asked questions: storage, handling and use of COVID-19 vaccines from the manufacturers: Moderna; Pfizer/BioNTech; University of Oxford/AstraZeneca - [link]

**WHO**
- Laboratory biosafety guidance related to coronavirus disease (COVID-19): interim guidance- [link]
- Contact tracing in the context of COVID-19 - [link]
- Risk communication & community engagement for COVID-19 contact tracing: interim guidance - [link]
- WHO public health checklist for controlling the spread of COVID-19 at ground crossings - [link]
- WHO recommends follow-up care, low-dose anticoagulants for COVID-19 patients- [link]

**Europe**
- EMA
  - COVID-19 vaccine safety update – Comirnaty (Pfizer/BioNTech COVID-19 vaccine) - [link]
  - EMA recommends COVID-19 Vaccine AstraZeneca for authorisation in the EU - [link]
  - Treatments and vaccines for COVID-19: authorised medicines - [link]

**UK**
- Arthritis and Musculoskeletal Alliance (UK)
  -- Principles for COVID-19 Vaccination in Musculoskeletal and Rheumatology for Clinicians - [link]
- Care Quality Commission (UK)
  -- Collaboration in urgent and emergency care - [link]
  -- Department of Health and Social Care
    -- Interim Clinical Commissioning Policy
    -- Sarilumab for critically ill patients with COVID-19 pneumonia (adults) - [link]
    -- Tocilizumab for critically ill patients with COVID-19 pneumonia (adults) - [link]
  -- Healthcare Safety Investigation Branch (HSIB)
    -- Interim bulletin: Oxygen issues during the COVID-19 pandemic - [link]
  -- NHS England
    -- Monitoring the quality of care and safety for people with a learning disability and/or people who are autistic in inpatient care - [link]
    -- COVID-19 Therapeutic Alerts
    -- Interleukin-6 inhibitors (tocilizumab or sarilumab) for critically ill patients with COVID-19 pneumonia (adults) - [link]
  -- Public Health England
    -- Guidance for investigating and managing individuals with a possible or confirmed SARS-CoV-2 Variant of Concern - [link]
  -- Specialist Pharmacy Services NHS UK
    -- Giving COVID-19 vaccine to individuals at extremes of bodyweight - [link]
    -- Summary of COVID-19 medicines guidance: Nutritional and inherited metabolic disorders - [link]
USA
- Centers for Disease Control and Prevention (CDC)
  -- Allergic Reactions Including Anaphylaxis after Receipt of the First Dose of Moderna Vaccine - link
  -- COVID-19 Vaccination Toolkits - link
  -- Interim Clinical Considerations
    --- For Use of mRNA COVID-19 Vaccines Currently Authorized in the United States - link
    --- Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination - link
- The Joint Commission
  -- Sentinel Event Alert shares concerns from health care workers during COVID-19 - link

JOURNAL ARTICLES
American Journal of Health-System Pharmacy (AHJP)
- Emergency preparation and mitigation for COVID-19 response in an integrated pharmacy practice model - link

Anaesthesia
- Mortality in patients admitted to intensive care with COVID-19: an updated systematic review and meta-analysis of observational studies - link

Annals of Internal Medicine
- Clinical Decision Making During the COVID-19 Pandemic - link
- ACP journal club
  -- The BNT162b2 (BioNTech/Pfizer) vaccine had 95% efficacy against COVID-19 ≥7 days after the 2nd dose - link
  -- Tocilizumab did not reduce hypoxemic respiratory failure or death in hospitalized patients with COVID-19 - link
  -- In inpatients with COVID-19, none of remdesivir, hydroxychloroquine, lopinavir, or interferon β-1a differed from standard care for in-hospital mortality - link

BMC Infectious Diseases
- Examining Australian public perceptions and behaviours towards a future COVID-19 vaccine - link

BMC Public Health
- Control of COVID-19 in Australia through quarantine: the role of special health accommodation (SHA) in New South Wales, Australia - link

BMJ
- News: Covid-19: People who have had infection might only need one dose of mRNA vaccine - link

British Journal of Clinical Pharmacology
- No association between use of ACE inhibitors or angiotensin II receptor blockers prior to hospital admission and clinical course of COVID-19 in the COvid MEdicaTion (COMET) study - link

Cochrane
- Coronavirus (COVID-19): evidence relevant to critical care - link

Emerging Infectious Diseases
- Post-Vaccination COVID-19 among Healthcare Workers, Israel - link

Frontiers in Medicine
- Face Mask Use in the Community for Reducing the Spread of COVID-19: A Systematic Review - link

Healthcare Quarterly
- Shortages of Palliative Care Medications in Canada during the COVID-19 Pandemic: Gambling with Suffering - link
  - Decontaminating N95 Respirators for Reuse in a Hospital Setting - link

Infectious Diseases
- A systematic review on the recurrence of SARS-CoV-2 virus: frequency, risk factors, and possible explanations - link

International Journal for Quality in Health Care
- Human factors and ergonomics systems approach to the COVID-19 healthcare crisis - link

JAMA
- Association of Intravenous Immunoglobulins plus Methylprednisolone vs Immunoglobulins Alone with Course of Fever in Multi system Inflammatory Syndrome in Children - link
- Viewpoint: Rapid Implementation of a Vaccination Superstation - link
- Viewpoint: SARS-CoV-2 Vaccines and the Growing Threat of Viral Variants - link

Lancet
- Safety and efficacy of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine: an interim analysis of a randomised controlled phase 3 trial in Russia - link
- Assessment, endoscopy, and treatment in patients with acute severe ulcerative colitis during the COVID-19 pandemic (PROTECT-ASUC): a multicentre, observational, case-control study – link
- SARS-CoV-2 persistence is associated with antigen-specific CD8 T-cell responses - link
- Azithromycin in patients admitted to hospital with COVID-19 (RECOVERY): a randomised, controlled, open-label, platform trial - link

Nature Partner Journal Clean Water
- A review of the impact of environmental factors on the fate and transport of coronaviruses in aqueous environments - link

New England Journal of Medicine (NEJM)
- Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine - link
- A Cluster-Randomized Trial of Hydroxychloroquine for Prevention of Covid-19 - link
- Perspective: Vaccine Innovations - Past and Future - link
- Audio Interview: A Covid-19 Conversation with Dr Anthony Fauci - link

New Scientist
- Will vaccines work on new variants? - link

Medical Journal of Australia
- Modelling the impact of relaxing COVID-19 control measures during a period of low viral transmission - link

MedRxiv
- Single Dose Vaccination in Healthcare Workers Previously Infected with SARS-CoV-2 - link

SN comprehensive clinical medicine
- A Systematic Review of Systematic Reviews on the COVID-19 Pandemic - link

Thorax
- Renin-angiotensin system blocker and outcomes of COVID-19: a systematic review and meta-analysis - link

REPORTS AND PUBLICATIONS – AUSTRALIA

Australian Institute for Health and Welfare (AIHW)
- Mental health services in Australia - link
- Australian Institute of Health and Welfare Corporate Plan 2020–21 to 2023–24 - link

TGA
- The Poisons Standard (the SUSMP) updated - link
- AusPARS:
  -- Epidyolex (Cannabidiol) - adjunctive therapy of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome
-- Terrosa (Teriparatide) – for osteoporosis a) in postmenopausal women and primary osteoporosis in men when other agents are considered unsuitable and when there is a high risk of fractures; and b) associated with sustained systemic glucocorticoid therapy in women and men at high risk for fracture
-- Cosentyx (Secukinumab) licence extension for nonradiographic axial spondyloarthritis (nr-axSpA), as part of axial spondyloarthritis (axSpA) with or without radiographic damage
- Australian prescription medicine decision summaries:
  -- Akليف (Trifarotene) cream for acne vulgaris of the face and/or the trunk in patients ≥ 12 years of age, when many comedones, papules and/or pustules are present.

Victorian Institute of Forensic Medicine
- Future Leaders Communiqué Volume 6 Issue 1 January 2021

REPORTS AND PUBLICATIONS – INTERNATIONAL

Agency for Healthcare Research and Quality (AHRQ) USA
- Treatments for Acute Pain: A Systematic Review - link
- Living Systematic Review on Cannabis and Other Plant-Based Treatments for Chronic Pain - link

British National Formulary (BNF) newsletter – January 2021
- New monographs (BNF): acalabrutinib, avatrombopag, mometasone furoate with glycopyrronium bromide and indacaterol, phenazone with lidocaine, and ozanimod.
- New monographs (BNF for Children): cobicistat and darunavir with cobicistat, and phenazone with lidocaine.
- MHRA advice on bupropion hydrochloride, ferric carboxymaltose, modafinil, and pirfenidone

Canadian Agency for Drugs and Technologies in Health
- Rapid Responses:
  -- Tailored Opioid Prescribing after Gynecologic Surgery: Clinical Effectiveness and Guidelines - link
  -- Stellate Ganglion Block for the Treatment Pain - link

electronic Medicines Compendium (eMC) (UK)
- New products
  - Leqvio (inclisiran)- for adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet, either alone or in combination with a statin or statin with other lipid-lowering therapies
  - Licence extension
  -- Tivicay (dolutegravir)- paediatric licence extension. Approved, in combination with other antiretrovirals, for the treatment of HIV in children ≥ 6 years old, weighing at least 14kg. A new dispersible formulation also recently approved in the EU.

European Medicines Agency (EMA)
- European CHMP approval recommendations:
  -- Bedaquiline (Sirturo) - paediatric license extension - as part of an appropriate combination regimen for pulmonary multidrug-resistant tuberculosis in adults and paediatric patients (5 -18 years and weighing ≥ 15 kg) when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability
  -- Bevacizumab (Alymsye and Oyavas) biosimilar
  -- Cenobamate (Ontozry) for adults with epilepsy
  -- Icosapent ethyl (Vazkepa) for cardiovascular events reduction in patients at high cardiovascular risk
  -- Natalizumab (Tysabri) - new strength, pharmaceutical form and route of administration
  -- Ofatumumab (Kesimpta) for active relapsing multiple sclerosis
  -- Pembrolizumab (Keytruda) paediatric license extension- monotherapy for patients aged ≥ 3 years with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option
  -- Pemigatinib (Pemazyre) for second-line treatment of advanced or metastatic cholangiocarcinoma
  -- Remimazolam (Byfavo) for procedural sedation
  -- Salmeterol / fluticasone (BroPair Spiromax and Seffalair Spiromax) for asthma
  -- Selinexor (Nexpovio) for relapsed and refractory multiple myeloma
  -- Somapacitan (Sogroya) for growth hormone deficiency in adults
Health Quality & Safety Commission New Zealand
- National medication chart toolkit, user guide and medication charting standard (updated) - link

Medicines and Healthcare products Regulatory Agency (MHRA)
- Early Access Medicines Scheme (EAMS) scientific opinion: Nivolumab with ipilimumab in the treatment of malignant pleural mesothelioma - link

National Institute for Health and Clinical Excellence (NICE) UK
- Suspected cancer: recognition and referral (NG12)
- Brain tumours (primary) and brain metastases in adults (NG99)
- DOAC Dipstick for detecting direct oral anticoagulants (MIB248)
- Faecal microbiota transplant for recurrent or refractory Clostridioides difficile infection (MIB247)
- Brolucizumab for treating wet age-related macular degeneration – (TA672)
- Mepolizumab for severe eosinophilic asthma – (TA671)

The King’s Fund (UK)
- Innovation in treatment for people with rarer or less well-recognised long-term conditions - link

MEDICATION SAFETY

electronic Medicines Compendium (eMC) (UK)
- Revised SPCs
  -- Rocephin (ceftriaxone) - encephalopathy reported, particularly in elderly patients with severe renal impairment or CNS disorders. If suspected (e.g. decreased level of consciousness, altered mental state), consider discontinuation.
  -- Calcort (deflazacort) - tumour lysis syndrome (TLS) reported in patients with haematological malignancies following use alone or in combination with other chemotherapeutics. Closely monitor patients at high risk of TLS and take appropriate precautions.
  -- Kivexa (abacavir and lamivudine) - updated with new information about the drug-drug interactions between abacavir and riociguat.
  -- Mayzent (siponimod) - Basal cell carcinoma listed as a potential adverse effect of treatment (common frequency), and the warnings/precautions section on cutaneous neoplasms updated.
  -- Enbrel (etanercept) – all products - updated with ADR addition of headache (frequency very common).
  -- Rinvoq (upadacitinib) - updated to include psoriatic arthritis and ankylosing spondylitis as additional licensed indications. Acne, bronchitis, herpes zoster, herpes simplex added as common ADEs.
  -- Bavencio (avelumab) -licence extension, for use as monotherapy for first-line maintenance treatment in locally advanced or metastatic urothelial carcinoma following platinum-based chemotherapy.
  -- Neupro (rotigotine) transdermal patch – all strengths – now includes information on symptoms of dopamine agonist withdrawal syndrome and reference to dopamine dysregulation syndrome, a potential adverse effect.
  -- ViePax XL (Venlafaxine)- notes observational data indicate an increased risk of postpartum haemorrhage following SSRI/SNRI exposure within the month prior to birth. Manufacturers advise to give in pregnancy only if the expected benefits outweigh any possible risk.

Food and Drug Administration (FDA) USA
- Information about Nitrosamine Impurities in Medications - link

Health Canada – MedEffect Notice
- Summary Safety Review:
  -- Sofosbuvir-containing products - potential risk of severe cutaneous adverse reactions - link
- Health Product Infowatch, January 2021
MIMS monthly updates – February 2021
- New Contraindications:
  -- Measles, mumps and rubella live virus vaccine (M-M-R II) should not be given to pregnant females. If vaccination of post-pubertal females is undertaken for protection against rubella, pregnancy should be avoided for one month following vaccination.
  -- Metronidazole (Metronidazole IV Infusion (Pfizer)) contraindicated in patients who have taken disulfiram within the previous two weeks; and with concomitant consumption of alcohol or products containing propylene glycol (or within three days after therapy with metronidazole).
  -- Monobasic sodium phosphate/dibasic sodium phosphate (Phospho-Soda) contraindicated in children under 18 years of age. Should not be used in combination with other laxative products containing sodium phosphate.

TGA
- Safety advisory: Pregabalin and gabapentin - enhanced warnings relating to abuse and dependence

PAPERS OF INTEREST

Annals of Internal Medicine
- The Use of Rifaximin in the Prevention of Overt Hepatic Encephalopathy after Transjugular Intrahepatic Portosystemic Shunt. A Randomized Controlled Trial - link
- ACP journal club
  -- In CKD, dapagliflozin reduced a composite of eGFR decline, end-stage kidney disease, or CV or renal mortality - link
  -- After TAVI, aspirin vs. aspirin + clopidogrel for 3 months reduced bleeding and a composite of bleeding and thrombotic events at 1 year - link
  -- Fluoroquinolones vs. amoxicillin–clavulanate or ampicillin–sulbactam were not linked to aortic aneurysm or dissection - link

Australian Health Review
- Is there unwarranted variation in obstetric practice in Australia? Obstetric intervention trends in Queensland hospitals - link

British Journal of Clinical Pharmacology
- Predicting mortality from acetaminophen poisoning shortly after hospital presentation - link
- Short Report: Atropine-induced toxicity after off-label sublingual administration of eyedrop for sialorrhea treatment in neurological disabled patients - link
- β-blockers associated hypoglycaemia: new insights from a real-world pharmacovigilance study - link
- Pharmacokinetics and Safety of Pegylated Recombinant Human Granulocyte Colony-Stimulating Factor in Children with Acute Leukemia - link
- Drug-induced peripheral edema: an etiology-based review - link
- Change in the regulatory framework for zolpidem: what is the impact on the landscape of the prescription of sedative medications? The French national ZORRO study - link

British Medical Journal (BMJ)
- Association between human papillomavirus vaccination and serious adverse events in South Korean adolescent girls: nationwide cohort study - link
- Therapeutics: Non-steroidal anti-inflammatory drugs (NSAIDs) for musculoskeletal pain - link

BMJ Open
- Changing mindsets about side effects - link

Circulation
- Gestational Diabetes History and Glucose Tolerance after Pregnancy Associated with Coronary Artery Calcium in Women during Midlife: The CARDIA Study - link

Cochrane
- Intermittent fasting for the prevention of cardiovascular disease - link
- Electrocoagulation for liver metastases - link
- Urgent-start peritoneal dialysis versus haemodialysis for people with chronic kidney disease - [link]
- Pulmonary rehabilitation for interstitial lung disease - [link]
- Antibiotics for hospital-acquired pneumonia in neonates and children - [link]
- Psychological therapies delivered remotely for the management of chronic pain (excluding headache) in adults - [link]

**Drug and Therapeutics Bulletin**
- Case Report - Quinidine hypersensitivity: a side effect of a forgotten antiarrhythmic - [link]

**Heart**
- Antiplatelet therapy in patients with myocardial infarction without obstructive coronary artery disease - [link]

**International Journal of Clinical Pharmacy**
- Report: Evaluation of the quality of ‘do not use’ medication abbreviation audits: a key enabler to successful implementation of audit and feedback - [link]
- Prevalence of non-adherence to antihypertensive medication in Asia: a systematic review and meta-analysis - [link]

**JAMA**
- Clinical Challenge: A Purpuric Rash - [link]
- Clinical Guidelines Synopsis - Management of Immunotherapy-Related Toxicities in Patients Treated with Immune Checkpoint Inhibitor Therapy - [link]

**JAMA Network Open**
- Effectiveness of a Female Community Health Volunteer–Delivered Intervention in Reducing Blood Glucose among Adults with Type 2 Diabetes. An Open-Label, Cluster Randomized Clinical Trial - [link]
- Evaluation of THC-Related Neuropsychiatric Symptoms among Adults Aged 50 Years and Older: A Systematic Review and Meta-regression Analysis - [link]

**JAMIA**
- A systematic review of contributing factors of and solutions to electronic health record–related impacts on physician well-being - [link]
- Comparison of an oncology clinical decision-support system’s recommendations with actual treatment decisions - [link]
- Renal medication-related clinical decision support (CDS) alerts and overrides in the inpatient setting following implementation of a commercial electronic health record: implications for designing more effective alerts - [link]

**Journal of Clinical Oncology**
- Neoadjuvant Chemotherapy, Endocrine Therapy, and Targeted Therapy for Breast Cancer: ASCO Guideline - [link]

**Journal of Clinical Oncology**
- Clinical Cancer Advances 2021: ASCO’s Report on Progress Against Cancer - [link]

**Journal of Pharmaceutical Policy and Practice**
- Commentary: Making the investment case for national regulatory authorities - [link]

**Journal of the Society for Simulation in Healthcare**
- Use of Simulation to Measure the Effects of Just-in-Time Information to Prevent Nursing Medication Errors. A Randomized Controlled Study - [link]

**Lancet**
- Long-term safety & efficacy of lumacaftor–ivacaftor therapy in children aged 6–11 years with cystic fibrosis homozygous for the F508del-CFTR mutation: a phase 3, open-label, extension study - [link]
- Chlorhexidine plus alcohol versus povidone iodine plus alcohol, combined or not with innovative devices, for prevention of short-term peripheral venous catheter infection and failure (CLEAN 3 study): an investigator-initiated, open-label, single centre, randomised-controlled, two-by-two factorial trial - [link]
- Review: Management of diabetes and hyperglycaemia in the hospital - link
- Therapeutics targeting the IL-23 and IL-17 pathway in psoriasis - link
- Biliary tract cancer - link
- Multiple myeloma - link
- Treatment of multiple myeloma-related bone disease: recommendations from the Bone Working Group of the International Myeloma Working Group - link
- Use of fibrinolytics and deoxyribonuclease in adult patients with pleural empyema: a consensus statement - link

Medical Journal of Australia
- Research Letter: Complementary medicine use by community-dwelling older Australians - link

National Institute for Health Research (NIHR) Signals
- Mental health problems in complex trauma: the most promising therapies are identified in a new review - link
- Dialysis for acute kidney injury can be safely delayed for many patients - link

New England Journal of Medicine
- Perspective: At the Cusp - Reimagining Infective Endocarditis Care amid the Opioid Epidemic – link, podcast link
- Dexmedetomidine or Propofol for Sedation in Mechanically Ventilated Adults with Sepsis - link
- Management of Antithrombotic Therapy after Acute Coronary Syndromes - link

Oxford Medicine
- Book: The Cognitive Autopsy: A Root Cause Analysis of Medical Decision Making - link

Patient Safety
- Health Information Technology–Related Wrong-Patient Errors: Context is Critical - link

Pediatrics
- Trends in Dispensed Opioid Analgesic Prescriptions to Children in South Carolina: 2010–2017 - link

Pharmaceutical Journal
- Pharmacist contributions to consultant-led post-take ward rounds: a service evaluation - link
- Case study: an error with a medicine containing arachis oil - link
- Case-based learning: shingles - link

Prescrire
- Prescrire International, Issue Number 223 February 2021 - link
-- Review: Ebola vaccine rVSV-Zebov (Ervebo®) in an outbreak of Ebola virus disease. Major reduction in incidence among those at risk for this often-fatal infection - link
-- New Products: Liraglutide, Cemiplimab, Blinatumomab, Osilodrostat, Fremanezumab, LipPEGfilgrastim
- Adverse Effects
-- Smoking cessation: toxic dose levels of certain drugs - link
-- Fluconazole: teratogenic, even with as little as just one 150 mg dose – link
-- Pregabalin abuse and dependence: on the increase in Europe and elsewhere - link
-- Liposomal forms of drugs - link
- Reviews:
-- Deep vein thrombosis and pulmonary embolism - link
-- Deep vein thrombosis or pulmonary embolism: choosing an oral anticoagulant - link
- Outlook: Towards better patient care: drugs to avoid in 2021 - link

Public Library of Science (PLOS)
- Evaluation of oral dextrose gel for prevention of neonatal hypoglycemia (hPOD): A multicenter, double-blind randomized controlled trial - link

Thrombosis and Haemostasis
- Anticoagulant Treatment for Splanchnic Vein Thrombosis in Liver Cirrhosis: A Systematic Review and Meta-Analysis - link
**COVID-19 RESOURCES & ARTICLES OF INTEREST**

Please click this link for the cumulative listing of COVID-19 resources in past TAG Mails.

### AUSTRALIAN

**Australian Commission on Safety and Quality in Health Care**
- COVID-19 Web resources, last updated 4 January 2021 - [link](#)

**Australian Government Department of Health**
- Epidemiology Report 33: Fortnightly reporting period ending 17 January 2021; technical supplement
- Australian Health Protection Principal Committee (AHPPC) statement on COVID-19 and influenza vaccination requirements for aged care workers - [link](#)
- Prime Minister’s update following the National Cabinet meeting on 20 January 2021 - [link](#)
- Coronavirus (COVID-19) at a glance infographic collection - [link](#)

**ACI Critical Intelligence Unit**
- Evidence check: Emerging evidence about COVID-19 vaccines - [link](#)

**Heart Foundation & Australian Cardiovascular Health and Rehabilitation Association (ACRA)**
- Position Statement on Cardiac Rehabilitation: Face-to-face and telehealth delivery options - [link](#)

**Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)**
- COVID-19 Vaccination in Pregnant and Breastfeeding Women (Updated Tue 26 January 2021)

**TGA**
- TGA provisionally approves Pfizer COVID-19 vaccine - [link](#)
- AusPAR: BNT162b2 (mRNA) – COMIRNATY vaccine - Approved for provisional registration
- International Coalition of Medicines Regulatory Authorities (ICMRA) statement for healthcare professionals: How COVID-19 vaccines will be regulated for safety and effectiveness - [link](#)
- Batch release assessment of COVID-19 vaccines - [link](#)
- COVID-19 vaccine: Information for consumers and health professionals - [link](#)
- Reporting suspected side effects associated with a COVID-19 vaccine - [link](#)

### INTERNATIONAL

**WHO**
- Covid-19 vaccines: safety surveillance manual - [link](#)
- Emergency Committee on COVID-19 advises on variants, vaccines - [link](#)
- COVID-19 Clinical management: living guidance, 25 January 2021 - [link](#)
- Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19, Interim guidance, 25 January 2021
- Online global consultation on contact tracing for COVID-19 - [link](#)
- Operational guidance: acceptance and uptake of COVID-19 vaccines, January 2021
- Operational guidance: COVID-19 vaccination data and information management, including monitoring of vaccine effectiveness, January 2021
- Operational guidance: evidence-based decision making process for developing national COVID-19 vaccination strategies, January 2021
- Operational guidance: management structure, advocacy and resources for COVID-19 vaccine deployment and vaccination, January 2021

**UK**
- Action on Smoking and Health (ASH) and Cancer Research UK
-- Report: Stepping up: The response of stop smoking services in England to toe COVID-19 pandemic
- Getting It Right First Time (GIRFT)
-- Clinical practice guide for improving the management of adult COVID-19 patients in secondary care
- GOV.UK
-- Supply chain workers crucial to vaccination programme to receive jabs - link
-- the green book, chapter 14a (COVID-19) – updated to include changes to the advice on timing of vaccine in those being given immunosuppressive treatments and further detail on history of previous allergies
-- NERVTAG paper on COVID-19 variant of concern B.1.1.7 - link
- NICE
-- Rapid evidence summary: Sarilumab for COVID-19
- Specialist Pharmacy Services NHS UK
-- Post-administration observation requirements for Pfizer-BioNTech COVID-19 Vaccine; AstraZeneca COVID-19 vaccine.
-- Issues to consider when defrosting the Pfizer-BioNTech COVID-19 vaccine - link
-- Using COVID-19 vaccines in patient taking immunosuppressive medicines - link

USA
- American Society of Health-System Pharmacists (ASHP)
-- ASHP discussion forum (Sign up for free) recent topics of discussion include: Late injection site reactions; Post-discharge VTE Prophylaxis in COVID-19 patients; 7th dose and/or pooling from the same lot vials; Vaccine for In-Patients; COVID-19 Vaccine Coordinator; and more
- Institute for Healthcare Improvement (IHI)
-- A Guide to Promoting Health Care Workforce Well-Being during and after the COVID-19 Pandemic
- ISMP
-- Learning from Errors with the New COVID-19 Vaccines - link; summary article
-- Medication Safety Alert! January 28, 2021
--- More on dilution errors with Pfizer-BioNTech COVID-19 vaccine
--- USP publishes COVID-19 vaccine toolkit
--- Additional COVID-19 resources

JOURNAL ARTICLES
American Journal of Health-System Pharmacy
- Advancing ambulatory pharmacy practice through a crisis: Objectives and strategies used in an ambulatory care action team’s response to the COVID-19 pandemic - link
- Developing statewide remdesivir use criteria - link

Annals of Internal Medicine
- Thrombosis, Bleeding, and the Observational Effect of Early Therapeutic Anticoagulation on Survival in Critically Ill Patients with COVID-19 - link
- The Proportion of SARS-CoV-2 Infections That Are Asymptomatic, A Systematic Review
- Letter: Reported Adverse Drug Reactions Associated with the Use of Hydroxychloroquine and Chloroquine during the COVID-19 Pandemic - link
- Opinion: Inclusion of Pregnant and Lactating Persons in COVID-19 Vaccination Efforts - link

Annals of Palliative Medicine
- Australian specialist palliative care’s response to COVID-19: an anonymous online survey of service providers - link

bioRxiv
- Preprint: mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants - link

BMJ
- Effect of tocilizumab on clinical outcomes at 15 days in patients with severe or critical coronavirus disease 2019: randomised controlled trial - link
- Managing the long term effects of covid-19: summary of NICE, SIGN, and RCGP rapid guideline

BMJ Annals of the Rheumatic Diseases
- Use of non-steroidal anti-inflammatory drugs and risk of death from COVID-19: an OpenSAFELY cohort analysis based on two cohorts - [link](#)

BMJ Open
- COVID-19 and healthcare workers: a rapid systematic review into risks and preventive measures - [link](#)

Cell Death and Differentiation
- Review: COVID-19 vaccines: where we stand and challenges ahead - [link](#)

Center for Clinical and Translational Research COVID-19 Clinical Trial Committee
- The development of a review and prioritization matrix during a pandemic - [link](#)

Clinical Infectious Diseases
- Drug-induced Liver Injury in a Patient with Coronavirus Disease 2019: Potential Interaction of Remdesivir with P-Glycoprotein Inhibitors - [link](#)

Infection Control & Hospital Epidemiology
- The Use of Procalcitonin as an Antimicrobial Stewardship Tool and a Predictor of Disease Severity in COVID-19 - [link](#)
- COVID-19 Research Agenda for Healthcare Epidemiology - [link](#)

JAMA
- Allergic Reactions Including Anaphylaxis after Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine - [link](#)
- Effect of Bamlanivimab as Monotherapy or in Combination with Etesevimab on Viral Load in Patients With Mild to Moderate COVID-19 A Randomized Clinical Trial - [link](#)

JAMA Internal Medicine
- Letter: Association of Smoking and Cumulative Pack-Year Exposure with COVID-19 Outcomes in the Cleveland Clinic COVID-19 Registry – [link](#)

JAMA Network Open
- Respiratory and Psychophysical Sequelae among Patients With COVID-19 Four Months After Hospital Discharge - [link](#)

JAMA Ophthalmology
- Unintended Consequences of Hand Sanitizer Use in the Coronavirus Disease 2019 Pandemic - [link](#)

JAMA Psychiatry
- Association of Psychiatric Disorders with Mortality among Patients with COVID-19 - [link](#)

Journal of Allergy and Clinical Immunology
- Letter: mRNA COVID-19 vaccine is well tolerated in patients with cutaneous and systemic mastocytosis with mast cell activation symptoms and anaphylaxis - [link](#)

Lancet
- Effect of pre-exposure use of hydroxychloroquine on COVID-19 mortality: a population-based cohort study in patients with rheumatoid arthritis or systemic lupus erythematosus using the OpenSAFELY platform - [link](#)
- α1-Antitrypsin deficiency and the risk of COVID-19: an urgent call to action - [link](#)
- SARS-CoV-2 vaccination for patients with inflammatory bowel disease: a British Society of Gastroenterology Inflammatory Bowel Disease section and IBD Clinical Research Group position statement
- Nebulised heparin for patients with or at risk of acute respiratory distress syndrome: a multicentre, randomised, double-blind, placebo-controlled phase 3 trial – [link](#)
- Effect of anakinra versus usual care in adults in hospital with COVID-19 and mild-to-moderate pneumonia (CORIMUNO-ANA-1): a randomised controlled trial - [link](#)
- Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBV152: a double-blind, randomised, phase 1 trial - [link](#)
- Quarantine and testing strategies in contact tracing for SARS-CoV-2: a modelling study - link
- Letter: The need for a global COVID-19 maternal immunisation research plan - link
- Commentary: The right place for IL-1 inhibition in COVID-19 - link
- Commentary: Optimism and caution for an inactivated COVID-19 vaccine - link

medRxiv
- Preprint: Trends, regional variation, and clinical characteristics of COVID-19 vaccine recipients: a retrospective cohort study in 23.4 million patients using OpenSAFELY - link

NEJM
- REGN-COV2, a Neutralizing Antibody Cocktail, in Outpatients with Covid-19 - link
- Beyond Politics — Promoting Covid-19 Vaccination in the United States - link
- Commentary: What Health Care Can Learn from Operation Warp Speed – link

PLOS ONE
- Converting the maybes: Crucial for a successful COVID-19 vaccination strategy - link

Science
- Model-informed COVID-19 vaccine prioritization strategies by age and serostatus – link
- Perspective: Optimizing age-specific vaccination - link

REPORTS AND PUBLICATIONS – AUSTRALIA

Agency for Clinical Innovation, NSW (ACI)
- BMT long-term follow up fact sheets - link
- Institute of Trauma and Injury Management - new web-based information system supporting trauma, retrieval and critical care across NSW - iTRACC.- link

AHHA
- Healthy People, Healthy Systems: A blueprint for outcomes focused, value-based health care - link
- Australian healthcare after COVID-19: An opportunity to think differently - link

Australian Commission on Safety and Quality in Health Care (ACSQHC)
- Antimicrobial Stewardship in Australian Health Care Book: Antimicrobial Stewardship in the Aboriginal and Torres Strait Islander population is the latest addition to the book - link

Australian Institute for Health and Welfare (AIHW)
- Aboriginal and Torres Strait Islander health expenditure estimates 2010-11 to 2016–17 - link

TGA
- TGA decision: Trientine Waymade (trientine dihydrochloride) approved to treat Wilson's disease patients intolerant to penicillamine.
- Ergometrine maleate injection (500 microgram/mL) ampoule - Alternative product approved to address expected shortage

REPORTS AND PUBLICATIONS – INTERNATIONAL

electronic Medicines Compendium (eMC) (UK)
- New products
  -- Bevespi Aerosphere (glycopyrronium bromide/formoterol fumarate dihydrate) inhalation-maintenance bronchodilator treatment to relieve symptoms in adults with COPD.
  -- Trixeo Aerosphere (formoterol fumarate dihydrate/budesonide/glycopyrronium) inhalation - maintenance treatment in adults with moderate to severe COPD who are not adequately treated by a combination of inhaled corticosteroid & long-acting beta2-agonist or combination of long-acting beta2-agonist & long-acting muscarinic antagonist.

European Medicines Agency (EMA)
- Human medicines: highlights of 2020 (overview of its key recommendations in 2020 on the authorisation and safety monitoring of medicines for human use - link

Food and Drug Administration (FDA) USA
- Advancing Health through Innovation: New Drug Approvals 2020 - link
- New Drug approvals
  -- Cabenuva (cabotegravir and rilpivirine) First extended-release (once-a-month), injectable drug regimen for adults living with HIV
  -- Cabenuva (cabotegravir;rilpivirine) combination tablet
  -- Verquvo (vericiguat) to reduce risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for HF or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.
  -- Vocabria (cabotegravir) 30 mg tablet in combination with Edurant (rilpivirine) 25 mg tablet for the short-term treatment of HIV1 infection in adults (before commencing Cabenuva to ensure medications are well tolerated);
  -- Cabometyx (cabozantinib) for patients with advanced renal cell carcinoma, as first-line treatment in combination with nivolumab.
  -- Lupkynis (voclosporin) capsule in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis
  - New indications
  -- Xalkori (crizotinib) for treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALKpositive
  -- Carbaglu (carglumic acid) for use as an adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia or methylmalonic acidemia

Healthcare Safety Investigation Branch (HSIB)
- Investigation into weight-based medication errors in children - link
- National Learning Report: Never Events: analysis of HSIB’s national investigations - link

Institute for Healthcare Improvement
- A Guide to Promoting Health Care Workforce Well-Being During and After the COVID-19 Pandemic - link

NHS England
- National Dose Banding Table – Irinotecan 20mgml
- Clinical Commissioning Policy: Addition of rituximab to first-line standard chemotherapy for CD20 positive B-cell precursor acute lymphoblastic leukaemia (Adults) - link
- Transformation of urgent and emergency care: models of care and measurement - link

National Institute for Health and Clinical Excellence (NICE) UK
- Abortion care Quality standard [QS199]
- Brigatinib for ALK-positive advanced non-small-cell lung cancer that has not been previously treated with an ALK inhibitor – guidance (TA670)
- Trifluridine–tipiracil for treating metastatic gastric cancer or gastro-oesophageal junction adenocarcinoma after 2 or more therapies - guidance (TA699)

Public Health England
- Avian influenza: PGD templates updates - link

Scottish Intercollegiate Guideline Network (SIGN) UK
- Minor update to guideline on management of osteoporosis and the prevention of fragility fractures: algorithm for detection and management of osteoporosis and recommendations for romosozumab use - link

World Health Organisation (WHO)
- Strengthening NCD service delivery through UHC benefit package: technical meeting report - link
- Meeting report of the WHO expert consultation on the definition of extensively drug-resistant tuberculosis - link
MEDICATION SAFETY

electronic Medicines Compendium (eMC) (UK)
- Revised SPCs
  -- NiQuitin (nicotine) patch - updated to emphasise requirement for safe disposal; nicotine doses tolerated by adult & adolescent smokers can produce severe toxicity in children. Pre-cessation regimen should not be used in people with known CVD without HCP evaluation of risk/benefit.
  -- Ofev (nintedanib) - updated with information on ischaemic colitis, reported in the post-marketing setting, and to note co-administration with oral hormonal contraceptives did not relevantly alter their pharmacokinetics. Fertility, pregnancy & lactation information has been updated.
  -- Piriton (chlorphenamine) - now notes a minimum dosing interval of 4 hours and states not to use for longer than 2 weeks without consulting a doctor, and to avoid use in elderly patients with confusion. Medical advice should be sought before using with other drugs that cause sedation.
  -- Valcyte (valganciclovir) 50 mg/mL Powder for Oral Solution - updated noting 100mg of sodium benzoate in each 12g bottle, equivalent to 1mg/mL after reconstitution. Benzoate salt may increase jaundice in newborn babies (up to 4 weeks old).
  -- Lamictal (lamotrigine) - updated to include warning on photosensitivity (frequency uncommon). In several cases, the reaction occurred with a high dose upon dose escalation or rapid up-titration. Advise patient to avoid exposure to sunlight/UV light and take protective measures.
  -- Ocrevus (ocrelizumab) - updated to include case reports of late onset of neutropenia (frequency unknown) at least 4 weeks after the latest infusion. In patients with signs and symptoms of infection, measurement of blood neutrophils is recommended.
  -- Ziagen (abacavir sulfate) – all products - in vitro study showed concomitant administration of single dose of riociguat (0.5 mg) to HIV patients receiving combination of abacavir/dolutegravir/lamivudine (600mg/50mg/300mg once daily) led to approx 3-fold higher riociguat levels. Riociguat dose may need to be reduced.
  -- Relestat (epinastine hydrochloride) eye drops - updated to warn of very rare reported cases of corneal calcification in association with the use of phosphate-containing eye drops such as Relestat, in some patients resulting in significantly damaged corneas.
  -- Benepali (etanercept) - updated to include Kaposi’s sarcoma (a rare type of cancer caused by a virus, which can affect the skin and mouth and potentially the internal organs) as adverse effect of (unknown frequenc).
  -- Medikinet (methylphenidate hydrochloride) - updated to include the following undesirable effects: dysphemia and trismus (unknown frequency).
  - Mekinist (trametinib) & Tafinlar (dabrafenib) - now report that sarcoidosis is an uncommon potential adverse effect of trametinib and dabrafenib combination therapy, though in the majority of cases treatment was maintained. It is important not to misinterpret sarcoidosis as disease progression.

Health Canada – MedEffect Notice
- GILENYA (fingolimod) - Risk of Liver Injury

Institute for Safe Medication Practices (ISMP) USA
- Hazardous Packaging Error involving certain cisatracurium products from Meitheal Pharmaceuticals
- Medication Safety Alert! January 28, 2021
-- Start the Year Off Right by Preventing These Top 10 Medication Errors and Hazards
-- Assuring proper mixing of mycophenolate suspension
-- Acute Care Action Agenda (October – December 2020)

PAPERS OF INTEREST

American Journal of Health-System Pharmacy (AHJP)
- Clinical review: Systemic targeted and immunotherapy for advanced hepatocellular carcinoma - link
- Comparison of intermittent audit vs daily documentation of pharmacist interventions – link
- Biosimilar formulary placement in Medicare Part D prescription drug plans: A case study of infliximab - link
- Association between opioid dose escalation and time to death in a comfort measures only population - link
- Effectiveness and impact of a structured research approach for health-system pharmacy administration and leadership residents - link
- Navigating uncharted waters: Developing a standardized approach for evaluating and implementing biosimilar products at a comprehensive cancer center - link
- ASHP Guidelines on Emergency Medicine Pharmacist Services - link
- The innovative role of an "opioid overdose prevention pharmacist" at a mental health teaching hospital - link
- A comprehensive approach to addressing the opioid epidemic in a large health system - link

Annals of Internal Medicine
- The Effect of Preconception-Initiated Low-Dose Aspirin on Human Chorionic Gonadotropin–Detected Pregnancy, Pregnancy Loss, and Live Birth. Per Protocol Analysis of a Randomized Trial

Australian Health Review, Journal of the Australian Healthcare & Hospitals Association
- Systematic review and content analysis of Australian health care substitute decision making online resources - link

British Journal of Clinical Pharmacology
- Impact of pharmacist-led medication therapy management in ambulatory elderly patients with chronic diseases - link
- Correlation between vancomycin clearance and cystatin C-based glomerular filtration rate in paediatric patients - link
- Pharmacokinetics of amoxicillin in obese and non-obese subjects - link
- Pharmacist led intervention on chronic pain management: A systematic review and meta-analysis - link
- Short Report: Evaluation of intravenous to oral antimicrobial switch at a hospital with a tightly regulated antimicrobial stewardship program - link

British Medical Journal (BMJ)
- Efficacy and safety of antidepressants for the treatment of back pain and osteoarthritis: systematic review and meta-analysis - link
- Practice pointer: Diagnosis and referral of adults with suspected bony metastases - link

BMJ Gut
- The influence of proton pump inhibitor therapy on the outcome of infliximab therapy in inflammatory bowel disease: a patient-level meta-analysis of randomised controlled studies - link

BMJ Open
- Evaluation of an implemented new insulin chart to improve quality and safety of diabetes care in a large university hospital: a follow-up study - link

BMJ Quality and Safety
- Association between intrahospital transfer and hospital-acquired infection in the elderly: a retrospective case–control study in a UK hospital network - link

Circulation – American Heart Association
- Psychological Health, Well-Being, and the Mind-Heart-Body Connection: A Scientific Statement from the American Heart Association - link
- Heart Disease and Stroke Statistics—2021 Update: A Report from the American Heart Association

Cochrane
- Beta-blockers versus placebo or no intervention for primary prophylaxis of oesophageal variceal bleeding in children with chronic liver disease or portal vein thrombosis - link
- Effect of atorvastatin on testosterone levels - link
- Topical antibiotic prophylaxis to reduce respiratory tract infections and mortality in adults receiving mechanical ventilation - link
- Ethosuximide, sodium valproate or lamotrigine for absence seizures in children and adolescents - link
- Interventions for treating iron deficiency anaemia in inflammatory bowel disease - link
Diabetes Care
- Effects of Vitamin C Supplementation on Glycemic Control and Cardiovascular Risk Factors in People with Type 2 Diabetes: A GRADE-Assessed Systematic Review and Meta-analysis of Randomized Controlled Trials - link
- Comparative Effectiveness and Safety of Sodium–Glucose Cotransporter 2 Inhibitors Versus Glucagon-Like Peptide 1 Receptor Agonists in Older Adults - link
- The Effect of Exenatide Once Weekly on Carotid Atherosclerosis in Individuals with Type 2 Diabetes: An 18-Month Randomized Placebo-Controlled Study - link

Drug and Therapeutics Bulletin
- Persistence of PIMs in older people – link
- Variation in statin prescribing across England - link

European Journal of Hospital Pharmacy
- Factors influencing the implementation of clinical pharmacy services on paediatric patient care in hospital settings - link
- Risk of acute kidney injury by initiation of non-steroidal anti-inflammatory drugs in hospitalised patients treated with diuretics and renin–angiotensin–aldosterone system inhibitors - link
- Case report: A patient with ulcerative colitis treated with a combination of vedolizumab and tofacitinib - link

European Heart Journal
- Valvular atrial fibrillation and a CHA2DS2-VASc score of 1—a statement of the ESC working group on cardiovascular pharmacotherapy and ESC council on stroke - link
- Cardiovascular health after menopause transition, pregnancy disorders, and other gynaecologic conditions: a consensus document from European cardiologists, gynaecologists, and endocrinologists

Health Expectations
- Development of a novel gout treatment patient decision aid by patient and physician: A qualitative research study - link
- What does safety in mental healthcare transitions mean for service users and other stakeholder groups: An open-ended questionnaire study - link

Internal Medicine Journal
- An Observational Study of the Incidence and Factors Associated with Patient Readmission from Home Based Care in the Hospital in the Home Program - link
- Effectiveness of a locality-based integrated diabetes care service on clinical outcomes - link

International Journal of Clinical Pharmacy
- Qualitative study of medication review in Flanders, Belgium among community pharmacists and general practitioners - link

JAMA
- Viewpoint: Revised UNAIDS/WHO Ethical Guidance for HIV Prevention Trials - link
- Review: Acute Pancreatitis - link

JAMA Dermatology
- Association of Secukinumab Treatment with Tuberculosis Reactivation in Patients with Psoriasis, Psoriatic Arthritis, or Ankylosing Spondylitis - link
- Association of Potent and Very Potent Topical Corticosteroids and the Risk of Osteoporosis and Major Osteoporotic Fractures - link
- Temporal Trends and Clinician Variability in Potassium Monitoring of Healthy Young Women Treated for Acne with Spironolactone – link
- Patient page: Allergic Contact Dermatitis

JAMA Network Open
- Physician, Practice, and Patient Characteristics Associated with Biosimilar Use in Medicare Recipients - link
- Evaluation of Ruxolitinib for Steroid-Refractory Chronic Graft-vs-Host Disease after Allogeneic Hematopoietic Stem Cell Transplantation - link
- Cost-effectiveness of Pembrolizumab as a Second-Line Therapy for Hepatocellular Carcinoma - link

**JAMA Oncology**
- Aspirin Use and Risk of Colorectal Cancer among Older Adults - link

**JAMA Ophthalmology**
- Association of Metformin Use with Age-Related Macular Degeneration. A Case-Control Study - link

**JAMIA (Journal of the American Medical Informatics Association)**
- A bottom-up approach to creating an ontology for medication indications - link
- Quality assessment of real-world data repositories across the data life cycle: A literature review - link
- Importance-aware personalized learning for early risk prediction using static and dynamic health data - link

**Journal of Clinical Oncology**
- Initial Management of Non-castrate Advanced, Recurrent, or Metastatic Prostate Cancer: ASCO Guideline Update - link

**Journal of the American Geriatrics Society**
- Transforming the Medication Regimen Review Process Using Telemedicine to Prevent Adverse Events - link

**Lancet**
- Biomarker-guided tuberculosis preventive therapy (CORTIS): a randomised controlled trial - link
- Outcomes of patients with chronic myelomonocytic leukaemia treated with non-curative therapies: a retrospective cohort study - link
- Seminar: Adrenal insufficiency - link
- Seminar: Classical Hodgkin lymphoma – link
- Review: Preservation of fertility in teenagers and young adults treated for haematological malignancies - link

**Molecular Diversity Preservation International (MDPI) – Pharmacy Journal**
- Experiences of the Medication Use Process by People with Intellectual Disabilities. What a Pharmacist Should Know! - link
- Community Pharmacist Telephonic Medication Reviews with Uncontrolled Asthma Patients: A Pilot Study – link
- Role of Nutrition Education in Pharmacy Curriculum—Students’ Perspectives and Attitudes - link
- Sentiment Analysis of Online Reviews for Selective Serotonin Reuptake Inhibitors and Serotonin–Norepinephrine Reuptake Inhibitors - link

**Medical Journal of Australia**
- Late mortality in people with cancer: a population-based Australian study - link

**National Institute for Health Research (NIHR) Signals**
- Older people move safely from hospital to home when staff communicate widely and bridge gaps in the system - link
- Aspirin could reduce the risk of heart attack or stroke in people with pneumonia - link
- Lansoprazole for persistent throat symptoms in secondary care: the TOPPITS RCT - link

**New England Journal of Medicine**
- Polypill with or without aspirin in Persons without Cardiovascular Disease - link
- Inhaled Treprostinil in Pulmonary Hypertension Due to Interstitial Lung Disease - link
- Levonorgestrel vs. Copper Intrauterine Devices for Emergency Contraception - link
- Cryoballoon Ablation as Initial Therapy for Atrial Fibrillation - link
- Cryoablation or Drug Therapy for Initial Treatment of Atrial Fibrillation - link
- Clinical practice: Atrial Fibrillation - link

**Pediatrics**
- Contemporary Management of Urinary Tract Infection in Children - link
TAG Mail – 21 Jan 2021

COVID-19 RESOURCES & ARTICLES OF INTEREST
Please click this link for the cumulative listing of COVID-19 resources in past TAG Mails.

AUSTRALIAN

Australian Government Department of Health
- CDNA National Guidance for Urban & Regional Aboriginal & Torres Strait Islander Communities for COVID-19 - link
- COVID-19 Australia: Epidemiology Report 32 (four-week report ending 03/01/21)

ACI
- Risk Monitoring Dashboard (20 Jan 2021) - link
- Evidence check: SARS-CoV-2 variants - link
- Evidence check: Ivermectin and COVID-19 (updated 15 Jan 2021) - link

Australian Institute for Health and Welfare (AIHW)
- Child protection in the time of COVID-19 - link

CEC
- Medication Safety Updates (last updated 15 Jan2021) - link

SHPA
- New open and accessible vaccine info hub
- A new member-only discussion forum for COVID-19 vaccines members can self-enrol here
- YouTube: Conversation with Cleveland Clinic on US vaccine logistics - link

TGA
- Face masks and COVID-19 - link; Post-market review of face masks: Outcomes and actions - link
- TGA grants additional provisional determination to Biocelect Pty Ltd (on behalf of Novavax Inc.) in relation to the COVID-19 Vaccine, NVX-CoV2373 - link
- Norwegian investigation of COVID-19 vaccination risks for elderly, very frail patients - link
- Ability of COVID-19 tests to detect emerging genetic variants of SARS-CoV-2 - link

INTERNATIONAL

WHO
- Science in 5 episode 21: COVID-19 origins of the virus - link
- The race for a COVID-19 vaccine, explained - link
- Who can take the Pfizer-BioNTech COVID-19 vaccine? - link
- How will we ensure fair access to COVID-19 vaccines? - link
- Governments push for Universal Health Coverage as COVID-19 continues to devastate communities and economies – link
- Background document on mRNA vaccine BNT162b2 (Pfizer-BioNTech) against COVID-19 - link
- Infection prevention & control (IPC) principles & procedures for COVID-19 vaccination activities - link
- Analysing and using routine data to monitor the effects of COVID-19 on essential health services: practical guide for national and subnational decision-makers - link
- Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing - link
- Genomic sequencing of SARS-CoV-2: a guide to implementation for maximum impact on public health - link
- SARS-CoV-2 genomic sequencing for public health goals: Interim guidance, 8 January 2021 - link

**Europe**

- Global regulators highlight key role of healthcare professionals in fostering confidence in COVID-19 vaccines - [link](#)

**UK**

- CEBM
  -- Baricitinib summary - [link](#)
  -- Healthcare Safety Investigation Branch (HSIB)
  -- Oxygen issues during COVID-19 pandemic - [link](#)

- NHS England
  -- SOP COVID-19 vaccine deployment programme: Frontline social care workers
  -- Instruction on timing of second dose of COVID-19 vaccinations - [link](#)

- NICE
  -- COVID-19 rapid evidence summary: Tocilizumab for COVID-19 (15/01/2021) [ES33](#)
  -- Everything you need to know about the COVID-19 therapy trials - [link](#)
  -- Ten things pharmacists should know about COVID-19 vaccines - [link](#)

- Specialist Pharmacy Services NHS UK
  -- Reporting suspected COVID-19 vaccine side effects, and potential product defects or counterfeit products - [link](#)

**USA**

- American Society of Health-System Pharmacists (ASHP)
  -- ASHP discussion forum ([Sign up for free](#)) recent topics of discussion include: Moderna vaccine (syringe stability; doses dependent on needle gauge used; 2nd dose in patients COVID-19+; muscle fasciculation cases); Vaccinating inpatients; Bamlanivimab

- CDC Morbidity and Mortality Weekly Report

**JOURNAL ARTICLES**

- Allergy – European Journal of Allergy and Clinical Immunology
  - EAACI statement on the diagnosis, management and prevention of severe allergic reactions to COVID-19 vaccines - [link](#)

- Annals of Internal Medicine
  - SARS-CoV-2 Vaccines: Much Accomplished, Much to Learn - [link](#)

- Australia and New Zealand Journal of Public Health
  - Communications in the time of a pandemic: readability of documents for public consumption - [link](#)

- BMJ
  - Editorial: Vaccinating against covid-19 in people who report allergies – [link](#)
  - Analysis: Mitigating ethnic disparities in covid-19 and beyond - [link](#)
  - What we know about covid-19 reinfection so far – [link](#)
  - News: Covid-19: What new variants are emerging and how are they being investigated? - [link](#)

- Cochrane
  - Care bundles for improving outcomes in patients with COVID-19 or related conditions in intensive care – a rapid scoping [review](#)
  - Special collections updates from 7/1/2021: support for wellbeing in the healthcare workforce; evidence relevant to critical care; regional anaesthesia to reduce drug use in anaesthesia and avoid aerosol generation; infection control and prevention measures; remote care through telehealth; evidence relevant to clinical rehabilitation

- European Journal of Hospital Pharmacy
- A prospective, observational study to evaluate adverse drug reactions in patients with COVID-19 treated with remdesivir or hydroxychloroquine: a preliminary report

Internal Medicine Journal
- Gut and glucose: an unusual first presentation of COVID-19 - link

JAMA
- Viewpoint: Funding of Pharmaceutical Innovation During and After the COVID-19 Pandemic - link
- Effect of Discontinuing vs Continuing Angiotensin-Converting Enzyme Inhibitors and Angiotensin II Receptor Blockers on Days Alive and Out of the Hospital in Patients Admitted with COVID-19: RCT

JAMA Internal Medicine
- Clinical Characteristics and Outcomes of Hospitalized Women Giving Birth With and Without COVID-19 - link
- Comparison of Saliva and Nasopharyngeal Swab Nucleic Acid Amplification Testing for Detection of SARS-CoV-2: A Systematic Review and Meta-analysis - link
- Risk Factors Associated With All-Cause 30-Day Mortality in Nursing Home Residents With COVID-19 - link

Journal of Inflammation Research
- Understanding COVID-19 Pandemic: Molecular Mechanisms and Potential Therapeutic Strategies. An Evidence-Based Review - link

Journal of Perioperative Practice
- Awareness of Human Factors in the operating theatres during the COVID-19 pandemic - link

Lancet
- Editorial: Vitamin D and COVID-19: why the controversy? – link
- Medium-term effects of SARS-CoV-2 infection on multiple vital organs, exercise capacity, cognition, quality of life and mental health, post-hospital discharge - link
- Correspondence: Thromboses and COVID-19: reducing inflammation in addition to thromboprophylaxis - link
- Assessing the importance of interleukin-6 in COVID-19 – correspondence & authors’ reply
- Renin–angiotensin system blockers and susceptibility to COVID-19: an international, open science, cohort analysis - link
- Impact of the COVID-19 pandemic on the detection and management of colorectal cancer in England: a population-based study - link
- Clinical characteristics and outcomes of COVID-19 in haematopoietic stem-cell transplantation recipients: an observational cohort study - link
- Effects of the COVID-19 pandemic on primary care-recorded mental illness and self-harm episodes in the UK: a population-based cohort study - link
- Development and validation of the ISARIC 4C Deterioration model for adults hospitalised with COVID-19: a prospective cohort study - link
- Prevalence and risk factors for delirium in critically ill patients with COVID-19 (COVID-D): a multicentre cohort study - link

MJA
- COVID-19 safety: aerosol-generating procedures and cardiothoracic surgery and anaesthesia — Australian and New Zealand consensus statement
- Outcomes for patients with COVID-19 admitted to Australian intensive care units during the first four months of the pandemic - link
- Perspective: COVID-19 and residential aged care: priorities for optimising preparation and management of outbreaks - link
- Letter in reply: Consensus statement: Safe Airway Society principles of airway management and tracheal intubation specific to the COVID-19 adult patient group - link
- Pre-print: High rate of persistent symptoms up to 4 months after community and hospital-managed SARS-CoV-2 infection - link
Nature
- Duration and key determinants of infectious virus shedding in hospitalized patients with COVID-19 - [link]
- Psychological characteristics associated with COVID-19 vaccine hesitancy and resistance in Ireland and the United Kingdom - [link]
- Perspective: Looking beyond COVID-19 vaccine phase 3 trials - [link]

NEJM
- A Neutralizing Monoclonal Antibody for Hospitalized Patients with Covid-19 - [link]
- Perspective: Vaccinating Children against Covid-19 — The Lessons of Measles - [link]

Pediatrics
- Factors Associated With Severe SARS-CoV-2 Infection - [link]
- Acute ANCA Vasculitis and Asymptomatic COVID-19 - [link]
- Enrolling Minors in COVID-19 Vaccine Trials - [link]

PLOS Medicine
- Comparative efficacy and safety of pharmacological interventions for the treatment of COVID-19: A systematic review and network meta-analysis - [link]

Vaccine
- Commentary: Anaphylactic reactions to novel mRNA SARS-CoV-2/COVID-19 vaccines - [link]

REPORTS AND PUBLICATIONS – AUSTRALIA

AHHA
- AHHA Healthcare in Brief (15 January 2021) - [link]

NSW Health Intranet
- Safety Notice 001/21: Discontinuation of nifedipine immediate release products (update) - [link]
- Safety Information 001/21: Minimising the risks of serious harm while switching antipsychotics - [link]
- Framework for Termination of Pregnancy in New South Wales - [link]

TGA
- Registration of new or extended uses of registered medicine:
  -- Insulin degludec; lixivatide (XULTOPHY) - as an adjunct to diet and exercise for the treatment of adults with T2DM to improve glycaemic control in combination with metformin, with or without other oral glucose-lowering medicinal products
  -- Ciclosporin (IKERVIS) - for treatment of severe keratitis in adult patients with dry eye disease which has not improved despite treatment with tear substitutes.

REPORTS AND PUBLICATIONS – INTERNATIONAL

Agency for Healthcare Research and Quality (AHRQ) USA
- Reducing inappropriate outpatient medication prescribing in older adults across electronic health record systems - [link]
- Algorithmic prediction of failure modes in healthcare - [link]
- Observational study of drug formulation manipulation in pediatric versus adult inpatients - [link]
- Treatments for Acute Pain: A Systematic Review - [link]
- Acute Treatments for Episodic Migraine - [link]
- Out-of-Pocket Spending for Retail Prescribed Drugs by Age and Type of Prescription Drug Coverage - [link]

Bowel Interest Group
- Cost of Constipation Report

Center for Implementation (TCI)
- Core Competencies for Implementation Practice - [link]
**Food and Drug Administration (FDA) USA**
- New Drug approvals
  -- **Vericiguat** (Verquvo™) a soluble guanylate cyclase (sGC) stimulator, indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for HF or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

**Healthcare Safety Investigation Branch**
- National Learning Report: Support for staff following patient safety incidents - [link](#)

**Open Access Text Book**
- Textbook of Patient Safety and Clinical Risk Management - [link](#)

**Scottish Intercollegiate Guideline Network (SIGN) UK**
- Management of osteoporosis and the prevention of fragility fractures - [link](#)

**Specialist Pharmacy Service (SPS) NHS UK**
- PGD template for the administration of benzylpenicillin injection - [link](#)

**The King’s Fund (UK)**
- Brexit and the end of the transition period: what does it mean for the health and care system? - [link](#)

**WHO**
- Policy [brief](#): Access to assistive technology
- Guidelines for establishing a poison centre - [link](#)
- Action framework for developing and implementing public food procurement and service policies for a healthy diet - [link](#)
- WHO Pharmaceuticals Newsletter - N°6, 2020

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**MEDICATION SAFETY**

**electronic Medicines Compendium (eMC) (UK)**
- Revised SPCs
  -- **Cyclopentolate Hydrochloride** 0.5%, Eye drops solution, Minims - Seizures, necrotising colitis, anaphylactic reaction/shock added as adverse effects.
  -- Neulasta (**pegfilgrastim**) products - now includes data from post-marketing observational study of pegfilgrastim in conjunction with chemotherapy and/or radiotherapy showing link to development of myelodysplastic syndrome and acute myeloid leukaemia in breast and lung cancer patients.
  -- Busilvex (**busulfan**) solution for infusion - updated to note increases in busulfan exposure have been observed when administered concomitantly with deferasirox. In those who are or have recently been treated with deferasirox, regularly monitor busulfan plasma concentrations and adjust dose if necessary.
  -- Darzalex (**daratumumab**) - updated to include cytomegalovirus infection as an adverse effect (1% incidence).
  -- Imbruvica (**ibrutinib**) - updated to note that cases of hepatitis E, which may be chronic, have occurred in patients treated with ibrutinib. Monitor patients for abnormal liver function tests.
  -- Rifadin (**rifampicin**) - updated to note that as rifampicin is a potent inducer of drug metabolizing enzymes and transporters, it may increase the activity of a co-administered pro-drug, where metabolic activation is required.
  -- Mezavant XL (**mesalazine**) - now includes hepatotoxicity as adverse event (unknown frequency).
  -- Yervoy (**ipilimumab**) - now includes warnings regarding increased risk of solid organ transplant rejection and haemophagocytic lymphohistiocytosis (HLH). Caution is advised as HLH has been observed with ipilimumab both as monotherapy and in combination with a PD-1 or PD-L1 inhibitor.
  -- Gilenya (**fingolimod hydrochloride**) – now includes acute hepatic failure as adverse effect (unknown frequency).
  -- Orkambi (**ivacaftor/lumacaftor**) – now includes bronchospasm as a common (≥ 1/100 to < 1/10) adverse reaction.
  -- Granocyte (**lenograstim**) pre-filled syringe - now highlights that cases of venous thromboembolism & arterial thromboembolism (e.g. myocardial infarction & cerebrovascular event) have been reported in donors treated with lenograstim. Closely monitor donors and patients with known risk factors.
-- **Propylthiouracil** - now notes that hypersensitivity reactions can occur, which may be associated with the development of anti-neutrophil cytoplasmic antibodies (ANCA).
-- Stelara (ustekinumab) - Hypersensitivity added as a rare potential adverse effect.
- Educational Risk Minimisation Materials for Medabon CombiPack (mifepristone 200 mg tablet and misoprostol 4 x 0.2 mg vaginal tablets) combination therapy for medical abortion.

**EMA**
- Pharmacovigilance Risk Assessment Committee (PRAC) concludes evaluation of risk of acute adrenal insufficiency in children when switching to Alkindi (hydrocortisone) granules - [link](#)

**TGA**
- Safety advisory: Medicines containing Eucommia ulmoides (known as Du-Zhong or Tu-chung)—contains latex - [link](#)

**PAPERS OF INTEREST**

**Australian Health Review**
- Medicine shortages: there are solutions! - [link](#)
- The effect of a state hospital formulary on medicines utilisation and implications for medicines policy in Australia - [link](#)

**British Journal of Clinical Pharmacology**
- Letter: Increasing pharmacotherapy safety at physicians’ career start—Presentation of a 10-item list with helpful hints - [link](#)

**British Journal of General Practice**
- GPs’ insights about discontinuing long-term antidepressant use: a qualitative study - [link](#)
- Does methenamine hippurate decrease urinary tract symptoms in community adult women: a systematic review and meta-analysis - [link](#)

**British Journal of Sports Medicine**
- Acute glycaemic management before, during and after exercise for cardiac rehabilitation participants with diabetes mellitus: a joint statement of the British and Canadian Associations of Cardiovascular Prevention and Rehabilitation, the International Council for Cardiovascular Prevention and Rehabilitation and the British Association of Sport and Exercise Sciences - [link](#)

**British Medical Journal (BMJ)**
- Clinical review: Management of non-alcoholic fatty liver disease - [link](#)
- Electronic health record alerts for acute kidney injury: multicenter, randomized clinical trial – [link](#)
- Home and Online Management and Evaluation of Blood Pressure (HOME BP) using a digital intervention in poorly controlled hypertension: randomised controlled trial - [link](#)

**BMJ Heart**
- Long-term survival benefit of ramipril in patients with acute myocardial infarction complicated by heart failure - [link](#)

**BMJ Open**
- Effect of the vancomycin minimum inhibitory concentration on clinical outcomes in patients with methicillin-susceptible Staphylococcus aureus bacteraemia: a systematic review and meta-analysis
- Acute pain management among patients with opioid maintenance therapy: specificities and difficulties identified in primary care: a qualitative study – [link](#)

**Circulation**
- Clinical Efficacy and Safety of Alirocumab after Acute Coronary Syndrome According to Achieved Level of Low-Density Lipoprotein Cholesterol: A Propensity Score-Matched Analysis of the ODYSSEY OUTCOMES Trial - [link](#)
- Apixaban or Vitamin K Antagonists and Aspirin or Placebo According to Kidney Function in Patients with Atrial Fibrillation after Acute Coronary Syndrome or PCI: Insights from The AUGUSTUS Trial - [link](#)
Clinics in Geriatric Medicine – Gastroenterology edition
- Esophageal and Gastric Motility Disorders in the Elderly - link
- Gastroesophageal Reflux Disease and Barrett Esophagus in the Elderly - link
- Nonsteroidal Anti-inflammatory Drugs, Anticoagulation, and Upper Gastrointestinal Bleeding - link
- Managing Gallstone Disease in the Elderly - link
- Fecal Incontinence in the Elderly - link
- Evaluation and Treatment of Constipation in the Geriatric Population - link
- Common Diarrheal Illnesses in the Elderly - link
- Functional Bowel Disease - link
- Nutrition and Weight Management in the Elderly - link
- Diverticulosis, Diverticulitis, and Diverticular Bleeding - link
- Upper Gastrointestinal Bleeding - link
- Inflammatory Bowel Disease in the Older Adult - link

Cochrane
- Antibiotic therapy versus no antibiotic therapy for children aged 2 to 59 months with WHO-defined non-severe pneumonia and wheeze - link
- Thrombolytic strategies versus standard anticoagulation for acute deep vein thrombosis of the lower limb - link
- Immediate-release methylphenidate for attention deficit hyperactivity disorder (ADHD) in adults - link
- Long-term effects of weight-reducing drugs in people with hypertension - link
- Atovaquone-proguanil for treating uncomplicated Plasmodium falciparum malaria - link
- Indomethacin for symptomatic patent ductus arteriosus in preterm infants - link
- Prophylactic antibiotics for adults with chronic obstructive pulmonary disease: a network meta-analysis - link

Diabetes Care
- Durable Effects of iGlarLixi Up to 52 Weeks in Type 2 Diabetes: The LixiLan-G Extension Study

European Heart Journal
- Alcohol consumption, cardiac biomarkers, and risk of atrial fibrillation and adverse outcomes - link

European Journal of Hospital Pharmacy
- Identification and safe storage of look-alike, sound-alike medicines in automated dispensing cabinets - link
- Severe and fatal medication errors in hospitals: findings from the Norwegian Incident Reporting System - link

Health Expectations
- Views about integrating smoking cessation treatment within psychological services for patients with common mental illness: A multi-perspective qualitative study - link
- Providing culturally safe care to Indigenous people living with diabetes: Identifying barriers and enablers from different perspectives - link

Internal Medicine Journal
- Dialysis and driving: An anonymous survey of patients receiving dialysis for end stage kidney disease - link
- Communicating deprescribing decisions made in hospital with general practitioners in the community: a qualitative study - link
- Documentation of Adverse Drug Reactions to Opioids in an Electronic Health Record – link
- Alcohol Misuse and Critical Care Admissions in the Northern Territory. - link
- Safety of RAPid INJECTion of Undiluted Ferric Carboxymaltose to Patients with Iron Deficiency Anaemia (RAPINJECT): A Phase II Single Arm study - link
- Barriers and challenges of returning patients back to community after renal transplantation in Central Australia - link
- Demystifying machine learning – a primer for physicians - link
- Diabetic ketoacidosis: a canary in the mine for mental health disorders? - link

International Journal of Clinical Pharmacy
- Duloxetine for the reduction of opioid use in elective orthopedic surgery: a systematic review and meta-analysis - link
- Medication reconciliation in the geriatric unit: impact on the maintenance of post-hospitalization prescriptions - link

**International Journal for Quality in Health Care**
- Measurement and Monitoring Patient Safety in Prehospital Care: A Systematic Review - link
- Does Implementation of a Tailored Intervention Increase Adherence to a National Safety and Quality Standard? A Study to Improve Delirium Care - link
- An Evidence-Based Oxytocin Protocol for the Third Stage of Labor to Improve Hemorrhage Outcomes - link
- Patient-Reported Outcome Measures in Mental Health Clinical Research: A Descriptive Review in Comparison with Clinician-Rated Outcome Measures - link

**JAMA**
- The Pharmacologic Treatment of Schizophrenia—2021 - link
- Effect of Oral Moxifloxacin vs Intravenous Ertapenem Plus Oral Levofoxacin for Treatment of Uncomplicated Acute Appendicitis: The APPAC II Randomized Clinical Trial - link (Editorial - Evolving Issues in the Use of Antibiotics for the Treatment of Uncomplicated Appendicitis)
- Effect of Endovascular Treatment Alone vs Intravenous Alteplase Plus Endovascular Treatment on Functional Independence in Patients With Acute Ischemic Stroke: The DEV1T Randomized Clinical Trial - link
- Effect of Mechanical Thrombectomy Without vs With Intravenous Thrombolysis on Functional Outcome Among Patients With Acute Ischemic Stroke: The SKIP Randomized Clinical Trial - link
- Interventions for Tobacco Cessation in Adults, Including Pregnant Persons: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force - link

**JAMA Cardiology**
- Assessing the Risks of Bleeding vs Thrombotic Events in Patients at High Bleeding Risk after Coronary Stent Implantation: The ARC–High Bleeding Risk Trade-off Model - link

**JAMA Network Open**
- Genetics of Smoking and Risk of Atherosclerotic Cardiovascular Diseases: A Mendelian Randomization Study - link
- Evaluation of Aspirin Use with Cancer Incidence and Survival among Older Adults in the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial - link
- Association of Immunosuppression and Viral Load with Subcortical Brain Volume in an International Sample of People Living With HIV - link
- Safety, Reactogenicity, and Health-Related Quality of Life after Trivalent Adjuvanted vs Trivalent High-Dose Inactivated Influenza Vaccines in Older Adults: A Randomized Clinical Trial - link
- Association of Pertuzumab, Trastuzumab, and Docetaxel Combination Therapy with Overall Survival in Patients with Metastatic Breast Cancer - link
- Evaluation of Dietary Niacin and New-Onset Hypertension among Chinese Adults - link
- Characterization of Ebola Virus–Associated Eye Disease - link
- Association of Gabapentinoids With the Risk of Opioid-Related Adverse Events in Surgical Patients in the United States - link

**JAMA Neurology**
- Findings of Efficacy, Safety, and Biomarker Outcomes of Atabecestat in Preclinical Alzheimer Disease: A Truncated Randomized Phase 2b/3 Clinical Trial - link
- Association of Pharmacological Interventions with Symptom Burden Reduction in Patients with Mild Traumatic Brain Injury: A Systematic Review - link

**JAMA Oncology**
- Comparison of Systemic Treatments for Metastatic Castration-Sensitive Prostate Cancer: A Systematic Review and Network Meta-analysis - link
- Frequency of and Factors Associated With Nonmedical Opioid Use Behavior Among Patients with Cancer Receiving Opioids for Cancer Pain - link

**JAMA Otolaryngology–Head & Neck Surgery**
- Association of Prolonged-Duration Chemoprophylaxis with Venous Thromboembolism in High-Risk Patients With Head and Neck Cancer - [link]

**JAMA Pediatrics**
- Association of Cannabis Use with Self-harm and Mortality Risk among Youths with Mood Disorders - [link]
- Risk of Substance Use Disorder and Its Associations With Comorbidities and Psychotropic Agents in Patients With Autism - [link]

**JAMIA (Journal of the American Medical Informatics Association)**
- Telemedicine, privacy, and information security in the age of COVID-19 - [link]
- Clinician involvement in research on machine learning–based predictive clinical decision support for the hospital setting: A scoping review - [link]
- A comparison of general and disease-specific machine learning models for the prediction of unplanned hospital readmissions - [link]
- Building longitudinal medication dose data using medication information extracted from clinical notes in electronic health records - [link]
- Building the evidence-base to reduce electronic health record–related clinician burden - [link]
- Electronic health records and clinician burnout: A story of three eras - [link]
- Measurement of clinical documentation burden among physicians and nurses using electronic health records: a scoping review - [link]
- Persistent inequitable design and implementation of patient portals for users at the margins - [link]
- The burden of the digital environment: a systematic review on organization-directed workplace interventions to mitigate physician burnout - [link]
- Evaluation of electronic health record-integrated digital health tools to engage hospitalized patients in discharge preparation - [link]

**Journal of Clinical Oncology**
- Development and Validation of a Risk Tool for Predicting Severe Toxicity in Older Adults Receiving Chemotherapy for Early-Stage Breast Cancer - [link]

**Journal of Palliative Medicine**
- Deficiencies with the Use of Prescription Drug Monitoring Program in Cancer Pain Management: A Report of Two Cases - [link]

**Journal of Pharmacy Practice and Research (JPPR)**
- A snapshot of the prescribing patterns and off-label use of gabapentinoid agents in tertiary care: a retrospective, cross-sectional, descriptive study - [link]

**Lancet**
- Machine learning-based prediction of adverse events following an acute coronary syndrome (PRAISE): a modelling study of pooled datasets - [link]
- The effect of vitamin D supplementation on acute respiratory tract infection in older Australian adults: an analysis of data from the D-Health Trial - [link]
- Effect of denosumab on osteolytic lesion activity after total hip arthroplasty: a single-centre, randomised, double-blind, placebo-controlled, proof of concept trial - [link]
- The metformin in tuberous sclerosis (MiTS) study: A randomised double-blind placebo-controlled trial - [link]
- Acrolein and other toxicant exposures in relation to cardiovascular disease among marijuana and tobacco smokers in a longitudinal cohort of HIV-positive and negative adults - [link]
- Mifepristone followed by misoprostol compared with placebo followed by misoprostol as medical treatment for early pregnancy loss (the Triple M trial): A double-blind placebo-controlled randomised trial - [link]

**Molecular Diversity Preservation International (MDPI) – Pharmacy Journal**
- Pilot Study of Electronic Nicotine Delivery Systems (ENDS) Cessation Methods - [link]
- Use of Alfentanil in Palliative Care - [link]
- Implementation of Smart Infusion Pumps: A Scoping Review and Case Study Discussion of the Evidence of the Role of the Pharmacist - [link]
Medical Journal of Australia
- Education: Sudden onset vision loss: an atypical presentation of giant cell arteritis and myeloproliferative neoplasm - link
- The prevalence and impact of unprofessional behaviour among hospital workers: a survey in seven Australian hospitals - link

New England Journal of Medicine
- Sotagliflozin in Patients with Diabetes and Recent Worsening Heart Failure - link
- Sotagliflozin in Patients with Diabetes and Chronic Kidney Disease - link
- Bupropion and Naltrexone in Methamphetamine Use Disorder - link
- Editorial: Polypills — A Central Strategy for Improving Cardiovascular Health - link
- Review article: Ewing’s Sarcoma - link
- Review article: Postinfectious Epigenetic Immune Modifications — A Double-Edged Sword - link

Pediatrics
- Comparison of Manual and Automated Sepsis Screening Tools in a Pediatric Emergency Department - link
- Standard versus Long Peripheral Catheters for Multiday IV Therapy: A Randomized Controlled Trial
- Use of E-cigarettes and Other Tobacco Products and Progression to Daily Cigarette Smoking - link
- Implementation of a Standardized Approach to Improve the Pediatric Discharge Medication Process - link

Pharmacotherapy
- Association of proton pump inhibitor use with endothelial function and metabolites of the nitric oxide pathway: a cross-sectional study - link
- Predictors of a Response to Dexametomidine in Intubated, Critically Ill Adult Patients - link
- Cisplatin-Induced Nephrotoxicity in an Outpatient Setting - link
- Performance of nasal methicillin-resistant Staphylococcus aureus screening for intra-abdominal infections in critically ill adult patients - link
- Methadone-Associated QT Interval Prolongation in Patients Undergoing Maintenance Therapy in an Urban Opioid Treatment Program - link
- Immunosuppression considerations in simultaneous organ transplant - link

Prescribe
- Adverse effects of cancer drugs: often downplayed in articles reporting results of clinical trials - link
- Treatment-resistant depression: avoid esketamine (Spravato°) - link
- SSRI antidepressants & pregnancy: long-term neuropsychiatric disorders in exposed children? - link

Public Library of Science (PLOS)
- Assessing the risk of ketoacidosis due to sodium-glucose cotransporter (SGLT)-2 inhibitors in patients with type 1 diabetes: A meta-analysis and meta-regression - link

Thrombosis and Haemostasis
- Use of Non-vitamin K Antagonist Oral Anticoagulants for Stroke Prevention across the Stroke Spectrum: Progress and Prospects - link
- Specific Point-of-Care Testing of Coagulation in Patients Treated with Dabigatran - link

TAG Mail – 14 Jan 2021

COVID-19 RESOURCES & ARTICLES OF INTEREST
Please click this link for the cumulative listing of COVID-19 resources in past TAG Mails.

AUSTRALIAN
Australian Government Department of Health
- Australia’s Epidemiology and COVID-19 Vaccine Roadmap - link
National COVID-19 Clinical Evidence Taskforce
- New and Updated recommendations as at 17/12/2020
- Statement on media release from REMAP-CAP, ACTIV-4 and ATTACC trials re anticoagulation 24/12/2020
  -- New Recommendations: Interferon β-1a (inhaled), Peginterferon lambda
  -- Updated Recommendations: remdesivir for adults, remdesivir for pregnant or breastfeeding women, interferon β-1a, human umbilical cord mesenchymal stem cell, sofosbuvir-daclatasvir

NSW Health
- COVID-19 variant - link

NSW Health Critical Intelligence Unit – Evidence checks
- Ivermectin and COVID-19 - link

NPS MedicineWise
- COVID-19 vaccines – are we there yet? - link
- Dexamethasone reduces mortality in patients seriously ill with COVID-19 - link
- Vaccines and COVID-19 - link

INTERNATIONAL
WHO
- Therapeutics and COVID-19 Living Guidelines 17 December 2020
- A year without precedent: WHO’s COVID-19 response - link
- Timeline: WHO’s COVID-19 response - link
- Vaccine related topics: Journey of a vaccine - link; Covid Vaccine Facts with the WHO's Dr. Kate O'Brien - link; WHO issues its first emergency use validation for a COVID-19 vaccine and emphasizes need for equitable global access - link
- Science in 5’ webinar series
  -- Episode 17 Vaccine approvals; Episode 18 Immunity after recovery from COVID-19; Episode 19 Prolonged symptoms after COVID-19; Episode 20 Variants & Vaccines
- ‘Explainers series’ – Vaccine development and distribution
  -- Part 1 How do vaccines work, Part 2 How are vaccines developed? Part 3 Manufacturing, safety and quality control of vaccines.

Canada
Health Canada
--Drug and Vaccine authorizations for COVID-19: Authorization with terms and conditions for bamlanivimab and Pfizer-BioNTech COVID-19 Vaccine - link

Europe
EMA
- EMA recommends COVID-19 Vaccine Moderna for authorisation in the EU - link
- Comirnaty COVID-19 vaccine - updated product information to clarify that each vial contains 6 doses of vaccine - link

UK
- Care Quality Commission
  -- COVID-19 Insight: Issue 6 - link
- Department of Health and Social Care
  -- Prioritising the first COVID-19 vaccine dose: JCVI statement - link
- GOV.UK
  -- Information on the new variant of the SARS-CoV-2 virus - link
- NHS England
  -- COVID-19 Vaccine Oxford AstraZeneca – movement of vaccine - link
  -- Community pharmacy local enhanced service – coronavirus vaccination - link
- MHRA
  -- Interim Position Statement Interleukin-6 inhibitors (tocilizumab or sarilumab) for patients admitted to ICU with COVID-19 pneumonia (adults) - link
-- COVID-19 vaccines (Pfizer/BioNTech and COVID-19 Vaccine AstraZeneca): current advice - link
-- Regulatory approval of COVID-19 Vaccine Moderna and AstraZeneca
-- Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca - link
-- How tests and testing kits for coronavirus (COVID-19) work - link
-- Access Consortium statement on COVID-19 vaccines evidence - link
-- NICE
-- COVID-19 rapid guidelines: Managing the long-term effects of COVID-19 (NG188); Vitamin D (NG187)
-- Public Health England
-- COVID-19 vaccination: information for healthcare practitioners - link
-- National protocol for COVID-19 Vaccine AstraZeneca (ChAdOx1-S [recombinant]) - link
-- National protocol for COVID-19 mRNA vaccine BNT162b2 (Pfizer/BioNTech) - link
-- COVID-19: pre-existing health conditions and ethnicity - link
-- Safety of COVID-19 vaccines when given in pregnancy guidance – link
-- Royal College of Paediatrics and Child Health (UK)
-- National guidance for the recovery of elective surgery in children - link
-- National guidance for the management of children with bronchiolitis and lower respiratory tract infections during COVID-19 - link
-- Royal Pharmaceutical Society – the Pharmaceutical Journal
-- The pandemic’s challenge to evidence-based medicine shows off-label use is an important tool
-- Scottish Intercollegiate Guideline Network (SIGN) Healthcare Improvement Scotland
-- Managing the long-term effects of COVID-19 guidelines - link
-- Specialist Pharmacy Service (SPS) NHS England
-- Answering your questions and getting in touch about the COVID-19 Vaccination Programme - link
-- Pfizer-BioNTech Vaccine: Preparation in Trusts - link; Vaccine Formulation information - link;
-- Transporting Vaccine from PCN Designated Sites to end user location - link
-- Summary of COVID-19 medicines guidance updates to the following topics: Allergy and immunology, Renal and urologic disorders, Haematological disorders, Obstetrics and gynaecology, Mental health and illness, Cardiovascular system disorders, Diabetes and more…

USA
-- FDA
-- FDA Statement on Following the Authorized Dosing Schedules for COVID-19 Vaccines - link
-- Alert Regarding SARS-CoV-2 Viral Mutation to Health Care Providers & Clinical Lab Staff - link
-- Moderna COVID-19 Vaccine Frequently Asked Questions - link
-- The Joint Commission
-- Joint Commission questionnaire identifies COVID-19 impact, challenges and needs among health care organizations - link

JOURNAL ARTICLES
American Journal of Health-System Pharmacy (AHJP)
-- Leveraging pharmacists to maintain and extend buprenorphine supply for opioid use disorder amid COVID-19 pandemic - link
-- Application of emergency preparedness principles to a pharmacy department’s approach to a “black swan” event—COVID-19 - link
-- A survey of US hospitals’ criteria for the allocation of remdesivir to treat COVID-19 - link

Annals of Internal Medicine
-- COVID-19 Vaccine: Promoting Vaccine Acceptance - link

BMJ
-- Practice Pointer: Returning to physical activity after covid-19 - link
-- Impact of cardiovascular disease and risk factors on fatal outcomes in patients with COVID-19 according to age: a systematic review and meta-analysis - link
-- A living WHO guideline on drugs for covid-19 – link

BioMedCentral
-- Corticosteroid use in COVID-19 patients: a systematic review and meta-analysis on clinical outcomes - link
British Journal of Clinical Pharmacology

Cochrane
- Renin-angiotensin system inhibitors for treating COVID-19 in adults - link

Critical Care
- Corticosteroid use in COVID-19 patients: a systematic review and meta-analysis on clinical outcomes - link

European Journal of Medical Research
- Review: Airborne transmission of COVID-19 and the role of face mask to prevent it: a systematic review and meta-analysis - link

International Journal for Quality in Health Care
- COVID-19 emergencies around the globe: China’s experience in controlling COVID-19 and lessons learned - link

JAMA
- Viewpoint: Genetic Variants of SARS-CoV-2—What Do They Mean? - link
- SARS-CoV-2 Transmission From People Without COVID-19 Symptoms - link

Lancet
- Prevalence and risk factors for delirium in critically ill patients with COVID-19 (COVID-D): a multicentre cohort study - link
- 6-month consequences of COVID-19 in patients discharged from hospital: a cohort study - link
- Continuation versus discontinuation of renin–angiotensin system inhibitors in patients admitted to hospital with COVID-19: a prospective, randomised, open-label trial - link

medRxiv
- Pre-print: Vitamin D supplementation to prevent acute respiratory infections: systematic review and meta-analysis of aggregate data from randomised controlled trials - link
- Pre-print: Interleukin-6 Receptor Antagonists in Critically Ill Patients with Covid-19 – Preliminary report - link

New England Journal of Medicine
- Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine - link
- Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine - link
- Interim Results of a Phase 1–2a Trial of Ad26.COV2.S Covid-19 Vaccine - link
- Early High-Titer Plasma Therapy to Prevent Severe Covid-19 in Older Adults - link
- Tocilizumab in Patients Hospitalized with Covid-19 Pneumonia - link
- Review article: Maintaining Safety with SARS-CoV-2 Vaccines - link

Pharmacy
- In the Eye of the Storm: The Role of the Pharmacist in Medication Safety during the COVID-19 Pandemic at an Urban Teaching Hospital - link

Thorax
- COVID-19, immunothrombosis and venous thromboembolism: biological mechanisms - link
- Current smoking and COVID-19 risk: results from a population symptom app in over 2.4 million people - link

REPORTS AND PUBLICATIONS – AUSTRALIA
Australian and New Zealand College of Anaesthetists & Faculty of Pain Medicine (ANZCA)
- Acute Pain Management: Scientific Evidence 5th edition - link

Agency for Clinical Innovation, NSW (ACI)
- Introducing iTRACC 2.0 - Supporting trauma, retrieval and critical care across NSW - link
- Consumer fact sheets: blood and marrow transplant - link

**AHHA**
- Understanding My Healthcare Rights: a guide for consumers – link; a summary booklet - link

**Australian Commission on Safety and Quality in Health Care (ACSQHC)**
- new resources for consumers on the [Australian Charter of Healthcare Rights](https://www.ackhc.gov.au/). The resources, a detailed guide and a summary booklet, are designed to support consumers to better understand their healthcare rights and what they can expect from the Australian healthcare system

**MIMS monthly updates – January 2021**
- New products include: Caplacizumab (Cablivi), Melatonin (Slenyto)
- Products with new indications: Dapagliflozin (Forxiga), Ustekinumab (Stelara)

**NSW Health Intranet**
- Information Bulletins:
  - Outpatient Pharmaceutical Arrangements and the Life Savings Drugs Program (IB2020_047) - link
  - Pharmaceutical Charges for Hospital Outpatients and Safety Net Thresholds (IB2020_048) - link
  - Policy directive: Authorised Nurse Immunisers (PD2020_050) updated - link
  - NSW Aboriginal Mental Health and Wellbeing Strategy 2020-2025 - link
  - Annual Report 2019-20 - link

**PBS**
- Post-market review of the use of biologics in the treatment of severe chronic plaque psoriasis - link
- Recommendations made by the PBAC – link

**Pharmacy Council of NSW**
- Applying the poisons legislation – practical tips - link

**TGA**
- Community Q&A: Modafinil: Why 'smart drugs' are not the brightest option - link
- Database of section 19A approvals to import and supply medicines to address medicine shortages
- Notice of final decision to amend the current Poisons Standard - nicotine
- TGA confirms nicotine e-cigarette access is by prescription only - link
- AusPARRs:
  - **Iodised oil** (Lipiodol Ultra Fluid®) - imaging agent for visualisation and localisation during Trans-Arterial Chemo-Embolisation of hepatocellular carcinoma (HCC) at intermediate stage in adults
  - **Influenza virus haemagglutinin** (Flucelvax Quad®) vaccine - for adults & children 9 years and older
  - **Larotrectinib** (Vitrakvi®) - for locally advanced or metastatic solid tumours that have a NTRK gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have either progressed following treatment or have no satisfactory alternative therapy.

**Victorian Institute of Forensic Medicine**
- Clinical Communicué Volume 7 Issue 4 December 2020

**REPORTS AND PUBLICATIONS – INTERNATIONAL**

**Agency for Healthcare Research and Quality (AHRQ) USA**
- Treatments for Acute Pain: A Systematic Review - link
- Acute Treatments for Episodic Migraine - link
- Diagnostic Errors in the Emergency Department: A Systematic Review - link
- Interventional Treatments for Acute and Chronic Pain: Systematic Review - link

**Canadian Agency for Drugs and Technologies in Health**
- Rapid response
  - Intrathecal Dexamethasone for Chronic Pain and Spinal Stenosis: Clinical Effectiveness and Guidelines - link
electronic Medicines Compendium (eMC) (UK)
- New products
  - Fintepla (fenfluramine) oral solution - for seizures associated with Dravet syndrome as an add-on therapy to other anti-epileptic medicines for patients ≥ 2 years of age
  - Phesgo (pertuzumab/trastuzumab) - for use in combination with chemotherapy in neoadjuvant & adjuvant setting in treatment of HER2-positive, early breast cancer and in combination with docetaxel in HER2-positive metastatic or locally recurrent unresectable breast cancer.
  - Tecartus (autologous anti-CD19-transduced CD3+ cells) for the treatment of adult patients with relapsed or refractory mantle cell lymphoma after two or more lines of systemic therapy including a Bruton's tyrosine kinase inhibitor.
  - Velphoro (sucroferric oxyhydroxide) oral powder - for control of serum phosphorus levels in adult CKD patients on haemodialysis or peritoneal dialysis and in paediatric patients age ≥ 2 years with CKD stages 4-5 or with CKD on dialysis.

Food and Drug Administration (FDA) USA
- FDA Approves First Generic of Drug Used to Treat Severe Hypoglycemia (Glucagon) - link
- New Drug approvals
  -- Tirbanibulin (Klisyri) - to treat actinic Keratosis of the face or scalp. Drug Trials Snapshot link
  -- Margetuximab (Margenza) - to treat HER2+ breast cancer. Drug Trials Snapshot link
  -- Relugolix (Orgovyx) - to treat advanced prostate cancer. Drug Trials Snapshot link
  -- Ansuvimab-zykl (Ebanga) - to treat ebola
  -- Vibegron (Gemtesa) - to treat overactive bladder
  -- Selinexor (Xpovio) – for refractory or relapsed multiple myeloma
  -- Osimertinib (Tagrisso) – adjuvant therapy for non-small cell lung cancer with EGFR mutations

Institute for Healthcare Improvement
- Building Health-Creating Systems - link

International Journal for Quality in Health Care
- An Evidence-Based Oxytocin Protocol for the Third Stage of Labor to Improve Hemorrhage Outcomes - link
- Clinical handover and handoff in healthcare: a systematic review of systematic reviews - link
- Effectiveness of health consumer representative involvement in implementation of interventions to change health professional behaviour - link

National Institute for Health and Clinical Excellence (NICE) UK
- Type 1 diabetes in adults: diagnosis and management – guideline (NG17)
- Type 2 diabetes in adults: management – guideline (NG28)
- Diabetes in pregnancy: management from preconception to the postnatal period –guideline (NG3)
- Diabetes (type 1 & type 2) in children & young people: diagnosis & management – guideline (NG18)
- Eating disorders: recognition and treatment –guideline (NG69)
- Suspected neurological conditions: recognition and referral (QS198)
- Encorafenib plus cetuximab for previously treated BRAF V600E mutation-positive metastatic colorectal cancer – (TA668)
- Antimicrobial prescribing: delafloxacin for acute bacterial skin and skin structure infections – evidence summary (ES32)
- Antimicrobial prescribing: cefiderocol – evidence summary (ES31)
- Pancreatitis – guidance (NG104)

Public Health England
- Guidance on the hepatitis B antenatal screening and selective neonatal immunisation pathway - link
- Wound aware: a resource for commissioners and providers of drug services - link

Royal Pharmaceutical Society
- Pharmacist-led feedback for prescribers cuts errors in hospital, study suggests - link
Specialist Pharmacy Services
- Extended-release methylphenidate: A review of the pharmacokinetic profiles of available products - link

The King’s Fund (UK)
- Community pharmacy explained - link
- 2020: the health policy year in 12 charts - link

World Health Organisation (WHO)
- Assessing the magnitude and nature of shortages of essential medicines and vaccines: focus on the WHO European Region (2020) - link

MEDICATION SAFETY
electronic Medicines Compendium (eMC) (UK)
- Revised SPCs
  -- Zytiga (abiraterone acetate) - anaphylactic reaction added as adverse effect
  -- Erleada (apalutamide) tablets - decreased appetite (very common frequency) and toxic epidermal necrolysis (unknown frequency) added as adverse events.
  -- Zithromax (azithromycin dehydrate) –updated to advise that limited published literature indicates azithromycin is present in human milk at an estimated highest median daily dose of 0.1 to 0.7 mg/kg/day; and no serious adverse effects on breast-fed infants observed.
  -- Madopar (benserazide hydrochloride, levodopa) prolonged release capsules - updated to note capsules contain soya oil, therefore contraindicated in patients allergic to peanut or soya.
  -- Zirabez (bevacizumab) - license extension for use in combination with paclitaxel, topotecan or pegylated liposomal doxorubicin for treatment of adults with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer under specific conditions.
  -- Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide fumarate) - Stevens - Johnson syndrome added as rare adverse event.
  -- Blincyto (blinatumomab) - indication updated to clarify that patients with Philadelphia chromosome positive B-precursor acute lymphoblastic leukaemia should have failed treatment with at least 2 tyrosine kinase inhibitors (TKIs) and have no alternative treatment options.
  -- Bosulif (bosutinib) - advises that exposure to direct sunlight or UV radiation should be avoided or minimised due to risk of photosensitivity.
  -- Dysport (botulinum toxin A) - hypoesthesia added as ADR (unknown frequency).
  -- Cortiment (budesonide) prolonged release tablets - provides details for use in the new indication of induction of remission in active microscopic colitis.
  -- Cipramil (citalopram) - includes information on peak LFT elevations being generally higher in paediatric patients than in older patients.
  -- Triumeq (dolutegravir/abacavir/lamivudine) - now states dolutegravir is excreted in human milk in small amounts and there is insufficient information on its effects in neonates/infants.
  -- Dupixent (dupilumab) - indication extended for use in children aged 6 to 11 years, for the treatment of severe atopic dermatitis, if they are considered candidates for systemic therapy.
  -- Empliciti (elotuzumab) - updated to advise women of childbearing potential use effective contraception during and for 120 days after treatment, dose for dexamethasone in combination with pomalidomide adjusted according to age, and to consult SPCs for other drugs in regimen before starting treatment.
  -- Innovaue (enalapril) - advises that patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.
  -- Vafar (ivacaftor) – includes information on peak LFT elevations being generally higher in paediatric patients than in older patients.

Kisplyx (lenvatinib) capsules – notes in trials for use in differentiated thyroid cancer, Asian patients had a 10% higher incidence of peripheral oedema, hypertension, fatigue, PPE, proteinuria, stomatitis, thrombocytopenia, and myalgia than Caucasians.
-- Lorviqua (lorlatinib) - psychotic effects & changes in mental status added as adverse effects.
-- Equasym (methylphenidate) - dysphemia (stuttering) added as adverse effect (unknown frequency).
-- Sandostatin (octreotide) –includes warning for cholangitis. Cases have been reported as a complication of choledolithiasis in the post-marketing setting.
-- Onpattro (patisiran sodium) infusion - pruritus added as an undesirable effect.
-- Pegasy's (peginterferon alfa-2a) - optic neuritis (inflammation of optic nerve) added as an undesirable effect (unknown frequency).
-- Keytruda (pembrolizumab) - Sjogren’s syndrome added as adverse event (frequency rare for monotherapy and in combination with chemotherapy and uncommon in combination with axitinib).

-- Crinone progesterone Vaginal Gel - headache, somnolence, abdominal pain have been removed as common side effects. Now states it has no influence on the ability to drive and use machines.
-- Zocor (simvastatin) – concomitant use of ticagrelor not recommended with doses of simvastatin greater than 40 mg due to increases in serum concentration of simvastatin, with a 2- to 3-fold increase in some individuals.
-- Xyrem (sodium oxybate) oral solution - updated with paediatric license extension (treatment of narcolepsy with cataplexy in children from > 7 years); a warning regarding sleep apnoea with advice to monitor for respiratory depression and addition of anxiety, bipolar disorder and psychosis as adverse events
-- Velphoro (sucroferric oxyhydroxide) - the indication for the control of serum phosphorus levels in patients with CKD stages 4-5 or with CKD on dialysis has been extended to include use in paediatric patients aged ≥ 2 years.
-- OBIZUR (susoctocog alfa) - advises that during the course of treatment, appropriate determination of Factor VIII levels is recommended to guide the dose to be administered and the frequency of repeated infusions.
- Depakote and Epilim (valproic acid and sodium valproate) - notes the safety profile in paediatrics is comparable to adults, some reactions are more severe or principally observed in children, e.g. particular increased risk of severe liver damage, pancreatitis, and psychiatric disorders e.g. aggression.
-- Betnesol-N (neomycin sulfate betamethasone sodium phosphate) Eye, Ear and Nose Drops - SPC highlights warnings of increased risk of ototoxicity with aminoglycosides administered to pts with mitochondrial mutations, particularly the m.1555A>G mutation, including cases where aminoglycoside levels were within recommended range (incidence unknown).

Food and Drug Administration (FDA) USA
- FDA warns consumers to avoid certain male enhancement and weight loss products sold through Amazon, eBay and other retailers due to hidden, potentially dangerous drug ingredients - link

Health Canada – MedEffect Notice
- Summary Safety Reviews:
-- Tamiflu (oseltamivir) and generics - potential risk of bleeding (haemorrhage) - link
-- Selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs) – potential safety issue: persistent, worsening or new symptoms of sexual problems (dysfunction) despite stopping treatment - link
-- Tramadol-containing products – potential risk of hallucinations - link
-- Carboplatin-containing products – potential risk of Posterior Reversible Encephalopathy Syndrome (PRES), a rare and serious brain condition - link
- Safety Information on Suboxone (buprenorphine and naloxone) and the risk of overdose or underdose when switching between dosage forms or routes of administration - link
- Health Product InfoWatch, December 2020
-- New information: Safety brief - Opioid safety reminders; Product monograph update - Valcyte (valganciclovir)

Institute for Safe Medication Practices (ISMP) USA
- Medication Safety Alert! January 14, 2021
-- Learning from Errors with the New Coronavirus Disease 2019 (COVID-19) Vaccines
-- Bamlanivimab confused with belimumab
-- PIQRAY (alpelisib) labeling confusion
-- Discard rufinamide oral suspension within 90 days of opening

Medicines and Healthcare products Regulatory Agency (MHRA) UK
- Guidance: Use of medicines in pregnancy and breastfeeding - link
- Guidance: Valproate use by women and girls - link
- Public Assessment Report of antiepileptic drugs: review of safety of use during pregnancy - link

- Drug Safety Updates
  -- Antiepileptic drugs in pregnancy: updated advice following comprehensive safety review - link
  -- Dimethyl fumarate (Tecfidera); updated advice on the risk of progressive multifocal leukoencephalopathy (PML) associated with mild lymphopenia - link
  -- Fingolimod (Gilenya): updated advice about risks of serious liver injury & herpes meningoencephalitis - link
  -- SSRI/SNRI antidepressant medicines: small increased risk of postpartum haemorrhage when used in the month before delivery - link
  -- Aminoglycosides (gentamicin, amikacin, tobramycin, and neomycin): increased risk of deafness in patients with mitochondrial mutations - link
  -- Systemic and inhaled fluoroquinolones: small risk of heart valve regurgitation; consider other therapeutic options first in patients at risk - link
  -- Erythromycin: caution required due to cardiac risks (QT interval prolongation); drug interaction with rivaroxaban - link; update on known risk of infantile hypertrophic pyloric stenosis - link

- Letters sent to Healthcare Professionals in November 2020:
  -- Ondexxya (andexanet alfa): avoid use of andexanet prior to heparinization
  -- Tecfidera (dimethyl fumarate): updated recommendations in the light of cases of progressive multifocal leukoencephalopathy (PML) in the setting of mild lymphopenia
  -- Gilenya (fingolimod): updated recommendations to minimise risk of drug-induced liver injury
  -- Rozlytrek (entrectinib): missing side effect in EU Patient Information Leaflet
  -- Solu-Medrone (methylprednisolone as sodium succinate): change from lactose-containing to a lactose-free formulation; risk of serious allergic reactions if formulations are confused
  -- Gliolan (5-aminolevulinic acid, 5-ALA): what to do in case of delayed surgery and information on fluorescence in non-high-grade glioma
  -- Midazolam maleate (Epistatus 10mg/1ml oromucosal solution, multidose bottle), unlicensed, emergency use medication for prolonged, acute, convulsive seizures: potential risk of incorrectly engaged child-resistant container closures

- Letters sent to Healthcare professionals in December 2020
  -- Systemic and inhaled fluoroquinolones: risk of heart valve regurgitation/incompetence
  -- Lorazepam (Ativan 4mg/ml): temporary supply of a different presentation and changes to the instructions
  -- Zerbaxa (ceftolozane/tazobactam) 1g/0.5g powder for concentrate for solution for infusion: global recall of product

MIMS monthly updates – January 2021
- New Contraindications:
  -- Cefotaxime sodium (DBL Cefotaxime Sodium for Injection) contraindicated with pregnancy and during lactation.
  -- Citalopram HBr (Cipramil) should not be used in combination with monoamine oxidase inhibitors (MAOIs), including selegiline in daily doses exceeding 10 mg/day.
  -- Metoclopramide HCl/paracetamol (Anagraine) contraindicated in children under 18 years of age.
  -- Vincristine sulfate (DBL) Injection contraindicated with intrathecal administration.
  -- Zoledronic acid (DBL Zoledronic Acid) contraindicated in patients with severe renal impairment (ClCr ≤ 30 mL/min).

TGA
- Recall: Infants’ Friend oral liquid recall due to presence of chloroform - link
- Recall: Tenofovir Disoproxil Emtricitabine Mylan 300/200 - potential for split tablets to lead to ineffective dose - link
- Safety advisory: Zostavax vaccine - risk of infection with the vaccine virus - link

PAPERS OF INTEREST
American Journal of Cardiology
- Meta-Analysis Evaluating the Efficacy and Safety of Low-Intensity Warfarin for Patients >65 Years of Age with Non-Valvular Atrial Fibrillation - link

**American Journal of Gastroenterology**
- Biologics during Pregnancy in Women with Inflammatory Bowel Disease and Risk of Infantile Infections. A Systematic Review and Meta-Analysis - link

**American Journal of Health-System Pharmacy (AHJP)**
- ASHP Guidelines on Medication-Use Evaluation - link
- Practice-enhancing publications about the medication-use process in 2019 - link
- Comparison of IV oncology infusions compounded via robotics and gravimetrics-assisted workflow processes - link
- Pharmacy-facilitated medication history program at a community teaching hospital: A pre-post study in an emergency department - link
- Bempedoic acid: Review of a novel therapy in lipid management - link
- Executive summary of the meeting of the 2020 ASHP Commission on goals: preparing the healthcare workforce for a digital future - link
- Navigating uncharted waters: Developing a standardized approach for evaluating and implementing biosimilar products at a comprehensive cancer center - link
- Critical care essentials for pharmacy trainees and new clinical practitioners - link
- Implementation of a pharmacist care manager model to expand availability of medications for opioid use disorder - link
- Preparing pharmacists to increase naloxone dispensing within community pharmacies under the Pennsylvania standing order - link
- Management of type 2 diabetes with oral semaglutide: Practical guidance for pharmacists - link
- Remote introductory pharmacy practice experiences focused on veterans prescribed chronic opioid therapy - link
- To crush or not to crush: A brief review of novel tablets and capsules prepared from nanocrystal and amorphous solid dispersion technologies - link
- In the midst of an opioid epidemic: Pharmacists on the frontline of substance use disorder treatment - link
- Evaluation of an opioid risk mitigation initiative for veterans undergoing hip or knee arthroplasty at San Francisco Veterans Affairs Heath Care System - link
- Atolevimab, Maftivimab, and Odesivimab-ebgn for Zaire ebolavirus - link
- Weight gain associated with insulin detemir vs insulin glargine in clinical practice: A retrospective longitudinal cohort study - link
- The substance use intervention team: A hospital-based intervention and outpatient clinic to improve care for patients with substance use disorders - link

**Arthritis and Rheumatology**
- Incidence, Clinical Features, and Outcomes of Late-Onset Neutropenia from Rituximab for Autoimmune Disease - link

**Australian Journal of Primary Health**
- Evaluation of academic detailing visits on GP knowledge and practice for statin use and management - link
- Why do people with long-term health needs see more than one GP?: a qualitative study - link
- Patient activation and Type 2 diabetes mellitus self-management: a systematic review and meta-analysis - link
- Adequacy of health literacy and its effect on diabetes self-management: a meta-analysis - link
- Effect of community mental health care programs in Australia: a systematic review - link

**BMJ Quality and Safety**
- The Irish National Adverse Event Study-2 (INAES-2): longitudinal trends in adverse event rates in the Irish healthcare system - link
- Quality & Safety in the Literature: March 2021 - link

**British Journal of Clinical Pharmacology**
- Adverse outcomes of proton pump inhibitors in patients with chronic kidney disease The CKD-REIN cohort study - link
- Safety of clonidine used for long-term sedation in paediatric intensive care: systematic review - link
- No population left behind: improving pediatric drug safety using informatics & systems biology - link
- Clinical correlates and outcomes associated with pregabalin use among people prescribed opioids for chronic non-cancer pain: A five-year prospective cohort study - link
- Trends in new prescription of gabapentinoids and of coprescription with opioids in the four nations of the United Kingdom, 1993-2017 - link
- Review: Ulipristal acetate: How to value safety in a new drug? - link
- Population pharmacokinetics of ganciclovir and valganciclovir in pediatric solid organ and stem cell transplant recipients - link
- Overcoming barriers to implementing precision dosing with 5-fluorouracil and capecitabine - link
- Pilot drug and therapeutic committee program in Sierra Leone: a descriptive mixed method study - link
- Proton pump inhibitors and risk of all-cause and cause-specific mortality: a cohort study - link
- Comprehensive evaluation of microneedle-based intradermal adalimumab delivery versus subcutaneous administration: results of a randomized controlled trial - link
- Domperidone and the Risks of Sudden Cardiac Death and Ventricular Arrhythmia: A Systematic Review and Meta-Analysis of Observational Studies - link

British Journal of General Practice
- GPs’ mindlines around deprescribing antihypertensives in older patients with multimorbidity: qualitative study - link

British Medical Journal (BMJ)
- Use of proton pump inhibitors to treat persistent throat symptoms: multicentre, double blind, randomised, placebo controlled trial - link
- Clinical Review: Axial spondyloarthritis: new advances in diagnosis and management - link
- Sodium-glucose cotransporter protein-2 (SGLT-2) inhibitors and glucagon-like peptide-1 (GLP-1) receptor agonists for type 2 diabetes: systematic review and network meta-analysis of randomised controlled trials – link
- Optimising antimicrobial stewardship interventions in English primary care: a behavioural analysis of qualitative and intervention studies - link

BMJ Open
- Coenzyme Q10 supplementation for prophylaxis in adult patients with migraine—a meta-analysis - link
- Association between tendon ruptures and use of fluoroquinolone, and other oral antibiotics: a 10-year retrospective study of 1 million US senior Medicare beneficiaries – link
- Are patients’ goals in treatment associated with expected treatment outcomes? Findings from a mixed-methods study on outpatient pharmacological treatment for opioid use disorder - link

Circulation
- How Should We Sequence the Treatments for Heart Failure and a Reduced Ejection Fraction? A Redefinition of Evidence-Based Medicine - link
- Efficacy of Ertugliflozin on Heart Failure-Related Events in Patients with Type 2 Diabetes Mellitus and Established Atherosclerotic Cardiovascular Disease: Results of the VERTIS CV Trial - link

Cochrane
- Blood pressure targets in adults with hypertension - link
- Metformin treatment before and during IVF or ICSI in women with polycystic ovary syndrome - link
- Levonorgestrel intrauterine system for endometrial protection in women with breast cancer on adjuvant tamoxifen - link
- Antenatal corticosteroids for accelerating fetal lung maturation for women at risk of preterm birth - link
- Treatment options for progression or recurrence of glioblastoma: a network meta-analysis - link
- Paracetamol/acetaminophen (single administration) for perineal pain in the early postpartum period - link
- Oral non-steroidal anti-inflammatory drugs (single dose) for perineal pain in the early postpartum period - link
- Interventions for treating leg ulcers in people with sickle cell disease - link
- Pharmacological interventions for self-harm in adults - link
- Behavioural interventions for smoking cessation: an overview and network meta-analysis - link
- Tyrosine supplementation for phenylketonuria - link
- Gabapentin add-on treatment for drug-resistant focal epilepsy - link
- Protocol: Pharmacological treatments for low back pain in adults: an overview of Cochrane Reviews

**Diabetes Care**
- Efficacy and Safety of Dulaglutide 3.0 mg and 4.5 mg Versus Dulaglutide 1.5 mg in Metformin-Treated Patients with Type 2 Diabetes in a Randomized Controlled Trial (AWARD-11) - link

**Emergency Medicine Journal**
- Improving outcomes for older people in the emergency department: a review of reviews - link

**European Heart Journal**
- Evolution of antithrombotic therapy in patients undergoing percutaneous coronary intervention: a 40-year journey - link
- Low-density lipoprotein cholesterol reduction and statin intensity in myocardial infarction patients and major adverse outcomes: a Swedish nationwide cohort study - link
- Effect of empagliflozin on exercise ability and symptoms in heart failure patients with reduced and preserved ejection fraction, with and without type 2 diabetes - link

**European Journal of Hospital Pharmacy**
- Burden of enteral supplement interactions with common antimicrobial agents: a single-centre observational analysis - link
- Acute onset psychosis with complex neurobehavioural symptomatology following the intramuscular injection of hyoscine butylbromide: a case report with an overview of the literature - link
- Pharmacotherapeutic management of Parkinson’s disease inpatients: how about asking hospital pharmacists? - link
- Impact of transplant pharmacists on length of stay and 30-day hospital readmission rate: a single-centre retrospective cohort study - link
- Levofloxacin induced bullous fixed drug eruption: a rare case report - link
- Position paper on patient safety - link
- Burden of enteral supplement interactions with common antimicrobial agents: a single-centre observational analysis - link
- Predictive performance of reported vancomycin population pharmacokinetic model in patients with different renal function status, especially those with augmented renal clearance - link

**European Journal of Clinical Pharmacology**
- What should patients do if they miss a dose? A systematic review of patient information leaflets and summaries of product characteristics - link
- Pattern of treatment of behavioural and psychological symptoms of dementia and pain: evidence on pharmacoutilization from a large real-world sample and from a centre for cognitive disturbances and dementia - link
- Serotonin syndrome by drug interactions with linezolid: clues from pharmacovigilance-pharmacokinetic/pharmacodynamic analysis - link
- Ceftriaxone dosing in patients admitted from the emergency department with sepsis - link
- Monte Carlo simulation evaluation of tigecycline dosing for bacteria with raised minimum inhibitory concentrations in non-critically ill adults - link
- Effects of a multifaceted intervention to promote the use of intravenous iron sucrose complex instead of ferric carboxymaltose in patients admitted for more than 24 h - link
- Benzodiazepine withdrawal in older people: what is the prevalence, what are the signs, and which patients? - link
- Quality of anticholinergic burden scales and their impact on clinical outcomes: a systematic review - link
- The clinical and educational outcomes of an inter-professional student-led medication review team, a pilot study - link
- Current evidence on the impact of medication optimization or pharmacological interventions on frailty or aspects of frailty: a systematic review of randomized controlled trials - link

**Health Technology Assessment**
- Non-benzodiazepine hypnotic use for sleep disturbance in people aged over 55 years living with dementia: a series of cohort studies - link
- Compression stockings in addition to low-molecular-weight heparin to prevent venous thromboembolism in surgical inpatients requiring pharmacoprophylaxis: the GAPS non-inferiority RCT - link

**Heart**
- Residual risks of ischaemic stroke and systemic embolism among atrial fibrillation patients with anticoagulation: large-scale real-world data (F-CREATE project) - link

**Implementation Science**
- Clinical decision support improves the appropriateness of laboratory test ordering in primary care without increasing diagnostic error: the ELMO cluster randomized trial - link

**Internal Medicine Journal**
- Accessible and affordable healthcare? Views of Australians with and without chronic conditions - link
- Group B Streptococcal bacteraemia - Changing trends in a tropical region of Australia – link
- High Frequency of Anticoagulation Management Errors Preceding Ischemic Strokes in Atrial Fibrillation - link
- Epidemiology and Microbiology of Severe Community-Acquired Pneumonia in Central Australia: A Retrospective Study - link

**International Journal of Clinical Pharmacy**
- Cancer pain management and the roles of pharmacists in China - link
- Stroke patients’ support: evaluation of knowledge, practices and training needs of French community pharmacists – link
- Gabapentinoid misuse, abuse and non-prescribed obtainment in a United States general population sample - link
- Effectiveness of ibuprofen plus paracetamol combination on persistence of acute musculoskeletal disorders in primary care patients - link
- Guideline-led prescribing to ambulatory heart failure patients in a cardiology outpatient service - link
- The role of a clinical pharmacist in spurious penicillin allergy: a narrative review - link
- Training pharmacy residents as transitions of care specialists: a united states perspective - link

**JAMA**
- Viewpoint: Balancing the Risks and Benefits of Benzodiazepines - link
- Viewpoint: Obesity Management in Women of Reproductive Age - link
- Effect of High-Dose Trivalent vs Standard-Dose Quadrivalent Influenza Vaccine on Mortality or Cardiopulmonary Hospitalization in Patients With High-risk Cardiovascular Disease: A Randomized Clinical Trial - link
- Effect of Digoxin vs Bisoprolol for Heart Rate Control in Atrial Fibrillation on Patient-Reported Quality of Life. The RATE-AF Randomized Clinical Trial - link

**JAMA Dermatology**
- Research Letter: Mucocutaneous Adverse Events Associated with Oral Sirolimus for the Treatment of Vascular Anomalies - link

**JAMA Internal Medicine**
- Treatment and Outcomes of Inpatient Hypertension among Adults with Noncardiac Admissions - link

**JAMA Network Open**
- Glaucoma in Adults—Screening, Diagnosis, and Management. A Review - link
- Management of Crohn Disease. A Review - link

**JAMA Neurology**
- Add-On Cannabidiol Treatment for Drug-Resistant Seizures in Tuberous Sclerosis Complex. A Placebo-Controlled Randomized Clinical Trial - link
- Assessment of Botulinum Neurotoxin Injection for Dystonic Hand Tremor. A Randomized Clinical Trial - link
- Prediction of Early Neurological Deterioration in Individuals with Minor Stroke and Large Vessel Occlusion Intended for Intravenous Thrombolysis Alone - link

JAMA Oncology
- Frequency of and Factors Associated with Nonmedical Opioid Use Behavior among Patients with Cancer Receiving Opioids for Cancer Pain - link
- Review: Treatment Deescalation Strategies for Nasopharyngeal Cancer - link
- Association of Osteonecrosis of the Jaw with Zoledronic Acid Treatment for Bone Metastases in Patients with Cancer – link

JAMA Pediatrics
- Risk of Substance Use Disorder and Its Associations with Comorbidities and Psychotropic Agents in Patients With Autism - link

JAMA Surgery
- Association of Fluoroquinolone Use with Short-term Risk of Development of Aortic Aneurysm - link; commentary

Journal of Health Services Research & Policy
- Working together to co-produce better health: The experience of the Collaboration for Leadership in Applied Health Research and Care for Northwest London - link
- Evidence-informed health care policy and practice: using record linkage to uncover new knowledge - link

Journal of the American Geriatrics Society
- Transforming the Medication Regimen Review Process Using Telemedicine to Prevent Adverse Events - link

Journal of Clinical Oncology
- Defining the Optimal Total Number of Chemotherapy Courses in Younger Patients with Acute Myeloid Leukemia: A Comparison of Three versus Four Courses - link
- Cardiac Safety of Osimertinib: A Review of Data - link
- Overview: Immunotherapy for Hematologic Malignancies - link

Journal of Pharmacy Practice and Research (JPPR)
- Standard of practice in oncology and haematology for pharmacy services - link
- The impact of pharmacist-led strategies implemented to reduce errors related to cancer therapies: a systematic review - link
- Postoperative pain management on discharge after day case gynaecologic laparoscopy - link
- A retrospective review examining intravenous iron infusion dosing methods - link
- Perceptions of hospital pharmacists and pharmacy technicians towards expanding roles for hospital pharmacy technicians: a cross-sectional survey - link
- Knowledge, attitudes, and practices of mothers on the use of oral rehydration salts in children with diarrhoea: a cross-sectional survey in Malaysia - link

Lancet
- Isoniazid preventive therapy plus antiretroviral therapy for the prevention of tuberculosis: a systematic review and meta-analysis of individual participant data - link
- Effects of dapagliflozin on major adverse kidney and cardiovascular events in patients with diabetic and non-diabetic chronic kidney disease: a prespecified analysis from the DAPA-CKD trial – link
- Effects of empagliflozin on estimated extracellular volume, estimated plasma volume, and measured glomerular filtration rate in patients with heart failure (Empire HF Renal): a prespecified substudy of a double-blind, randomised, placebo-controlled trial - link
- APOE and Alzheimer's disease: advances in genetics, pathophysiology, and therapeutic approaches - link
- Ultra-early tranexamic acid after subarachnoid haemorrhage (ULTRA): a randomised controlled trial - trial
- Review: Acute flaccid myelitis: cause, diagnosis, and management - link
- Viewpoint: The case for an HIV cure and how to get there - link
- Position paper: International consensus on a standard set of outcome measures for child and youth anxiety, depression, obsessive-compulsive disorder, and post-traumatic stress disorder - link
- Forecasting seizure risk in adults with focal epilepsy: a development and validation study - link
- Myelodysplastic syndrome and acute myeloid leukaemia in patients treated with PARP inhibitors: a safety meta-analysis of randomised controlled trials and a retrospective study of the WHO pharmacovigilance database - link
- The effect of vitamin D supplementation on acute respiratory tract infection in older Australian adults: an analysis of data from the D-Health Trial - link

**National Institute for Health Research (NIHR) Signals**
- Spironolactone is not an effective treatment for one type of irregular heartbeat, research shows - link

**New England Journal of Medicine**
- Clinical Practice: Osteoarthritis of the Knee - link
- Review: Pathophysiology of Inflammatory Bowel Diseases - link
- Review: Systemic Therapy for Estrogen Receptor–Positive, HER2-Negative Breast Cancer - link
- Changes in Seizure Frequency and Antiepileptic Therapy during Pregnancy - link

**Pediatric Quality and Safety**
- Effectiveness of Pediatric Asthma Pathways in Community Hospitals: A Multisite Quality Improvement Study - link
- A Standardized Protocol for the Management of Appendicitis in Children Reduces Resource Utilization - link

**Public Library of Science (PLOS)**
- Assessing the risk of ketoacidosis due to sodium-glucose cotransporter (SGLT)-2 inhibitors in patients with type 1 diabetes: A meta-analysis and meta-regression - link

**The British Journal of Psychiatry**
- Incidence of neurodegenerative and cerebrovascular diseases associated with antihypertensive drug classes - link

**Therapeutics and Clinical Risk Management**
- Risk of True Allergy to Local Anesthetics: 10-Year Experience from an Anesthesia Allergy Clinic in China - link
- Drugs for the Treatment of Chronic Hand Eczema: Successes and Key Challenges - link
- Update on Safety Profiles of Vitamins B1, B6, and B12: A Narrative Review - link

**Thrombosis Research**
- Twice- or Once-Daily Dosing of Direct Oral Anticoagulants, a systematic review and meta-analysis - link
- Effectiveness and safety of direct-acting oral anticoagulants compared to vitamin K antagonists in patients with left ventricular thrombus: A meta-analysis - link