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ABSTRACT BOOK

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Pharmacoepidemiology and Pharmacovigilance research methods

Validation of major and all bleeding phenotyping algorithm on electronic health records

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Biography:

Aaron Yap is a data analyst at the Vigilance and Compliance Branch, Health Sciences Authority, Singapore. He works in the Active Safety Surveillance Analytics Team to monitor the safety of medicines and vaccines. A pharmacist by training, he graduated with a BSc Hons. in Pharmacy from the National University of Singapore in 2018. He is currently in his final year studying MSc Epidemiology at the London School of Hygiene and Tropical Medicine.

Aims/Objectives: Bleeding is an important health outcome of interest in epidemiological studies. We aimed to develop and validate rule-based algorithms to identify major bleeding and all bleeding within real-world electronic healthcare data.

Methods: We took a random sample (n=1630) of patient admissions to Singapore public hospitals from 2019 and 2020, stratifying by hospital and year of admission. We adopted the International Society on Thrombosis and Haemostasis definition for major bleeding. Presence of major bleeding and all bleeding were ascertained by two annotators through chart review. A total of 630 and 1,000 records were used for algorithm development and validation, respectively. We formulated two algorithms: sensitivity and positive predictive value (PPV)-optimized algorithms. A novel combination of hemoglobin tests patterns and diagnosis codes were used in the final algorithms.

Results: The prevalence of incident major bleeding and all bleeding events in our study population was approximately 5.0% and 13.5%, respectively. In the validation study, diagnosis codes alone yielded low sensitivities for major bleeding (0.14) and all bleeding (0.24), although specificities and PPV were high (>0.97). For major bleeding, the sensitivity-optimized algorithm had much higher sensitivity and negative predictive value (NPV) (sensitivity=0.94, NPV=1.00), however false positive rates were also relatively high (specificity=0.90, PPV=0.34). PPV-optimized algorithm had improved specificity and PPV (specificity=0.96, PPV=0.52), with little reduction in sensitivity and NPV (sensitivity=0.88, NPV=0.99). For all bleeding events, our algorithms had less optimal performances, with lower sensitivities (0.53 to 0.61).

Conclusion: The use of diagnosis codes alone misses many genuine major bleeding events. We have developed major bleeding algorithms with high sensitivities which can be used in conjunction with chart reviews to ascertain events within populations of interest.

Keywords: major bleeding, electronic health records, phenotyping, validation

Effect of four antimalarial treatments on haematocrit in children in southwest Nigeria

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Biography:

Dr. Zacchaeus Olofin is a medical doctor and a Clinical Pharmacologist. He bergs a bachelor's degree in Medicine and Surgery at the University of Ibadan in 2012. He also bergs a Master of Science degree in Pharmacology and Therapeutics from the same institution in 2018. Presently running a doctoral degree in Pharmacology and Therapeutics from the same institution. Dr. Olofin is a researcher with bias in Pharmacoepidemiology. He has been doing research in the field of Pharmacoepidemiology for over 6 years and has over two manuscripts awaiting publication.

Aim/Objective: Anaemia in malaria has both central (dyserythropoiesis) and peripheral causes (phagocytosis of both infected and uninfected erythrocytes and haemolysis). Some antimalarial drugs also cause intravascular hemolysis leading to anemia. However, it is often difficult to disentangle the anemia effect of malaria from its treatments.
The aim of this study was carried out to compare the change in hematocrit following four antimalarial treatments.

Methods: Data were extracted from 313 case record forms of children that met the eligibility criteria aged 3-119 months enrolled in antimalarial clinical trials in Southwest Nigeria between 1998 and 2014. Change in haematocrit level from baseline through 28 days follow up period were compared among children treated with artemether-lumefantrine (82), artovaquone-proguanil (41), artesunate-amodiaquine (156) and chloroquine (34).
Repeated measures analysis was done by fitting a general linear model (GLM).
Results: The median age of the study population was 25 months and 54% were males. The mean differences (95% CI) in haematocrit from baseline were 4.7% (95% CI = 3.6, 5.8), 4.4% (95% CI = 2.7, 6.0), 3.8% (95% CI = 3.0, 4.7) and 2.4% (95% CI = 0.5, 4.4), for artemether-lumefantrine, artovaquone-proguanil and artesunate-amodiaquine and chloroquine, respectively. Using the general lineal model, repeated measure analysis showed that there were significant differences in the mean haematocrit level over the 28-day follow-up among the four treatment groups ($p<0.05$).

Conclusions: All children experienced increases in haematocrit after treatment, artemether-lumefantrine appearing to result in a greater increase in haematocrit than other antimalarial drugs.

Key words: Anaemia, Haematocrit, Antimalarial Drugs

Defining liver-injury outcomes and exposures using routine clinical database for pharmacoepidemiology analyses

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Biography:

Suniti is a medical doctor in her third year working in the public health sector in South Africa. She completed her Masters in Public Health (MPH) from the University of Cape Town this year. Her interests lie within the fields of epidemiology, biostatistics, HIV/AIDS and liver injuries. She was able to merge her clinical interests and expanding skillset in pharmacoepidemiology within her MPH thesis.

Objectives

There is limited data from randomised controlled trials that report incidence of liver injury in South Africa in PLHIV on first-line antiretroviral therapy (ART). We used routinely collected data to define liver injury outcomes and drug exposures to determine incidence of, and risk factors for, liver injury and liver injury-related hospitalisations in this population.

Methods

We used routine clinical data from Aid for AIDS (AfA), a private sector HIV disease management programme. The AfA database does not explicitly record adverse drug reactions or adverse events; so we used this routinely collected data to define our exposures and outcomes. We used accurately recorded ICD10 codes, hospital admission dates and routinely captured laboratory data (alanine aminotransferase) to construct liver injury and liver injury-related hospitalisation outcomes defined as ALT≥200 IU/L and ALT≥200 IU/L with an ICD10 code that suggested liver injury, respectively. We used prescription records to define exposure to specific ART regimens. We estimated exposure to anti-tuberculosis treatment by combining prescriptions with relevant ICD10 codes (these included rifampicin-containing treatments, prophylaxis or TB-related hospitalisations), up until six months from the first claim date.

Results

We included 92,757 adult PLHIV in our study cohort in whom the incidence of liver injury-related hospitalisations was 0.04 (95% confidence interval: 0.03-0.05) per 100person-years. Anti-tuberculosis treatment, and being on efavirenz- or nevirapine-based regimens were all strongly associated with liver injury-related hospitalisations, with hazard ratios of 5.68 (2.58-12.48), 1.97 (0.69-5.58) and 3.56 (0.93-13.65) respectively, in cox regression models adjusted for age, sex, CD4 count and viral load at ART initiation, and alcohol-induced pathology.

Conclusions

Routine clinical databases may be an efficient and effective resource for pharmacovigilance in PLHIV in resource limited settings.

Keywords

Liver injury, PLHIV, pharmacoepidemiology, routine clinical database

Assessment of Safety Profile of Secukinumab in Real-World Scenario Using FAERS Database

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Biography:

Dr. Ashwin Kamath is an Associate Professor of Pharmacology at Kasturba Medical College, Mangalore. He is currently involved in conducting secondary data research to understand drug safety and contribute to rational use of drugs.

Aim/Objective: Secukinumab is an anti-IL-17 monoclonal antibody approved for the treatment of psoriasis. Its long-term safety, especially in the real-world setting, needs to be established. This study aimed to describe the adverse events (AE) reported with secukinumab use using the United States Food and Drug Administration Adverse Event Reporting System (FAERS) database and compare these with those reported with the use of other biologics and non-biological drugs approved for psoriasis.

Methods: A case–non-case study was conducted using FAERS data files containing AE reports for the period 2015-2021. Primary or secondary suspect medications indicated in psoriasis were identified and analyzed. Medical dictionary for regulatory activities (MedDRA version 24.1) was used to analyze the adverse event terms. To detect potential safety signals of AE from secukinumab use, disproportionality analysis was employed by utilizing proportional reporting ratio (PRR) and reporting odds ratio (ROR); PRR > 2 and ROR > 2 with the lower bound 95% confidence interval > 1 were considered significant.

Results: A total of 365590 adverse event reports were identified from the FAERS database; of these, 44761 reports involved use of secukinumab. Safety signals were identified for ocular infections and gastrointestinal adverse events at the standardised MedDRA query level. Safety signals for oral candidiasis, oral herpes, conjunctivitis, eye infections, ulcerative colitis, etc., were identified at the preferred term level.

Conclusion: The findings of our study regarding the safety profile of secukinumab in patients with psoriasis are consistent with the findings of earlier studies, such as the increased risk of infections and inflammatory bowel disease. However, our study also identified additional safety signals, such as increased risk of eye infections, spinal pain, liver injury, pyelonephritis, etc., that need to be further evaluated for a potential causal relationship with secukinumab using prospective clinical studies.

Keywords: Secukinumab, psoriasis, adverse effects, biologics

Physician Perspectives on Poisoning: Necessity of a Mobile Application Solution

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Biography:

Aadrika is an enthusiastic intern at Kasturba Hospital, Department of Pharmacy Practice, MCOPS, MAHE, Manipal. Currently in the final year of her Doctor of Pharmacy (PharmD) course, she has a strong academic background and a passion for making a positive impact in healthcare.

Aadrika has achieved significant milestones in her field, including the publication of her article titled "Pharmacological actions and underlying mechanisms of Catechin: A review" in the esteemed journal Mini-Reviews in Medicinal Chemistry (Link: https://pubmed.ncbi.nlm.nih.gov/34477517/). She has also co-authored an article entitled "Isolation of Microbes possessing magnetosomes and their potential role in Drug delivery" in the "Research Journal of Pharmacy and Technology" (Link: https://rjptonline.org/HTMLPaper.aspxJournal=ResearchJournal of Pharmacy and Technology;PID=2020-13-10-86).

Driven by a desire to address healthcare challenges, Aadrika conducted research as part of her final year project. She performed qualitative interviews with 15 Emergency Care Physicians to gain insights into the challenges associated with treating pesticide poisoning. Her work aims to enhance the understanding and management of poisoning cases.

Aadrika possesses expertise in various areas of pharmacy practice, including clinical research, patient counseling, therapeutic drug monitoring, medication management, and pharmacokinetic dosing.

Beyond her professional pursuits, Aadrika is deeply interested in promoting holistic well-being. She has a keen interest in yoga and meditation, actively volunteering for organizations such as Art of Living. Aadrika believes in the power of these practices to improve mental health and overall well-being.

Beyond her professional pursuits, Aadrika is deeply interested in promoting holistic well-being. She has a keen interest in yoga and meditation, actively volunteering for organizations such as Art of Living. Aadrika believes in the power of these practices to improve mental health and overall well-being.

With her diverse skill set, passion for healthcare, and dedication to personal growth, Aadrika is poised to make a meaningful contribution to the field of pharmacy and advocate for holistic wellness.

INTRODUCTION:

Pesticide poisoning poses a global challenge, contributing significantly to morbidity and mortality rates. The main factors behind this issue are delayed diagnosis and treatment. The recurring evidence showcases a lack of awareness regarding the obstacles physicians encounter and the absence of dedicated educational resources and interventional tools such as poison specific mobile applications to aid diagnosis and treatment.

OBJECTIVE:

The objective of this study was to assess the need for the development of Mobile Application through qualitative, semi-structured, in-depth interviews of Physicians and PG residents.

METHODOLOGY:

We performed in-depth, semi-structured qualitative interviews with 15 physicians and PG residents from the Emergency Medicine Department. The interview guide was validated using the "Interview protocol refinement methodology". Prior consent was obtained, and interviews were conducted either face-to-face or via telephone, with audio recordings made. Verbatim transcription of the interviews was completed, and thematic analysis was conducted using NVivo software.

RESULTS:

Thematic analysis helped identify the barriers in timely diagnosis and treatment of poisoning cases. The themes encompassed current management and identification approaches, the reference materials they use to

expand their knowledge base, the barriers they face in identifying and treating poisoning cases, and the desired features of a mobile application. Our study highlights the need for a mobile application with several essential features, such as availability of demographics-specific information, offline accessibility, and a cost-free subscription. Additionally, including visual aids along with general management guidelines, specific antidotes, and locally available formulations. would be beneficial.

CONCLUSION:
The qualitative interviews provide a roadmap for the development and implementation of the mobile application in the clinical settings. Developing this application can help address the gaps in literature while helping the physicians in early diagnosis of the source of poison in the emergency settings.

Keywords: Pesticide poisoning, Mobile application, Physicians, Management.

Real-world evidence of non-adherence and non-persistence to antiretroviral among PLWH in Belgium

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Biography:

Dr ILBOUDO Dieudonné is a medical Doctor and holds a master's degree in Pharmacovigilance and Pharmacoepidemiology. His area of interest is research on the use of drugs in the population. He is particularly interested in the use of drugs, their real effectiveness and their safety in particular populations such as the elderly, pregnant women and children.

He is the doctor in charge of the Bérégadougou Medical Centre/Banfora Health District (Burkina Faso) where he is responsible for coordinating and implementing activities to promote maternal and child health.

He is currently enrolled in a PhD in Public Health at the "Université Libre de Bruxelles" with the aim of evaluating the use of ARVs in vulnerable populations in Belgium.

Objective: To date, little is known at the national level about the non-adherence and non-persistence to antiretroviral for people living with HIV (PLWH) treated in Belgium. We aimed to evaluate the real-world non-adherence and non-persistence to ART after 12 months of follow-up in PLWH.

Methods: A retrospective analysis of longitudinal was conducted using the Pharmanet database from January 1, 2018 to December 31, 2021 among adult patients in Belgium. Non-adherence was assessed over a 12-month follow-up period and reported as the proportion of days covered (PDC). Non-persistence was assessed as the first 90-day gap in treatment discontinuation. Modified Poisson regression and Cox proportional hazard models were generated to assess the factors related of non-adherence and non-persistence, respectively.

Results: Overall, of the 15291 PLWH received at least 02 ARV and 65.6% were men. After 12 months of follow-up, non-adherence to ART was 40.4% (95%CI: 39.6 – 41.2) whilst non-persistence was 11.9% (95%CI: 11.5, 12.5). Non-Adherence was higher among women (adjusted prevalence ratio [aPR] 1.25, (95% Confidence Interval [CI]: 1.21, 1.29), people living in Brussels-capital region (aPR: 1.15 [95% CI: 1.10, 1.19]) and Walonia region (aPR: 1.09 [95% CI: 1.05, 1.14]), MTR (aPR: 3.28, [95% CI: 3.15, 3,43]). Also, non-persistence was higher among women (adjusted hazard ratio (aHR) 2.04, (95% Confidence Interval [CI]: 1.79, 2.32)), young people (18 to 34 years, aHR : 2.02 (95% CI:1.41, 2.88) and 35 to 49 years, aHR : 1.74 (95% CI:1.24, 2.44)), Brussels-capital region (aHR: 1.27 (95% CI:1.07, 1.51)) and MTR regimen (aHR: 3.69 (95% CI:2.99, 4.57)).

Conclusion: Among PLWH in Belgium, non-adherence and non-persistence differences were observed between age, gender, and geographical region. Strategies that focus younger women in the Brussels-capital region and facilitate the transition from MTR to STR should be prioritized to achieve the impact in reducing non-adherence in Belgium.

Drug safety risk monitoring, evaluation and prevention

Rising Star Awardee: Nicotine Replacement Therapy on Maternal-Neonatal Outcomes and Smoking Cessation in Pregnant Women

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Biography:

I, Mr. Christy Thomas, focused and dedicated researcher in the field of Pharmacy Practice, specializing in Meta-research, Pharmacoeconomics, and environmental epidemiology in oncology. I completed my M.Pharm. with a Gold medal from NIPER Hajipur and am currently pursuing my Ph.D. in the Department of Pharmacy Practice at NIPER Guwahati.

As a researcher, I have a diverse range of interests, including environmental pharmacoepidemiology, conducting targeted and systematic reviews, meta-analysis, pharmacoepidemiology, health economics and outcome research, and pharmacovigilance.

Currently, I am engaged in an ambitious Ph.D. thesis on the topic "Assessment of prevalence, risk factors, management, and economic burden of gallbladder cancer among the northeast population of India: a hospital-based prospective observational cohort study." The research aims to address the significant prevalence of gallbladder cancer in India, particularly in the northeast India region, and explore its impact on the economy and patients. By investigating epidemiological risk factors such as the carcinogenic role of heavy metals in drinking water, therapeutic management, and the economic burden of gallbladder cancer, I am aiming to contribute valuable insights to the field.

This study is the first of its kind to comprehensively examine the economic burden and carcinogenic role of heavy metals in drinking water in gallbladder cancer in the country. I believe my work has the potential to shape clinical practices, inform policy decisions, and improve patient outcomes.

Objective:
To assess the impact of NRT on maternal and neonatal outcomes, and smoking cessation in pregnant women.

Methodology:
A systematic search of multiple databases like PubMed, Cochrane CENTRAL, Google Scholar, Scopus, and ClinicalTrials.gov was performed to identify eligible studies from the inception to 31st May 2023. A combination of keywords, MeSH terms, and entry terms on Nicotine Replacement Therapy, and Pregnancy was used in combination with Boolean operators. All randomized controlled trials (RCTs) investigating the efficacy and maternal or neonatal outcomes of NRT in pregnant women compared with placebo or active comparator were included in the study. The Fixed or Random-effects model was used based on the heterogeneity identified using I^2 statistic and Cochran's Q test.

Results:
Out of 131 non-duplicate research articles identified through database searching, a total of 20 high-quality studies with 11,052 patients, were included in this study. NRT was significantly associated with an increased risk of neonatal deaths (OR=2.89; 95% CI:1.18, 7.07; P=0.02), low birth weight (OR=1.32; 95% CI: 1.08, 1.62; P=0.007), and caesarean delivery (OR=1.35; 95% CI: 1.02, 4.21; P=0.0005). On the other hand, NRT reduced the risk of congenital abnormalities (OR=0.62; 95% CI: 0.41, 0.95; P=0.03), assisted vaginal delivery (OR=0.72; 95% CI: 0.55, 0.95; P=0.02), and premature rupture of membrane (OR=0.29; 95% CI: 0.13, 0.68; P=0.004). Additionally, smoking cessation was found to be significantly higher in the NRT group compared to the control.

Conclusion:

The use of NRT in pregnant women is associated with both benefits and risks. NRT was found to increase the risk of neonatal deaths, low birth weight, and caesarean delivery, but it was also associated with a reduced risk of congenital abnormalities, assisted vaginal delivery, and premature rupture of membranes. Moreover, NRT was found to be effective in increasing smoking cessation among pregnant women compared to the control group.

Prospective Observational Pilot study of ADR as Prescribing Cascade amongst Elderly Patients

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Biography:

Ravinandan A. P. completed his B.Pharm and M.Pharm at JSS College of Pharmacy. Having 14 years of teaching experience and 10 years of research experience. As of today, 21 articles have been published in various national and international journals. Delivered 15 talks as a speaker or presenter at conferences or workshops. completed the role of scientific poster or session evaluator at five conferences or workshops. Being a program coordinator, I organized more than 20 major events like conferences, workshops, training sessions, and webinars. I have given an interview in mass media like TV news channels and All India Radio.

Aim/Objective:
To identify, document, report and analyze the reported adverse drug reactions due to prescribing cascade amongst elderly patients.

Methods: In a tertiary care hospital in Tumkur, South India, a prospective, observational, and pilot study was carried out. The study's data was obtained by utilizing the relevant data collection forms. The study comprised patients aged 65 and up who had been prescribed at least one medicine. The information gathered was entered into Microsoft Excel for PC analysis.

Results: A total of 40 patient data points were collected, among which 31 (77.5%) were male and 9 (22.5%) females. The average age was found to be 75.02 years. The majority of the patients are suffering from hypertension [21 (52.5%)] and type 2 diabetes mellitus [18 (45%)]. Because of the ageing process, 22 (55%) patients hematology and electrolyte reports were found abnormal. All the patients (100%) were prescribed polypharmacy, and among those, aspirin was commonly prescribed to 13 (32.5%). In the collected patient's data, these PCs are identified and assessed.

- Ciprofloxacin Steven Johnson Syndrome Pheniramine & Levocetrizine
- Nonsteroidal Anti-inflammatory Drugs Gastritis Pantoprazole
- Insulin Hypoglycaemia Dextrose
- Aspirin Gastric Irritation Pantoprazole
- Dapagliflozin General infections Antibiotics

Conclusion: ADRs are misjudged as new medical conditions, and new drugs are prescribed to manage them, intentionally or unintentionally. Prescribing cascades are the advanced stage of drug-related problems. Prescribing cascades unnecessarily leads to an increase in treatment costs, morbidity, and mortality. Preventing these cascades requires a better understanding of drug side effects and ADRs profiles by HCP. Hence, an in-depth study takes an hour in clinical research

Keywords: Drug related problems, Adverse drug reaction, prescribing cascade, elderly

Drug storage capacity of health systems in eight low- and lower-middle-income countries

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Biography:

Shariful Hakim is a statistics lecturer at Chander Hat Degree College in Nilphamari, Bangladesh. He earned a Master of Science in Statistics from Shahjalal University of Science and Technology in Sylhet, Bangladesh. His current research interests are on the development and evaluation of complex survey data-driven statistical approaches in public health and epidemiology (e.g., noncommunicable diseases, essential medicines, and infection prevention and control).

He does studies to learn how health systems in low-income nations may enhance people's health. He has five scholarly articles published in prestigious international journals, including two on the availability of essential drugs for diabetes and cardiovascular disease. and participated at international conferences.

Aim/Objective

Good drug storage practices within a health system contribute to medication integrity, patient safety, and efficient healthcare delivery. We aimed to evaluate the drug storage capacity within the health systems of eight low- and lower-middle-income countries (LLMICs).

Methods

We conducted a multicountry study of data from nationally representative Service Provision Assessment surveys in eight countries (Afghanistan, Bangladesh, Haiti, the Democratic Republic of the Congo, Malawi, Nepal, Senegal, and Tanzania) across three regions. We included facilities that store antibiotics, general medicines, vaccines, or contraceptive commodities. We examined four indicators to assess the drug storage capacity: medicines are off the floor and away from the wall; medicines are protected from water; medicines are protected from the sun; the storage area is free of rodent evidence; and the storage room is well ventilated. To investigate variation by country, facility type (hospital or non-hospital), facility ownership (government or private), and facility location (urban or rural), we estimated sample-weighted proportions of drug storage practices availability.

Results

We analyzed data from 8,561 health facilities (815 hospitals and 7,775 non-hospitals). Of all the good drug storage criteria, 96% of facilities storing medicines are shaded from the sun, while 81% of facility storage areas are not free of rodents in all the study countries. Overall, 66% of medical facilities satisfied all five storage requirements. In the Democratic Republic of the Congo, nearly 42% of facilities lack any drug storage practices, whereas in Bangladesh, 21% of facilities possess all the indicators of effective drug storage. In general, good drug storage practices were more readily available at government hospitals and rural facilities.

Conclusion

Steps must be taken to maintain optimal drug storage practices in health facilities for the provision of quality healthcare services and to improve patient outcomes in LLMICs.

Keywords: health system, drug storage, service provision assessment survey.

Thrombosis risk Following the First-Dose ChAdOx1 nCoV-19 Vaccine in Patients Undergoing Hemodialysis

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Biography:

Dr. Shao has published 68 SCI-indexed publications with the H-index of 14, mainly focusing on healthcare database studies and systematic reviews with meta-analyses. His research has led to citation by the COVID-19 review articles of JAMA and Science, treatment consensus of American Diabetes Association and European Association for the Study of Diabetes, and official report of heart diseases and stroke statistics from American Heart Association. He has received the 13th ISPE-ACPE Rising Star Award to recognize as a junior investigator with significant research contributions to pharmacoepidemiology.

Aim:
The ChAdOx1 nCoV-19 vaccine is associated with vaccine-induced thrombosis and thrombocytopenia (VITT). Patients with end-stage renal disease (ESRD) under hemodialysis are at elevated risk of heparin-induced thrombocytopenia, which shares similar mechanisms with VITT. We aimed to examine the risk of VITT after the first dose of ChAdOx1 nCoV-19 vaccine using a self-controlled case series analysis (SCCS).

Methods:
Drawing from the largest multi-center electronic medical records database in Taiwan, we identified adult patients between 1st December, 2020, and 31st December, 2021, who received a first dose of ChAdOx1 nCoV-19 vaccine and had an outcome of thrombocytopenia, venous thrombosis, or arterial thrombosis. Patients were assigned to either the hemodialysis or non-dialysis cohorts. We calculated the incident rate ratios (IRRs) of outcomes in different risk periods, compared to the baseline periods.

Results:
We identified 59 hemodialysis patients (mean age: 64.7 years) and 41 non-dialysis patients (mean age: 67.4 years) with an outcome. The SCCS analyses showed, for the hemodialysis group, a significantly increased risk of outcomes during the period 31 to 60 days post-exposure (IRR: 2.823; 95% CI: 1.423-5.600). However, in non-dialysis patients there was no increase in risks during any of the post-exposure risk periods.
Conclusion: For ESRD patients under hemodialysis, the first dose of ChAdOx1 nCoV-19 vaccine was associated with a 2.8-fold increase in risk of thrombosis.

Assessment of Therapeutic Drug Monitoring Services at A Secondary Care Hospital

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Biography:

I am a full-time Research Scholar at the Dept. of Pharmacy Practice, JSS College of Pharmacy, Mysuru, Karnataka, India.
My research work is focused on drug utilization evaluation (in psychiatric patients, community pharmacies, and ambulatory patients), and drug safety in special populations (elderly, pregnant women, and pediatrics). I have been a principal investigator in community-based studies that assessed the epidemiological profile of prediabetics/newly detected diabetics in India and the Middle East.
I am also involved in developing scales that assess the satisfaction of patients with healthcare services provided and assessing medication adherence.
Additionally, through my educational research, I have developed the problem-based learning (PBL) and the team-based learning (TBL) modules to effectively deliver the course content in the "Pharmacoepidemiology and Pharmacoeconomics" course of JSS Academy of Higher Education & Research, Mysuru, Karnataka, India.
I do collaborate with M. Pharm. and PharmD colleagues at my institution and design various pharmacoepidemiologic studies. We have published our pharmacoepidemiology studies in indexed journals.

Aim: To assess the therapeutic drug monitoring services at a secondary care hospital.

Methods: This prospective study was conducted over one year in a secondary care hospital. The clinical and demographic details of all the patients undergoing therapeutic drug monitoring (TDM) services at the study site were carefully reviewed and documented. The clinical details such as diagnosis, medications used with their dose, route, frequency, and duration, the reason for TDM, drugs assayed, observed serum drug concentration, target serum drug concentrations, and clinical pharmacists' recommendations were captured. The data was analyzed and presented descriptively.

Results: A total of 53 patients underwent 133 episodes of TDM services. Most of the patients were children (33/53, 62.2%) and males (38/53, 71.6%). Seizure disorder was the most common diagnosis (43, 81.1%) and valproic acid was the most frequently used drug (30, 56.6%). Therapeutic confirmation (124/133, 93.2%) was the most frequent reason for TDM, followed by routine monitoring (4/133, 3%), lack of therapeutic effectiveness (3/133, 2.2%), and suspected toxicity (2/133, 1.5%). In seventy-two (54.1%) episodes the observed serum drug concentration was within the recommended reference range, whereas, lower in 41 (30.8%) and higher in 18 (13.5%) episodes. In both the episodes (gentamycin and paracetamol) where TDM was carried out to assess the suspected toxicity the serum drug concentration was high. Dose escalation (35/41), no change in the dosage regimen (4/41), and patient education to enhance medication adherence (2/41) were the clinical pharmacists' recommendations in patients with lower serum drug concentrations. There were no changes made to the dosage regimen in most of the episodes (16/18) where serum drug concentration was high, except in two episodes the drug was stopped.

Conclusion: The TDM services at the secondary care hospital have optimized patient management through dose individualization.

Keywords: Dosage regimen, serum drug concentration, therapeutic drug monitoring, therapeutic range.

A Disproportionality analysis between MTOR Inhibitors and interstitial lung diseases: FDA Database

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Biography:

I am a Pharm D student at the Kerala University of Health Sciences, Thrissur, Kerala and I am interested in attending the ISPE Asian Conference on Pharmacoepidemiology. I have been studying pharmacy for five years, and I have completed several rotations in different settings, such as hospital, community, and ambulatory care. I have a keen interest in pharmacovigilance. I have participated in several workshops and seminars on pharmacovigilance, where I learned about the latest trends and challenges in this field. Also, I have also conducted a research project in the area of pharmacovigilance using data mining with disproportionality analysis. My goal is to become a clinical pharmacist who can provide patient-centered care and optimize medication therapy outcomes. Besides, I have a strong passion to involve in research. I believe that attending this conference will help me expand my knowledge and skills in the field of pharmacoepidemiology and pharmacovigilance, as well as network with other professionals and experts from around the world.

Aim: This study aims to find out the potential safety signal associated between mTOR inhibitors and ILD by Food and Drug Administration Adverse Event Reporting System (FAERS) databases.
Methods: Publicly available FAERS database was used to perform a case/non-case retrospective disproportionality analysis (2009Q1 to 2022Q3). OpenVigil 2.1MedDRA v24 was used to extract and filter data from the FAERS database. The preferred term used for the study was “interstitial lung disease” and the drugs included ere everolimus, sirolimus, and temsirolimus. Reporting odds ratio (ROR), proportional reporting ratio (PRR), and information component (IC) were used to detect signals.

Results: Overall, 62,117 AE reports related to mTOR inhibitors were recorded during the period. Of these 1,027 AE reports on ILD were submitted to the FAERS database. Everolimus accounted for 723, sirolimus for 191, and temsirolimus for 113 cases of ILD reports associated with mTOR inhibitors. On performing age and gender stratification, it was found that the age group of 19-64 years and the female sex had the highest signal strength.

Conclusion: This study has shown positive signals for ILD with everolimus, sirolimus, and temsirolimus which were not yet established in clinical trials. Further study with well-designed epidemiological data is required to validate these results.

Keywords: Mammalian target of rapamycin inhibitor, Interstitial lung disease, Pharmacovigilance, safety signals.

Pharmaceutical policy and administration / Pharmacoepidemiology and traditional medicines

Rising Star Awardee: Changes in Antibiotic Prescribing Patterns in Taiwan during the COVID-19 pandemic

Mr Hsiang-Te Tsai[1,2], Mr Avery Shuei-He Yang[1], Dr Catrin E Moore[2], Dr Edward Chia-Cheng Lai[1], Dr Yingfen Hsia[2,3]
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Biography:

Daniel Hsiang-Te Tsai is a clinical pharmacist with a master's degree in pharmacoepidemiology. He specialises in using big data analysis to evaluate the safety, effectiveness, and potential factors associated with medications. His expertise includes using claims databases to assess rare neurological diseases and integrating electronic health records for validation. In addition, he is also actively involved in the development of the BESTMED project, focusing on the intersection of AI and geriatric medicine. Through this project, he aims to leverage AI techniques to enhance healthcare delivery and improve outcomes for older patients.

AIM/OBJECTIVE To investigate antibiotic prescribing patterns for pneumonia treatment in Taiwan during the COVID-19 pandemic.

METHODS We conducted a population-based cross-sectional study using data from the National Health Insurance Database (NHID) to include patients diagnosed with pneumonia between January 2015, and December 2020. Patients with confirmed viral pneumonia were excluded to avoid misclassification. We calculated the defined daily doses (DDDs) using the WHO ATC index for both the hospital and community. Antibiotics were classified using the 2021 WHO AWaRe classification. The interrupted time series analyses were performed to assess the change of antibiotic use before and during the COVID-19 pandemic.

RESULTS
A total of 1,778,931 pneumonia episodes were included between 2015 and 2020. The average age of patients included was 54.4 ± 33.2 years and 59.5% of patients were male. A total of 87.8 million DDDs and 5.0 million DDDs were prescribed to treat pneumonia in the hospital and community, respectively. The annual data showed that the percentages of DDDs prescribed in hospital were stable from 15.3% in 2015 to 14.7% in 2020. We observed a decrease in community antibiotic use from 15.3% in 2015 to 13.0% in 2020. The use of Access antibiotics significantly reduced in hospitals during the COVID pandemic (reduced by 0.005% per month, $P < 0.01$). Similarly, there was a reduction of Access antibiotics use in the community (reduction of 0.006% per month, $P < 0.01$).

CONCLUSION Our results showed a decrease of the use of Access group antibiotics to treat patients with pneumonia before and during the COVID-19 pandemic in Taiwan.

Keywords: antibiotics, AWaRe classification, COVID-19 pandemic

Economic Burden of Gallbladder Cancer in Northeast India: A Cost Analysis Study

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Biography:

Krishna Undela completed his M.Pharm (Pharmacy Practice) from the National Institute of Pharmaceutical Education and Research (NIPER) Mohali in 2012, and his Ph.D. from the JSS Academy of Higher Education & Research, Mysuru in 2019. He worked as a Lecturer in the Department of Pharmacy Practice at JSS College of Pharmacy, Mysuru, between October 2012 and August 2020. Thereafter, he started working as an Assistant Professor in the Department of Pharmacy Practice at NIPER Guwahati. He teaches subjects like Clinical Pharmacy, Pharmacoepidemiology, Pharmacoeconomics, Pharmacovigilance, Pharmacotherapeutics, and Evidence-Based Medicine. His thrust research areas are medication safety in special populations, medication therapy management in chronic diseases, pharmacovigilance data analysis, and evidence synthesis.

Krishna Undela has experience in conducting various Pharmacoepidemiological studies in hospital and community settings. He received the 2015 Endeavour Executive Fellowship from the Department of Education, Australian Government, to undertake three months of training on "Advanced Pharmacoepidemiology and Quality Use of Medicines" at the University of South Australia, Adelaide, Australia. He received travel grants from the International Society for Pharmacoepidemiology (ISPE) to attend ISPE conferences held in Hong Kong (in 2013), Taiwan (in 2014), Thailand (in 2015), and the USA (in 2021) as a delegate, and Australia (in 2017), China (in 2018), Japan (in 2019), Korea (in 2021) and Taiwan (in 2022) as an Educational Session Speaker. He also received a travel grant from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) to attend the ISPOR European Congress held in Austria in 2016. Recently, he attended The Global Health Network Conference 2022 at the University of Cape Town, South Africa, as a fully sponsored delegate.

Krishna Undela also has expertise in conducting Systematic reviews and Meta-analysis and has published papers in various peer-reviewed reputed journals, which are well cited. He presented one of his meta-analysis papers on 'Statin use and risk of Parkinson's disease' at the 20th World Congress on Parkinson's Disease and Related Disorders held in Geneva, Switzerland, in 2013. Currently, there are more than 90 scientific publications to his credit. The total citations of his publications are 1100+ with an h-index of 16 and an i10-index of 18.

Krishna Undela delivered over 150 lectures at various national and international conferences on Pharmacoepidemiology, Pharmacovigilance, Pharmacoeconomics, Clinical Pharmacy, and Systematic Review & Meta-analysis.

Krishna Undela is currently a Leader of the International Society of Pharmacovigilance (ISoP) South Asian Chapter, a Member of ISPE's Asian Conference on Pharmacoepidemiology (ACPE) International Steering Committee, ISoP Special Interest Groups on Medication Errors & Drug Safety in Older Patients, and ISPE Pediatric Special Interest Group. Krishna Undela is the Coordinator of the Adverse Drug Reaction Monitoring Centre, Atal Incubation Centre, and Bio-NEST at NIPER Guwahati.

Objectives: To quantify the Years of Potential Productivity Life Lost (YPPLL), productivity loss, and Disability Adjusted Life Years (DALY) due to Gallbladder Cancer (GBC) in northeast India.

Methods: We have followed an incidence-based prospective approach and screened the patients registered in the Gastrointestinal-Gallbladder (GI-GB) Department of a tertiary care cancer hospital in northeast India over a period of nine months from August 2022 to April 2023. Patients aged ≥18 years and diagnosed with GBC were included in the study. By considering the life expectancy of the Indian population (72.2 years for men and 69.5 years for women), we have estimated YPPLL, productivity loss through the human capital approach, and DALY by using the R software DALY calculator.

Results: Out of 647 newly registered patients, 274 were included and followed up for a period of three months. During the follow-up period, 73 GBC patients died, out of whom 61 died prematurely (18 males and 43 females). The premature mortality of GBC patients accounted for 994 YPPLL, 1007 DALY, and a productivity

loss of USD 1,331,595. Female gender, older age, and advanced stage of cancer contributed significantly to YPPLL, productivity loss, and DALY.

Conclusion: Given the number of premature deaths associated with productivity loss and disease burden, policymakers should prioritize strategies for the prevention and management of GBC in the northeast region of India.

Keywords: Economic Burden, Gallbladder Cancer, Productivity Loss, Disability Adjusted Life Years.

Discontinuation of Oral Anticoagulation after Minor Bleeding in Patients with Atrial Fibrillation

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Biography:
Project researcher of the Department of Healthcare Quality Assessment, The University of Tokyo, Japan.

Aim/Objective
Minor bleeding concerns frail elderly patients with atrial fibrillation (AF) on oral anticoagulants (OACs), potentially leading to drug discontinuation and increased stroke risk. This study examines the association between OAC discontinuation and subsequent adverse events following minor bleeding in a community-based population of elderly AF patients.

Methods
This cohort study used a Japanese governmental claims database (Shizuoka Kokuho Database). Patients aged ≥65 years with AF initiating direct OACs (DOACs) between 2013 and 2020 were included. Minor bleeding, defined as outpatient bleeding diagnoses not leading to hospitalizations within a year, was identified. Patients discontinuing DOACs in the same month as minor bleeding were categorized as discontinuers, the others as continuers. In a 1:4 propensity score-matched cohort based on age, sex, comorbidities, and electronic frailty index, the incidence of stroke/transient ischemic attack (TIA) and major bleeding was compared between the two groups using Fine–Gray models, accounting for death as a competing risk.

Results
Among 2,745 patients experiencing minor bleeding, the median age was 79 years (25th–75th percentile: 74–84), with 45.4% women. A total of 3.8% (103/2,745) discontinued DOACs in the same month as minor bleeding. After propensity score-matching, the discontinuation group (n=103) had an event rate per 100 person-years of 2.9 (10/350.3 person-year) for stroke/TIA and 0.9 (3/350.3 person-year) for major bleeding, while the continuation group (n=412) had rates of 0.9 (12/1386.5 person-year) for stroke/TIA and 0.4 (6/1386.5 person-year) for major bleeding. Discontinuation was associated with a higher risk of stroke/TIA (subdistribution hazard ratio, sHR [95% CI]: 2.79 [1.22-6.38]), while the association with subsequent major bleeding was not evident (sHR [95% CI]: 1.67 [0.42-6.74]).

Conclusion
Discontinuation of DOACs following minor bleeding was associated with elevated stroke/TIA risk among elderly AF patients. This highlights the importance of considering DOAC continuation instead of discontinuation based solely on minor bleeding events.

Survival Analysis and Predictors of Breast Cancer Mortality: 10 Years Cohort Study

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Biography:

Dr. Uday Venkat Mateti is currently working as an Assistant Professor in the Department of Pharmacy Practice, NGSM Institute of Pharmaceutical Sciences, Nitte (Deemed to be University), Mangaluru, Karnataka. He is the Faculty Advisor of ISPOR Student Chapter-Nitte University. He has contributed six book chapters for the textbooks and includes many publications in national and international journals. He received research grants from the Indian Council of Medical Research, International Society of Oncology Pharmacy Practice, and Royal Society of Tropical Medicine and Hygiene. He has been awarded travel grants from the International Society for Pharmacoeconomics and Outcomes Research, International Society for Pharmacoepidemiology, Multinational Association of Supportive Care in Cancer, European Society for Medical Oncology, Indian Council of Medical Research, and International Society of Hypertension for his scholarly work. Dr. Mateti's specialized areas include Pharmacoepidemiology, Patient Safety, Patient-Reported Outcomes, Pharmacoeconomic Modelling, and Pharmaceutical Care.

Objective:
To identify the predictors of mortality and estimate survival among breast cancer patients.

Methods:
A retrospective cohort study was conducted in a tertiary care hospital. The case sheets of all breast cancer patients diagnosed and treated between January 2012 and December 2021 were obtained from the medical record department. All the patients or patients' parties were contacted via phone to learn about the patient's survival status and mortality history. The case sheets needing more information, incomplete data and those who didn't respond to phone calls were excluded from the study, whereas the remaining were included. Further, the data obtained were analyzed using SPSS v.23. The study employed the Kaplan-Meier curve and Log-Rank test to estimate the likelihood of breast cancer survival. The Cox regression model was utilized to identify factors associated with mortality among patients with breast cancer.

Results:
Among the 367 subjects enrolled in the present study, the 5-year and 10-year mortality rates were 31.61% and 35.15%, respectively. Further, we found that stage of cancer (p=0.00), tumour grade (p=0.00), nodal status (p=0.00), ER receptors (p=0.009), PR receptors (p=0.032), surgical therapy (p=0.00), radiotherapy (p=0.017), cycle (p=0.00) and adherence to chemotherapy (p=0.00) were the predictors which have significantly associated with mortality among breast cancer patients. Additionally, the 5-year and 10-year survival rates were 68.39% and 64.85% among breast cancer patients, respectively.

Conclusion:
The overall survival of breast cancer participants (68.39% and 64.85%) is lower than in developed countries. Establishing a rural cancer centre with proper resources and infrastructure, boosting early diagnosis via the mass screening of women, and adequate education/awareness could play a vital role in alleviating mortality among breast cancer patients.

Keywords: Breast cancer, Mortality, Predictors, Survival analysis

Patient’s perceptions on medicine price reform, affordability, and availability in Sri Lanka

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Biography:

A final year student following Bachelors of Pharmacy at General Sir John Kotelawala Defense University, Sri Lanka

Objective: To survey the patient’s perception of the price reform, availability and affordability of medicines in Sri Lanka.

Methodology: A prospective cross-sectional study was conducted on patients/guardians (n=204) who purchase medicines from retail pharmacies to assess the perception of the impact of the reform of medicine prices, availability, and affordability using an interviewer-administered questionnaire. The study included fifty (50) selected medicines from the Revised Essential Non-Communicable Diseases (NCD) medicine list 2022 of Sri Lanka.

Results: 199 (97.5%) participants confirmed that there is a difference between the prices of medicines before and after price reform. 82 (40.2%) believe the price increment has increased 2-3 folds higher. Most participants (29%) had an income between LKR. 50,000 - 70,000. Only 25 (12.3%) said medicines were affordable. 101 (49.5%), said they could not afford their medicines while 78 (38.2%) said it is manageable. 171 (85.5%) participants mentioned that they inquire about cheaper brands, and 76 of them purchased those since they could not afford the prescribed brands while 95 purchased branded ones with difficulties. Out of 200 participants, 35 (17.2%) were unaware of the shortage of medicines then, while 57 (27.9%) said medicines were available in limited amounts. 51 (25.0%) said there was a shortage earlier, but now medicines are available.

Conclusion: According to the survey, higher prices of medicines were not affordable for the majority of the participants. Also, there is a shortage of medicines with the ongoing economic crises in Sri Lanka. The authorities should take measures to reduce the prices of essential medicines, secure patients' basic health needs, and avoid future healthcare costs due to the current situation's adverse outcomes.

Keywords: patient’s perception, price reform, affordability, availability

Decision algorithm to predict diagnosis of neglected tropical disease- A comprehensive review

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Biography:

I am a Research Scholar from the Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, MAHE, Manipal. Currently working in the area of Artificial Intelligence which aligned with my doctoral research is in the development of a tool to differentiate neglected tropical infections using artificial intelligence.

Objective:
Due to overlapping clinical symptoms the diagnosis of neglected tropical disease (NTDs) are more complicated and time-consuming. Technology-integrated decision tool are considered to be emerging areas in the medical field. In this regard, we aimed to conduct a comprehensive review of different decision algorithms used to predict the diagnosis of NTDs from published literature.

Method:
A literature study on the use of machine learning in making decisions regarding NTDs was conducted using a combination of keywords. NTDs, machine learning, decision algorithm, and decision tree are the keywords used that help in obtaining the related articles. The articles which are primary research and published in English language up-to April 2023 were included. The studies with a decision model incorporating the clinical symptoms and laboratory investigation were included for analysis.

Result:
Among published reports, five studies were eligible for final analysis. In included studies, two studies were published on diagnosis of dengue and three studies on differential diagnosis. Among two dengue studies, Tanner L et. al used C4.5 algorithm (specificity 90.1% & sensitivity 71.2%) and Vernon J. Lee et. al used Rpart algorithm (specificity 52% & sensitivity 99%) for diagnosis. Fathima SA et. al was able to differentiate arboviral infections by using SVM (specificity 97.57% & sensitivity 47.23%) and Naive Bayes algorithm (specificity 5.03% & sensitivity 98.77%). The prediction model developed by Shenoy S et. al used Naïve Bayes (specificity 73.4% & sensitivity 73.5%), Multi-Layer Perceptron (specificity 71.4% & sensitivity 71.4%), and Multinomial Logistic Regression (specificity 70% & sensitivity 70%) for differentiating four different NTDs. Mitra S et. al used multivariate logistic regression in developing six different scoring models where model 2 (specificity 77% & sensitivity 85%) was considered to be simple and rapid.

Conclusion:
Present review shows that machine learning can be used as a diagnostic tool for differentiating NTDs.

Saturday, 28 October 2023

Pharmacoepidemiology and Pharmacovigilance research methods / Pharmacogenomics research and drug safety

Implementation of childhood immunization registry and safety surveillance in a sentinel site.

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Biography:

I am currently a full-time Research scholar with two years of research experience in the field of vaccine safety. I completed my Doctor of Pharmacy in 2019 and had one year of teaching experience. As an active pharmacist in the AEFI causality investigation and assessment team at JSS Hospital, Mysuru, I am happy to share my research experience with my peer scholars. My valuable contributions to the community such as addressing vaccine hesitancy, and vaccine safety concerns, solving community-level vaccine-related problems and educating parents etc mark me as an enthusiastic researcher. As a frequent mediator between the public and healthcare workers, I will be a representative for the large population of my community regarding vaccine-associated subjects.

Aim

To analyse the utilization patterns of childhood immunization via implementing a digital registry. To conduct an active childhood vaccine-safety surveillance for addressing any safety concerns among the parents.

Methodology

The study was a registry-based active surveillance, carried out in an immunization site (recognized sentinel site by WHO) over a period of two years. All children who were immunized from the study site were included in the study. Two-phased telephone-based surveillance was carried out following 7 days and 30 days of post-immunization. The demographic and post-immunization details (adverse events following immunization (AEFI)) of the study population were documented in the registry. Each reported AEFI were categorized according to the WHO's AEFI causality assessment algorithm.

Results

During the study period, the registry accounted for 12,714 vaccine doses received by 4371 vaccine beneficiaries. The most utilized vaccine among the study population was Oral Polio Vaccine (OPV)(23.86%), while the least utilized vaccine was Human Papilloma Vaccine (HPV) (0.05%). Various population characteristics such as delayed immunization (4.67%), low-birth weight (36.10%), underweight (17.75%), male predominance (55.66%), pre-existing conditions (2.01%, vaccine miss-outs (3.40%) were observed via the newly implemented vaccine-registry. An AEFI incidence rate of 51.73% (n=2261) was reported, of which only 16 events were serious and 22..03% were categorized as vaccine product-related reactions. Predictors for developing AEFIs among the children such as male gender, age category (first year), low-birth weight, type and dose of vaccine(p-value>0.0001) were identified.

Conclusions

The study could conclude that lack of knowledge leads to low utilization of optional vaccines and gender inequality for optional vaccines need to be addressed immediately. The valuable contributions of a digital registry in a small society promise assured benefits for a national-wide single database in the country. This study could ensure the safety profile of various childhood vaccines.

Keywords: Active vaccine-safety Surveillance, AEFI, Childhood Vaccines, Registry.

Evaluation and implementation of collaborative transitional care for asthma and COPD patients

Neha Raji John[1], Evaluation and implementation of collaborative transitional care for asthma and COPD patients Shilpa Palaksha[1], Evaluation and implementation of collaborative transitional care for asthma and COPD patients Iaraplang Lyngdoh[2], Evaluation and implementation of collaborative transitional care for asthma and COPD patients Sriram Murugesh[3], Evaluation and implementation of collaborative transitional care for asthma and COPD patients Adithya Shanker[4]
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Biography:

I am a student in JSS College of Pharmacy, Mysuru, Karnataka, India. I'm currently pursuing my 6th year (internship) in PharmD.

Aim:
This study aims to Evaluate and Implement Collaborative Transitional Care for COPD and Asthma patients.

Method:
A randomized interventional study was conducted in a tertiary care hospital among Asthma and COPD patients for a period of 6 months. The patients were randomized into case and control groups for both asthma and COPD respectively, to assess the symptom control and HRQoL, using standard validated questionnaires and were followed up at the end of 30 days, 60 days, and 90 days to compare the subsequent scores between the 2 arms of their diagnoses.

Results:
A total of 351 out of 382 enrolled patients completed the study. Majority of the COPD patients recruited were males, (66.93% from a total of 251) whereas, the majority in asthma patients were females, (73% from a total of 100). When the AQLQ scores were compared between the 2 arms of asthma patients, the improvement in the HRQoL was found to be statistically significant in the interventional group (5.91 +/- 0.289; p = <0.05) compared to the control group (4.623 +/-0.476; p = >0.05). When the SGRQ scores were compared between the 2 arms of COPD patients, a difference was noted but was not statistically significant (control group; 20.093 +/- 6.695; p = <0.05 and interventional group; 21.137 +/- 8.94; p = <0.05), the improvement seen in the interventional group had a positive effect on the patient's HRQoL. The variation in the outcomes could be attributed to not employing stratified randomization. The patients were satisfied with the intervention and had better symptom control.

Conclusion:
This study draws a conclusion that transitional care is helpful in improving the clinical outcomes and a trained pharmacist can act as an educator and help enhance the transitional care and the mental well-being of a patient.

Keywords: Asthma; COPD; HRQoL; Transitional Care

Drug Related Problems Among Elderly Patients: Prospective Interventional Study

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Biography:
Bindu V M, Department of Pharmacy Practice JSS College of Pharmacy JSS Academy of Higher Education & Research, Mysuru – 570015, Karnataka, India

Objectives:
To assess the incidence of drug related problems among geriatric patients

Methodology:
A prospective interventional study was carried out in a tertiary care hospital in southern India over a span of six months. All the patients aged ≥ 60 years were monitored from admission to discharge for any drug-related problems. The DRPs were classified according to the Hepler and Strand classifications. Adverse drug reactions were assessed for causality using the WHO-UMC Probability Scale and severity using Hartwig's. The data obtained were assessed categorically and represented as [n (%)].

Results: A
total of 282 patients were enrolled in the study, [160 (56.73%)] were male and [122 (43.26%)] were female, and the majority belonged to the young-old age group [185 (66%)]. A total of 723 DRPs were identified among 76.78% of study subjects, and the majority were drug-drug interactions at [527 (72.89%)]. The majority of the DDIs were caused by furosemide [41 (5.67%)], followed by insulin [34 (4.70%)] and tramadol [22 (3.04%)], of which the DDIs commonly observed were pharmacodynamic [412 (56.98%)] and moderate [446 (61.68%)] in nature. A total of 38 ADRs were identified, with a rate of 5.25%. According to the WHO Probability Scale, out of 38 ADRs, [14 (36.84%)] were probable and [24 (63.15%)] were possible, while [19 (50%)] were possible and [19 (50%)] were probable according to Naranjo's Algorithm. The majority of the 38 ADRs reported were of Level 3 severity, with [3 (34.21%)] followed by Level 4(a) [11 (28.94%)] respectively using the Modified Hartwig and Siegel ADR assessment scale.

Conclusion:
Among geriatric inpatients, drug-related issues were remarkably common. Co-morbidities and polypharmacy significantly increased a patient's risk of developing DRPs.. In order to avoid DRPs in these patients, specific measures must be taken. DRPs in geriatric inpatients were also observed to be decreased by clinical pharmacists' intervention.

Effectiveness and safety of Xuebijing treatment for COVID-19 patients: a retrospective cohort study with propensity score matching

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Biography:
Meng Zhang is a PhD candidate in department of Epidemiology and Biostatistics at the School of Public Health, Peking University.

Aim/Objective:
Xuebijing (XBJ) injection is an intravenous herbal-based preparation widely used in China to treat severe pneumonia and sepsis. Although it has been recommended to treat severe COVID-19 cases in the six successive versions of the COVID-19 Diagnosis and Treatment Protocol issued by the Chinese Health Commission, evidence for its effectiveness in treating COVID-19 is still insufficient. Therefore, we aimed to assess the effectiveness and safety of XBJ treatment in COVID-19 patients.

Methods:
This multicenter retrospective cohort study included COVID-19 patients admitted to four hospitals in Wuhan, China from December 19th, 2019 to April 26, 2020. Data on patients' characteristics, treatments, and outcomes were extracted from electronic medical records. The association of XBJ use with mortality and negative conversion rate of Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) was evaluated through conditional logistic regression in a 1:4 propensity score matched (PSM) cohort, as well as logistic regression without matching as sensitivity analysis.

Results:
Of the 2147 severe and critically severe patients included, 10.7 % received XBJ treatment. PSM analysis showed no significant association between XBJ use and mortality (adjusted odds ratio (OR), 0.68 [0.41, 1.14], P=0.142). Additionally, XBJ use was not significantly associated with the negative conversion rate of SARS-CoV-2 in the PSM model (adjusted OR, 2.33 [0.70, 7.73], P=0.167). The incidences of acute kidney injury (crude rate, 15.3% vs. 7.1%; adjusted OR, 0.92 [0.55, 1.52], P=0.761) and acute liver injury (crude rate, 27.2% vs. 16.8%; adjusted OR, 1.15 [0.80, 1.63], P=0.446) were comparable among patients receiving XBJ treatment and those not.

Conclusion:
The study found no significant association between XBJ use and reduction of mortality and the negative conversion rate of SARS-CoV-2 in severe and critically severe COVID-19 patients. Furthermore, XBJ use did not result in a statistically higher incidence of acute kidney injury and acute liver injury.

Keywords: Xuebijing; COVID-19; association; safety; traditional Chinese medicine; retrospective study

Predictive association of CYP2C9/VKORC1 genetic polymorphisms with bleeding risk of warfarin therapy

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Biography:

Dr. Mohitosh Biswas is currently serving as Associate Professor at the Department of Pharmacy of Rajshahi University, Bangladesh. Dr. Biswas completed his PhD degree from the School of Biomedical Sciences and Pharmacy, Faculty of Health and Medicine, The University of Newcastle, Australia in 2018. Dr. Biswas has completed postdoctoral research (02 years) from the Pharmacogenetics and Personalized Medicine (PPM) laboratory, Department of Pathology, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand. To date, Dr. Biswas has published 47 peer-reviewed journal articles, of which some have been published in high-quality international scholarly journals including nature portfolio, with over 100 cumulative impact factors.

Objectives:
Safety or effectiveness of warfarin may be affected by genetic variability of CYP2C9 or VKORC1. Patients may be at risk of bleeding events if carrying CYP2C9*2 (rs1799853), CYP2C9*3 (rs1057910) or VKORC1c.-1639G>A (rs9923231) genetic variants. It was aimed to determine the predictive risk phenotypes based on genetic polymorphisms of CYP2C9*2,*3 and VKORC1 collectively in 26 population participated in 1000 Genomes project.

Methods:
Allele frequency of CYP2C9*2,*3 and VKORC1 were obtained from 1000 Genomes project Phase III in line with Fort Lauderdale principles. Predictive phenotypes were assigned based on carrying of characteristics alleles. Association of predicted risk phenotypes with the safety or effectiveness of warfarin was gained from the CPIC/FDA pharmacogenomics based dosing guidelines.
Results: Out of 2504 participants of 1000 Genomes project, it was found that 69.8% (95% CI 68%-72%) were predicted to be warfarin normal responders, 28.2% (95% CI 26%-30%) of sensitive responders and 2.0% (95% CI 1%-3%) of highly sensitive responders due to the carrying of different combinations of CYP2C9*2, *3 and VKORC1 alleles. Among these, sensitive and highly sensitive responders (30.2%; 95% CI 28%-32%) were considered risk phenotypes as predicted to increase the risk of bleeding events at standard dose of warfarin. Predicted risk phenotypes were prevalent highest in East Asia (15.8%; 95% CI 14%-17%), followed by European (6.1%; 95% CI 5%-7%), South Asian (3.9%; 95% CI 3%-5%), American (3.6%; 95% CI 3%-4%) and African population (0.3%; 95% CI 0%-1%), respectively. Prevalence of risk phenotypes in different ethnic groups were statistically significant ($p<0.00001$).

Conclusion:
About a third of world population was predicted to increase the risk of bleeding events at standard dose of warfarin due to the inheritance of CYP2C9 and VKORC1 variants. Precision medicine of warfarin therapy may be achieved through consideration of pharmacogenomics of both CYP2C9 and VKORC1 variants.

Keywords: Genetic polymorphisms, CYP2C9/VKORC1, safety, pharmacogenomics

ABCC8 gene polymorphism and pancreatic function of sulphonylurea-treated type 2 diabetes patients

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Biography:

Dr. Navin Kumar Loganadan is the Head of Pharmacy Services at the Endocrine Institute, Putrajaya Hospital in Putrajaya, Malaysia. Dr. Navin has 15 years of experience as a Diabetes Care Clinical Pharmacist in the Diabetes Medication Therapy Adherence Clinic (DMTAC) in the Ministry of Health, Malaysia. He graduated with a Bachelor of Pharmacy (Hons) and obtained a Master of Clinical Pharmacy, both from Universiti Kebangsaan Malaysia. He then received his Doctor of Philosophy (Ph.D.) from the University of Malaya in the field of pharmacogenomics of antidiabetic therapy. His role in DMTAC involves managing medication-related problems of type 2 diabetes patients mainly medication adherence, insulin dosage adjustments, injection technique, and hypoglycemia management. He works as a member of the Putrajaya Hospital's Endocrine Team comprising consultant endocrinologists, dieticians, and diabetes educators. His research area is mainly in the field of diabetes, particularly the clinical response to antidiabetic therapy, the pharmacist's role in diabetes management, and pharmacogenomics. He has presented his research at several international conferences including that of the American Diabetes Association and International Diabetes Federation. Dr. Navin is also among the 20 global recipients of the 'Next Generation Scientist Award 2016' by the University of Basel, Switzerland. He has also received training at the Diabetes Research Program, New York University, the USA in the field of pharmacogenomics of type 2 diabetes. Besides, he was conferred the 'Young Investigator Award' by the National Diabetes Institute of Malaysia in 2009. He is currently the Chairman of the Diabetes Clinical Pharmacy Subcommittee, the Ministry of Health, Malaysia. He has also been appointed as the Advisor for the Practice Transformation Programme – Diabetes by the International Pharmaceutical Federation (FIP) in 2021 which is responsible for strengthening the role of pharmacists in diabetes management across the world.

Aim/Objective:
We investigated the association of rs757110 ABCC8 gene polymorphism with beta cell function and insulin resistance of type 2 diabetes patients on maximal doses of sulphonylurea.

Methods:
This is a post-hoc analysis of the SUCLINGEN study which included type 2 diabetes patients on either glibenclamide 20mg daily, gliclazide 320mg daily, or gliclazide modified release 120mg daily in combination with metformin 1g daily. Blood samples of subjects were taken at baseline for fasting glucose and fasting insulin, which was used to construct the homeostatic model assessment of beta-cell function (HOMA2-%B) and insulin resistance (HOMA2-IR). Their DNA was extracted and genotyped for rs757110 ABCC8 gene polymorphism using a TaqMan genotyping assay (Applied Biosystems, U.S).

Results:
Of the 401 subjects in the final analysis, the median HOMA-%B was 54.3% (IQR 35.2 – 80.1) while the median HOMA2-IR was 2.2 (IQR 1.5 – 3.0). Although the risk allele homozygotes (CC genotype) had a lower median HOMA2-%B of 48.2% (IQR 34.2 – 76.9)] compared to the AC genotype [56.3% (IQR 35.2 – 87.0)] and wildtype AA genotype [53.8% (IQR 37.5 – 77.0)], this difference was not statistically significant ($p>0.05$). There was also no significant difference in HOMA2-IR among the three genotypes [AA: 2.1 (1.5 – 3.1), AC: 2.2 (1.6 -2.9), and CC: 2.3 (1.3 – 3.4), $p>0.05$].

Conclusion:
Despite being associated with poor sulphonylurea response and sulphonylurea failure in the clinical setting, the rs757110 ABCC8 gene polymorphism does not seem to be associated with the insulin-secreting capacity of type 2 diabetes patients. This is unlike the polymorphisms associated with the metabolism of sulphonylureas

like the CYP2C9 gene polymorphisms found to increase sulphonylurea blood concentrations and response. More studies are warranted to explore the mechanism of how the rs757110 ABCC8 gene polymorphism causes the reduced response with sulphonylurea therapy.

Keywords:
ABCC8 gene, diabetes, beta-cell, sulphonylurea

Drug safety risk monitoring, evaluation and prevention

The impact of home medications reviews on the medication regimen complexity

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Biography:

Shrey Seth is a recent Doctor of Pharmacy graduate from Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education. His research interests lie in the field of attaining the best therapeutic outcomes through the development of novel and innovative interventions to optimize medication compliance further improving clinical outcomes and minimizing the associated morbidity and mortality.

Aim/Objective:
The aim of the study was to assess the impact of home medications reviews (HMRs) on the medication regimen complexity using a validated scoring system.

Methods:
A retrospective analysis of 196 HMRs initiated by the general practitioners (GPs) for patients with complex medication regimens (defined presence of 5 or more medications and multiple dosing schedules). The medication regimen complexity index (MRCI) was used to measure the medication regimen complexity at two separate time points, i.e., at baseline and following pharmacists' recommendations (under the assumption that all pharmacists' recommendations were accepted by the GPs). Wilcoxon sign rank test was used to estimate the difference between the scores.

Results:
A total of 792 recommendations were made by the pharmacist (mean 4.04 recommendations per HMR), amongst which dosage and frequency adjustment, laboratory monitoring and therapeutic monitoring were the most common type of recommendations collectively accounting for almost half of the recommendations. The Median MRCI at baseline was found to BE 38 (IQR= 29.375 - 48.25). The difference between the baseline and post-recommendation scores was found to be statistically insignificant ($p = 0.932$).

Conclusion:
Our study fails to demonstrate a significant impact of HMRs in reducing the medication complexity. Although the pharmacists' recommendations failed to improve the MRCI, it isn't an accurate depiction of the overall contribution of the HMR services. Further studies are necessitated to distinguish the clinical association between the medication regimen complexity and health outcomes in patients with complex medication regimens.

Keywords: Home medications reviews, medication regimen complexity index, pharmacy services, complex medication regimens

Analysing the Effectiveness of Clinical Pharmacists' Interventions in Addressing Drug-Related Problems Among Cancer Patients with Polypharmacy

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Biography:

An inmate of JSS from past 6 years.

Aim/ Objective: This study aims to evaluate the effectiveness of clinical pharmacists' interventions in managing drug-related problems (DRPs) in cancer patients who are on multiple medications.

Methods: A prospective interventional study was conducted for a period of 8 months in a cancer speciality hospital in South India. During each visit, patients were followed up and DRPs were identified. Observed DRPs were classified according to PCNE classification V9.1 and appropriate interventions were made by clinical pharmacists.

Results: A total of 120 patients were included in the study. A total of 1741 DRPs were identified, 50.83%% were related to treatment safety with an adverse drug event (possibly) occurring, (with an average of 14.50 DRPs per patient) with 1769 underlying causes. A total of 2403 interventions were proposed to health care professionals or patients. Of these, 84.72% were accepted, and 64.73% of all DRPs were fully resolved following interventions by clinical pharmacists.

Conclusion: Clinical pharmacists may play a vital role in managing and resolving DRPs among cancer patients with polypharmacy.

Keywords: Oncology, Polypharmacy, DRPs and Pharmacist Intervention

Development and Validation of Self-Administration Medication Error (SAME) tool in patients.

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Biography:

Dr Anusha Natarajan is currently working as Assistant Professor in Dept. of Pharmacology in Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER), Puducherry, India. Her major area of research is Pharmacoeconomics with special interest in rational use of medicines.

Objectives:
To develop & validate SAME tool in patients of a tertiary care hospital

Methods:
The SAME tool was developed and validated among a cluster of 4 experts using a 4-point Likert scale (1 = not relevant, 2 = somewhat relevant,3 = relevant, 4 = very relevant). Ratings 3 and 4 was considered as a 'favorable' whereas 1 and 2 was considered as 'unfavorable' response and the question is relevant and irrelevant respectively. Content Validity Index (CVI) of the individual items was assessed to be above the cut-off value of 0.78. The questionnaire was pre-tested on a sample of 40 subjects. Cronbach's alpha test was used to test the reliability of the SAME tool.

Results:
In our study, majority were females (60%), and males (40%). Among the participants with the diagnosis, Epilepsy (26.8%), Hypertension (56.09%), DM (43.9%), among which 63.41% were on Polypharmacy (≥2 medications). Using Cronbach alpha test, value is (0.815) positive and >0.7, the tool is considered reliable and acceptable. By Pearson correlation, the validity of the tool is evaluated and a value is found to be highly significant (<0.01). The observed correlation coefficient is more than critical values at 0.01 level (0.2605), which makes the tool highly valid.

Conclusion:
Our study suggested that there is a high prevalence of self-administration medication error and high incidence of ADR related to self-administration errors. This can be prevented by shorter regimen. A validated tool to assess self-administration errors will help in identifying the problems caused by it. This tool will help in reducing the prevalence of errors in a tertiary care hospital and proper monitoring of the medication administration.

Key words: SAME tool, Self-administration errors, Medication error, Adverse events.

Evaluation of drug dose adjustment among patients with renal impairment

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Biography:

A highly motivated and dedicated PharmD intern with a strong passion for research and related fields. Krishna p is currently pursuing their Doctor of Pharmacy degree and has actively engaged in various research projects during their academic journey. Their exceptional enthusiasm for advancing patient care in the field of nephrology and pharmacotherapy has led them to explore the optimal use of medications in individuals with renal disease. With a keen interest in evidence-based medicine, krishna has actively contributed to the study, applying their knowledge and skills to investigate medication dosing adjustments in renal patients.

Aim/Objective

Chronic kidney disease (CKD) often necessitates dosage adjustments for medications to ensure efficacy and minimize toxicity. This study aimed to identify medications requiring dosage adjustments in patients with renal disease and determine the most appropriate dosages based on kidney function.

Methods

This cross-sectional observational study was conducted at the IP & OP Department of Nephrology, Government Medical College in Kannur over a six-month period. Data from 150 CKD patients were collected and analyzed. Patient demographics, including age, gender, and serum creatinine levels, were recorded. Medication prescriptions were assessed to identify the most common drug combinations and determine which medications required dosage adjustments.

Results

The study cohort comprised 66% male and 34% female CKD patients, primarily aged 51 to 70 years. Serum creatinine levels ranged from 5 to 10 mg/dl in 60% of the patients. Among the prescribed medication combinations, the most common included Lasix, Atorvastatin, and Ceftriaxone (12%), while the least common involved Ofloxacin and Atorvastatin (1.3%). Out of the 29 medications evaluated, 14 required dosage adjustments in CKD patients, whereas 15 did not. Medications such as Ofloxacin, Clindamycin, and Ranitidine required dose adjustments. Notably, 26% of the medications prescribed to CKD patients needed dosage modifications. Diuretics and H2 blockers, particularly ranitidine, were frequently adjusted based on renal function.

Conclusion

This study highlights the importance of dosage adjustments in patients with renal disease. Approximately one-fourth of the medications prescribed to CKD patients required dosage modifications, indicating the need for individualized therapy. Diuretics and H2 blockers were frequently prescribed in renal failure and often required adjustments. Failure to modify doses may lead to increased toxicity and adverse effects in CKD patients. These findings underscore the significance of personalized medicine in optimizing therapy for individuals with renal impairment.

Tamsulosin increases the risk of poor glycemic control among patients with type 2 diabetes: a nationwide population-based study

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Biography:

Minh-Ha Nguyen is a pharmacist trained in the UK. He has been practicing clinical pharmacy in the UK and Vietnam.

He was appointed a lectureship at the University of Medicine and Pharmacy at Ho Chi Minh city in 2020. At the moment, he's on a fellowship to do pharmaco-epidemiology research at Yonsei University, Seoul, South Korea.

Objective: There are conflicting findings on the association between the use of 5-alpha reductase inhibitors and the risk of developing type 2 diabetes mellitus (T2DM) in patients with benign prostatic hyperplasia. Furthermore, there is a lack of evidence on the effect of using 5-alpha reductase inhibitors on glycemic control in patients with T2DM. We aimed to investigate the risk of poor glycemic control in finasteride (one of 5-alpha reductase inhibitors) users compared with tamsulosin users among patients with T2DM.

Methods: Using hospitalization and pharmaceutical dispensing data in New Zealand (2006–2017), patients with T2DM were identified. Dates of drug initiation (finasteride/ tamsulosin) were used as index date. Patients with insulin prescription before study index date were excluded from the study. The final study cohorts comprised of patients with finasteride monotherapy (n=2425) and tamsulosin monotherapy (n=991), all of patients were men. First insulin prescription was used as a surrogate end-point for poor glycemic control. We fitted a Cox proportional hazard model to estimate the risk of insulin prescription associated with finasteride monotherapy relative to tamsulosin monotherapy, adjusting for age, ethnicity, diabetes duration (years since T2DM onset), comorbidities, and history of drug usage (ACEi, ARBs, beta-blockers statins, diuretics). Patients had to have a record of at least 3-month of dispensing of the interest medication in order to be included in the study. A 3-month lag-time was applied to both cohorts to avoid protopathic bias. Additional sensitivity analyses were conducted by creating a pseudo-population with balanced covariates using propensity score (PS) matching. We fitted Cox-proportional hazard models on these pseudo-populations, keeping the variables consistent with the original model, to obtain hazard ratios.

Results: During the mean follow-up time of 2.5 years (SD 1.88), 282 (86 tamsulosin and 196 finasteride users) patients were prescribed insulin. Tamsulosin users were at a significantly higher risk of insulin prescription (adjusted hazard ratio, 1.45; 95% confidence interval, 1.09–1.92) compared with finasteride users. In pseudo-population, the adjusted hazard ratio for insulin prescription (tamsulosin use vs finasteride use) was 1.52 (95% confidence interval, 1.09–2.13)

Conclusion: Our findings suggest that, among men with T2DM, tamsulosin users are at higher risk of poor glycemic control compared with finasteride users. Our study findings are consistent with potential risk increases between 23% and 96% on the marginal hazard ratio scale.

Development of strategies to address vaccine hesitancy.

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[1]JSS College of Pharmacy, Mysuru, , India, [2]JSS Medical College, Mysuru , , India, [3]Gulf Medical University, , UAE

Biography:

Since 2020, I am in the field of vaccinology by choosing the topic "Development of strategies to address vaccine hesitancy" for my PhD research work. Thus, I got various opportunities and exposure to know in depth about vaccines, its safety, public attitude to vaccines and what are their concerns and worries regarding immunization. Till date I have published articles in reputed journals regarding the Adverse events following COVID-19 vaccination: first 90 days of experience, COVID-19 vaccine triggered autoimmune hepatitis: case report, following more articles in processing, which are having the results of vaccine hesitancy to Optional vaccines, Mandatory vaccines, COVID-19 vaccines, Social media influence on vaccination decision making, and Socio-behavioural attitude to vaccines & its impact on pharmaco-economics. As a budding person in the field of vaccinology, I have made educational tools (posters, animated short videos and booklets) to make the awareness to the public. The strategies I developed to address the vaccine hesitancy is having a great impact on the vaccine coverage in the study Centre. And as academic ambitious person, I am updating my knowledge about vaccines by attending various vaccinology courses conducted across the globe.

Aim: To assess the vaccine hesitancy among different stakeholders of vaccination, to develop and implement strategies to address vaccine hesitancy.

Method: A mixed method, web-based, cross-sectional study conducted for one year. Eligible participants were enrolled for the study after obtaining the informed consent. The study tool used was the WHO Strategic Advisory Group of Experts on Immunization Working Group developed Vaccine Hesitancy Questionnaire.

Results: During the study period, 800 subjects who fulfilled the study criteria were enrolled in the study and one left the study by not giving the consent. In the Phase-1 (pre-Interventional), 40.75% (n=326) of parents and 59.25% (n=474) of Future parents were participated. The prevalence of vaccine hesitancy was 70.25% (n=562). In Phase-2, suitable multicomponent interventions tools were developed to address the concerns of study population. The hesitancy/ refusal rate was declined to 12.46% (n=83) in the Phase-3 (Post-interventional). The greatest impact of the intervention was initial 65.62% (n=525) which improved to 96.39% (n=642) by confirming that they will vaccinate or had vaccinated their children. Decision-making around vaccines can be tied to a number of worries about safety, scepticism, social connections and media influences, which can collectively result in a tangle of vaccine hesitancies. This was an evident to the increased confidence in vaccine that at post interventional study, 96.54% (n=643) opted "Yes" for the question "Do you believe that vaccines can protect children from serious diseases?" However, 19.3% (n=16) have confirmed that they are hesitant or refusers to specific vaccination after the educational intervention.

Conclusion: The health care system is having a hard time coping with vaccine hesitancy, but to date, there are no specific methods and tools that can address the identified concerns. Individuals who are vaccine-hesitant are a mixed group with heterogeneous concerns about vaccines.

Post-marketing drug effectiveness and safety evaluation

In-utero Gabapentin Exposure and attention-deficit hyperactivity disorder risk: A population-based cohort study

Alekhya Lavu[1], Dr Payam Peymani[1], Dr Silvia Alessi-Severini[1], Dr Chelsea Ruth[2], Dr Jamison Falk[1], Dr Kaarina Kowalec[1], Dr Christine Leong[1], Dr Laila Aboulatta[1], Dr Lara Haidar[1], Shelley Derksen[3], Dr Marcus C. Ng[4], Dr Padma Kaul[5], Dr Joseph Delaney[1], Dr Sherif Eltonsy[1]
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Biography:

Alekhya is a fourth-year Ph.D. candidate at the College of Pharmacy, University of Manitoba. Prior to her enrollment at the University of Manitoba in 2019, she successfully obtained a PharmD degree from Manipal College of Pharmaceutical Science, Manipal Academy of Higher Education. Her specialization lies in the fields of drug safety and pharmacoepidemiology, with a particular focus on investigating the effects of medications during pregnancy and their impact on neonatal safety outcomes.

As part of her Ph.D. program, Alekhya has undertaken a series of significant research projects. She will be conducting a systematic review and meta-analysis, along with two population-based cohort studies. These studies will specifically examine the use of antiseizure medications during pregnancy and the potential adverse effects on neonatal health. Alekhya's research endeavors are generously supported by both provincial and national research funds, providing her with the necessary resources to carry out her studies effectively. Her ultimate goal is to develop advanced research skills that will establish her as a successful and accomplished pharmacoepidemiologist

Aim

Gabapentin is a new-generation antiseizure medication approved for epilepsy. Due to the perceived safety in pregnancy and efficacy in reducing pain, there has been an increase in the off-label use of gabapentin. We aim to study whether the association between gabapentin treatment during pregnancy and the risk of attention deficit hyperactivity disorder (ADHD) risk differs among all pregnant people.

Methods

We conducted a population-based cohort study among pregnant people in Manitoba, Canada from 1998 to 2021. We examined the association between gabapentin exposure in-utero during 2nd and 3rd trimesters and the risk of ADHD in infants. We conducted Cox proportional hazards regression models and adjusted for maternal age, pain diagnoses, psychiatric disorders, diabetes, hypertension, urban/rural, socioeconomic status, multiple births and teratogenic drugs exposure in 1st trimester.

Results

Among 1057 pregnant people exposed to gabapentin, we found a significant increased risk of ADHD with an adjusted hazard ratio (aHR) of 1.82, 95%CI (1.10-3.02) in infants, when compared with infants of gabapentin unexposed pregnant people.

Conclusion

Gabapentin exposure in pregnant people was associated with a significant increased risk of ADHD in infants. Clinicians should be aware of the benefits and potential risks of prescribing gabapentin during pregnancy.

Keywords : Gabapentin, Epilepsy. Safety, Neonatal outcomes

The 13-valent Pneumococcal Conjugate Vaccine in Reducing Childhood Hospitalised Invasive Pneumococcal Diseases

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Biography:

Daniel Hsiang-Te Tsai is a clinical pharmacist with a master's degree in pharmacoepidemiology. He specialises in using big data analysis to evaluate the safety, effectiveness, and potential factors associated with medications. His expertise includes using claims databases to assess rare neurological diseases and integrating electronic health records for validation. In addition, he is also actively involved in the development of the BESTMED project, focusing on the intersection of AI and geriatric medicine. Through this project, he aims to leverage AI techniques to enhance healthcare delivery and improve outcomes for older patients.

AIM/OBJECTIVE

To investigate the effect of the 13-valent pneumococcal conjugate vaccine (PCV13) in reducing childhood invasive pneumococcal diseases (IPDs) in hospital settings.

METHODS

The systematic review included only English articles focusing on PCV13 and childhood IPDs in hospital from January 2010 until March 2023. Childhood IPDs were defined as either children or adolescents diagnosed with septicaemia, pneumonia, or meningitis. Data on numbers of IPD cases before and after the introduction of PCV13 were extracted to estimate the changes in IPDs. We described the mean case difference rate per year using percentages and a 95% confidence interval (95% CI). A random effect meta-analysis was performed to estimate pooled case difference rates. Subgroup analysis further focused on the case difference in children with IPD risk factors or co-morbidities.

RESULTS

A total of 21 studies were included in the systematic review. There was a total of 9,447 IPD cases during the pre-PCV13 and 6,654 cases in the post-PCV13 period. The mean case difference rate per year was -35% (95% CI -21 to -51%). For the PCV13 targeted population (aged <2 years), there were 2,903 cases of IPD pre-PCV13 and 1,714 cases of IPD post-PCV13. The mean case difference rate for the targeted population was -36% (95% CI -23 to -49%). For children with IPD risk factors or co-morbidities, we observed a mean case difference rate of -29% (95% CI -8 to -55%) IPD cases (pre-PCV13 period: 2,505 cases; post-PCV13: 2,771 cases).

CONCLUSION The introduction of PCV13 was associated with a lower rate of IPDs among hospitalised children. As the emerging serotype replace, further investigation should identify risk factors and all-cause mortality associated with childhood IPDs.

Keywords: 13-valent pneumococcal conjugate vaccine, invasive pneumococcal disease

Cardiovascular risks in schizophrenia patients treated with paliperidone palmitate once-monthly injection (PP1M)

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Biography:

Li Yan is Manager in Epidemiology at Global Epidemiology Organization, Johnson & Johnson. Li's current research focuses on the safety and effectiveness evaluations of CNS drugs and post-approval commitment studies in several TAs using real-world data in Asian populations.

Li has extensive experience in conducting large-scale epidemiological and interdisciplinary research projects. Prior to joining the Johnson & Johnson, Li completed his post-doctoral training with Boya Fellowship at Peking University, where he participated in the building of China Health and Retirement Longitudinal Study (CHARLS), which is a nationally representative cohort focusing on economic status, health and ageing, as well as led several epidemiological sub-studies from this cohort. Li also worked as a research epidemiologist in an environmental health study linking air pollution exposure to cardiopulmonary outcomes at King's College London, where he led development of research plans and data collection.

Li earned a Ph.D. in Clinical Medicine Research from Imperial College London in UK, and a MSc in Epidemiology & Biostatistics as well as a BMed in Preventive Medicine from Peking University in China.

Aim/Objective

Schizophrenia is one of the leading causes of disability worldwide. PP1M was developed to improve medication adherence for maintenance treatment. It's well known that patients with schizophrenia have higher risks of cardiovascular events. However, little is known about the cardiovascular risks of schizophrenia patients treated with PP1M in Asia. This study aimed to estimate the incidence of cardiovascular events after initiating PP1M treatment and evaluate the cardiovascular risk associations compared with oral second-generation antipsychotics(SGAs).

Methods

Data from Taiwan's National Health Insurance Research Database(NHIRD) were used to identify a cohort of adult patients with schizophrenia who received SGAs from 2013 to 2018. Patients who initiated PP1M treatment were enrolled, and they were propensity matched 1:1 to patients initiating a new oral SGA for comparative analysis, based on demographics, clinical characteristics and treatment history at baseline following the prevalent new-user design to enhance comparability. Study endpoints included serious cardiovascular events(SCEs, including severe ventricular arrhythmia and sudden death), expanded serious cardiovascular events(eSCEs, further included acute myocardial infarction and ischemic stroke), and cardiovascular hospitalizations. A Cox regression model was used to assess risk associations.

Results

11,023 patients initiating PP1M treatment were identified (49.5% women; mean age 43.2). During 11,469.7 person-years of observation, 45 SCEs occurred with overall incidence rate of 3.9(2.9-5.2) per 1000 person-years. The incidence rates for eSCEs and cardiovascular hospitalizations were 7.9 and 52.0 per 1000 person-years, respectively. In matched cohort analysis (N=10,115), the hazard ratios(HRs) between initiating PP1M and a new oral SGA for SCEs, eSCEs and cardiovascular hospitalizations were 0.86(0.55-1.36), 0.88(0.63-1.21), and 0.78(0.69-0.89), respectively.

Conclusion
This study reported population-based incidence of cardiovascular events in schizophrenia patients initiating PP1M treatment. PP1M treatment was not associated with increased risks of SCEs but potentially associated with lower risks of cardiovascular hospitalizations compared to oral SGAs.

Keywords
SGAs, PP1M, Cardiovascular risk, Taiwan's NHIRD

A Nationwide Safety Surveillance Analysis of COVID-19 mRNA Vaccines in Singapore

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Biography:

Desmond Teo is a Data Analyst at the Vigilance and Compliance Branch, Health Sciences Authority, Singapore. He works in the Active Safety Surveillance Analytics Team to monitor the safety of medicines and vaccines. A pharmacist by training, he graduated with a BSc Hons. in Pharmacy from the National University of Singapore (NUS). He is currently in his final year in the MSc in Biomedical Informatics program at the Yong Loo Lin School of Medicine, NUS.

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Background: The real-world safety profile of COVID-19 mRNA vaccines remains incompletely understood. We sought to identify and validate potential safety signals associated with COVID-19 mRNA vaccines.

Methods: We performed a nationwide post-market safety surveillance analysis in vacinees aged 5 years and above, up till mid-September 2022. Observed over expected (O/E) analyses were performed to identify potential safety signals among eight shortlisted adverse events of special interest (AESIs): strokes, cerebral venous thrombosis (CVT), acute myocardial infarction, myocarditis/pericarditis, pulmonary embolism, immune thrombocytopenia, convulsions and appendicitis. Self-controlled case series analyses (SCCS) were performed to validate signals of concern, occurring within 42 days of vaccination.

Results: Elevated risks were observed via O/E analyses for the following AESIs: myocarditis/pericarditis, [rate ratio (RR): 3.66, 95% confidence interval (95% CI): 2.71 to 4.94], appendicitis [RR: 1.14 (1.02 to 1.27)] and CVT [RR: 2.11 (1.18 to 3.77)]. SCCS analyses generated corroborative findings: myocarditis/pericarditis, [relative incidence (RI): 6.96 (3.95 to 12.27) at 1 to 7 days post-dose 2], CVT [RI: 4.30 (1.30 to 14.20) at 22 to 42 days post-dose 1] and appendicitis [RI: 1.31, (1.03 to 1.67) at 1 to 7 days post-dose 1]. Booster dose 1 continued to be associated with higher rates of myocarditis/pericarditis [RR: 2.30, (1.39 to 3.80) and 1.69, (1.11 to 2.59)] at 21- and 42-days post-booster dose 1, respectively. Males aged 12 to 17 exhibited the highest risks of both myocarditis/pericarditis [RI: 6.31 (1.36 to 29.3)] and appendicitis [RI: 2.01 (1.12 to 3.64)] after primary vaccination. Eleven out of 16 CVT cases occurring within 42-days of vaccination were in males aged 50 years and above.

Conclusion: Myocarditis/pericarditis, appendicitis and CVT associated with COVID-19 mRNA vaccines have been identified in a setting with very few COVID-19 infections. Males at various ages appear to be at higher risk of all three AEs identified.

Investigating Mortality Outcomes of Different ARNi &ACEi/ARBs Dose Strengths: A Real-World Analysis

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Biography:

Dr.Yasmin is currently a senior research specialist at ALNAS Hospital, and a visiting lecturer for the PharmD program at Alexandria University. Previously, she was a research fellow at the Division of General Internal Medicine and Primary Care at Brigham and Women's Hospital. Her main research interest is in the field of comparative effectiveness research using electronic medical records and registries. She is the heart failure national representative for Egypt (HFA Young Ambassador) for the European Society of Cardiology (ESC).
In addition to her scientific research experience, Dr. Elsobky has a special interest in assessing various pharmacy pedagogies to enhance pharmacy learning experiences. Her passion for education and innovative approaches have been recognized through her receipt of educational research grants, including the California Northstate University - Institute of Teaching and Learning Excellence and the CNU-ITLE HEALTHCARE EDUCATION GRANT Award, HEGA, AY 2019-2020.
Dr.Elsobky has been awarded numerous awards for her contributions to the field, including the Egyptian Knowledge Bank Trainer Champion in 2019, the Fulbright Scholarship in 2021, the Best Poster Award at ASPET 2022, and the Best PhD Thesis Award at CardioEgypt 2023.

The European Society of Cardiology recommends the use of angiotensin-receptor-neprilysin-inhibitors (ARNI) as the initial therapy for stable heart failure patients with reduced ejection fraction(HFrEF) due to their demonstrated benefits on mortality. However, in real-world clinical practice, many HFrEF patients fail to reach or maintain the target doses of ARNI. This study aimed to investigate the impact of different dose strengths of ARNI and angiotensin-converting-enzyme inhibitors/angiotensin-receptor-blockers (ACEi/ARBs) on mortality in HFrEF-patients using 6 years of real-world data.

The researchers conducted a retrospective longitudinal cohort study using electronic-medical-record data from Brigham and Women's Hospital from July-2015 to August-2021. They compared mortality among HFrEF-patients based on three prescription patterns: (a) up-titration to the recommended high dose, (b) up-titration to a low/medium dose, and (c) no up-titration throughout the follow-up period. They used statistical methods such as propensity score matching, Kaplan-Meier analysis, and log-rank tests to compare survival curves between different dose groups in each treatment category.

Among the HFrEF patients, 1725 pairs could be matched between the groups. Only 15.7% of patients reached the target dosage of ARNI, while 27.8% achieved target dose with ACEi/ARBs. The results showed that patients who reached and maintained the target dose of ARNI had a significantly longer mean survival time compared to those on ACEi/ARBs. Patients who experienced titration but ended up with a medium/low dose of ARNI also had better survival outcomes compared to those on ACEi/ARBs. Conversely, patients who did not experience any up-titration had poorer survival outcomes on both ARNI and ACEi/ARBs.

The study's findings indicate that among HFrEF patients in real-world practice, achieving and maintaining the target dose of ARNI is associated with better outcomes compared to no up-titration or titration to a low/medium dose. These results have important implications for clinical practice, emphasizing the importance of optimizing ARNI dosage in HFrEF patients.

Use cases of a pregnancy algorithm

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Biography:
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Objective: Typically, medicine/vaccine safety in pregnancy data is generated post-marketing. To help plan post-marketing pregnancy studies such as pregnancy registries, it is important to understand medication uptake and characteristics of pregnant patients to inform study design. Creation of new algorithms to identify pregnancies in large real-world healthcare datasets to inform on pregnancy exposure can help to aid planning of post-marketing studies.

Methods: An algorithm was developed to calculate the number of pregnant women, receiving a drug or have a disease of interest, in a US database. The algorithm can identify pregnancies, pregnancy length, assign trimesters, and determine outcomes including pregnancy losses based on diagnostic (ICD 9/10) and procedural codes (CPT). This algorithm has potential to be standardized and utilized in other databases.

Results: This pregnancy algorithm is intended to inform on pregnancy exposures. This algorithm has been used to support post-marketing study planning to assess how many pregnant women may be in the population with a certain disease to provide information as to why it is or is not possible to do a study in pregnancy post-marketing. It has been used to provide context to ongoing pregnancy registries that weren't recruiting patients and to provide information to regulators about whether the reason for low recruitment was due to women not using the drug or that women just weren't enrolling in the registry. The algorithm has also been used routinely to provide data to regulators on how many pregnant women have been potentially exposed to a medication for labelling discussions.

Conclusion: The next steps in optimizing the algorithm are to make it open source which will hopefully allow it to be used in multiple geographies and work with multiple health record coding systems.

Keywords: drug safety, insurance claims data, pregnancy algorithm

Drug utilization evaluation studies

Advanced Treatments in Patients with Inflammatory Bowel Disease in Japan

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Biography:
Associate Director, Global Epidemiology, APAC
BA (Kyoto), MD (Kobe), MSc (LSHTM), PhD (Hokkaido)
Worked as hospitalist/ER physician before joining pharma.
R&D and MAF experiences for > 10 years

Objective
To describe index and subsequent use of biologics or JAK inhibitors among Japanese patients with inflammatory bowel disease (IBD).

Methods
This retrospective cohort study used the Japan Medical Data Center database, which contains claims data from 14 million individuals in Japan. Patients who were diagnosed with Crohn's disease (CD) or Ulcerative colitis (UC), and received advanced therapy, including biologics and JAK inhibitors, between January 1, 2010 and Sep 30, 2022 were included. Patients aged at least 15 years old were required to have no treatment with advanced therapies within 6-month prior to the initiation of index treatments of interest: adalimumab, infliximab, vedolizumab, golimumab, ustekinumab and tofacitinib for CD and UC in Japan. Frequency and proportion of biologics or JAK inhibitors used by line of therapy was described.

Results
The number of eligible patients with CD and UC in the study period were 1,115 and 1,942, respectively. Among patients with CD, the distribution of index treatment for adalimumab, infliximab, ustekinumab and vedolizumab was 41.4%, 37.4%, 18.2%, and 3.0%, respectively. Among patients with UC, the distribution of index treatment for infliximab, adalimumab, vedolizumab, golimumab, tofacitinib and ustekinumab was 33.6%, 24.8%, 17.5%, 11.2%, 7.3% and 5.6%, respectively. Among patients switched to 2nd line treatment, the most common treatment in CD or UC was ustekinumab (47.3%, 112/237) or infliximab (18.9%, 129/683), respectively.

Conclusion
The most common index advanced treatment in patients with CD and UC between 2010 and 2022 was adalimumab and infliximab, respectively. The most common 2nd line treatment in CD and UC was ustekinumab and infliximab, respectively. Findings from this study, which analyze the real-world distribution of advanced therapy in Japan over the last 10 years when new therapeutic options have become available, may be valuable to inform the management of patients with IBD.

Keywords: Crohn's disease, Ulcerative colitis, biologic, Japan

State sector utilization of antineoplastics in Sri Lanka - 2008 to 2022

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Biography:

Dr. Danushi Gunasekara is currently working as a lecturer in clinical pharmacology and therapeutics at the Faculty of Medicine, General Sir John Kotelawala Defence University. She has a background in Medicine and Health Technology Assessment

Aim/Objective: To determine the trends in utilisation of antineoplastics and recommend ways to optimise procurement.

Methods: Aggregated data on total issues and costs of classes L01 and L02 (WHO Anatomical Therapeutic Chemical code) utilised in the state sector hospitals were retrieved from the Medical Supplies Division database from year 2008 to 2022. The essential medicines were coded according to the WHO EML for year 2021. Drug utilisation was estimated as total number of grams consumed per year per medicine.

Results: The usage and cost of L01 and L02 had increased from 2008 to 2020 by nearly 6-fold. A marked increase was seen in the utilisation of L01E (protein kinase inhibitors), L01F (monoclonal antibodies and antibody drug conjugates) and L01B (antimetabolites). In 2015, 37 of 42 medicines and in 2020, 55 of 58 medicines listed in the WHO-EML were available in the state sector. Imatinib and cetuximab contributed to the highest cost. The expenditure for non-essential medicines has increased to around 49.3% by 2022 compared to 23.86% in 2008. The number of non-EML medicines used was highest in L01E and L01F groups. These were mainly targeted therapies for breast, colorectal and non-small cell lung cancer. Availability had reduced by 54% after 2020 possibly due to the pandemic compounded by the economic crisis. The greatest drop was seen in the issues of L01A (89%), L01C and L01D with the smallest drop seen in L01F (6%) despite the high cost for some non – essential medicines.

Conclusion: Our study provides evidence that the economic crisis will lead to financial toxicity and distress to low-income patients unless timely rational procurement measures are implemented. Priority should be given for medicines listed in the WHO -EML with health technology assessment considered prior to inclusion of non-essential medicines in the state formulary.

Keywords: Antineoplastics, drug utilisation

Antiretroviral Therapy Utilization among pregnant women and Mother-To-Child Transmission in Benin

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Biography:

Pharmacist with a master degree in epidemiology and public health intervention as well as pharmacoepidemiology/pharmacovigilance. Currently doing a phD degree.

Objectives: To analyze the utilization of antiretroviral therapy (ART) among pregnant women and the rate of Mother-To-Child Transmission (MTCT) of HIV from 2015 to 2022 in Benin, and project trends for the year 2025.

Methods: Cross-sectional nation-wide data on the Prevention of the MTCT cascade was obtained from the District Health Information Software version 2 (DHIS2), a web platform used for data management and analysis purpose. The DHIS2 has been operational in Benin since 2014. ART uptake and MTCT rate indicators from 2015 to 2022 were examined via a time series analysis and linear regression was employed to assess the statistical significance of the observed trends. Finally, an Autoregressive Integrated Moving Average (ARIMA) model was utilized to forecast ART utilization and MTCT rate based on aggregated data.

Results: The number of pregnant women receiving Antenatal Care (ANC) was 386,009 in 2015 and 678,087 in 2022. The percentage of women tested for HIV also showed an upward trend, rising from 91.3% in 2015 to 99.1% in 2022 (p=0.044). Furthermore, the proportion of pregnant women who tested positive for HIV and received ART significantly increased from 65.9% in 2015 to 99.7% in 2022 (p=0.005). In terms of MTCT, the transmission rate significantly decreased from 10.6% in 2015 to 1.6% in 2021, with a slight increase to 1.8% in 2022 (p=0.003). The ARIMA (0,2,0) forecast model predicts that ART utilization will reach 100%, and that the MTCT rate will be 2.4% by 2025.

Conclusion: ART utilization among pregnant women in Benin improved since 2015 and is projected to reach full coverage by 2025. Further research is necessary to understand the increasing trend in the MTCT rate from 2021 and thus take appropriate measures to avoid a relapse in the HIV vertical transmission in Benin.

Keywords: Antiretroviral Therapy, pregnant women, Benin, mother-to-child transmission.

Insights on HIV Prophylaxis among Exposed Infants and Mother-To-Child Transmission in Burkina-Faso

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Biography:

Pharmacist with master degree in epidemiology and public health intervention. Currently doing my phD in public health.

Objective: To analyze the utilization of Antiretroviral (ARV) prophylaxis among HIV-Exposed infants and the rate of Mother-To-Child Transmission (MTCT) of HIV from 2013 to 2020 in Burkina-Faso, and project trends for the year 2025.

Methods: Repeated Cross-sectional analysis was performed on data extracted from the District Health Information Software (DHIS2) a web-based open-source software platform used for health information management which has been operational in Burkina-Faso since 2013 . ARV prophylaxis and MTCT rate indicators from 2013 to 2020 were examined via a time series analysis and linear regression was used to assess the statistical significance of the observed trends. Finally, an Autoregressive Integrated Moving Average (ARIMA) model was utilized to forecast ART utilization and MTCT rate based on aggregated data.

Results: The number of infants born to HIV-Positive mothers was 3,180 in 2013 and 2,126 in 2020. The proportion of HIV-Exposed infants tested for HIV at 18 months increased but not significantly from 21.0% in 2013 to 26.9% in 2020 (p=0.14). Furthermore, the proportion of HIV-Exposed infants who received ARV prophylaxis significantly increased from 64.3% in 2013 to 86.8% in 2020 (p=0.036). In terms of MTCT, the transmission rate globally decreased from 12.9% in 2013 to 9.3% in 2020 but there were peak increases in 2014 (14.7%) and 2016 (31.6%). The ARIMA (0,2,0) forecast model predicts that ARV prophylaxis utilization and MTCT rate will respectively be 86.9% and 9.9% by 2025.

Conclusion: ARV prophylaxis for HIV-exposed infants improved but fell short of the 2020 target in Burkina-Faso. Projections suggest the 2025 target may also be missed without prompt action. More efforts are needed to eliminate MTCT by 2030.

Keywords: Antiretroviral therapy, mother-to-child transmission, Benin.

Comparative analysis of Naimatevir/Ritonavir and Azavudine in elderly COVID-19 patients

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Biography:

Dr Shang is a senior clinical pharmacist. She is a qualified Medication Therapy Management pharmacist by the American Pharmacist Association.

Her research expertise is pharmaceutical neurotoxicology. As an early career researcher, she led on publishing eight original articles. Her current research in pharmacy practice field applying evidence-based pharmacy, pharmacoeconomics, and methodology to evaluate medication effectiveness and safety.

Nan has been actively involved in the pharmacy practice society and network in China. She serves as a member of the Pharmaceutical Epidemiology Committee of the Chinese Pharmaceutical Pharmaceutical Epidemiology. She is the Deputy Director of the Treatment of Drug Monitoring and Research Professional Committee of Shanxi Provincial Pharmacology. She is also the editor of the academic journal "Drug Epidemiology" and "China Pharmacy."

Objective:
To compare the safety and effectiveness of Naimatevir/Ritonavir and Azvudine in elderly COVID-19 patients.

Methods:
This study included elderly COVID-19 patients (age ≥65) diagnosed and hospitalized between December 2022 and February 2023, and were divided into Naimatevir/Ritonavir and Azvudine treatment groups. Analysis was conducted on patient demographics, medication information, laboratory parameters, and treatment outcomes. Chi-square test, multiple linear regression analysis, and multivariable Cox proportional hazards regression were employed to evaluate the safety and effectiveness of the treatments in the two groups.

Results:
This study included 416 elderly COVID-19 patients, with 140 in the Naimatevir/Ritonavir group and 276 in the Azvudine group. After propensity score matching, there were no significant differences in demographic characteristics between the two groups (P>0.05). There was a statistically significant difference in the duration of medication between the two groups (P<0.01). The Naimatevir/Ritonavir group had a higher incidence of elevated alkaline phosphatase (62.86% vs. 43.12%) and elevated urea (50.71% vs. 31.52%) compared to the Azithromycin group (P<0.05). There was a significant difference in the time to the RT-PCR cycle threshold (Ct) values> 35 between the two groups (P<0.05). But no significant differences in survival status during hospitalization or time to Ct values> 35 between the two groups. Factors influencing ΔCt values included medication, age, and duration of medication (P<0.05). The risk of death increased with older age (HR=1.06, 95% CI: 1.02, 1.10), and patients with more than 20 concomitant medications had a 4.65-fold increased risk of death (HR=5.65, 95% CI: 2.00, 15.96).

Conclusion:
Both Naimatevir/Ritonavir and Azvudine showed effectiveness in elderly COVID-19 patients but with differences in safety and time to Ct values> 35. Further studies with a larger sample size are necessary to validate the drug's safety and effectiveness, as well as to investigate potential long-term effects and drug interactions.

Keywords: Naimatevir/Ritonavir; Azvudine; elderly patients

Evaluation of antimicrobial stewardship metrics in general surgery wards

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Biography:

Looking for a learning opportunity in an R&D set up to gain knowledge with respect to drug discovery and development. During my academic tenure, also want to gain insight in early stages of drug discovery and development. As well as drug utilization research.

Aim/Objectives:
To evaluate the antimicrobial stewardship metrics amongst the patients admitted to the general surgery wards.

Methods:
A prospective interventional study was carried out in the surgery wards of a tertiary care teaching hospital for six months. All patients of any gender aged ≥ 18 years admitted to the general surgery ward receiving at least one antimicrobial agent were included in the study. The antimicrobial metrics- Daily Defined Dose (DDD), Days of Therapy (DOT), Length of Therapy (LOT), Antimicrobial Free Days, and antimicrobial resistance trends. Wilcoxon signed-rank test was used to compare DDD vs DOT values. The data obtained was assessed categorically.

Results:
A total of 554 patients were admitted to the study site over a period of six months amongst whom 337 (60.83%) were excluded, and 217 (29.16%) were eligible and included. Of 217 patients [125 (57.60%)] were males and [92 (42.40%)] were females receiving at least one antimicrobial. The mean age and length of stay were 47.2 ± 16.66 years and 7.03 ± 3.25 days, respectively. The mean total antimicrobial usage is measured by the number of DDDs per 1000 patient days and DOTs per 1000 patient days was found to be 6273.919 ± 7842.411 and 4491.776 ± 1665.571, respectively. In the 36 commonly used antimicrobial drugs the difference between the DDDs and DOTs was classified as major [24 (77.42%)], moderate [5 (16.13%)], and minor [7 (22.58%)]. The LOT and antimicrobial resistance trends were 8271.89 LOT per 1000 patient days and 9.21%.

Conclusion:
Antimicrobial stewardship programs play a vital role in the rational prescribing of antimicrobial agents. Clinical pharmacists are critical in the implementation of an ASP through involvement in monitoring, etc. Most antimicrobials used in this study have differing DDDs/1000 patient-days and DOTs/1000 patient-days because administering dose is dissimilar from WHO-assigned DDD.

Keywords:
Antimicrobial stewardship; resistance; metrics

Evidence-based medicine / Evidence-based pharmacy

Identifying Risk Factors for Polio Vaccine-Associated Paralytic Poliomyelitis: A Systematic Review

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Biography:

Saad Khan is a 6th year Doctor of Pharmacy (PharmD) student at Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal. He is currently a PharmD intern at Kasturba Hospital, Manipal, working on therapy management, medication order reviews, and patient counseling.

For his final year project, Saad conducted research work to gain valuable insights into difficulties associated with diagnosing and treating pesticide poisoning by conducting qualitative interviews involving emergency care physicians. Through his work, the objective was to enhance understanding and management of pesticide poisoning cases.

Possessing a wide range of skills and a determined commitment to healthcare and well-being, Saad is looking forward to have a significant influence in the field of pharmacy and healthcare.

BACKGROUND:
Vaccine-associated paralytic poliomyelitis (VAPP) is a rare but serious adverse effect of oral poliovirus vaccines. The switch from Inactivated Polio Vaccine (IPV) to Oral Polio Vaccine (OPV) was made to generate herd immunity against poliovirus but was found to be associated with paralytic poliomyelitis.

OBJECTIVES:
The objective of this study is to determine underlying risk factors for VAPP in polio vaccine recipients.

METHODOLOGY:
A comprehensive literature search was performed including PubMed, Embase and Scopus from inception up until March 2021. The search included “VAPP” AND “Case Reports” as keywords. Interventional, observational, experimental studies published in languages other than English were excluded. The quality of the included articles was assessed using a checklist developed by Murad et al. All the included articles were screened for the presence of risk factors that make individuals prone to developing VAPP.

RESULTS:
Initially, a total of 323 articles were retrieved from three databases after removal of duplicates with 57 from PubMed, 44 from Embase, 297 from Scopus. These articles were subjected to title and abstract screening. Out of these, 31 articles passed through full text screening which included 30 case reports and 1 case series. Our analysis identified two significant risk factors: immunodeficiency and perianal abscess in 11 and 2 patients, respectively. Individuals with immunodeficiency are inherently more vulnerable to infections and are less capable of mounting an effective immune response against the attenuated poliovirus present in the OPV. Additionally, the presence of a perianal abscess suggests a potential impairment in the body's ability to combat infections, increasing the likelihood of adverse effects following vaccination, including VAPP.

CONCLUSION:
To mitigate the occurrence and impact of VAPP, healthcare professionals must implement preventive strategies, such as pre-vaccination screenings for risk factors like immunodeficiency and perianal abscess, among others.

Keywords:
VAPP, Polio vaccine, Immunodeficiency

COVID-19 vaccine efficacy and influenza activity: A systematic review and network meta-regression

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Biography:
The presenting author is a graduate student from the Department of Epidemiology and Biostatistics, School of Public Health, Peking University.

Aim/Objective:
To understand whether the level of influenza activity has interaction on COVID-19 vaccine efficacy.

Methods:
This study was designed as a systematic review and network meta-regression. We identified and reviewed preprint and peer-reviewed articles published from January 1, 2017 to January 24, 2023. Randomized controlled trials (RCTs) of COVID-19 vaccine efficacy in any population were eligible. The positive rates of influenza viruses at national or regional level were used as the proxy of influenza activity, which was calculated using laboratory surveillance data reported from the Global Influenza Surveillance and Response System (GISRS) and categorized as low activity (<3%) and high activity (≥3%). We used a Bayesian network meta-regression model to estimate the interaction between influenza activity and COVID-19 vaccine efficacy [(1-odds ratio) * 100%].

Results:
In this systematic review, we included 43 studies from 18 countries. It was showed that all COVID-19 vaccines, including inactivated (IV), protein subunit (PS), RNA and non-replicating viral vector (VVnr) vaccines, have protection against SARS-CoV-2 infection. Considering the average influenza activity during the study period, the interaction coefficients and corresponding 95% confidence intervals (CIs) for IV, PS, RNA and VVnr vaccines were 0.14 (-0.42, 0.70), 0.05 (-0.26, 0.36), -0.04 (-1.17, 1.11) and 0.02 (-0.45, 0.48), respectively. Regardless of the low or high influenza activity, RNA VE were the highest, with the protection of 49% (43%, 55%) and 42% (-53%, 84%). With the level changing from low to high, IV VE had the most variation from 44% (31%, 56%) to 34% (-6%, 62%), followed by PS (36% to 33%) and VVnr (32% to 29%) vaccines.

Conclusion:
The pooled estimates of COVID-19 vaccine efficacy decreased under the higher influenza activity, but no significant interaction observed. The status of influenza infection was recommended to report in RCTs for further evidence.

Keywords: COVID-19 vaccine; Influenza; Efficacy; Interaction

Impact of Medication Therapy Management Services on Patients Treated with Oral Anticoagulants

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Biography:

Ms. Santosha Vooradi is currently working as Ph.D Research Scholar in the Dept. of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, MAHE, Manipal. Ms. Vooradi research interests include Pharmacoepidemiology, Patient Safety, Developing Patient Information Leaflets, Pharmacoeconomics and Outcomes Research. Ms. Vooradi has published 5 papers in the peer reviewed journals. Ms. Vooradi has participated and presented the papers at both national and international Conferences. She is also a reviewer for Clinical Epidemiology and Global Health and Indian Journal of Pharmaceutical Education and Research, Research abstract Reviewer for International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Conferences- Annual Meetings, Asian Conferences and European Conferences, since 2014.

Objectives:

To develop and validate the information leaflets and to assess medication therapy management (MTM) services on knowledge and adherence in patients treated with oral anticoagulants.

Methods:

A prospective observational cohort study was conducted in surgery, cardiology, and cardiothoracic surgery departments. Ethical approval was obtained before the initiation of the study. Patient information leaflets (PILs) on oral anticoagulants were prepared and validated by an expert panel. Multiple-choice questions (MCQs) were prepared for the knowledge assessment based on the PILs content and validated with an expert committee using Lawshe's content validity. The knowledge and adherence outcomes of the patients were assessed at baseline and after four months of MTM services. The pre and post-outcomes were evaluated using a paired t-test with a p-value of <0.05 was considered statistically significant.

Results:

Content validity was supported by content validity index of 0.8 for the MCQs questionnaire with a Cronbach's value >0.89. A total of 83 patients participated in the study. The mean age of the study population was 51±14.85 years. The commonly prescribed oral anticoagulant was acenocoumarol (31%). The mean number of medications per prescription was 4.69±1.99. The baseline knowledge and adherence scores were 48.31±19.24 and 76.20±12.44, respectively. The post-knowledge and adherence scores after MTM services were 74.57±13.81 and 83.13±9.64, respectively. Fifteen adverse drug reactions were observed above, with an INR range >6.

Conclusion:

The pharmacist-led MTM services significantly improved the knowledge (p=0.000) and adherence (p=0.000) of the patients treated with oral anticoagulants. Anticoagulation management service will help identify the patient's disease and monitor the therapy. The pharmacist's role in such services will be helpful for physicians to optimize and maintain the dose.

Keywords: Anticoagulant, Medication Therapy Management, Patient Information Leaflets, Validation

Impact of clinical pharmacist on medication adherence amongst patients with cancer

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Biography:

The author completed her PharmD in 2016 after which she pursued her residency specializing in oncology in 2018. She is the first pharmacy residency graduate in India. She is now currently working as a lecturer in the Department of pharmacy practice, JSS College of Pharmacy, Mysuru and concurrently pursuing her doctoral studies in geriatric oncology. She has 4 publications in the field of oncology and has presented her work at many national and international conferences.

Objective:
To determine the impact of clinical pharmacist services on medication adherence in cancer patients
Methodology: A prospective interventional study was conducted in a south Indian tertiary cancer hospital for a period of 6 months where adult cancer patients of either gender were enrolled into the study. Outpatients except for daycare patients, patients with cognitive impairment and loss of consciousness were excluded from the study. All necessary data like patient demographics, diagnosis, stage of cancer, and current treatment were obtained from various data sources including medical records, treatment charts, direct patient interviews etc.The Clinical pharmacists services like patient counselling and medication reconciliation was provided to improve adherence whenever the patient visited the hospital. The adherence to medications were assessed using Medication Adherence Rating Scale (MARS) at baseline and at the end of the study to determine the impact.

Results:
A total of 120 patients were enrolled into the study. The majority (60%) of the study population were middle-aged females. Around 25% of the patients had at least one comorbidity. At baseline, only 40.8% of the patients were adherent to their medications. But, at the end of the study, the adherence improved with 71.66% of the study participants showing good adherence.

Conclusion:
Continuous interventions by a clinical pharmacist can positively impact medication adherence in patients with cancer.

Keywords: Medication Adherence, Cancer, Clinical Pharmacist

Human health risk assessment of arsenic-contaminated drinking Water in Indian endemic regions

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Biography:

I, Mr. Christy Thomas, focused and dedicated researcher in the field of Pharmacy Practice, specializing in Meta-research, Pharmacoeconomics, and environmental epidemiology in oncology. I completed my M.Pharm. with a Gold medal from NIPER Hajipur and am currently pursuing my Ph.D. in the Department of Pharmacy Practice at NIPER Guwahati.

As a researcher, I have a diverse range of interests, including environmental pharmacoepidemiology, conducting targeted and systematic reviews, meta-analysis, pharmacoepidemiology, health economics and outcome research, and pharmacovigilance.

Currently, I am engaged in an ambitious Ph.D. thesis on the topic "Assessment of prevalence, risk factors, management, and economic burden of gallbladder cancer among the northeast population of India: a hospital-based prospective observational cohort study." The research aims to address the significant prevalence of gallbladder cancer in India, particularly in the northeast India region, and explore its impact on the economy and patients. By investigating epidemiological risk factors such as the carcinogenic role of heavy metals in drinking water, therapeutic management, and the economic burden of gallbladder cancer, I am aiming to contribute valuable insights to the field.

This study is the first of its kind to comprehensively examine the economic burden and carcinogenic role of heavy metals in drinking water in gallbladder cancer in the country. I believe my work has the potential to shape clinical practices, inform policy decisions, and improve patient outcomes.

Objectives: To assess the human health risks associated with the contamination of Arsenic (As) in drinking water in India.

Methods: A systematic literature search to identify epidemiological studies was performed in PubMed, Scopus, and Google Scholar from inception to May 1st, 2023. The U.S. Environmental Protection Agency (USEPA) model was used to assess cancer and non-cancer risks in adults and children. The Incremental Lifetime Cancer Risk (CR) and Hazard Quotient (HQ) were used to determine cancerous and non-cancerous risk levels in exposed populations. The cancer slope factor (1.5 mg/kg-bw/day) and oral reference dose of As were adopted from US EPA (2005) screening levels. Uncertainty analysis carried out using Monte Carlo method. Meta-analysis was performed using a Z-score approach to estimate differences in effect size.

Results: We found a total of 960 studies through a database search, of which 16 studies with 1,349 samples from eight states in India were included. In all those regions, the cancerous risk through exposure to As contaminated drinking water was higher (CR:1.69x10¬-6 to 0.11) than the safety level of USEPA. The non-cancerous risk assessment showed that six states had HQ values above 1 (HQ=1.13 to 247.49), suggesting health effects in children and adults. Compared to other states, the cancerous and non-cancerous risks in states near the Indo Brahmaputra Gangetic plane were higher in the order of West Bengal (CR=0.01, HQ=22.81), Bihar (CR=0.002, HQ=5.87), Uttar Pradesh (CR=0.001, HQ=4.2) and Assam (CR=0.001, HQ=4.1). Meta-analysis of the data indicates that the average effect size using Z-score was -0.0056 (95% CI: -0.34, 0.33).

Conclusions: Our findings suggested that the As-contaminated drinking water in India, poses significant cancer and non-cancer risks, making the population susceptible to health hazards in the future. We recommend health authorities conduct constant monitoring of As contaminations and implement purification improvement programs to manage health risks.

Comparative effectiveness of GLP-1 analogs and SGLT-2 inhibitors versus either agent alone

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Biography:

Dr. Richeek Pradhan is a clinical pharmacologist and pharmacoepidemiologist working with large claims and electronic health record datasets to examine the comparative safety and effectiveness of anti-hyperglycemic medications. He combines novel technologies such as natural language processing with conventional methods such as claims data, thereby harnessing the strengths of routinely collected clinical data to infer causality in observational settings.

Aim: T
his study aims to determine whether the combination use of glucagon-like peptide 1 receptor agonists (GLP-1 RAs) and sodium-glucose co-transporter-2 (SGLT-2) inhibitors (GLP-1 RA-SGLT-2) is associated with a decreased risk of cardiovascular events and serious renal outcomes among patients with type 2 diabetes, compared to either agent alone.

Methods:
This population based cohort study used the Clinical Practice Research Datalink, United Kingdom, to assemble two active comparator, prevalent new user cohorts. Time-conditional propensity scores were generated and used to match GLP-1 RA-SGLT-2 inhibitor combination users to SGLT-2 inhibitor and GLP-1 RA users, separately. Cox proportional hazards models were fitted to estimate the hazard ratios and 95% confidence intervals of major adverse cardiovascular events (MACE), heart failure, and serious renal outcomes for combination GLP-1 RA-SGLT-2 inhibitor use.

Results:
Compared with GLP-1 RAs alone, the addition of SGLT-2 inhibitors to GLP-1 RAs were associated with a decreased risk of MACE (113 vs 45 events per 100 person years; hazard ratio 0.70, 95% confidence interval 0.49 to 0.99) and serious renal disease (51 vs 13 events per 100 person years; hazard ratio 0.43, 0.23 to 0.80). The addition of GLP1-RAs to SGLT-2 inhibitors, compared to SGLT-2 inhibitor s alone, was associated with a decreased risk of MACE (141 vs 55 events per 100 person years; hazard ratio 0.71, 0.52 to 0.98) and serious renal outcomes (26 vs 10 events per 100 person years; hazard ratio 0.67, 0.32 to 1.41); however, the latter confidence intervals included the null value.

Conclusion:
In this population-based cohort study, combination GLP-1 RA-SGLT-1 inhibitor use was associated with a reduced risk of MACE and serious renal outcomes compared with each drug separately in patients with type 2 diabetes, with the addition of an SGLT-2 inhibitor to existing treatment of GLP-1 RAs showing more prominent beneficial results.

Rational drug use / Prevention of medication errors and drug misuse/abuse / Post-marketing drug effectiveness and safety evaluation

Benzodiazepine receptor agonists prescribing for insomnia in Chinese primary healthcare facilities

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Biography:

Peking University, School of Pharmaceutical Science. Postdoc, Pharmacy Administration and Clinical Pharmacy. Aug 2021-Jul 2023

Harvard Medical School and the Harvard Pilgrim Health Care Institute. Research Fellow, Health Policy Research, Department of Population Medicine. Sep 2019-Aug 2020

Peking University, School of Pharmaceutical Science. PhD, Pharmacy Administration and Clinical Pharmacy. Sep 2018-Jul 2021

Peking University, School of Pharmaceutical Science. MSc, Pharmacy Administration and Clinical Pharmacy. Sep 2016-Jul 2018

Peking University, School of Pharmaceutical Science BSc, Pharmaceutical Science. Sep 2012-Jul 2016

Equitable access to and appropriate use of medicines

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Objective: This study aimed to describe the benzodiazepine receptor agonist (BZRA) prescribing rate for insomnia among adult patients in primary healthcare facilities (PHFs) in China.

Methods: Outpatient visits of patients who 1) aged 18 and above, 2) were diagnosed with insomnia, 3) had no diagnosis of anxiety or depression, and 4) prescribed with at least one BZRA, at all 67 PHFs in Dongcheng district in Beijing were included. De-identified information including patient demographics, diagnoses, and medications prescribed were digitally extracted. The primary outcome was the prescribing rate of benzodiazepines between 2016 and 2022. The secondary outcome was the average daily dosage of each BZRA

in 2022, compared with recommendations of relevant clinical guidelines in China. Descriptive statistics were used to illustrate outcomes.

Results: A total of 18,807,266 outpatient visits were identified between 2016 and 2022, of which 928,688 visits (536,856 [57.8%] by female patients) were eligible for inclusion. The overall prescribing rate of benzodiazepines increased from 2016 (18,910 of 54,350 [34.8%]) to 2020 (111,271 of 177,065 [62.8%]), and then with a slightly decline to 59.4% in 2022 (112,538 of 189,399). The largest increases were found in patients aged ≥85 years (33.3%) and 75-84 years (28.0%). In 2022, the prescribing rate of benzodiazepines increased with patient age (18-44 years, 45.7%; 45-64 years, 56.3%; 65-74 years, 58.1%; 75-84 years, 63.1%; ≥85 years, 66.4%). Estazolam (110,328 of 190,018 [58.1%]) and zopiclone (72,030 of 190,018 [38.0%]) were the most commonly prescribed BZRAs in 2022. The mean daily dosages of all prescribed BZRAs for older adults were similar to those for adults. Most BZRAs were prescribed for older adults at a dosage two times higher than recommendations in guidelines.

Conclusion: This study observed that benzodiazepines were substantially over-prescribed and showed a rapid upward trend of use for adult insomnia patients in Chinese PHFs.

Community pharmacist's perspectives on antibiotic use and antimicrobial resistance: a qualitative study

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Biography:

Dr. Rosy Raju is a dedicated research scholar specializing in the field of antimicrobial resistance (AMR) among community pharmacists and community health workers in India. With a passion for improving healthcare outcomes and combatting the global challenge of AMR, Dr. Rosy Raju has dedicated their career to understanding the factors contributing to the misuse and overuse of antibiotics in community settings. Currently pursuing a doctoral degree in Pharmacy Practice at JSS Academy of Higher Education & Research, Dr. Rosy Raju has been actively involved in designing and implementing studies to investigate the knowledge, attitudes, and practices of community pharmacists and health workers in relation to antibiotic use. Their research aims to identify key areas of intervention that can effectively address the issue of AMR at the grassroots level.

Through her research and advocacy efforts, Dr. Rosy Raju envisions a future where community pharmacists and health workers in India are empowered with the necessary knowledge and resources to combat AMR effectively. Their work exemplifies their commitment to improving public health outcomes and safeguarding the effectiveness of antibiotics for future generations.

Community pharmacists (CPs) are ideally positioned to contribute to tackling the issue of antimicrobial resistance through their expertise, knowledge, and advice on the use of medications. Lack of awareness and education among CPs are the prime reasons for the dispensing of antibiotics without prescription in developing countries contributing to antimicrobial resistance.
Aim: To explore the factors leading to AMR and the pattern of antibiotic dispensing among community pharmacists.

Method: This qualitative study was conducted using a semi-structured interview guide among 24 CPs from rural and urban areas of Karnataka, India. In order to obtain individual points of view, in-depth face-to-face interviews with selected community pharmacists were conducted and the audio-recorded interviews with transcripts were analyzed. The semi-structured interviews followed a framework that explored the participants' perspectives in three main areas: (1) Antibiotic dispensing practices of CPs; (2) understanding of AMR; and (3) Factors leading to AMR

Result: Out of 24 CPs 45.8% (11) were less aware of the term antimicrobial resistance. Commonly dispensed antibiotics without prescription were Azithromycin (100%), Amoxicillin-clavulanate (95.8%), Cefixime (92%), Ciprofloxacin (83.3%), Levofloxacin (79.1%), Cefpodoxime (66.6%) and Cefotaxime (54.1%). The factors leading to AMR observed through interviews included patient factors like the inability to purchase a full course of antibiotics, stopping antibiotics if felt better after one or two doses of antibiotics, and a lack of trust in the pharmacist’s advice, unaffordability to consult a physician and using leftover antibiotics. About 54.1% of study participants requested training related to antimicrobial resistance.

Conclusion: The community pharmacists perceived that the behavior of patients and the societal environment contributed to irrational antibiotic use and the subsequent development of AMR. They suggested a need for proper training, and public awareness in order to improve future antibiotic use and reduce AMR.

Keywords: Community pharmacist, Antibiotics, Antimicrobial resistance

Clinical Pharmacist-driven Handshake Antibiotic Stewardship -Effective model for Antibiotic Optimization in Surgery

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Biography:

Hi, I am Ann Vazhayil Kuruvilla, Pharm. D currently pursuing PhD in Pharmacy on Assessment and Implementation of Antibiotic Stewardship in Surgery wards in a tertiary care hospital. I served as a Clinical pharmacist and preceptor for 5 years and 3 months as faculty, Department of Pharmacy Practice, JSS College of Pharmacy/JSS Medical College and Hospital, Mysuru. I was also a Clinical Research Co-Ordinator for Phase III Cardiovascular drug trial for 5 years. I have 14 publications till date which includes conference proceedings and full length research papers.

Background : Antibiotic stewardship programmes (ASPs) are particularly important for surgical specialties due to their substantial impact on the use of prophylactic antibiotics and the treatment of surgical infections.

Objectives : To assess and compare the pre- and post-implementation phases of Handshake Antibiotic Stewardship Programme in surgical units of a tertiary care hospital

Methods : This prospective interventional study was carried out in 3 phases: pre-intervention, intervention, and post-intervention. Appropriateness of antibiotic use and other outcomes were assessed in both pre - and post-intervention phases. The clinical pharmacist worked collaboratively with the surgeons and a microbiologist in developing the antibiotic guidelines by the Consensus method during the intervention phase. Post-intervention, whenever the clinical pharmacist noticed a non-adherence to the guidelines, the concerned surgeons were reinforced on adhering to the guidelines in their daily practice. The paired t-test , Wilcoxon sign rank test and Chi-square test were used for the statistical analysis. The data was analyzed using SPSS 26.0 version and the results with $p< 0.05$ were considered statistically significant.

Results : During the pre-and post-phases,614 and 623 patients were enrolled respectively. Most (66.77%) of the patients had undergone surgery and major category of antibiotic use was prophylaxis. There was a statistically significant ($p< 0.001$) decrease in the days of administration of surgical antimicrobial prophylaxis and a significant increase in the administration of surgical antimicrobial prophylaxis as single dose during the post-phase. The post-intervention phase witnessed a statistically significant reduction in DDD and DOT per 1000 patient days of few antibiotics. A statistically significant improvement in appropriate antibiotic use was noticed during post-phase. There was a significant reduction in the length of stay during the post-phase. Net cost saving of 784346.02 INR post-intervention was achieved.

Conclusions : ASP implementation can improve the appropriateness of antibiotic use and is cost-saving.

Pharmacist's Intervention: Medication Adherence and Quality of Life in Oral Oncolytics Patients

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Biography:

I am a student at the National Institute of Pharmaceutical Education and Research in Guwahati. Currently pursuing my studies in pharmaceutical sciences, my research project focuses on the topic of 'Pharmacist's Intervention: Medication Adherence and Quality of Life in Oral Oncolytics Patients.' This study aims to examine the impact of pharmacist intervention on medication adherence and the overall quality of life in patients receiving oral oncolytics. Through this research, I am dedicated to contributing valuable insights to the field of clinical pharmacy and pharmaceutical sciences, with a particular focus on optimizing patient care in oncology. I am excited to present my findings at ACPE 2023 and engage in meaningful discussions with fellow researchers and experts in the field

Objective:
This study aimed to implement clinical pharmacist services and evaluate their impact on medication adherence and quality of life (QoL) in patients receiving oral oncolytics.

Methods:
A prospective interventional cohort study was conducted at a cancer speciality hospital between August 2022 and April 2023. The study included patients aged 18 years and above who were receiving oral chemotherapy. The intervention group received personalized medication counselling and educational materials, while the control group received standard care. Medication adherence was assessed using the Morisky Medication Adherence Scale (MMAS-8), and QoL was evaluated using the EQ-5D-5L and EORTC QLQ-C30 questionnaires.

Results:
A total of 202 participants were randomly assigned to either the intervention or control group. The intervention group demonstrated a significantly higher change in medication adherence compared to the control group [mean difference (MD) 0.66±0.09, $p<0.01$)]. Furthermore, the intervention had a positive and significant effect on specific aspects of functioning and QoL. The intervention group showed improvements in overall role functioning (MD 0.06±0.02, $p=0.03$), cognitive functioning (MD 0.08±0.03, $p=0.01$), and social functioning (MD 0.12±0.03, $p<0.01$), along with a decrease in overall pain (MD -0.06±0.05, $p=0.03$) compared to the control group. The analysis of self-reported questionnaires revealed important findings regarding non-adherence factors in both the intervention and control groups. The primary factors contributing to non-adherence were consistently associated with feelings of depression or being overwhelmed (98.0%), perceiving the treatment as complex (94.0%), and facing challenges in reaching the hospital easily (51.0%).

Conclusion:
Pharmacist-led interventions have demonstrated the potential in improving medication adherence and health outcomes among various patient populations. Personalized medication counselling aimed to address adherence barriers and enhance patient understanding. This study provides valuable insights into the impact of pharmacist interventions on medication adherence and QoL in cancer patients receiving oral chemotherapy.

Keywords: Oral oncolytics, pharmacist, QoL, medication adherence

In-utero Antiseizure Medication Exposure and Attention Deficit Hyperactivity Disorder: Population-based Cohort Study

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Biography:

Alekhya is a fourth-year Ph.D. candidate at the College of Pharmacy, University of Manitoba. Prior to her enrollment at the University of Manitoba in 2019, she successfully obtained a PharmD degree from Manipal College of Pharmaceutical Science, Manipal Academy of Higher Education. Her specialization lies in the fields of drug safety and pharmacoepidemiology, with a particular focus on investigating the effects of medications during pregnancy and their impact on neonatal safety outcomes.

As part of her Ph.D. program, Alekhya has undertaken a series of significant research projects. She is conducting a systematic review and meta-analysis, along with two population-based cohort studies. These studies will specifically examine the use of antiseizure medications during pregnancy and the potential adverse effects on neonatal health. Alekhya's research endeavors are generously supported by both provincial and national research funds, providing her with the necessary resources to carry out her studies effectively. Her ultimate goal is to develop advanced research skills that will establish her as a successful and accomplished pharmacoepidemiologist.

Objective

Antiseizure medication (ASM) exposure in utero has been associated with an increased risk of various adverse birth outcomes including neurodevelopmental outcomes. We aim to study whether the association between ASMs treatment during pregnancy and attention deficit hyperactivity disorder (ADHD) differs among infants of all pregnant people, pregnant people with epilepsy (PPWE), and pregnant people without epilepsy (PPWOE).

Methods

We conducted a population-based retrospective cohort study of pregnant people in Manitoba, Canada, from 1998 to 2021. We examined the association between ASMs exposure during 2nd and 3rd trimesters and the risk of ADHD in infants of all pregnant people, PPWE and PPWOE. We conducted Cox proportional hazards regression models and adjusted for maternal age, pain diagnoses, psychiatric disorders, diabetes, hypertension, urban/rural, socioeconomic status, multiple births, and teratogenic drugs exposure in 1st trimester.

Results

We included 297,734 pregnant people in our cohort, including 4,187 ASM-exposed pregnant people, 881 PPWE, and 3,306 PPWOE. In infants of pregnant people exposed to ASMs inutero, we observed a significant increase in the risk of ADHD with an adjusted hazards ratio (aHR) of 1.28, 95%CI (1.08-1.52) compared with infants of unexposed pregnant people. We found a non-significant increased ADHD risk (aHR 0.77, 95%CI (0.53-1.11)) among infants of ASM-exposed PPWE when compared with unexposed PPWE. In infants of ASMs exposed PPWOE, we observed a significant increased risk of ADHD (aHR 1.40, 95%CI (1.13-1.73)) when compared with infants of unexposed PPWOE.

Conclusion

ASM exposure in pregnant people was associated with a significant increase in ADHD risk. ASMs for non-epilepsy indications must be rationalized, especially when alternate treatments are safer for pregnant people.

Larger studies among PPWE are recommended to better identify and separate the effect of ASMs from underlying epilepsy.

Keywords: Antiseizure medications, epilepsy, attention deficit hyperactivity disorder, safety

Effectiveness of influenza vaccination and age as effect modifier: meta-analysis and meta-regression

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Aim/Objective:
Under the global risk of strong epidemic rebound of influenza after COVID-19 outbreak, the study aimed to provide comprehensive and updated evaluation of the seasonal influenza vaccine effectiveness (IVE) and explore the potential effect modifiers.

Methods:
We conducted a systematic review, meta-analysis and meta-regression. We searched PubMed, Web of Science, China National Knowledge Infrastructure and Wanfang for literature published between 2017 and 2022. We included all test-negative design studies with IVE estimates against laboratory-confirmed influenza, irrespective of age, enrollment setting and comorbidity status of study participants. Pairs of reviewers independently screened the studies, abstracted the data, and appraised the risk of bias. We estimated pooled IVE using random-effects meta-analysis, and conducted meta-regression with study site, age, sex and comorbidity included as explanatory variables and odds ratio as outcome variable. This study was registered with PROSPERO, number CRD42023404081.

Results:
We identified 1520 publications and included 191 in the meta-analysis after screening. Pooled IVE was 41.4% (95% CI, 39.2–43.5) for any type of influenza, 42.2% (95% CI, 39.5–44.7) for type A, 55.5% (95% CI, 52.6–58.1) for A/H1N1, and 26.8% (95% CI, 23.4–30.0) for A/H3N2; IVE was 44.6% (95% CI, 41.0–48.0) for type B, 47.2% (95% CI, 38.1–54.9) for B/Yamagata, and 40.6% (95% CI, 23.7–53.7) for B/Victoria. Among children aged< 18 years and elderly aged ≥ 65 years, pooled IVE against influenza was 52.3% (95% CI, 48.2-56.2) and 31.4% (95% CI, 26.0-36.4), respectively. Meta-regression demonstrated the elderly (β=0.224, 95%CI: 0.081-0.367) and young adults aged 18-64 years (β=0.187, 95%CI: 0.075-0.299) were associated with reduced IVE compared with children.

Conclusion:
Influenza vaccination was moderately effective against laboratory-confirmed influenza, but IVE varied substantially across virus types and age groups. Vaccine improvements are needed urgently to generate greater protection for elderly and for A/H3N2 than current ones.

Keywords: Influenza; Vaccine effectiveness; Test-negative design; Systematic review