RUTGERS HEALTH
Ernest Mario School of Pharmacy

RUTGERS PHARMACY RESEARCH DAY

Posters will be presented on

Friday, April 25, 2025

2:00 - 3:30 PM

at the

Ernest Mario School of Pharmacy

John L. Colaizzi Atrium

160 Frelinghuysen Road, Piscataway NJ 08854

Provides a great opportunity to learn about the administrative, basic and translational, and clinical research conducted within the School of Pharmacy

- In-Person Event
- Open to the Rutgers Pharmacy Community

For more information, please contact:

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Welcome to the 2025 Rutgers Pharmacy Research Day!

Welcome to the 2025 Rutgers Pharmacy Research Day! This is an incredible venue to showcase the innovative research conducted at the Ernest Mario School of Pharmacy. Our world-class research is advancing basic science and improving human health, through the discovery of new pharmaceuticals, innovative technologies, and best practices in healthcare. Nationally and internationally recognized for the caliber of our research program, our school consistently ranks as one of the top 15 recipients among 142 accredited schools of pharmacy in funding from the National Institutes of Health.

The School of Pharmacy researchers collaborate on multidisciplinary work among our departments and across the university. As the state university of New Jersey, Rutgers serves a state that is home to leading hospitals and clinical care centers as well as 15 of the world's largest pharmaceutical companies. In this dynamic research environment, pharmacy scientists and clinicians find broad opportunities for exciting clinical, industry, and academic collaborations.

Rutgers Pharmacy Research Day is an opportunity to experience our collaborative, supportive pharmacy research community of faculty, postdoctoral fellows, graduate students, and undergraduate students. This event showcases high-impact research in the core areas of Administrative and Regulatory Science, Basic Science, Clinical Science and Translational Science.

We thank the presenters today for sharing their innovative work with the broader School of Pharmacy community!

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Proceedings of the 2025 Rutgers Pharmacy Research Day

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Abstract 1

Trend Analysis of Outcome Measures for Oral Antipsychotic Trials in Schizophrenia: Implications for Formulary Placement

Sana Mansuri, Sinduja Sivakumar, Laasya Akurati, Michael Toscani

Rutgers, The State University of New Jersey, Ernest Mario School of Pharmacy

Healthcare insurance formularies require patients to trial two preferred second-generation antipsychotics (SGAs) before seeking prior authorization for branded SGAs, ensuring cost-effectiveness. With seven new oral SGAs entering the market in the next three years, refining formulary criteria is critical. This project reviews phase 3 trials of preferred, branded, and investigative SGAs, identifying key trial endpoints to differentiate individual antipsychotics. We conducted a literature search of sponsor-initiated phase 3 trials investigating oral SGAs in schizophrenia. Trials of FDA-approved or investigational drugs in the U.S. were included. A comprehensive list of primary and secondary endpoints was compiled, highlighting the nine most clinically relevant endpoints. FDA guidance on schizophrenia trials provided additional insights. A comparative data table was created to aid in differentiating SGAs. Findings were cross-reviewed by team members. A total of 31 trials and articles were reviewed, with 28 selected based on drug characteristics, trial phase, and sponsor. We identified seven efficacy endpoints—PANSS, CGI, PSQI, PSP, MATRICS, SQLS, and BARS—and two safety endpoints—extrapyramidal symptoms and weight gain—offering a well-rounded assessment of schizophrenia treatment. PANSS was consistently used across all SGAs except clozapine and quetiapine, while CGI remained a reliable metric for assessing illness severity. BPRS, historically used in trials for five preferred SGAs, has largely been phased out except for Fanapt trials. Despite quantitative symptom assessments, the FDA lacks standardized endpoint parameters and definitions of clinically significant improvements. This review highlights standardized efficacy and safety scales across historical and emerging antipsychotics, with evolving endpoints enhancing patient assessments. FDA guidance suggests shorter trials and a 19-item PANSS scale, though clarity on clinical significance is lacking. Future research should reassess branded SGA coverage and access to long-acting injectables, ensuring broader treatment accessibility.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Industry Fellow

Abstract 2

Artificial Intelligence (AI) Tools in Pharmaceutical Medical Information Inquiry Management

Mark Abdelmalek and Daniel Abazia

Rutgers, The State University of New Jersey, Ernest Mario School of Pharmacy, Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF), Piscataway, NJ and Sanofi, Medical Information, Bridgewater, NJ

Objective: This study evaluated the effectiveness of AI tools in managing Medical Information Requests (MIRs) by assessing their ability to provide accurate responses, relevant references, and publication summarization in a multiphase study.

Method: Eight AI tools were assessed using a predefined rubric to evaluate their responses to MIRs. The top five tools were then re-evaluated using their paid versions (if available) to determine improvements in performance. Additionally, the best-performing tools were tested for their ability to summarize open-access scientific publications.

Results: The study followed a phased approach. Phase 1 assessed AI tools against standardized MIRs, scoring responses based on accuracy, depth, and citation practices. In Phase 2, premium versions of the top tools were re-evaluated to determine if they enhanced response quality. Phase 3 tested AI tools' ability to retrieve and summarize peer-reviewed publications. Additionally, the study analyzed how AI tools handled MIRs for drugs launched in 1998, 2017, and 2023, assessing their adaptability to varying data availability. Findings suggested that while all tools generated responses, variations existed in style and citation accuracy. Standardized formatting was used to ensure fair comparisons.

Conclusion: This study provided a structured evaluation of AI tools in medical information workflows, highlighting their capabilities and limitations. It acknowledged challenges such as limited tool selection and database update constraints. Findings offered insights into AI adoption in pharmaceutical inquiry management, optimizing efficiency while recognizing areas for improvement and innovation.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

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Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Industry Fellow

Abstract 3

Applications of Artificial Intelligence (AI) and Machine Learning (ML) Methods in Oncology Clinical Trial Enrollment: A Literature Review

Yoo Meen Suh, Candice Drinkwater, Inhyeok Hwang, Michael Toscani

Rutgers, The State University of New Jersey, Ernest Mario School of Pharmacy, Dept. of Pharmacology and Toxicology, Piscataway, NJ; Daiichi Sankyo, Basking Ridge, NJ

Purpose: Clinical trials are essential for advancing cancer research, yet only 7.1% of cancer patients enroll. Identifying eligible patients is complex and time-consuming. AI is emerging as a tool to streamline and enhance trial enrollment. This review summarizes the current AI/ML landscape in oncology trial enrollment, focusing on the methods used and their impact.

Methods: A comprehensive literature review was conducted across PubMed, Ovid Medline, Embase, and ClinicalTrials.gov, supplemented by a grey literature search. Studies from January 2023 to August 2024 were included. Eligible articles focused on AI-driven patient enrollment in cancer trials. Non-research articles, commentaries, editorials, conference proceedings, opinion pieces, and non-human studies were excluded. Key search terms included AI, machine learning, NLP, oncology, clinical trials, enrollment, and screening. Screening and data extraction followed a two-step quality control process, with discrepancies resolved by consensus.

Results: Of 695 articles identified, 685 were screened, and five met the inclusion criteria. Two addressed general cancer, one focused on breast cancer, one on brain cancer, and one on liver cancer. Three studies used AI to analyze EHR data, while two identified prospective patients. Four developed NLP systems, and one used a licensed AI model. AI significantly improved enrollment efficiency, with one algorithm reducing screening time from 150 to 2 hours (98.7% reduction). AI also enhanced diversity by identifying underrepresented populations.

Conclusion: AI and ML streamline oncology trial enrollment by reducing screening time and improving efficiency. These tools enhance trial precision and support personalized cancer treatment. However, further validation is needed across diverse patient populations and cancer types to ensure clinical trial enrollment accuracy, transparency, and scalability.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Industry Fellow

Abstract 4

Comparison of US FDA and EMA Risk Minimization Strategies for Products with Eliminated REMS with ETASU and EU aRMMs

Tiffany Dominic, Jamie Wilkins, Ana Carolina da Silva Macarenco

Rutgers, The State University of New Jersey, Ernest Mario School of Pharmacy, Rutgers Institute for Pharmaceutical Industry Fellowships; Pfizer, Worldwide Safety, Risk Management Center of Excellence

Objectives: Compare U.S. Food & Drug Administration (FDA) and European Medicines Agency (EMA) required risk minimization strategies for products with an eliminated Risk Evaluation and Mitigation Strategies (REMS) with elements to assure safe use (ETASU) and additional risk minimization measures in the EU.

Method: The REMS Public Dashboard (RPD) identified products once requiring REMS with ETASU that are now eliminated. Rationale was collected from Drugs@FDA, Drug Safety Communications, and the RPD. The EMA European Public Assessment Report (EPAR) was utilized for aRMMs and rationale.

Results: 44 products were identified. After eliminating duplicates, products part of shared systems and those never licensed by EMA centralised procedure, 7 remained: emtricitabine/tenofovir disoproxil fumarate (DF), epoetin alfa, eltrombopag, darbepoetin alfa, romiplostim, rosiglitazone and dofetilide. Rosiglitazone and dofetilide were excluded as they never simultaneously required aRMMs and REMS. Of the remaining 5 products, 2 (epoetin alfa and darbepoetin alfa) were not included as the REMS and aRMMs addressed differing risks. Emtricitabine/tenofovir DF's aRMMs and REMS consisted of educational materials. The REMS was eliminated as FDA determined non-REMS materials and clinical guidelines provide awareness and knowledge regarding the risk. The aRMMs are ongoing in the EU. The REMS was implemented for 83.5 months; the aRMMs have been implemented for 87.9 months. Eltrombopag's REMS required stakeholders to certify and enroll while the aRMMs consisted of educational materials. Both the REMS and aRMMs were eliminated/discontinued, but due to different reasons. The aRMMs were discontinued as the educational materials are now part of standard care and the safety profile is currently reflected in the product information. Rationale for the REMS elimination is outlined later in the abstract. The REMS was implemented for 67.9 months, the aRMMs for 86.2 months.
Romiplostim's REMS was also restrictive and required HCPs and institutions to certify. The aRMMs consisted of educational materials. The aRMM educational materials were later revised to only address a risk not addressed by the REMS. The REMS was implemented for 149.2 months; the aRMMs to address the same risk was 105.2 months. The REMS for romiplostim and eltrombopag were modified to eliminate the ETASU as FDA decided long-term safety data would be best collected through ongoing studies. The modified REMS required a one-time distribution communication plan for both products. Both REMS ultimately were eliminated.

Conclusion: While there have been >100 products requiring REMS or aRMMs since introduction of the requirements, differences in regulatory conclusions resulted in 3 products having REMS with ETASU and aRMMs for the same or similar risks, allowing evaluation of programmatic structure, rationale for elimination, and length of duration. Eltrombopag had its aRMMs and REMS discontinued/eliminated based on different rationale from each regulator, despite addressing the same safety concern. Emtricitabine/tenofovir DF's aRMMs remain ongoing as the EMA determined the safety concern is still present, despite the FDA eliminating the REMS requirement. Romiplostim's aRMMs and REMS previously addressed the same safety concerns, but no longer requires REMS or aRMMs to address the risks. In the aggregate, a common rationale by the FDA for eliminating a REMS was HCP awareness of the risk. No trends for rationale of aRMM discontinuation were observed. There have been numerous discussions regarding evaluation of risk minimization strategies. A study by Huynh et al., concluded multiple implementation frameworks such as RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) and others can be utilized for REMS assessments and evaluation. Additionally, the Prescription Drug User Fee Act Goals for 2023-2027 includes updating or creating new policies to assess if a REMS is still necessary. On a similar note, the draft for GVP Module XVI Revision 3 discusses risk awareness forms and calls for regular evaluation to assess if an aRMM has been integrated into clinical practice and can be discontinued. Therefore, there is no surprise that the current landscape from both regulatory bodies includes goals through the upcoming years to enhance the assessment of aRMMs and REMS through the evaluation of risk awareness and clinical practice integration and potential remains for a more efficacious way to evaluating these safety strategies and allow elimination, when possible.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Industry Fellow

Abstract 5

A Survey Exploring the Role, Structure, and Strategic Impact of Medical Reviewers within Promotional Review Teams

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Medical reviewers assess promotional materials to ensure content is scientifically accurate and rigorous, non-misleading, well substantiated, and presented with necessary context. Recent data on the role of medical reviewers in promotional review teams, both within and outside MI departments, as well as the use of third-party support and contributions to brand and medical strategy, remains limited. An anonymous, voluntary online 28-question survey was emailed to ~350 current Rutgers PharmD fellows. Select fellows had 14-calendar days to complete the survey (Jan. 21, 2025 – Feb. 4, 2025), with a reminder email sent out on Jan. 28, 2025. Nine Rutgers PharmD fellows completed the survey. Dedicated medical review teams were most reported to perform medical review for promotional materials (78%). Of those who claimed that promotional medical reviewers evaluate other materials (n=4), 100% review non-promotional pieces and 75% review independent medical education pieces. Of those who noted that medical reviewers have responsibilities outside of review (n=6), involvement in creating medical information materials (67%), conference/congress planning (50%), and sales training (50%) were most common. When asked how they play a role in developing strategy, the most common responses were collaboration with the marketing team during concept development (89%) and early collaboration with the marketing team on new campaigns (56%). Most respondents (56%) indicated they only use internal, and 44% use both internal and outsourced medical reviewers. Medical reviewers are a cross-functional asset whose skills go beyond simple fact checking. With a larger sample size, further research should be conducted to assess how medical reviewers can play a more effective role within brand and medical strategy as to allow for the enhancement and development of the role.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Industry Fellow

Abstract 6

Identifying Barriers to Expanded Access Program (EAP) Patient Enrollment in the Hematology/Oncology Community

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Background/Rationale: Expanded access programs (EAPs) provide a pathway for patients with serious or life-threatening conditions to obtain investigational treatments outside of clinical trials, when no satisfactory or comparable treatment options exist, or they do not qualify for a clinical trial. Utilization is limited by challenges including poor access to information, lack of response from drug sponsors on ability to supply drug, and more.[1] This study aims to gauge the baseline knowledge gaps and barriers that may deter oncology/hematology pharmacists from enrolling patients into an EAP.

Objectives: Assess the knowledge of US academic and community oncology/hematology pharmacists regarding Expanded Access Programs (EAPs), and identify barriers to patient access through these programs

Methods: Dissemination of a Rutgers eIRB approved, protocol #Pro2024000713 voluntary Qualtrics survey through the Hematology/Oncology Pharmacy Association's (HOPA) email list. The research survey was sent only to US members who practice clinical oncology/hematology pharmacy in academic and/or community settings. Students, residents, fellows, technicians, and pharmaceutical industry members were excluded from the study. The survey was disseminated in June and open until the end of July.

Results: After reviewing 38 survey responses, our findings suggest pharmacists working in an academic setting were more aware of EAPs than those working in a community setting. 69% of participants have requested use of a drug through an EAP. However, most participants (63%) were slightly knowledgeable or not knowledgeable at all when it comes to finding access to investigational drugs for patients via EAPs. The information sources varied amongst pharmacists, with the most common being the pharmaceutical manufacturer (59%). The top barriers included time to enroll patients (66%), documentation burden (59%), and lack of familiarity with EAP processes (56%).

Discussion/Conclusions: Pharmacists, as part of the interprofessional collaborative care team, play a critical role in decision making during a patient's treatment journey. EAPs are an option for patients who have limited, or no treatment options remaining. This study identifies key knowledge gaps and barriers to treatment access via EAPs. These results provide an opportunity to close these knowledge gaps and barriers related to EAPs by providing continuing education credits to pharmacists in the academic and community settings. Informing oncology/hematology pharmacists in both academic and community centers on EAPs allows opportunity to educate and offer alternative treatment options to patients, providing hope to patients and families. Further research will be needed to assess the unmet educational needs and the potential benefits of this on patient care and outcomes.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Funding: RPIF

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Industry Fellow

Abstract 7

Generative Artificial Intelligence-Enabled Efficiencies in Authoring Patient Response Documents (PRDs) in Medical Information

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Objective: To compare the quality and time needed to create PRDs authored by humans only (Control Arm) versus those created by humans with the assistance of an internally approved Generative Artificial Intelligence (GenAI) tool (GenAI Arm).

Methods: Thirty PRDs were created for 5 self-administered products, covering three topics: stability and storage, administration technique, and injection site reactions. In the GenAI Arm, a single selected prompt was used in the internal web version of the tool to generate an initial draft of the PRD using the available United States Prescribing Information (USPI). Final drafts were completed by humans. In the Control Arm, PRDs were authored by humans using the USPI as the basis. The time from PRD initiation to the final version, along with quality and readability were assessed.

Results: Fifteen PRDs were created by humans and 15 by implementing the GenAI tool into the human authoring process. The mean time for PRD creation was similar in both arms (22 minutes in the GenAI arm versus 24 minutes in the control arm). Readability assessments showed that most PRDs were at middle school grade level for both the GenAI arm (60.00%) and control arm (66.67%). The first draft generated by the GenAI arm was of high accuracy (93.33%) and completeness (66.67%).

Conclusion: Although the time savings analysis indicate that the GenAI Arm required less time to create PRDS compared to the Control Arm, the results were not significant. However, the quality of the initial draft generated by the GenAI Arm was high, with an accuracy of 93.33% and completeness of 66.67%. Readability was comparable between the two arms, with the GenAI Arm at 60.00% and the Control Arm at 66.67%. These results highlight the GenAI tool's preciseness and thoroughness, indicating its potential to revolutionize the current processes of creating PRDs.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Fellow

Abstract 8

Looking Beyond Detection: Evaluating Value and Providing Recommendations to Enhance Patient Access to Multi Cancer Detection Tests for Equitable Care

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Purpose: Cancer is a major global health challenge and the second leading cause of death in the US, accounting for about 600,000 deaths annually. The US spends roughly $200 billion on cancer treatment each year, with patients paying $20 billion out-of-pocket. As cancer progresses, treatment costs rise, underscoring the need for early detection. Alarmingly, 57% of cancer deaths occur from types that aren't currently screened. Multi- cancer early-detection (MCED) tests aim to detect signals from multiple cancers, enhancing screening for rarer types. This literature review examines the accessibility of MCED tests and identifies opportunities to improve patient access to these vital screenings.

Methods: A comprehensive review of existing literature was performed utilizing the following publication databases: MEDLINE (Ovid), Google Scholar, Embase, and PubMed. The following keywords and Medical Subject Headings (MeSH) terms were included in the search: "Multi Cancer Detection Test" (MCD), "Multi cancer Early Detection Test" (MCED), "Cancer screening", "Early detection", "Accessibility", "Health Equity", and "Diversity, Equity, and Inclusion (DEI)". Articles were included in the study if they matched the following inclusion criteria: published within the past five years (2019-2024), contain at least three keywords or MeSH terms, evaluates Galleri and CancerSEEK MCED tests, include sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), cancer-signal origin (CSO), and true-positive-to-false-positive ratio (TP:FP) statistical tests to evaluate the efficacy of MCED tests.

Results: There are various MCED tests in development that have demonstrated high efficacy and accuracy. The two leading MCED tests are Galleri and CancerSEEK, developed by GRAIL and Exact Sciences. The Galleri test works by detecting specific DNA methylation patterns in circulating cfDNA. Galleri had an overall sensitivity of 66.3%, 98.4% specificity, PPV and NPV of 75.5% and 97.6% respectively, and 62.9% CSO. In comparison, CancerSEEK detects tumor DNA mutations and cancer-specific protein biomarkers. CancerSEEK had an overall sensitivity of 23.5%, 98.9% specificity, PPV and NPV of 19.4% and 99.3% respectively, and 62.9% CSO. While these tests demonstrate significant efficacy, addressing the diversity inherent in cancer diagnoses is essential from the early stages. Tumor heterogeneity may greatly impact evaluation of cancer early detection tests. Therefore, inclusive, population-based studies are needed for diverse and comprehensive evaluations. Furthermore, increasing accessibility, particularly for minority groups, is vital for equitable healthcare. This approach not only enhances the generalizability of the results but also ensures that advanced diagnostic tools are distributed fairly, ultimately contributing to improved cancer outcomes for underserved populations.

Conclusion: This literature review aimed to assess the accessibility of current multi-cancer early detection tests and identify opportunities to enhance patient access. MCED tests not only detect multiple cancer types from a single test, but also demonstrate a PPV averaging between 40-50%, a number considerably higher than those of single-cancer tests currently recommended by the US Preventive Services Task Force (USPSTF). With future population studies needed to assess the value of current and future MCED testing initiatives, MCED tests hold a promising potential to transform early cancer diagnosis and access to patient care.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF), Industry Pharmacists Organization (IPhO)

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 9

A Retrospective Analysis of Gastrointestinal Prophylaxis Appropriateness in a General Medicine Population at a Community Hospital

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Rutgers, The State University of New Jersey, Ernest Mario School of Pharmacy, Faculty, Piscataway, NJ; Hunterdon Medical Center, Flemington, NJ

Gastrointestinal (GI) prophylaxis employs the use of Proton Pump Inhibitors (PPIs) or Histamine-2 Receptor Antagonists (H2RAs) to suppress gastric acid secretion and reduce risk of complications such as GI bleeding and stress ulcers. The purpose of this retrospective chart review is to evaluate prescriber's orders for the appropriateness of GI prophylaxis in a general patient population at Hunterdon Medical Center. By optimizing use of these medications, patients can potentially have improved outcomes and decreased polypharmacy burden. A retrospective chart review was conducted using medication administration reports generated by the electronic health record (EHR). A data collection sheet was used to document patient demographics, medication used, route/frequency, indication if included, visit problem, coagulopathy, if the patient was on steroids, any prior history of GI bleed, order prescriber, and if the patient was discharged with the medication. Patients were included if they were 18 years or older, admitted to the general medicine unit, and received at least one dose of a study medication within the study timeframe of April 3rd, 2024 to July 3rd, 2024. Descriptive statistics were used for data analysis. The primary endpoint was the assessment of appropriateness of GI prophylaxis use. Secondary endpoints were incidence of adverse events related to GI prophylaxis use and continued use of these medications on discharge. The retrospective analysis of the use of PPIs and H2RAs for GI prophylaxis was valuable in determining a 37.1% no indication rate amongst famotidine and pantoprazole orders, with 34% of these additionally being discharged with patients. From this data, the institution could potentially benefit from education programs to ensure that proper indications are provided for each mediation order by providers. Additionally, an initiative to evaluate PPI and H2RA prescriptions and possibly de-prescribe in the outpatient setting could help to optimize patient care and reduce unnecessary therapy.

Program Affiliations: KNIGHT ScholaRx

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 10

A Review of Evidence Behind the Safety and Efficacy of Sunscreen Agents

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The journey from ancient olive oil to modern sun protection factor is a testament to how far sun protection has evolved. Just a century ago, sunscreens were nonexistent; today, pharmacy shelves are stocked with various options. However, this evolution brings a critical need to understand not only the progress made but also the safety and effectiveness of these products. This literature review evaluates the proper usage, safety, and effectiveness of sunscreens, with key concerns including consumer adherence to usage guidelines and potential toxicity from benzene.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 11

Assessing the Availability of Patient Assistance Programs in the Pediatric Population Across Common Drug Classes

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Patient assistance programs (PAPs) are initiatives designed to improve access to necessary medications while reducing financial burdens. These programs offer free or discounted drugs to eligible patients based on insurance, income, and other criteria. Pediatric patients, like adults, require management for chronic conditions that often necessitate high-cost medications. Therefore, PAPs are crucial for pediatric populations, though there is limited knowledge about their availability and eligibility requirements. This project aimed to systematically examine PAPs and evaluate their accessibility for pediatric patients across common drug classes. Ten drug classes frequently used in both pediatric and adult patients were evaluated, including those for venous thromboembolism, diabetes, heart failure, hypertension, and asthma. Brand-name medications offered through pharmaceutical manufacturers' PAPs were analyzed. Each drug was reviewed for FDA approval age, available formulations, and the manufacturer. A detailed internet search of manufacturer websites was conducted to assess the availability of PAPs for pediatric patients. A total of 61 medications were included in the analysis. For medications with available PAPs for patients under 18, additional information was collected on insurance eligibility, income requirements, citizenship status, and prescriber attestations, which indicate whether off-label use is allowed if deemed medically necessary. Of the 61 drugs reviewed, 35 had PAPs available for pediatric patients. Five medications, though not FDA-approved for children under 18, had PAPs available if prescribed as medically necessary. The insulin class had the highest availability, with 19 out of 21 insulins included. Of the 27 drugs without available PAPs for pediatric use, many were FDA-approved for children. The majority of PAPs required the disclosure of financial information, including family size and income. PAPs are moderately available for pediatric patients, but off-label use limits access. Strict eligibility requirements and complex application processes pose additional barriers, particularly for low-income families.

Program Affiliations: EMSOP Faculty/Mentor Research

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 12

Benchmarking the Evolutionary Trends in Rheumatoid Arthritis Rating Scales

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Rheumatoid arthritis (RA) is a progressive autoimmune disorder affecting over 1.3 million adults in the US, with annual costs exceeding $39 billion. Effective management is crucial due to its significant impact on quality of life and healthcare resources. This literature review analyzes the historical development and refinement of RA rating scales, assessing their impact on clinical practice and patient outcomes. We focused on how advancements of outcome measurements, including biomarker integration, have enhanced disease management and personalized treatment.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 13

Effectiveness of Pharm.D.-Integrated Mental Health Electives for Improving Perceptions of Mental Health Conditions Among Pharmacy Students

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Despite rigorous training for delivering patient care in traditional Pharm.D. curricula, pharmacy students receive little to no standardized training on mental health counseling. Consequently, issues pertaining to mental health stigma and intervention persist among them. Pharmacists play a crucial role in delivering effective interventions without disconnecting from mental health aspects. A curriculum-integrated elective on mental health support can effectively address mental health stigma, improving pharmacy student outcomes in personal and clinical respects. This study aims to investigate the impact mental health electives have on improving pharmacy students' perceptions of addressing mental health issues, providing insight into the benefits of implementing them as a standard in Pharm.D. curricula. This literature review was conducted via Google Scholar and PubMed. Search terms included "mental health," "stigma", "pharmacy students," and "course." Studies published from 2018 to 2024 were selected and appraised. Across six studies, participation in a mental health elective resulted in significant decreases in stigma across several psychiatric scales and improved attitudes towards mental health. Such courses produced an increased willingness to engage in conversation, encourage help-seeking behavior, and an increased capacity to positively interact with patients regarding mental health concerns. However, gaps exist regarding what specific aspects of these courses make them effective relative to studies on other Pharm.D. programs. By reducing stigma and incorporating mental health support into standard curricula, attitudes toward mental health issues among pharmacy students can be improved as they become better-equipped to efficiently recognize and address them. Such points to further studies on correlations between competency in mental health and future interactions with patients and health professionals under stressful work settings, as well as pharmacy students applying such methodologies for their own mental health issues to consequently apply to patients. Eliminating barriers in mental health benefits both future health professionals and patients.

Program Affiliations: American Association of Psychiatric Pharmacists Research Committee & Journal Club

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 14

Evaluating Readability and Risk Communication in Direct-to-Consumer Prescription Drug Advertisements in Alignment with the Food and Drug Administration Clear, Conspicuous, and Neutral Final Rule

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The Food and Drug Administration's (FDA) Clear, Conspicuous, and Neutral (CCN) Final Rule, (compliance date of November 20, 2024), requires direct-to-consumer (DTC) prescription drug advertisements to use consumer-friendly language when presenting major side effects and contraindications. Reducing medical jargon and improving accessibility remain challenges. This study evaluates comprehension barriers in DTC prescription drug advertisements and their alignment with the CCN Final Rule by assessing the whole advertisement, not just the risk information. This retrospective observational study analyzed English DTC prescription drug advertisements from 2019 to 2024 that lasted one minute (±15 sec) and included audio and on-screen text discussing benefits and risks. Advertisements about non-pharmaceutical or over-the-counter products were excluded. A total of 353 advertisements were sourced from iSpot.tv and randomized in Excel. After removing duplicates to keep one advertisement per drug and ensuring at least five advertisements per therapeutic area, the final sample included 59 advertisements across Endocrinology, Gastroenterology, Psychiatry, Neurology, Oncology, and Respiratory. Audio and on-screen text were transcribed, excluding unrelated content. Readability was assessed using Microsoft Word's Flesch Reading Ease (FRE), Flesch-Kincaid Grade Level (FKGL), and Passive Sentences percentage. Risk Speech Rate was calculated as words per second for risk discussions. FRE scores ranged from ~45 to ~65, with most advertisements rated "fairly difficult" to "difficult," highlighting the need for simpler language. Audio FRE scores were ~18% to ~34% higher than on-screen text, suggesting better comprehension. FKGL scores slightly exceeded the average U.S. adult reading level. Passive sentence use was low, improving clarity, while Risk Speech Rate was ~26% to ~34% faster than the typical English-speaking American speech rate, potentially impairing comprehension. Limitations include the non-validated Risk Speech Rate metric and exclusion of visual aids, which may impact comprehension. Further research should assess whether readability and clarity improve after the FDA CCN Final Rule compliance date.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 15

Evaluating the Impact of Pharmacy Services on Emergency Department Operations and Patient Care: A Pre- and Post-Intervention Quality Improvement Survey in a Small Community Hospital

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This study evaluates the impact of pharmacy services in the emergency department (ED) at Robert Wood Johnson University Hospital in Hamilton, NJ, a small community hospital that currently lacks a dedicated ED pharmacist. In the absence of an on-site pharmacist, medication-related inquiries from ED staff are addressed through centralized pharmacy services via electronic or telephone communication. Integrating a pharmacist into the ED could improve patient outcomes by enhancing medication reconciliation, identifying adverse drug events, reducing the time for medication admixture and administration, and improving workplace satisfaction. To identify gaps in current ED practices, a survey was conducted with ED staff, including physicians, physician assistants, and nurses. This survey, conducted prior to pharmacy integration, assessed staff perceptions of decentralized pharmacy services and their role within the ED team, helping to pinpoint unmet needs and optimize pharmacy services in the ED. Following this, for several weeks, advanced pharmacy practice experience (APPE) students and a clinical pharmacist provided temporary ED services, including staff education, chart reviews, triaging medication-related questions, and patient counseling. Additionally, data was collected to track APPE student interventions and whether they were accepted or rejected by providers. During this period, an educational session was also delivered to ED staff and evaluated through a questionnaire to assess its impact. This study aims to identify the gaps ED staff experience due to the lack of pharmacy presence, with plans for further assessment in the future following consistent pharmacy presence in the ED.

Program Affiliations: Research (Elective) Course: N/A

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 16

Evaluation of Enhancing Safe Fentanyl Patch Assessment and Administration in an Acute Care Community Hospital

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Medication patches provide a non-invasive drug delivery method but pose safety challenges for healthcare providers, particularly with high-risk medications like fentanyl. Safe administration requires proper site assessment, removal of previous patches, and validation of opioid tolerance to reduce the risk of respiratory depression and unintended exposure. Medication patch safety requires a multidisciplinary approach to ensure best practices. This study evaluates a process change aimed at improving the safe utilization of medication patches at an acute care community hospital. In May 2023, a structured “medication patch check process” (MPCP) was implemented in the electronic health record (EHR) as a nursing work task linked to the medication administration record (MAR). The MPCP was designed to prompt nursing staff during each shift to verify and document active patches for patients with patch orders. Additionally, a waste documentation process for controlled substance patches was introduced to ensure consistency in tracking patch disposal. A retrospective review compared fentanyl patch administration before (January 2023) and after (January 2024) the process change. After implementation, MPCP compliance was 50% (68/136). Among 558 possible MPCPs, 140 (25.1%) resulted in a “Patch Verified in the MAR,” with 121 (89.0%) marked as completed, 38 (27.9%) skipped, and 44 (32.3%) removed. Skin assessments and documentation of previously applied patches remained inconsistent both before and after the intervention. Additionally, appropriate wasting of fentanyl patches in the automated dispensing cabinet (ADC) was only 1.5%, highlighting ongoing challenges in safe disposal. This is the first known evaluation of an MPCP and its impact on patch verification and safety. While the process helped structure workflow, nurse adoption varied. The plan-do-check-act model can support ongoing optimization of medication patch administration and disposal. Future efforts should refine EHR work tasks, enhance compliance, and assess patient safety outcomes.

Program Affiliations: N/A

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 17

Evaluation of Titration Practices at a Community Hospital

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Rutgers, The State University of New Jersey, Ernest Mario School of Pharmacy, Robert Wood Johnson University Hospital - Hamilton

Purpose: The Joint Commission (TJC) is a regulatory body whose mission is to continuously improve health care for the public. One of the responsibilities of TJC is to evaluate how accurately titration parameters are followed according to physician orders. This community hospital has created a policy for acceptable ranges of titration parameters per titratable medication. This policy has been accepted but not widely implemented. Our research aims to assess the compliance of titratable medication orders with regard to the accepted titration policy as well as prescriber workflow interruptions due to overly narrow titration orders for complex patient needs.

Methods: A utilization review report, including all medications dispensed in April 2024, was filtered to identify titratable infusions which were then sorted into categories listed in the hospital's titration policy (e.g sedatives, vasopressors). All titratable infusions administered to patients 18 or older in the critical care areas were included in the evaluation. Excluded orders were those that were never titrated, titrated for less than 2 hours, used during hospice, or were retrieved by the automated dispense system (ADS). The researchers evaluated each titration within the first 24 hours of the order and documented the study number, medication, starting dose, titration dose, date, time between titrations, rate difference between titrations, documented titratable goal, nursing comments, ordering provider, location of titration, and time of day the titration took place. Each titration was evaluated to determine if it was an occurrence and/or a modified order. Occurrences are defined as titrations that did not fall within the prescriber's ordered time or rate of the titration parameters. Modified orders were determined if the prior order was stopped or discontinued and a new order was placed with the same medication but different titration parameters. The data was analyzed to determine the number of occurrences that followed the accepted titration policy guidelines, how many prescriber interruptions were due to modifications, and which time of day occurrences are most likely to occur.

Results: Seventy-eight out of 196 orders met the inclusion criteria which resulted in 597 total titrations for the month of April 2024. Of the 597 titrations, there were a total of 142 occurrences (24%), of which 60 occurrences (42%) would have met the hospital's policy for titration ranges. Of the modified orders, 11/78 (14%) were clearly documented. Four of the 11 (36%) were modified to utilize the approved titration policy. Between 11pm - 7am, 197 titrations took place resulting in 27 occurrences (14%), between 3pm - 11pm there was 50 occurrences out of 195 titrations (26%), and between 7am - 3pm there was 68 occurrences out of 201 titrations (34%). The occurrences were categorized according to inappropriate rate adjustments (80), incorrect timing between titrations (35), and both inappropriate time and rate (27). The 3 most common medications comprising the majority of occurrences were norepinephrine (47), dexmedetomidine (36), and diltiazem (14). An additional 141 titrations did not have the proper documentation of the titratable goal making it difficult to evaluate why the medication was being titrated. These additional titrations were not considered occurrences.

Conclusion: This study revealed that the approved policy would have resulted in a 42% improvement in order compliance consistent with TJC expectations. Provider order interruptions would be reduced by 14%, as inferred by modified orders. The majority of occurrences took place from 7am - 3pm. Limitations to the study include the clear documentation of modified orders and the established time cutoff for documented goals were not clinically driven. Further research needs to be conducted to evaluate additional causes of noncompliance, why occurrences are most frequent during the day, and how compliance has improved since April 2024.

Program Affiliations: KNIGHT ScholaRx

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 18

From animal sedative to “skin eating” street drug: a literature review analyzing illicit drug trends to predict the potential trajectory of xylazine

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Rutgers, The State University of New Jersey, Ernest Mario School of Pharmacy

Background: Xylazine, also known as “Zombie drug”, is a non-opioid sedative approved in the U.S. for veterinary medicine. Yet human consumption may cause serious side effects such as intractable necrotic skin ulcers. In 2023, the White House declared fentanyl adulterated with xylazine as an emerging threat due to increasing reports that have detected xylazine mixed with illegally made fentanyl (IMF). This literature review study analyzes the relationship between xylazine and fentanyl in overdose cases to identify key patterns that can inform the development of targeted intervention and harm reduction strategies, aiming to mitigate xylazine adulteration in the illicit drug market.

Methods: A systematic literature review using the database PubMed and government resources from the Drug Enforcement Agency (DEA) and the National Center for Biotechnology Information (NCBI) was conducted, which included the following keywords: “Xylazine,” “Fentanyl,” “Overdose Patterns,” “Trends,” “Race,” “Age,” and “Test Strips.” Exclusion criteria were any populations outside the United States and resources published over 5 years before the start of this study.

Results: This review explores trends in the addition of xylazine as a filler in fentanyl supply in the U.S. by analyzing historical fentanyl data. Based on past fentanyl usage and current data on xylazine-related deaths in the U.S., the emergence of xylazine appears to follow a similar path as fentanyl, with the highest prevalence of xylazine-related deaths in the Northeast, followed by the South, then the West. Xylazine follows similar socioeconomic patterns for fentanyl overdoses: there was an increased prevalence in metro areas with higher poverty rates classified by greater economic and family distress. This trend was also consistent with males in their twenties to fifties having higher overdose-related deaths compared to those who are female and/or belong to other age groups. Public data also identifies a correlation between overdose deaths involving xylazine and fentanyl, with xylazine-related deaths showing an exponential rise from 2018 to 2021. However, while there are many fentanyl intervention strategies available, such as fentanyl test strips, opioid use disorder (OUD) medications, and naloxone, the only method of detecting and treating suspected xylazine exposure currently is xylazine test strips.

Conclusion: The dangers of xylazine use are emerging, but the drug remains unscheduled as it slowly encroaches into public health. With the “Combating Illicit Xylazine Act” under review, it is critical to utilize this time to develop targeted xylazine intervention strategies. Acknowledging the differences between treatment options of fentanyl and xylazine, this review serves to suggest improved methods and resources targeted towards vulnerable populations. This need is heightened as xylazine adulteration continues to rise and as more potent sedatives, such as medetomidine, become more prevalent in illicit drug supplies.erature review analyzing illicit drug trends to predict the potential trajectory of xylazine

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 19

Gender Disparities in Psychiatric Diagnosis and Treatment

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This literature review observes how physicians' gender biases affect the diagnosis and treatment of psychiatric disorders, specifically focusing on Attention Deficit Hyperactivity Disorder (ADHD), eating disorders, and Borderline Personality Disorder (BPD). The research aimed to identify specific gender biases in clinicians' opinions and determine their origins, as well as to assess whether general physicians and psychiatrists differ in diagnosis timelines and accuracy. Gender bias in the diagnosis and treatment of psychiatric disorders is well-documented, with certain conditions often stereotypically attributed to one gender, leading to differential diagnoses and treatment outcomes. ADHD and eating disorders, which are often diagnosed more frequently in one gender, were chosen for analysis. BPD, known for having nearly equal diagnostic rates across genders, served as a control to examine how clinicians approach both genders in diagnosis.

A mixed-method design was employed, incorporating a literature review of available studies on diagnostic differences between males and females. The analysis involved both qualitative and quantitative data from medical journals, focusing on practitioner beliefs, clinician anecdotes, diagnostic timelines, diagnostic rates, and treatment approaches. The results indicated that BPD, while once perceived as predominantly affecting women, is now recognized to occur at similar rates across genders, though treatment still tends to be female-focused. ADHD was found to be diagnosed more frequently in males in clinical settings, with a higher male-to-female ratio in clinical versus population-based samples. Additionally, physicians were found to be reluctant to diagnose men with eating disorders, and when diagnosed, these cases were often unspecified.

This study concludes that gender stereotypes influence the diagnosis and treatment of psychiatric disorders, leading to misdiagnosis, poorer treatment adherence, and lower patient satisfaction, particularly for those of the minority gender. Further research is needed to explore the impact of gender biases on clinical outcomes and to promote more equitable care.

Program Affiliations: American Association of Psychiatric Pharmacists Research Committee & Journal Club

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 20

Investigating Gaps in Available USP-Verified Supplements for Individuals with Dietary Restrictions

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Purpose: Dietary supplements do not require FDA testing for market entry even though they are consumed by 73% of American adults. The United States Pharmacopeia (USP) label indicates third-party verification for quality and safety. However, no previous research has analyzed which USP-Verified Supplements adhere to a non-meat diet: the vegetarian submarket targets 6% of Americans. This study examines the availability of USP-Verified supplements for individuals with dietary restrictions and proposes solutions to increase non-meat options.

Methods: USP-Verified supplements (n=155) were identified from Quality-Supplements.org. Exclusion criteria included products not available for commercial sale (n=1). Each supplement was classified by delivery form, supplement type, and ingredient sourcing content (meat, non-meat, or uncertain due to the presence of non-source specified use of stearate). Ingredient lists were individually pulled from e-commerce sites.

Results: Of the 154 USP-Verified Supplements, most were meat-based (n=106, 69%), while the rest were either uncertain (n=33, 21%) or non-meat (n=15, 10%). All softgels (n=56) and gummies (n=35) contained meat. Tablets (n=48) and capsules (n=10) varied, while caplets (n=3) were strictly uncertain and liquids (n=2) were strictly non-meat. Breakdown of supplement type indicates that multivitamins (n=30) were all meat-based except for one available for geriatric females. Minerals (n=13) and fish oil (n=12) contained no non-meat options. Vitamins (n=57) and “other dietary supplements” (n=39) were predominantly meat-based (n=34, n=23), followed by uncertain (n=19, n=9).

Conclusion: Supplement manufacturers should investigate vegetable-based sourcing of stearate ingredients to address increased market share. Dietary restricted individuals would be able to access previously uncertain supplements (n=33), including minerals. Additional research should investigate other third-party testing (NSF/ConsumerLabs), differences between vegetable and meat-sourced stearate, and individually contacting “uncertain” supplement companies for their stearate sourcing.

Program Affiliations: N/A

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 21

Longitudinal Analysis of Pharmacy Student Feedback for Interprofessional Education (IPE) Activities During 2022-2023 and 2023-2024

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Background/Purpose: Interprofessional education (IPE) equips healthcare students to collaborate effectively in diverse teams for optimal patient care. The IPE Committee at Rutgers EMSOP oversees and evaluates IPE activities in coordination with other health profession schools. To assess their effectiveness, we analyzed student feedback from the 2022-2024 IPE events.

Objectives: This study aims to identify key takeaways, areas for improvement, and overall student perceptions regarding these collaborative learning experiences.

Methods: Pharmacy students at EMSOP completed a 16-item Qualtrics survey for each IPE activity they attended. The survey included twelve rating-scale questions, four Likert-scale questions, and two open-ended feedback questions. Data was collected from the 2022-23 (n=82) and 2023-24 (n=186) academic years. Quantitative analysis was performed on ordinal data, while qualitative thematic analysis identified recurring themes. Longitudinal and categorical analyses were used to assess trends and activity-specific feedback for optimizing future IPE activities.

Results: IPE event feedback from 2022-2024 reveals trends in participation, representation, and areas for improvement. Survey responses more than doubled from 82 to 186, likely due to more available events, increased Pharmacy student participation, and improved survey distribution. Representation across the 12 events was more balanced in 2023-2024, compared to 2022-2023 when nearly half of responses came from the dental and stroke case events. Although the percentage of highest ratings (“strongly agree” or “excellent”) decreased, the rise in total responses suggests broader participation while indicating areas for continued enhancement. Qualitative feedback revealed consistent key takeaways, with students emphasizing improved communication skills, particularly through the SBAR (Situation, Background, Assessment, and Recommendation) approach, and a greater appreciation for interdisciplinary collaboration. Areas for improvement included longer discussion times, more diverse group representation, and a shift toward in-person events. Notably, concerns about facilitator bias, a major issue in 2022-23, were absent in 2023-24, suggesting progress in this area.

Program Affiliations: Interprofessional Education Committee

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 22

Navigating Regulatory Challenges in Oncology Drug Development: A Literature Review

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With the development of oncological treatments becoming more precise, targeted to more advanced cancer types, and more focused on minimizing off-target effects, regulatory affairs teams in pharmaceutical companies have experienced shifting challenges when it comes to the drug approval process and compliance with federal regulations. Regulatory affairs teams in the cancer space face unique challenges related to balancing regulations concerning patient safety and adverse effects with effective treatment. Some of these key issues include the new debate surrounding maximum tolerated dose (MTD) and optimal dosage, communicating with federal regulators regarding expedited pathways considering the drug testing models, and accounting for patient diversity and disease complexity.

Our objective is to highlight the unique challenges faced by regulatory affairs teams in the field of oncological research, focusing on the multifaceted considerations that regulatory affairs teams must balance, such as diverse patient populations, complex disease mechanisms, evolving dosage guidelines, and the regulatory approval process for potentially beneficial cancer treatments.

A literature review was conducted by the authors to identify articles which address current oncology drug approval and submission rates as well as challenges faced by regulatory affairs teams within the oncology therapeutic field.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 23

Perceptions of Psychiatric Care Amongst Formerly Incarcerated Individuals

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This study explores the experiences of formerly incarcerated individuals with psychiatric care, addressing a critical gap in the literature on their disproportionately high rates of mental health disorders. The research aims to identify barriers hindering effective provider-patient relationships, investigate the underlying causes through interviews, and educate future healthcare professionals using the findings. A mixed-methods approach will be employed, incorporating both quantitative surveys and qualitative interviews. Fifty participants will be recruited from Reddit and Quora communities focused on formerly incarcerated individuals, with recruitment posts designed to foster trust and transparency. Participants will complete a 10–15 minute survey assessing their attitudes toward mental health services and recovery during and after incarceration, with each receiving a $10 retail store gift card as compensation. Survey respondents may volunteer for follow-up interviews, from which ten individuals will be randomly selected. These interviews, conducted remotely via Zoom by AAPP student members, will use questions developed in collaboration with a campus counselor specializing in opioid rehabilitation. The insights gathered will highlight participants' lived experiences with psychiatric care, and data analysis will identify key themes and actionable takeaways. Ultimately, the findings will inform the development of a curriculum for pharmacy and medical students, enhancing their understanding of mental health challenges faced by formerly incarcerated individuals and improving intervention strategies for this underserved population.

Program Affiliations: American Association of Psychiatric Pharmacists Research Committee & Journal Club

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Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 24

Racial and Ethnic Disparities found in Phase II and Phase III Clinical Trials of Multiple Sclerosis Therapy

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Published literature has shown that minority groups in America have been disproportionately suffering from Multiple Sclerosis more than their white counterparts. In spite of having worse outcomes, these racial minorities have had little representation in clinical trials for highly efficacious therapy. This research will evaluate the current clinical trials in MS to assess diversity in enrolled patients. A literature review was conducted on PubMed and ClinicalTrials.gov. The condition entered was multiple sclerosis and the interventions were any of the high-efficacy therapies including ofatumumab, ocrelizumab, natalizumab, alemtuzumab, or cladribine. A total of 30 clinical trials involving all the highly efficacious MS medications resulted. Out of the total 5,069 participants spanning the 14 trials analyzed for race, only 589 participants identified as African-American, Asian, American Indian or Alaskan Native, Mixed Race, or Other. This means that only 11.6% of clinical trials for the most efficacious drugs in treating MS are non-white people. More research must be done to find out the reason for this severe racial underrepresentation to improve outcomes in the future.

Program Affiliations: N/A

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 25

Review of Quality of Life Measurement Prevalence in CAR-T Therapy Clinical Trials: Assessing and Addressing Challenges

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CAR-T therapy, while highly effective, often presents significant challenges and side effects that impact patients' quality of life (QoL). Despite the frequent use of QoL metrics in traditional cancer treatments, they remain underutilized in CAR-T therapy clinical trials. This study examines the prevalence of QoL as an endpoint in current clinical trials to highlight gaps in its assessment and emphasize the need for its inclusion as a key outcome measure.

A PubMed literature review was conducted to assess the impact of six FDA-approved CAR-T cell therapies on patient QoL, focusing on treatment-related side effects, emotional and psychological stressors, and overall treatment experience. Additionally, Phase 2-4 clinical trials from clinicaltrials.gov were analyzed for five FDA-approved CAR-T therapy indications: large B-cell lymphoma (LBCL), follicular lymphoma (FL), multiple myeloma (MM), mantle cell lymphoma (MCL), and B-cell acute lymphoblastic leukemia (ALL). After applying exclusion criteria, 92 studies were included and categorized by indication. The presence of QoL as a primary or secondary endpoint and the patient-reported outcome measurement tools used were assessed.

Of the 92 trials analyzed, 34 (37%) included a QoL measurement as a secondary endpoint, while none used QoL as a primary or exploratory endpoint. Multiple myeloma trials showed the highest prevalence of QoL assessment (54.2%), followed by B-cell lymphoma (38.6%), B-cell ALL (20%), and combined B-cell ALL and B-cell lymphoma (14.3%). Most trials prioritized survival metrics such as progression-free survival and overall survival over QoL measures.

While QoL remains secondary in CAR-T clinical trials, its inclusion in some studies is promising. As CAR-T therapies advance, it is crucial to evaluate both QoL and survival metrics with equal emphasis in upcoming trials. Future research should integrate QoL assessments alongside survival outcomes to provide a more comprehensive evaluation of CAR-T therapy, enabling better-informed treatment decisions for patients and providers.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 26

Update on the Management of Plaque Psoriasis in Children and Adolescents

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Purpose: Biologic agents are increasingly prescribed for pediatric plaque psoriasis, yet some healthcare plans require patients to fail topical treatments first. This review examines biologic therapies' impact on remission and quality of life. Our goal is to provide evidence supporting biologics as the preferred treatment for severe pediatric cases, shifting the focus from step therapy failures to patient well-being.

Methods: Biologic agents (etanercept, secukinumab, adalimumab, ustekinumab) were identified using the 2020 AAD-NPF pediatric psoriasis guidelines. A literature review was conducted via PubMed, EMBASE, Clinicaltrials.gov, and EBSCOHost, applying filters for recency, full-text availability, and English language. Key search terms included pediatric plaque psoriasis and specific biologic agents. Package inserts provided data on clinical trial evidence and adverse effects. Treatment efficacy was assessed using PASI 75/90 and IGA mod 2011, while safety was evaluated by reported adverse effects. Quality of life improvements were measured via CDLQI, where lower scores indicate less impact on daily life. Studies comparing biologics to systemic treatments were prioritized.

Results: Thirty-five studies were reviewed, including RCTs, case studies, and systematic reviews. Systematic reviews indicate that adalimumab, etanercept, and ustekinumab result in significantly higher rates of achieving PASI 75 compared to methotrexate. At 6 months, 12 of 30 patients (40.0%) on methotrexate achieved PASI 75, while 20 of 28 patients (71.4%) on biologics did so ($P=0.02$). Secukinumab demonstrated superior efficacy to etanercept at 12 weeks (PASI 90: 72.5% vs. 29.3%, $P<0.05$). Both etanercept and ustekinumab significantly improved CDLQI scores, reducing them by 69% and 78%, respectively.

Conclusion: Our review supports biologics over traditional therapies for pediatric plaque psoriasis, with adalimumab, etanercept, ustekinumab, and secukinumab showing superior efficacy and quality-of-life improvements. Further research should explore how emerging treatments compare to these biologics.

Program Affiliations: N/A

Poster Category: Administrative & Regulatory Science

Primary Author Title: Pharm.D. Student

Abstract 27

Loss of Surfactant protein (SP)-D alters lung metabolome and lipidome in rodents after exposure to ozone

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Ozone is an air pollutant that causes lung injury and alters lung function, especially in vulnerable populations including the elderly and individuals with co-morbidities. The effects are more pronounced after prolonged ozone exposure. Inflammatory macrophages have been implicated in ozone toxicity. We previously showed that ozone induced injury and macrophage accumulation in the lung are exacerbated in mice lacking surfactant protein (SP)-D. Herein we assessed the effects of loss of SP-D on the metabolomic and lipidomic profiles in the lung following prolonged inhalation of ozone. We hypothesize that metabolic/lipidomic alterations in macrophages following ozone exposure may contribute to the hyperinflammatory response in SP-D-/- mice. Mice (WT and SP-D-/-) were exposed to air or ozone (1.5 ppm, 2 h), twice a week, for 3.5 wk. Bronchoalveolar lavage fluid (BAL) was collected 24 h after the last exposure. Polar and lipid metabolites were extracted from BAL, separated, identified and quantified by chromatography, high-resolution MS and LC-MS respectively. Exposure of SP-D-/- mice to ozone significantly increased the number of cells, protein, and total phospholipid levels in BAL, when compared to WT mice, suggesting disruption to alveolar-epithelial barrier. Exposure of mice to ozone altered polar metabolites. Whereas 69 metabolites increased in WT mice after ozone, 13 increased in SP-D-/- mice; 91 metabolites decreased in WT mice as opposed to 141 in SP-D-/- mice. Analysis of the lipidome showed that exposure to ozone increased 32 and decreased 243 lipids in WT mice; 57 lipids increased and 201 decreased in SP-D-/- mice. Whereas 3 lipids increased significantly in WT mice after ozone exposure, 16 lipids decreased in SP-D-/- mice. These data suggest that loss of SP-D decreases polar metabolites involved in protein and nucleic acid synthesis, and increases lipids linked to surfactant synthesis in the lung after ozone-induced lung injury. Identifying the biochemical pathway mediated by these metabolites will provide a better understanding of the role of surfactants in chronic lung pathologies.

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Poster Category: Basic and Translational Science

Primary Author Title: Faculty

Abstract 28

Targeting Mitochondrial Dynamics in Drug-Resistant Acute Leukemia

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Acute myeloid leukemia (AML) is the most common and deadliest leukemia in adults. Venetoclax, a novel and highly effective oral medication, has been approved by the FDA for treating AML. This drug acts as a BH3 mimetic, inducting the mitochondrial-dependent intrinsic apoptotic pathway in the leukemic cells. Despite its effectiveness, approximately 30% of patients with AML do not initially respond to venetoclax, and many who do respond eventually relapse within a few months into venetoclax-based treatment. Our goal is to understand the underlying molecular mechanisms of resistance to this valuable drug, and other members of its class, with the aim to improve their efficacy in AML treatment. Using genome-wide CRISPRi screens and advanced microscopy, we have previously pinpointed mitochondrial adaptations as key to venetoclax resistance in AML. Resistant AML cells modify their mitochondrial structure and function to evade apoptosis, through the notable upregulation of OPA1 and CLPB. The mitochondrial chaperonin CLPB interacts with the mitochondrial-shaping protein OPA1 to regulate its proteolytic cleavage, thus maintaining the mitochondrial architecture. Ablating CLPB or OPA1 enhances BH3 mimetics-induced apoptosis by promoting cristae remodeling, mitochondrial stress, and cell cycle arrest. Importantly, novel and safe OPA1 inhibitors re-sensitized AML patient-derived xenografts to venetoclax ex vivo and in vivo. This highlights the potential of targeting mitochondrial dynamics to overcome therapy resistance in leukemia. Overall, this study uncovers the precise role of mitochondrial structure in therapy resistance in AML and proposes new therapeutic strategies for this devastating disease.

Program Affiliations: NA

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Poster Category: Basic and Translational Science

Primary Author Title: Postdoctoral Associate

Abstract 29

Impact of Acute Ozone Exposure on Locomotion, Anxiety-like Behavior, and Microglia Cells in Rats

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Ozone is a highly reactive air pollutant known to cause lung injury, impaired pulmonary function, and generate reactive oxygen and nitrogen species, which contribute to ozone toxicity. Pulmonary oxidative stress has been linked to increases in circulating serum amyloid A and IL-1β, which can damage the blood brain barrier and cause cognitive impairments. While chronic exposure to ozone is known to impair cognition, increase anxiety-like behaviors, and reduce locomotion, the effects of acute ozone exposure remain unknown and were the focus of this investigation.
Sprague Dawley rats (male, 7 wk) were exposed to filtered air, 800 ppm, or 2,000 ppm ozone for 3 hr in whole body chambers. Immediately after exposure, rats were tested for 10 min in A) an open field test, then B) a light/dark box test to identify changes in locomotive and anxiety-like behaviors, respectively. Video recordings were analyzed for changes after exposure to ozone compared to air. Immediately after behavioral testing, rats were sacrificed, the cerebellum isolated, fixed, paraffin embedded, sectioned, and stained for expression of Iba1, a marker of microglia cells, by immunohistochemistry. Iba1+ microglia in the molecular, granular, and white matter regions of the cerebellum were quantified. Data were analyzed using a one-way ANOVA paired with a Tukey posthoc test; $p<0.05$.
In the open field test, ozone exposure dose-dependently reduced measures of locomotor activity, including speed, acceleration, and distance traveled relative to air controls. Ozone at 2,000 ppb also caused a significant decrease in anxiety-like behavior, as measured by reduced supported rearing and decreased transitions compared to air-exposed rats. Iba1+ microglia were significantly increased in the white matter region following 2,000 ppb ozone compared to air-exposed rats. Future studies will assess the persistence of ozone-induced behavioral changes and mechanisms underlying ozone-induced cognitive impairments.

Program Affiliations: Joint Graduate Program in Toxicology

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Poster Category: Basic and Translational Science

Primary Author Title: Postdoctoral Associate

Abstract 30

Development, Optimization, and Evaluation of a Crystal-Free Diclofenac Sodium Gel for Topical Application

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Purpose
Topical semisolid products may contain drugs in dissolved or suspended forms. A dissolved drug is readily absorbed, while a suspended drug must dissolve before absorption. The physical state of the drug affects its release and bioavailability. This study aims to optimize the preparation of a crystal-free diclofenac sodium gel, which is challenging due to the pH-dependent solubility of diclofenac and the acidic nature of the gelling agent.

Method
Diclofenac sodium gels were prepared by optimizing manufacturing parameters, including gelling agent addition speed, stirring rate, solubilization time, and stirrer type. The process involved dispersing the gelling agent in water, solubilizing preservatives and the drug in propylene glycol, neutralizing the dispersion with sodium hydroxide to form a gel base, and adding the drug solution. The gels were examined visually, and their drug content along with Q3 properties, such as appearance, pH, and water activity were documented. In vitro release testing (IVRT) studies were performed, and the release rates were measured.

Results
Several parameters affected diclofenac sodium crystal formation:
- Dispersion: Slow addition of the gelling agent and medium stirring resulted in clump-free dispersions.
- Solubilization: Heat ensured complete solubilization, preventing crystal formation.
- Stirring: A paddle-type stirrer with bidirectional mixing helped avoid crystallization.
- Neutralization: Adjusting the pH to 7.3-7.5 was crucial to prevent crystal formation.
- Miscellaneous: Controlled, slow addition of the drug and appropriate container and batch size were critical.

The optimized method produced a 500 g batch of clear, smooth, and crystal-free gel with a pH of 7.50 ± 0.01, water activity of 0.9613 ± 0.0003 at 25°C, and 98.44 ± 2.49% drug content. The optimized gel showed a drug release rate of 79.53 ± 2.95 µg/cm2/h.

Conclusions
Optimization of manufacturing parameters resulted in a stable, crystal-free 0.5% diclofenac sodium gel with optimal physicochemical and in vitro release properties.

Program Affiliations: Graduate Program in Pharmaceutical Science

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Poster Category: Basic and Translational Science

Primary Author Title: Postdoctoral Associate

Abstract 31

Engineering an Ex Vivo Human Endometrium Spheroid Model for Studying the Effects of Xenobiotic Exposure on Women's Early Pregnancy Success

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Pregnane x receptor (PXR; NR1I2) is a nuclear receptor and ligand activated transcription factor that regulates the expression of genes critical for drug disposition, including drug-metabolizing enzymes and transporters. PXR also plays a role in regulating the transactivation of hepatic genes involved in bile acid (BA) synthesis, conjugation, and efflux transporters. Disruption of PXR functions and BA homeostasis have been associated with metabolic dysfunction-associated steatohepatitis (MASH) pathogenesis. MASH is a severe form of metabolic dysfunction-associated steatotic liver disease (MASLD) that initially manifests as steatosis and can further progress to inflammation, fibrosis, cirrhosis, and even hepatocellular carcinoma. PXR is a well-known ligand-dependent xenobiotic sensor involved in drug metabolism, drug-drug interactions, and as a physiological sensor involved in endobiotic metabolism in diverse cellular processes. Our current understanding of PXR regulation of its hepatic functions in endobiotic metabolism including BA in a ligand-independent manner through post-translational modification, such as phosphorylation, is extremely limited. PXR has a conserved phosphorylation motif in its ligand binding domain, Ser347 in mice and Ser350 in humans. Mutation of this conserved phosphorylation motif of PXR in vitro alters human PXR transcriptional activity; however, the mechanism remains elusive. In this study, mice with a PXR Ser347Ala knock-in mutation (PXR-KI) were utilized to investigate the role of ser347 phosphorylation site in regulating PXR functions in modulating BA synthesis, metabolism, and signaling pathways during MASH development. Six-week-old male wildtype (WT), and PXR-KI mice, both on the C57BL/6J genetic background, were fed a high fat diet (HFD; diet with 40 Kcal% palm oil fat, 20 kcal% fructose, and 2% cholesterol), or a chow control diet (CCD) for 16 weeks. Serum, ileum, and liver tissues were collected for further analysis. On HFD diet, WT mice showed a significant decrease in mRNA levels of hepatic genes related to BA synthesis (Cyp27a1, Cyp7b1, Cyp2c70), and a significant increase in (Cyp7a1) vs WT on CCD. On the other hand, PXR-KI on HFD mice showed a significant decrease in (Cyp2c70, Cyp7b1) vs WT mice on HFD. The relative mRNA expression of BA conjugation gene (Baat) was decreased in PXR-KI compared to WT mice on HFD and PXR-KI on CCD. The ileal gene expression of Fgf15 was significantly elevated, and Shp showed a trend of upregulation in the PXR-KI on HFD as compared to WT on HFD. Additionally, the relative mRNA levels of Oatp1a1 transports were significantly decreased in the PXR-KI HFD compared to either WT HFD or PXR-KI CCD groups while those of Ntcp and Bsep were decreased in PXR-KI HFD vs PXR-KI CCD. Our data showed that mutation of Ser347 phosphorylation site in mouse PXR alters BA synthesis, metabolism, conjugation, and signaling pathways, thereby affecting BA pool during MASH development suggesting the importance of this site in regulating PXR function to maintain BA homeostasis and prevent from fatty liver disease development.

Program Affiliations: Joint Graduate Program in Toxicology

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Poster Category: Basic and Translational Science

Primary Author Title: Postdoctoral Associate

Abstract 32

Lipid Imbalance in Brain Extracellular Vesicles after Pulmonary Exposure to Nitrogen Mustard in Rats

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Background: Nitrogen mustard (NM) reportedly causes structural abnormalities in the brain that manifest clinically as seizures, agitation, confusion, and long-term cognitive impairment. The etiology of neuropathological and neurobehavioral changes after NM exposure are unknown. NM, an alkylating agent that causes DNA damage also causes lipid peroxidation through inducing nitrative and oxidative stress. We previously reported NM induced lipid imbalance in lungs.

Hypothesis: NM might induce lipid dysregulation in the brain following pulmonary exposure. Lipid imbalance is a key feature of neurodegenerative diseases. We analyzed brain derived exosomes, small extracellular vesicles (EVs) arising from the endosomal-lysosomal pathway that participate in lipid transport. We speculated that NM induced neurological impairment might be related to endosomal-lysosomal pathway disruption via altered exosome secretion and lipid transport.

Methods: Male Wistar rats (~ 8 wk) were treated with NM (0.125 mg/kg) or PBS (n = 8 rats/group) intratracheally. Animals were euthanized 3, 7, 14, and 28 d later via exsanguination. Brain EVs were isolated from intact brain ((-) cerebellum) by spontaneous EVs-release (24 h) in serum-free suspension cultures, enriched for small EVs (sequential centrifugation and 0.2-mm syringe filtering), and purified with precipitation solution (24 h), centrifugation, and column filtration. EV populations were characterized by the expression of CD63 and AChE. Total protein, cholesterol, and APOE were quantitated.

Results: Increased CD63+ exosomes were observed at 3 d and 14 d post-NM, with no significant changes in APOE. A strong positive linear association between APOE and CD63+ exosomes was noted in controls; but not observed after NM. Cholesterol increased at 3 d but decreased thereafter. At 14 d and 28 d post-NM, AChE+ exosomes significantly decreased. AChE was negatively associated with cholesterol in controls but positively associated with cholesterol after NM; levels of AChE+ exosomes were also negatively associated with CD63+ exosomes.

Conclusions: NM pulmonary exposure causes a loss in cholesterol transport by CD63+ exosomes, likely due to a dis-association with ApoE. CD63+ exosomes may undergo a compensatory increase in secretion to maintain cholesterol trafficking, whose cargo concentrations decreased over time. Our AChE results affirm reports that cholesterol levels can alter brain AChE activity. NM induced neuropathology may be due to lipid imbalance through disruption of the endo-lysosomal pathway involving cholesterol carrying exosomes.

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Poster Category: Basic and Translational Science

Primary Author Title: Postdoctoral Associate

Abstract 33

Streamlining SuFEx Inhibitor Development: A Unified Approach Using Orthogonal Sulfinate Protecting Groups

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Sulfonyl fluorides (SFs) have gained significant importance due to their classification as a click reaction and therefore have seen increased use in drug discovery and biochemistry. Their use, however, is complicated by the methods by which they are synthesized and their general synthetic instability. This results in sulfonyl fluorides being introduced late in a synthetic route with minimal structural diversity. Masking the reactivity of a sulfonyl fluoride by protecting the parent sulfinate is one method to resolve these issues. Currently available sulfinate protecting groups (SPGs) exhibit minimal, if any, stability under harsher synthetic conditions commonly required for assembling complex structures, limiting their utility in multi-step synthetic routes. In this study, three novel SPGs have been designed to enable access to a broader chemical space of SF derivatives. This includes the discovery of two novel, photolabile sulfinate protecting groups (SPGs), para-methoxybenzyl Rongalite and ortho-nitrobenzyl Rongalite that can be directly converted to the sulfonyl fluoride by irradiating with blue LEDs. Both SPGs exhibited enhanced stability under diverse synthetic conditions, enabling their incorporation early in synthetic routes, successful progression through multiple transformations, and subsequent mild deprotection to yield SFs. Interestingly, the third SPG was designed with the aim of enabling bidirectional SO2 functionalization. A bifunctional redox-active reagent was developed, capable of generating a sulfinyl radical under photocatalytic conditions, which can then directly install the SPG on a variety of substrates, including previously challenging ring structures. Overall, these newly designed SPGs offer a more versatile and robust approach to access a diverse range of SF-containing molecules.

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Poster Category: Basic and Translational Science

Primary Author Title: Ph.D. Student

Abstract 34

CLPB modulates mitochondrial morphology and Venetoclax resistance in acute myeloid leukemia via OPA1 Regulation

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Acute myeloid leukemia (AML) is the most common leukemia in adults and also affects children. The FDA has approved Venetoclax, a selective BCL2 antagonist, for treating AML. However, resistance to this medication often develops following extended treatment, underscoring the need for a deeper comprehension of the underlying mechanisms. Our previous results have shown that CLPB plays a key role in the acquisition of Venetoclax resistance in AML, but its precise function in leukemia mitochondria remains unknown. By utilizing CRISPR-Cas9 technology and electron microscopy in human AML cell lines, we demonstrated that CLPB is crucial in the proteolytic regulation of the mitochondrial shaping protein OPA1. CLPB is a mitochondrial intermembrane space AAA+ domain–containing disaggregase, which we showed directly interacts with OPA1. For its proper function within mitochondria, OPA1 is constitutively cleaved under steady-state conditions by proteases, such as the metalloendopeptidase OMA1, and this processing is further induced under stress conditions. Ablation of CLPB leads to excessive OPA1 proteolytic cleavage, accumulation of abnormal mitochondria with wider cristae, and increased sensitization to the apoptosis-inducing agent, Venetoclax. In contrast, OMA1 deletion in AML cells results in inadequate OPA1 processing and resistance to programmed cell death. Importantly, loss of OMA1 rescues the CLPB-mediated abnormal OPA1 processing, cristae narrowing, and downstream susceptibility to apoptosis. Overall, our data propose that CLPB regulates mitochondrial cristae morphology and cell death in AML cells via its direct interaction with the master regulator of mitochondrial dynamics, OPA1, safeguarding it from OMA1 proteolysis. All these insights imply that targeting the regulation of mitochondrial architecture could offer a viable strategy to overcome Venetoclax resistance in leukemia.

Program Affiliations: Graduate Program in Pharmaceutical Science

Poster Category: Basic and Translational Science

Primary Author Title: Ph.D. Student

Abstract 35

Differential Regulation of Placental OATP Transporters at Low Oxygen Concentrations

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The placenta is a dynamic tissue that begins as a hypoxic tissue with oxygen levels around 3% until blood flow increases and oxygen concentrations rise to 8% during the second and third trimesters. However, pregnancies with complications can decrease blood flow, resulting in reduced oxygen concentrations later in gestation. Organic anion transporting polypeptide (OATP) transporters are responsible for the cellular uptake of endobiotics and xenobiotics in the placenta. In this study, we sought to determine whether varying oxygen concentrations will alter the mRNA expression and functional uptake of OATPs in a human immortalized trophoblast cell line. For this purpose, JAR choriocarcinoma cells were exposed to 20%, 8%, and 3% oxygen levels for 24 hours and OATP mRNAs were quantified by qPCR. To confirm that hypoxic responses were activated, downstream targets of hypoxia inducible factor-1α (HIF-1α) including glucose transporter 1 (GLUT1), heme oxygenase 1 (HO-1), and vascular endothelial growth factor receptor 1 (VEGFR1) were quantified. Compared to atmospheric oxygen levels (20%), GLUT1 mRNAs were increased 4-fold and 8-fold in trophoblasts exposed to 8% and 3% oxygen, respectively. Similarly, VEGFR1 mRNA levels were up-regulated by 3-fold at 8% oxygen and HO-1 mRNA levels was increased by 2-fold at 3% oxygen. To see how varying oxygen tensions contributes to differential OATP response, time-dependent expression of 1 μM sodium fluorescein uptake experiment at 10, 20, 30, and 40 minutes was performed. Compared to 20% oxygen, 8% and 3% oxygen exposure increased uptake of fluorescein. Next, OATPs mRNA levels were tested to see which OATP isoforms were differentially regulated. Compared to 20% oxygen exposure, trophoblasts exposed to 3% oxygen exhibited a 50% decrease in OATP4A1 mRNAs. OATP1B3 decreased 1-fold from 8% to 3% oxygen. Conversely, OATP2B1 mRNAs increased 10- and 20-fold in trophoblasts exposed to 8% and 3% oxygen, respectively. OATP3A1 mRNAs were also up-regulated by 3-fold at 3% oxygen. These data suggest that OATPs are differentially regulated under low oxygen concentrations and may impact uptake of OATP substrates, including drugs and nutrients in the placenta.

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Funding: NA

Poster Category: Basic and Translational Science

Primary Author Title: Ph.D. Student

Abstract 36

Microcystin-LR Uptake by OATP Transporter Isoforms Expressed in Reproductive Tissues

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Background and Purpose: Rising global temperatures and eutrophication of waterways by fertilizer over-enrichment has led to a significant increase in the incidence and intensity of cyanobacterial harmful algal blooms (cyanoHABs) worldwide. CyanoHABs release cyanotoxins, including Microcystin-Leucine-Arginine (MC-LR), which has been identified as a potent hepatotoxin, nephrotoxin, neurotoxin, and more recently as a reproductive toxin. MCs require active uptake into cells through organic anion transporting polypeptide (OATP) transporters. Prior studies of liver and brain enriched OATP isoforms suggest that MC-LR is a substrate for OATP1B1, 1B3, and 1A2, but not 2B1. Defining the MC-LR transport by OATP isoforms enriched in the ovaries and placenta informs risk characterization for MC-LR reproductive toxicity. We hypothesize that OATP2A1, 3A1, 4A1, and 5A1 mediate transport of MC-LR to varying degrees.

Methods: HEK293 cells overexpressing OATP1A2, 2A1, 2B1, 3A1, 4A1, and 5A1 and their corresponding empty vector control cells were suspended and exposed to the OATP substrate fluorescein (1 μM, 10 min) or MC-LR (1 μM, 1 hr). Next, cells were immediately incubated at 4°C to terminate active uptake and then washed, lysed, and proteins extracted. SDS-PAGE and western blotting was performed using an antibody specific to protein-bound arginine MC congeners. HEK293 overexpressing OATP1A2 serves as a positive control for MC-LR transport.

Results: In HEK293 empty vector cells, no uptake of MC-LR was observed. In HEK293 cells overexpressing OATP3A1, 4A1, and 5A1, there was active uptake of MC-LR, as evidenced by strong immunostaining of MC-LR-bound protein at 37 and 25 kDa, and to a lesser extent, 30
kDa.

Conclusions: Current investigations are underway to determine the contribution of OATP2A1 and OATP2B1 in MC-LR transport and determine the kinetics of uptake and inhibition by each isoform. In conclusion, this study will be important for identifying the specific OATP isoforms capable of MC-LR transport in reproductive tissues.

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Poster Category: Basic and Translational Science

Primary Author Title: Ph.D. Student

Abstract 37

Selective Receptor Modulation During Melatonin Renoprotection Against Vancomycin Toxicity

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Background and Purpose: Acute kidney injury (AKI) is frequently observed with the empirical use of the antibiotic vancomycin in hospitalized patients with presumed methicillin-resistant staphylococcus aureus infection. To combat oxidative and cellular stress responsible for vancomycin nephrotoxicity, melatonin, a preferred sleep medication in hospitals, has emerged as a potential intervention. Beyond its radical scavenging properties, we have previously demonstrated that melatonin prevents vancomycin-induced apoptosis through G-protein coupled receptors, melatonin receptor type 1 (MT1) and type 2 (MT2). Recent research suggests differential regulation of MT receptors by melatonin and heterogeneous expression of MT2 in kidneys. In this study, we sought to characterize the contributions and regulation of MT receptor isoforms 1 and 2 in human kidney cells to elucidate the mechanisms underlying melatonin renoprotection.

Methods: Human kidney proximal tubule HK-2 cells were treated with melatonin (1-100 μM) for 24h. qPCR and western blotting were performed to assess the expression of MT1 and 2. To examine the role of its metabolite in mediating melatonin protection, HK-2 cells were pretreated with melatonin 32 μM for 24h, followed by co-incubation with vancomycin (4-6 mM). The individual role of MT receptors was tested using FDA-approved MT1/2 agonists (ramelteon, 1-1,000 nM; tasimelteon, 0.1-50 nM), the nonselective MT1/2 antagonist luzindole (1-5 μM), and the MT2 antagonist 4-P-PDOT (10-20 nM). Cytotoxicity was assessed every 4 hours by propidium iodide (PI) staining using a Cytation 5 imager.

Results: MT1 mRNA was predominantly expressed in HK-2 cells. Despite the significantly lower expression of MT2, both nonselective and MT2-specific inhibition similarly reduced the antiapoptotic effects of melatonin. Conversely, differential effects were observed with increasing concentrations of MT receptor agonists, with no antiapoptotic effect above 1-10 nM. Instead, treatment with melatonin exceeding 10 μM resulted in a significant down-regulation of MT2 protein (up to 43%), but upregulation of MT1 (up to 3-fold).

Conclusion: The antiapoptotic effect of melatonin is primarily mediated through MT receptor activation, particularly MT2. The altered expression of MT receptors may be a mechanism behind the differential efficacy of MT receptor agonists against vancomycin toxicity. Ongoing in vitro studies aim to unravel the differential internalization and desensitization mechanism of MT receptors by melatonin and its analogs.

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Poster Category: Basic and Translational Science

Primary Author Title: Ph.D. Student

Abstract 38

The Role of GCN2 in Lung Injury and Inflammation Caused by Ozone Inhalation in Mice

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Ozone is a criteria air pollutant known to cause oxidative stress and lung injury. The alveolar epithelium is a main target of inhaled ozone; damage initiates an inflammatory response characterized by an accumulation of macrophages in the lungs. In response to mediators present in the tissue microenvironment (e.g., TLR4 agonists, TNFα, oxidized lipids, ROS), infiltrating macrophages become activated, releasing inflammatory mediators that contribute to acute lung injury. Research herein is focused on analyzing potential biochemical pathways regulating macrophage activation. The integrated stress response (ISR) is a signaling network involved in maintaining cellular homeostasis; activation of the ISR leads to upregulation of genes that repair cellular damage or induce apoptosis. ISR activation is dependent on phosphorylation of eukaryotic initiation factor alpha (eIF2α). General control nonderepressible 2 (GCN2) is a key kinase that phosphorylates eIF2α; this occurs in response to oxidative stress. ISR signaling through GCN2 promotes both pro- and anti-inflammatory responses. We hypothesize that ISR signaling through GCN2 plays a role in regulating macrophage activation following ozone exposure.
Male and female C57BL/6 Wild-Type (WT) and whole-body GCN2-/- mice (11-14 wk) were exposed to air or ozone (0.8 ppm) in a Plexiglass chamber for 3 h. Bronchoalveolar lavage (BAL) fluid was collected 24 h later and analyzed for total protein, IgM and cell content. Lung cells were stained with myeloid specific antibodies and analyzed by flow cytometry. Left lung lobes were fixed in 10% formalin, paraffin embedded, and sectioned. Expression of cleaved caspase 3 was assessed by immunohistochemistry.
In GCN2-/- mice exposed to ozone, a significant increase in total protein compared to air-exposed mice was observed, demonstrating alveolar epithelial injury. Cleaved caspase 3, a marker of apoptosis, was upregulated in bronchial and alveolar epithelia of WT mice; this was blunted in GCN2-/- mice. In lungs of GCN2-/-, but not WT mice, significant neutrophilia was evident. Exposure of WT mice to ozone resulted in an increase in CD45+CD11b+Ly6G+ neutrophils, with no effect in GCN2-/- mice. Numbers of CD45+CD11b+Ly6G- infiltrating macrophages also increased in WT mice following ozone exposure; the majority of these cells were CD206+Ly6C- suggesting a pro-resolution phenotype. In GCN2-/- mice, the effect of ozone on these cells was blunted. Ozone did not have an effect on the number of CD45+CD11b-Ly6G- resident alveolar macrophages nor their pro-resolution phenotype (SiglecF+CD11c+CD206+Ly6C-) in either WT and GCN2-/- mice.
Both WT and GCN2-/- mice exhibit alveolar epithelial injury following ozone exposure, as evidenced by the increases in BAL protein. Findings that cleaved caspase 3 expression is reduced in lungs of GCN2-/- mice suggests that injury to the epithelium is not due to apoptosis. Ozone exposure resulted in an accumulation of pro-resolution macrophages in WT, but not GCN2-/- mice. This indicates that GCN2 plays a role in regulating the macrophage response to ozone-induced lung injury. Future studies will investigate how loss of GCN2 controls macrophage functioning following ozone exposure.
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Primary Author Title: Ph.D. Student

Abstract 39

Gestational Exposure to Particulate Matter Alters Placental Glucose Transporter Expression

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Background and Purpose: Particulate matter (PM) is a growing concern in the scope of air pollution due to the association with adverse health effects. Laboratory and epidemiological studies support an association between PM exposure during pregnancy and the development of fetal growth restriction (FGR). Fetal growth is driven by the delivery of nutrients from the maternal blood to the fetal blood, which is regulated by the placenta. Glucose is the primary growth-related nutrient delivered by the placenta, mainly by primary glucose transporter (GLUT) 1 which is abundantly localized to the cell membrane. Secondary GLUTs 3 and 4 are mainly intracellular with minimal expression on the membrane. Collectively, we hypothesize that under the stressful conditions elicited by PM exposure, the placenta has compromised glucose transport that perpetuates the development of FGR. Given that placental handling of nutrients and responses to environmental stressors are sex-dependent, we anticipate sex-specific responses in transporter expression.
Methods: Pregnant Sprague Dawley rats were exposed to a target concentration of 10 mg/m3 nano-sized TiO2 aerosols to represent ultrafine PM (<100 nm in diameter) from gestational day (GD) 4-19 for 4-5 hours a day. On the night of GD 19, dams were fasted for 16 hours before sacrifice on GD 20. Maternal and fetal blood glucose was measured using a commercially available glucometer. After sacrifice, uterine horns were removed, and four placentas (two from each sex) were collected. A half (sagittal cut) from each placenta was saved in 10% neutral buffered formalin for immunohistochemistry (IHC) and immunofluorescence (IF) confocal microscopy. Additionally, a quarter from each placenta was snap frozen in liquid nitrogen and stored at -80°C for RNA isolation and qRT-PCR to quantify the abundance of GLUT 1, 3 and 4.
Results: The fasted blood glucose of exposed dams was higher than those in the control group (73.5 ± 5.3 mg/dL vs 61.1 ± 4.1 mg/dL; p=0.08) while fetal blood glucose levels were unaffected. Preliminary qRT-PCR data on placental GLUT 1, 3 and 4 showed no changes at the transcriptional level, but analysis of DAB intensity on IHC stained placentas showed a significant reduction in relative GLUT1 protein expression (0.96 ± 0.02 in control vs 0.88 ± 0.03 in exposed). This observation was accompanied by a significant increase in relative GLUT4 expression, driven by female derived placentas (0.82 ± 0.17 in control females vs 1.57 ± 0.22 in exposed females).

Conclusions: In conclusion, gestational exposure to particulate matter has a negative effect on the primary placental glucose transporter, GLUT1. Alone, this response could impair fetal glucose access. Upregulation of placental GLUT4 acts as a compensatory mechanism to rescue glucose transport. Future studies aim to measure maternal insulin as a mechanism for GLUT4 upregulation and translocation, and localize GLUT expression using IF to differentiate between membrane bound (active) or cytosolic (inactive) transporters to provide clarity to the functionality of these modifications. Moreover, this research highlights the need to examine other growth-related nutrients, including oxygen, as a mechanism for PM-induced FGR.

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Poster Category: Basic and Translational Science

Primary Author Title: Ph.D. Student

Abstract 40

Dysregulation of epithelial cell adhesion and cell-cell communication in Göttingen minipig skin following exposure to sulfur mustard

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Sulfur mustard (SM; bis(2-chloroethyl) sulfide) is a highly reactive bifunctional alkylating agent and a potent skin vesicant. In human skin, SM causes inflammation and blistering. During skin injury, cell-cell adhesion and communication are disrupted. E-cadherin and β-catenin form a cadherin/catenin complex that controls adhesion, migration, and proliferation of keratinocytes. Also important is connexin43, a gap junction cell-cell communication protein involved in organizing adherens junctions. We have been using the Göttingen minipig model to investigate mechanisms of skin injury and wound repair following SM exposure. Herein, the role of cell adhesion and communication proteins in SM toxicity was investigated. Using an IACUC approved protocol, air control or saturated SM vapor caps were placed on the dorsal flanks of male Göttingen minipigs (3-months-old) for 30min (MRIGlobal). After 48h, SM wounded sites were debrided daily for 7d with wet-to-wet saline gauze. Animals were euthanized 9, 28, and 60d post-SM and full thickness skin biopsies prepared for immunohistochemical analysis. Primary antibodies against E-cadherin, β-catenin, connexin43, and phospho-connexin43(S368) and appropriate IgG controls were used. In control animals, E-cadherin and β-catenin were expressed throughout all viable layers of the epidermis. SM reduced E-cadherin and β-catenin expression 9-28d post-exposure; a marked reduction was noted in the stratum basale. In contrast, connexin 43 was contiguously expressed within the stratum granulosum of control skin. Phosphorylation of connexin43 is a dynamic process that modulates gap junction permeability. A marked upregulation of connexin43 and phospho-connexin 43(S368) was evident in the stratum spinosum and stratum granulosum 9-28d post-SM. All proteins were approaching control levels by 60d post-SM. These data indicate that there are dynamic changes between skin cells which contribute to epidermal injury and repair. Further studies evaluating mechanisms controlling epithelial cell adhesion and cellular communication will assist in the development of therapeutics that promote wound repair following exposure to SM.

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Poster Category: Basic and Translational Science

Primary Author Title: Ph.D. Student

Abstract 41

Myeloid Specific Ablation of Acat-1 leads to increased foam cell formation and changes in retinoid metabolism

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After lung injury, there is an important shift between inflammation and resolution. Macrophages play a large role in this shift, as they move from a pro-inflammation to a pro-resolution phenotype. Failure to resolve leads to prolonged inflammation and can result in pulmonary fibrosis. Failure to resolve is associated with the presence of large, lipid-laden macrophages (foam cells), in a wide variety of fibrotic lung diseases. Acyl coenzyme A acyltransferase-1 (Acat-1) catalyzes the conversion of free cholesterol to cholesterol esters which are required for the formation of lipid droplets. Previously, we have shown that intratracheal installation of an Acat-1 inhibitor reduces bleomycin (ITB) mediated lung injury and reduces foam cell formation in the lung. However, myeloid specific Acat-1 knockout (Acat1-M/-M) mice show increased signs of injury following ITB. Lipid droplets are one of the principal storage sites of antioxidant retinoids in the lung macrophage. We hypothesized that Acat1-M/-M mice have dysregulated retinoid metabolism, due to the lifelong loss of cholesterol ester formation. This lack of retinoid utilization leads to improper inflammatory resolution, specifically in macrophages, leading to increased lung injury.

A Cre-LoxP system was used to generate Acat1-M/-M mice using the LysM promoter to target myeloid cells. Male and female Acat1-M/-M mice were given ITB or PBS controls on day 0 and sacrificed day 7. Bronchoalveolar lavage (BAL) and lung tissue were collected. Cytospins of BAL cells were performed and stained with Hema 3 Stat Pack. Retinoids in lung tissue were measured using HPLC. Immunofluorescence was performed using antibodies for smooth muscle actin (SMA) and perilipin2 (Plin2). Quantitative analysis was performed using a two-way ANOVA, with data shown as mean ± standard error of the mean and significance $p < .05$ compared to WT PBS (*) and WT ITB (#). Qualitative assessment of the immunofluorescence was done to assess for lung injury.

An increased number of large, vacuolated macrophages were observed in BAL fluid of ITB treated animals compared to PBS (26±2%* vs 4±1%). In Acat1-M/-M, ITB increased the number of large, vacuolated macrophages compared to WT control (40±6%*# vs 6±2%). Measurements of lung retinoids showed a trend of WT mice losing retinyl esters after ITB (114±31 vs 53±10 ng/ µg DNA $p = 0.07$) while the Acat1-M/-M were not altered by ITB (103±26.4 vs 124±34 ng/µg DNA). Immunofluorescence showed an increase in smooth muscle actin (SMA) of the Acat1-M/-M ITB compared to WT ITB, showing a proliferative response to ITB in Acat1-M/-M. This observation may indicate myofibroblast formation, which is a key step in fibrotic lung disease. Acat1-M/-M also increase in perilipin2 (Plin2) after ITB compared to WT.

Within Acat1-M/-M mice, ITB appears to lead to an increase in proliferation and a failure of macrophages to die. This may result in an increased fibrotic response compared to the WT. Increased SMA staining around airways of Acat1-M/-M mice is consistent with increased fibrosis, but this response may be more evident at later time-points. The increase of Plin2 staining may indicate an increase in lipid droplet formation in the lung of Acat1-M/-M mice in response to injury. The reduction of retinyl esters after lung injury suggests that lifelong ablation of ACAT leads to a loss of cellular defenses, whereas acute Acat1 inhibition inhibits the formation of foam cells. We propose that macrophages require Acat-1 to properly resolve lung inflammation and this effects lung retinoid metabolism during acute injury.

Program Affiliations: Joint Graduate Program in Toxicology

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Poster Category: Basic and Translational Science

Primary Author Title: Ph.D. Student

Abstract 42

Direct Inhibitors of Keap1-Nrf2 Protein-Protein Interaction Reduce Oxidative Stress in Breast Cancer by Nrf2 activation

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Oxidative stress within most cells can present a harmful array of effects such as DNA or protein damage which can induce inflammation or cell death. Cellular mechanisms such as the activation of an antioxidant transcription factor Nrf2 can greatly reduce the amount of oxidative stress present in the cell. The transcription factor Nrf2 can be activated translocating into the nucleus to bind to antioxidant response elements (AREs) to upregulate over 250 genes that are involved in reducing oxidative stress, such as NAD(P)H quinone dehydrogenase 1 (NQO1) and Heme oxygenase-1 (HO-1). While electrophiles or reactive oxygen species (ROS) can activate Nrf2 signaling by interacting with cysteines of Keap1, direct inhibitors of Keap1-Nrf2 protein-protein interaction (PPI) noncovalently bind to the Keap1 Kelch domain to induce Nrf2 activation. Over 60 different Keap1-Nrf2 PPI inhibitors were tested to identify lead compounds. These compounds were divided into four groups in relation to how the structure differed to each other. Estrogen receptor-negative breast cancer MCF10DCIS.com cells were treated with 10 μM of Keap1-Nrf2 PPI inhibitors. mRNA was extracted after 48-hour treatment and RT-qPCR analysis was performed to compare Nrf2 target gene expression level. The results showed that the mRNA level of antioxidant gene NQO1 was increased by the treatment with the Keap1-Nrf2 PPI inhibitors. To test reduction of oxidative stress in cells by Keap1-Nrf2 PPI inhibitors, 2',7'-dichlorofluorescin diacetate (DCFDA) assay was used in MCF10DCIS.com cells. DCFDA is deacetylated by intracellular esterases, producing 2′,7′–dichlorofluorescin (DCFH), a non-fluorescent and membrane-impermeable compound that reacts with intracellular ROS producing fluorescent 2',7'-dichlorofluorescein (DCF). Measurement of DCF demonstrated that the reduction of ROS in cells is evident by the treatment with Keap1-Nrf2 PPI inhibitors. The findings suggest that the Keap1-Nrf2 PPI inhibitors have an antioxidant activity by activating Nrf2, which may serve as cytoprotective agents in breast cancer.

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Primary Author Title: Ph.D. Student

Abstract 43

Protein-Arginine Deiminase-4 (PAD4) Contributes to Coagulation Activation in Chemical-Induced Acute Liver Injury

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Background: During tissue injury, there is significant crosstalk between the inflammatory and the hemostatic responses, which is often described as “thromboinflammation.” Thromboinflammation has been shown to exacerbate tissue injury in a variety of settings, and neutrophil extracellular traps (NETs) contribute to this process. During tissue injury, NETosis occurs when activated neutrophils expel their DNA, histones and cellular proteins. Protein arginine deiminase 4 (PAD4) is a key enzyme that drives NET formation by catalyzing the citrullination of histones.

Aim: Given the association of PAD4 and NETs with thrombosis, our study aims to test the hypothesis that PAD4 drives coagulation activation in experimental acute and chronic liver injury.

Methods: 8-week-old male and female C57BL/6J and whole-body PAD4 knockout (PAD4 -/-) mice were given a single injection of carbon tetrachloride (CCl4, 1ml/kg, i.p) or vehicle (corn oil) to induce acute liver injury. In additional studies, mice were given twice-weekly injections of CCl4 or vehicle for six weeks to induce liver fibrosis. Liver tissue, citrated plasma, and serum were collected at 24 h after challenge to assess NET formation, coagulation activation, and acute hepatotoxicity.

Results & Conclusions: Acute liver injury was observed in wild-type mice 24 hours after one challenge of CCl4, characterized by increased centrilobular hepatocellular necrosis and serum alanine aminotransferase (ALT) activity. Elevated levels of plasma thrombin anti-thrombin (TAT) complexes were observed after CCl4 challenge, demonstrating increased coagulation activity. Interestingly, increased citrullinated histone H3 (CitH3), nucleosomes, and myeloperoxidase-DNA (MPO-DNA) complexes were observed in the plasma of CCl4-challenged wild-type mice, indicating elevated biomarkers of PAD4 activity and NET formation. Similarly, increased Padi4 gene expression and intrahepatic NET formation was detected in CCl4-challenged wild-type mice. Following acute CCl4 challenge in PAD4 -/- mice, plasma and intrahepatic NET biomarkers were not detected, and coagulation activity was reduced by ~50% compared to wildtype mice. Interestingly, there was no difference in plasma TAT, serum ALT, and hepatic collagen deposition between wild-type and PAD4 -/- mice in chronic CCl4 challenge, suggesting PAD4 has a more prominent role in acute liver injury over hepatic fibrosis. In conclusion, these results identify a unique link between PAD4-mediated NET formation during CCl4-induced acute liver injury.

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Poster Category: Basic and Translational Science

Primary Author Title: Ph.D. Student

Abstract 44

Environmentally-Induced Peripartum Cardiomyopathy: a Vascular-Hormonal Hypothesis

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Peripartum Cardiomyopathy (PPCM), an idiopathic form of heart failure, is characterized by left ventricle systolic dysfunction and develops during pregnancy or in the postpartum period. Currently, PPCM is a leading cause of maternal death, with incidence climbing and estimated at 1 in 1000-4000 live births in the USA. While epidemiological evidence associates particulate matter (PM) exposure with the development of pregnancy-specific cardiovascular diseases, the role of PM in the development of PPCM is currently unknown. Furthermore, nonclinical and clinical data indicate a role for pregnancy-driven hormonal changes, mainly through the cleavage of prolactin, in PPCM development and progression. In our laboratory, we have developed a pregnant rodent model of environmentally-induced systolic cardiac dysfunction, including significant reductions in ejection fraction and fractional shortening, reminiscent of the human PPCM phenotype. Therefore, the purpose of this study was to evaluate the role of pregnancy-induced hormonal changes on the cardiac perturbations observed in our model.

Using our custom whole-body rodent inhalation facility (IEStechno, Morgantown, WV), we exposed pregnant Sprague Dawley rats to nano-titanium dioxide (nano-TiO2) powder (Aeroxide, Parsippany, NJ), a surrogate for ultrafine PM. Rats were exposed from gestational day (GD) 5 – GD 19 to nano-TiO2 occupationally-relevant concentrations (9.72 mg/m3 ± 1.83). Biochemical and mechanistic evaluations will be conducted on GD 20 to evaluate pregnancy driven endocrine and cardiac changes. Care was taken to reduce diurnal hormone variability. Enzyme linked immunosorbent assays (ELISA) will be used to identify systemic levels of pregnancy related hormones (i.e., prolactin, estradiol, and progesterone) and the enzyme responsible for prolactin cleavage, Cathepsin D (CTSD) in plasma samples. While quantitative reverse transcription polymerase chain reaction (RT-qPCR) and western blot analysis will be used to evaluate gene transcription and proteins involved in hormone function and pregnancy induced cardiac remodeling in cardiac tissue samples. Interestingly, preliminary ELISA results reveal a significant reduction (-48%, p=0.04) in systemic prolactin levels. This decrease may be due to the proteolytic cleavage of prolactin to vasoinhibin, the vascular toxicant theorized to induce endothelial and cardiomyocyte damage in PPCM. Studies are currently underway to quantify plasma levels of CTSD to clarify its relationship with prolactin. Subsequent work will investigate local transcriptional changes and quantitative protein measurements of prolactin and CTSD in maternal cardiac samples to elucidate their role in our environmental model of PPCM.

Overall, the current data demonstrates a role for prolactin in our model of PPCM; however, mechanistic investigation is warranted to understand its role in the development and progression of PPCM . This work will continue to focus on local mechanistic changes occurring in the maternal heart at GD 20. Future studies will aim to investigate local concentrations of pregnancy hormones and CTSD in coronary effluent collected in ex vivo cardiac perfusion studies to identify clinical biomarkers for therapeutic intervention.

Program Affiliations: Joint Graduate Program in Toxicology

Funding: BMS Fellowship

Poster Category: Basic and Translational Science (e.g., bench research, animal studies, pharmacology, pharmacokinetic, dose-ranging studies)

Primary Author Title: Ph.D. Student

Abstract 45

Effects of Blocking PXR at Ser347 Phosphorylation Site on Bile Acid Metabolism in Diet induced Metabolic Dysfunction-associated Steatohepatitis in Mice

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Background and Purpose: The pregnane x receptor (PXR; NR1I2) is a ligand-activated transcription factor that regulates the expression of many genes involved in endobiotic and xenobiotic metabolism. Emerging evidence suggests that PXR plays a critical role in maintaining bile acid (BA) homeostasis by regulating genes associated with BA metabolism, conjugation, and transport. Disruption of BA homeostasis and/or PXR functions have been implicated in the progression of metabolic dysfunction-associated steatohepatitis (MASH). Recent studies have highlighted the importance of post-translational modifications, particularly phosphorylation, in modulating PXR activity. PXR has a conserved phosphorylation motif in its ligand-binding domain, Ser347/Ser350, in mouse and human PXR, respectively. Mutation of this motif affects human PXR transcriptional activity. However, the role of phosphorylation at this site in regulating PXRmediated hepatic functions, particularly regulation of BA homeostasis during MASH development, remains unknown. Our previous studies have investigated the effects of blocking PXR Ser347 phosphorylation on BA metabolism and signaling pathways during MASH development in mice. Because individual BA plays differential roles in regulating MASH
development, in the current study, we focused on determining the BA profiles.

Methods: Six-week-old male wild-type (WT) and PXR-KI mice (PXR Ser347Ala knock-in mutation) were fed either a high-fat diet (HFD; diet with 40 Kcal% palm oil fat, 20 kcal% fructose, and 2% cholesterol) or a chow control diet (CCD) for 16 weeks. BA profiling and quantification using LCMS/MS were conducted for serum, liver, and small intestine tissues.

Results: In serum, the total BA concentration was elevated while C4 concentration, a marker for the activity of CYP7A1, a rate-limiting enzyme for BA synthesis, was significantly decreased in the PXR-KI mice compared to WT mice on HFD, indicating altered BA metabolism. In WT mice, compared to CCD, HFD feeding resulted in a serum BA pool showing higher percentages of TMCA (9.09%), TUDCA (4.41%), and MDCA (17.05%) but reduced TDCA (3.85%). In the liver, there was an increase in TMCA (9.21%), b-MCA (18.68%), TUDCA (3.17%), and TCDCA (5.11%), but a decrease in TCA (45.76%). In the PXR-KI mice, compared to CCD, HFD feeding resulted in a more conjugated and hydrophilic serum BA pool with higher levels of primary BAs. The serum BA pool of PXR-KI mice on HFD compared to PXR-KI CCD showed higher percentages of TMCA (10.90%) and TCA (57.16%) but reduced w-MCA (0.82%), a-MCA (0.78%), b-MCA (5.68%), UDCA (0.66%), and CA (5.33%). In the liver, TCA percentages increased (62.99%) while TMCA (12.26%), TUDCA (2.68%), and w-MCA (0.31%) were decreased. In the small intestine, there was an increase in TMCA (20.91%), TUDCA (2.65%), and TCDCA (3.39%), and a decrease in w-MCA (0%), a-and b-MCA (0.43%, 0.77%). In contrast, compared to WT mice on HFD, PXR-KI mice on HFD revealed a serum BA pool with more TCA (57.16%) but reduced CDCA (0.69%), CA (5.33%), MDCA (2.82%), and TUDCA (2.12%). The liver BA pool showed elevated levels of TMCA (12.26%) and TCA
(62.99%) but decreased a-and b-MCA (1.19%, 8.27%). In the small intestine, there was a decrease in TMCA (20.91%) and TUDCA (2.65%) but increased CA (11.56%) percentages. This result suggests that in serum and liver of PXR KI HFD mice, the BA pool tends to be more conjugated and hydrophilic with higher levels of primary BAs, while the BA pool in the small intestine tends to be more unconjugated than that in WT HFD mice.

Conclusions: the study showed that blocking PXR Ser347 phosphorylation site in mice altered BA levels and composition in serum and liver, which was associated with more severe liver damage. This suggests an important role of phosphorylating PXR at Ser347 in regulating its function to maintain BA homeostasis and alleviate hepatotoxicity and MASH disease progression.

Program Affiliations: Joint Graduate Program in Toxicology
Funding: NA
Poster Category: Basic and Translational Science
Primary Author Title: Ph.D. Student

Abstract 46

Improved Transdermal Delivery of Diclofenac Sodium using Mango Seed Kernel Starch Nanoparticles

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Introduction:
The purpose of this study was to prepare and characterize diclofenac-containing nanoparticles obtained from starch isolated from mango seed kernels and compare the transdermal permeation of the drug-loaded nanoparticles with an ethanolic solution of diclofenac sodium using donated human cadaver skin and Franz diffusion cells.MSKS, an agro-industrial byproduct, is cost-effective and holds potential as a pharmaceutical excipient.
Methods:
Starch was extracted from mango seed powder using the alkaline method. It was identified by FTIR and characterized for physicochemical properties and compared with corn starch.MSKS nanoparticles (MSKSNPs) were prepared using mild alkali hydrolysis and ultra-sonication. Drug-loaded MSKSNPs were developed using the ethanol injection method using diclofenac sodium and characterized for physicochemical properties. The in vitro permeation testing (IVPT) was performed in vertical Franz diffusion cells (Logan, USA) to study the transdermal permeability of MSKSNPs using human cadaver skin using MSKSNPs aqueous solution as test and diclofenac ethanolic solution (DE) as control.
Results:
The % yield of MSKS varied with the solid-to-solvent ratio and drying method. The MSKS showed similar physicochemical properties to corn starch. The average particle size of drug-loaded nanoparticles was 140±3.6 nm with a polydispersity index of 0.42±0.03. Transmission Electron Microscopy confirmed their globular structure with sizes below 100 nm. X-ray diffraction showed a reduced crystal size of diclofenac (14 nm) compared to the pure drug (33 nm), confirming amorphous MSKSNPs. Drug-loaded MSKSNPs had an EE of 82.34±5.2%. The cumulative drug release at 6, 12, and 24 hours was 25.58±1.3 µg/cm², 59.68±2.98 µg/cm², and 127.46±6.37 µg/cm² for MSKSNPs and 2.36±0.11 µg/cm², 10.83±0.54 µg/cm², and 26.56±1.32 µg/cm² for DE. Diclofenac in the epidermis was 5.97±0.30 µg/mg (MSKSNPs) vs. 3.71±0.19 µg/mg (DE), and in the dermis was 0.82±0.04 µg/mg vs. 0.21±0.01 µg/mg, respectively.
Conclusion:
MSKSNPs were successfully synthesized and showed enhanced transdermal permeation compared with the ethanolic drug solution.

Program Affiliations: Graduate Program in Pharmaceutical Science

Funding: Funding for conducting this research was provided by the Center for Dermal Research, Rut-gers-The State University of New Jersey, 145 Bevier Road, Piscataway, NJ 08854.

Poster Category: Basic and Translational Science

Primary Author Title: Ph.D. Student

Abstract 47

Targeting the Ocular Surface for Prolonged Release: Synergistic Polymer Combinations for the Development of an Ocular Drug Delivery Vehicle (ODDV)

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Ocular drug delivery vehicles have been explored for the sustained release of ophthalmic formulations for the prevention of rapid clearance from the eye via the tear ducts or loss as a result of mechanical shear such as blinking. Contact lenses, implants, and in situ gelling systems have been researched for their promise to extend residence time of topical therapies on the eye.1-3 Mono- and divalent cations (Na+, K+, and Ca2+) and mucins present in tear fluid (MUC5AC and MUC2) and the ocular surface (MUC1, MUC4, MUC16) allow for activation of polymers to form a gel network and provide targets for mucoadhesive components. We set out to discover novel combinations of polymers whose gelling mechanisms took advantage of the physiologic properties of the ocular surface while producing a synergistic effect in the form of increases in rheological parameters. Simulated tear fluid (STF) was used to mimic the presence of cross-linking ions in human tear fluid. Early screenings gave multiple potential synergistic combinations in the form of large fold changes in the gel strength when compared to singular polymers. Elastic modulus (G') > viscous modulus (G") and frequency independence were used as benchmarks for candidate selection. Two lead candidates were examined using a full suite of rheological testing, including amplitude, frequency, and viscosity sequences. These candidates, carrageenan and hyaluronan, demonstrated significant differences ($p < 0.0001$) in gel strength in combination when compared to polymer alone. An increase in G' and viscosity of a gelling ocular drug delivery vehicle is optimal for the sustained release of its therapeutic cargo. Along with increased gel strength, shear thinning behavior allows the formulation to better resist removal by shear. Increasing viscosity and adhesion to the mucus membrane along the eye may also prevent nasolacrimal drainage, improving the pharmacokinetics of ophthalmic agents.

Program Affiliations: Joint Graduate Program in Toxicology

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Poster Category: Basic and Translational Science (e.g., bench research, animal studies, pharmacology, pharmacokinetic, dose-ranging studies)

Primary Author Title: Ph.D. Student

Abstract 48

Design of a SARS-CoV-2 papain-like protease inhibitor with antiviral efficacy in a mouse model

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Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) encodes two key proteases essential for its replication, making them prime targets for antiviral therapies. While drugs targeting the main protease (Mpro) are currently in use, alternatives are needed to combat emerging SARS-CoV-2 variants and drug-resistant mutations. The papain-like protease (PLpro) of SARS-CoV-2 is a promising yet challenging target for drug development. In our recent study, we utilized a newly identified Val70Ub binding site in PLpro to design and synthesize a series of biarylphenyl PLpro inhibitors. The co-crystal structures of eight lead compounds revealed that they bind to both the Val70Ub site and the established BL2 groove near the S4 subsite, further validating our design strategy. These lead compounds inhibited PLpro with inhibitory constant (Ki) values ranging from 13.2 to 88.2 nM. Among these, the in vivo lead Jun12682 demonstrated exceptional antiviral activity against SARS-CoV-2, including strains resistant to nirmatrelvir, with EC50 values between 0.44 and 2.02 μM. Jun12682 also exhibited favorable oral pharmacokinetics, with a bioavailability (F) of 72.8%, and showed no toxicity. In a mouse model of SARS-CoV-2 infection, oral administration of Jun12682 significantly improved survival, reduced body weight loss, decreased lung viral titers, and prevented lung tissue damage. These findings highlight the potential of biarylphenyl PLpro inhibitors as promising oral antiviral agents against SARS-CoV-2. Moreover, these inhibitors offer hope for the development of effective treatments for other coronaviruses and emerging viral threats, providing a vital tool in the ongoing fight against viral pandemics.

Program Affiliations: Graduate Program in Medicinal Chemistry

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Poster Category: Basic and Translational Science (e.g., bench research, animal studies, pharmacology, pharmacokinetic, dose-ranging studies)

Primary Author Title: Ph.D. Student

Abstract 49

Assessing Renoprotective Effect of Melatonin in Antibiotic-Induced AKI

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Globally, over 13 million cases of Acute Kidney Injury (AKI) are diagnosed yearly, and drugs are the primary factor of approximately a quarter of these cases. More specifically, antibiotics are implicated in nearly half of all drug-induced AKI diagnoses. It is typical for hospitalized patients to require one or multiple antibiotics, significantly increasing their risk of AKI. Approximately 14-37% of hospitalized adults will incur drug-induced, based on the definition upon diagnosis. The mechanisms of antibiotic-induced AKI are not clear but is suggested to induce mitochondrial dysfunction and oxidative stress in proximal renal tubular cells, leading to kidney damage.

Agilent Seahorse assays allow for real-time analysis of live cell bioenergetics, measuring oxygen consumption rate and extracellular acidification rate. Metabolic activity of tubular epithelial cells (HK-2 cell line) was assessed using a Seahorse xFe96 and oxygen consumption rate was measured using a Seahorse Mitochondrial Stress Assay kit. HK-2 cells were seeded at 4.0 x 10^4 cells/well and conditions included 24-hour pretreatment of cells with 16uM and 32uM melatonin, as well as 1mM, 2mM, and 4mM vancomycin. Likewise, cells were also subjected to co-treatment of each concentration of melatonin and vancomycin for 24 hours prior to Seahorse experimentation. Acknowledging melatonin as an antioxidant, we expect improved mitochondrial function of groups that were pretreated with the compound.

Following the 24-hour treatment of each condition, Seahorse results present improved bioenergetics of cells treated with both melatonin concentrations and 4mM vancomycin compared to cells treated with only 4mM vancomycin. This is exemplified by significance in comparable maximal respiration of these group. Significance was not found for comparable groups treated with 1mM vancomycin and 2mM vancomycin. A cell viability assay will also be conducted to assess the viability of cells treated with vancomycin and melatonin.

Program Affiliations: Graduate Program in Pharmaceutical Science

Funding: NA

Poster Category: Basic and Translational Science (e.g., bench research, animal studies, pharmacology, pharmacokinetic, dose-ranging studies)

Primary Author Title: Ph.D. Student

Abstract 50

Quantification of myoglobin oxidation as a surrogate for nitric oxide in the uterine vasculature of rats after particle inhalation throughout pregnancy: a novel detection method

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Purpose: The present study aims to use a multi-omics approach to investigate the mechanisms of chemotherapy-induced primary ovarian insufficiency (POI), a common side effect in young female cancer patients receiving gonadotoxic anticancer agents and marked by the depletion of ovarian follicles, mainly primordial follicles, before 40 years.

Methods: Five-day-old CD-1 female mice were intraperitoneally administrated with a one-time-clinically relevant dose of 10 mg/kg doxorubicin (DOX), a commonly used chemotherapeutic drug for multiple cancers, especially leukemic patients. The ovaries were collected 6 hours post-injection for multi-omics analysis, including transcriptomics, proteomics, phospho-proteomics, and metabolomics. Additionally, the ovaries treated with the same condition were dissociated into single cells for single ovarian somatic cells and oocytes SMART-Seq2 analysis.

Results: The ovary transcriptomic and proteomic analyses revealed the activation of the p53 signaling pathway following DOX treatment. The phosphor-proteomic analysis confirmed the activation of DNA damage response (DDR) signaling indicated by the hyperphosphorylation of ataxia telangiectasia mutated (ATM), checkpoint kinase 1 and 2 (CHEK1/2), and TAp63α, a p53 family member protein abundantly expressed in oocytes. Moreover, multi-omics analysis of ovaries identified several molecules and signaling pathways that have not been reported to regulate DOX-induced ovarian toxicities, including MRN complex, protein degradation, SWI/SNF chromatin remodeling complex, histone modification, and oxidative phosphorylation. The single-cell SMART-seq 2 analysis revealed distinctive transcriptomic changes between oocytes and pre-granulosa cells in response to DOX treatment. Several signaling pathways were selectively altered in oocytes or pre-granulosa cells. For instance, the NFκB signaling pathway was uniquely activated in oocytes, while the cytoskeleton-related pathways were exclusively changed in pre-granulosa cells.

Conclusion: The multi-omics analysis provides information on classic and novel signaling pathways crucial for elucidating chemotherapy-induced POI mechanisms. This is important for the development of therapeutic strategies to preserve young female cancer patients' fertility and ovarian endocrine functions.

Program Affiliations: Joint Graduate Program in Toxicology

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Poster Category: Basic and Translational Science (e.g., bench research, animal studies, pharmacology, pharmacokinetic, dose-ranging studies)

Primary Author Title: Ph.D. Student

Abstract 51

Insight on the Signaling Pathway of Ursodeoxycholic Acid (UDCA) using the Novel In Vivo Low Bile Acid Model

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Bile acids (BAs) are endocrine steroid acids essential in lipid absorption and the absorption of lipid soluble vitamins. BAs also act as endogenous signaling molecules that involve the modulate signaling pathways critical for cholesterol and BA homeostasis within the gut-liver axis. The purpose of this study is to investigate the role of individual BAs in modulating signaling pathways using novel Cyp7a1/Cyp7a1 double knockout (DKO) mice. Cyp7a1 and Cyp27a1 are genes essential for BA synthesis and therefore, a Cyp7a1/Cyp7a1 DKO mouse model is significantly deficient in endogenous BA. This model provides a unique opportunity to study the distinct roles of individual BAs on signaling pathways without the interference of an diverse endogenous BA profile in vivo. Within this novel low BA model, we hypothesize that cholic acid (CA), deoxycholic acid (DCA), and ursodeoxycholic acid (UDCA) BA feeding differentially activates FXR signaling, inflammation, and oxidative stress. In an acute feeding study, both male and female wild-type (WT) and DKO mice were administered diets containing physiological concentrations of the individual BAs – CA, DCA or UDCA. Gene expression and protein levels related to BA synthesis, homeostasis, transport, oxidative stress, and inflammation were measured, along with FXR activation markers. BA profiles in the liver, serum, gallbladder, and small intestine were analyzed using LC-MS/MS, and liver histology was performed to assess cytotoxicity. Ursodeoxycholic acid (UDCA) is a BA chosen in this feeding study due to its anti-apoptotic, anti-inflammatory, and protective effects on cholangiocytes. UDCA is a hydrophilic and cytoprotective secondary BA produced in humans and many other species. UDCA can also be pharmaceutically derived as an epimer of the hydrophobic primary BA chenodeoxycholic acid (CDCA) and is a first-line treatment for primary biliary cholangitis (PBC). The concentrations of UDCA used in this feeding study were 0.3 and 1%, both of which are physiological concentrations of UDCA. Preliminary data indicates that feeding DKO mice with UDCA decreases the expression of proinflammatory genes, compared to WT mice with slight species differences in males and females. Understanding these mechanisms can enhance our knowledge of BA-related pathophysiology, offering insights into liver diseases such as metabolic associated fatty liver disease (MAFLD) and PBC. The novel DKO mouse model, with a significantly reduced and proportionate BA pool, provides a promising tool for studying individual BA functions in vivo, facilitating targeted therapeutic strategies for BA dysregulation in human diseases.

Program Affiliations: Joint Graduate Program in Toxicology, Pharm.D. Honors Research Program, Pharm.D./Ph.D. Program

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Poster Category: Basic and Translational Science (e.g., bench research, animal studies, pharmacology, pharmacokinetic, dose-ranging studies)

Primary Author Title: Pharm.D/Ph.D. Student

Abstract 52

Cinnamon Flavoring in E-Cigarettes Impairs Mitochondrial Metabolism and Membrane Polarization in Precision Cut Lung Slices (PCLS)

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Harmful algal blooms (HABs) are increasing in prevalence and severity as a result of global warming, with rising temperatures creating more favorable conditions for the growth of cyanobacteria. HABs are capable of producing toxic metabolites, known as cyanotoxins. The most prominent class of cyanotoxins found in freshwater worldwide are microcystins. In order to exert their toxicity, microcystins must enter cells by active transport via organic anion transporter polypeptides (OATPs). While microcystins have been well characterized to be hepatotoxic and nephrotoxic, there is increasing interest in investigating microcystins as a reproductive toxin. In this study, we sought to assess the ability of MC-RR to enter and accumulate in human placental cells. For this purpose, we exposed three types of placental trophoblast cell lines – cytotrophoblast cells (JAR and BeWo) and extravillous trophoblast cells (HTR8/SVneo) – to increasing concentrations of MC-RR (0.1, 1, and 10 μM) over a duration of 3 hours. Western blotting was performed to observe the presence of MC-RR-bound proteins using a microcystin-specific antibody at 36 kDa. Significant uptake of MC-RR was observed at the highest concentration (10 μm) for all 3 cell lines. However, only the HTR8/SVneo cells exhibited significant uptake of MC-RR at the 0.1 μm concentration. Furthermore, when comparing uptake across the 3 cell lines. BeWo cells had 6.4% and 17.4% greater uptake of MC-RR (10 μm) than JAR or HTR8/Svneo, respectively. These results demonstrate that the HAB toxin, MC-RR, is a substrate for placental OATPs, and reveals that the placenta is a potential target of cyanotoxin injury. Ongoing studies are evaluating the susceptibility of human placenta cells to cyanotoxin cytotoxicity and identifying the specific OATP transporters responsible for uptake.

Program Affiliations: Joint Graduate Program in Toxicology, Pharm.D. Honors Research Program, Pharm.D./Ph.D. Program

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Poster Category: Basic and Translational Science (e.g., bench research, animal studies, pharmacology, pharmacokinetic, dose-ranging studies)

Primary Author Title: Pharm.D/Ph.D. Student

Abstract 53

Lipid nanoparticle delivery of TGF-β mRNA mitigates inflammation and tissue damage in an acute lung injury model

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Current approaches for treatment of ALI focus on inhalation delivery, which, effective for upper-airway disease, is inadequate for ALI since therapeutics do not readily reach the lower respiratory tract. Moreover, inhalation delivery of therapeutics for ALI to the upper airways have resulted in impaired inflammation resolution and fibrosis. To bridge this clinical gap, we have developed a novel lipid nanoparticle delivery system, with specificity to the lower airways after intravenous (IV) administration. Herein we have used the novel lipid nanoparticle for targeted mRNA delivery of a pro-resolution cytokine to the lung in a model of ALI induced by intratracheal bleomycin administration (ITB). One-component Ionizable Amphiphilic Janus Dendrimers (IAJDs) were co-assembled with transforming growth factor beta (TGF-β) mRNA for these studies. To assess delivery and toxicity, IAJDs/TGF-β mRNA (10, 20, 30 g) were administered to control BALB/c mice via retro-orbital injection. Lung, liver, spleen, and kidney were analyzed 24 hr later. IAJDs/TGF-β mRNA (10 g) were next administered IV to mice treated IT with PBS control or bleomycin (3 units/kg) to assess their ability to blunt ALI. Three days later, lung tissue and bronchoalveolar lavage fluid (BAL) were collected; hematoxylin and eosin-stained sections were examined for histopathology. Cells recovered from BAL and lung digests were analyzed by flow cytometry for changes in alveolar and interstitial macrophages. These studies demonstrate that we can successfully deliver the pro-resolution cytokine, TGF-β, to the lung parenchyma using mRNA packaged in a novel lower lung specific lipid nanoparticle delivery system. This resulted in reduced inflammatory macrophage activation and consequent ALI. These findings demonstrate that mRNA can be selectively directed to the lower lung resulting in target gene translation and protein expression. The fact that IV administered IAJDs/TGF-β mRNA reduced inflammation and ALI suggest a highly novel approach to mitigating lung injury induced by pulmonary toxicants.

Program Affiliations: Joint Graduate Program in Toxicology, Pharm.D. Honors Research Program, Rutgers Honors College, Pharm.D./Ph.D. Program

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Poster Category: Basic and Translational Science (e.g., bench research, animal studies, pharmacology, pharmacokinetic, dose-ranging studies)

Primary Author Title: Pharm.D/Ph.D. Student

Abstract 54

Role of PGC-1β in Macrophage Proresolution Activation Following Ozone Exposure

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Background and Purpose: Inhalation of ozone causes airway inflammation and exacerbation of preexisting lung disease in both healthy and susceptible groups. Lung macrophages play a key role in the response to ozone-induced lung injury by orchestrating the initiation and resolution phases of inflammation. These distinct activities are mediated by proinflammatory and proresolution macrophages, respectively. The transcriptional coactivator PPARγ coactivator-1β (PGC-1β) modulates the activity of transcription factors involved in proresolution activation and oxidative hosphorylation, a metabolic pathway involved in proresolution activation. We previously demonstrated loss of PGC-1β reduces macrophage spare respiratory capacity, a parameter of mitochondrial oxidative phosphorylation. Thus, we hypothesized PGC-1β promotes macrophage proresolution activation following ozone exposure.

Methods: A conditional Cre-lox knockout mouse model in which PGC-1β is deleted in CX3CR1+ lung macrophages was used for our studies. CX3CR1-Cre; PGC-1βflx/flx (PGC-1β KO) and PGC-1βflx/flx (WT) male and female mice were exposed to ozone (0.8 ppm, 3 hr). Seventy-two hours later, lungs were digested and CX3CR1+ macrophages collected by magnetic separation. Total RNA was extracted in TRIzol (Thermo Fisher), and cDNA synthesized using a qScript cDNA synthesis kit. Real-time PCR was performed using TaqMan master mix and primers for Cpt1a, Cd163, Retnla, Gapdh, Actb, and 18s rRNA. Gene expression changes were normalized to geometric mean of Gapdh, Actb, and 18s rRNA expression.

Results: Expression of Cpt1a, a key enzyme enabling transport of fatty acids into the mitochondria, was reduced following ozone exposure; loss of PGC-1β attenuated this response. Ozone exposure also caused a reduction in expression of Cd163, a marker of proresolution activation; this response was partially reduced in mice lacking PGC-1β. In male, but not female mice, exposure to ozone resulted in upregulation of Retnla, another marker of proresolution activation; this was attenuated by deletion of PGC-1β.

Conclusion: Taken together, these data suggest that ozone alters macrophage oxidative metabolism in a PGC-1β dependent manner; moreover, the development of proresolution macrophages requires the activity of PGC-1β

Program Affiliations: Joint Graduate Program in Toxicology, Pharm.D. Honors Research Program, Pharm.D./Ph.D. Program

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Poster Category: Basic and Translational Science

Primary Author Title: Pharm.D. Student

Abstract 55

A Novel Function of the KCNB1 Channel in Regulating Hypothalamic Activity

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Data shows that the KCNB1 channel is expressed in POMC neurons in the Arcuate Nuclei and seems essential in managing and regulating leptin-dependent metabolic processes. We find phenotypic and metabolic abnormalities due to KCNB1 truncation (Null). We hypothesize that KCNB1 truncation leads to hypothalamic disfunction and leptin metabolism alterations. We think it does that by interacting with leptin receptor (LepR). This project aims to investigate the role of the KCNB1 in Leptin-dependent mechanisms, behavioral and anatomical.

Program Affiliations: Aresty Research Program

Poster Category: Basic and Translational Science

Primary Author Title: Pharm.D. Student

Abstract 56

Computational Modeling of Sulforaphane: A PK/PD Approach to Gene Expression and Dosage Optimization

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Pharmacokinetic (PK) and pharmacodynamic (PD) modeling software plays a crucial role in optimizing drug dosing strategies and understanding mechanistic pathways. This study employs a two-compartment PKPD modeling approach to analyze the time-dependent expression of key antioxidant and detoxification genes following sulforaphane (SFN) administration. Using specialized modeling software, we generated concentration-time curves and mRNA expression profiles for NQO1, Keap1 (HO-1), Nrf2, GPx1, Maf, and GSTT1. Simulation tools were utilized to predict dosage modifications' impact on gene expression and therapeutic efficacy. The study highlights the application of computational modeling in drug development, enabling precise simulation of drug effects and guiding future research in oxidative stress-related therapies.

Program Affiliations: Graduate Program in Pharmaceutical Science

Poster Category: Basic and Translational Science

Primary Author Title: Pharm.D. Student

Abstract 57

Mucin Response Is Mediated by Ozone and Sex Independently

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Ozone (O_3) is a highly reactive environmental toxicant when inhaled causes injury to the lungs. In these studies, we hypothesize that inhaled O_3 induces changes in GI structure and function. We evaluated GI toxicity in male (M) and female (F) C57BL6 mice (age 17-18 weeks) following acute (24hr) pulmonary exposure to 0.8ppm O_3 exposure or air (AIR) for 3 hours acute (A), or a 1.5 ppm O_3 or AIR for 2 hours twice weekly for 6 weeks chronic (C). Distal colon was collected, washed with PBS, and prepared for histology. Goblet cells were visualized using Alcian blue/periodic acid-Schiff stain (ABPAS), which binds to mucins. ABPAS analysis revealed that O_3, after 24hr and 6 weeks, caused mucosal surface erosion and enlarged goblet cells in both male and female colon. Male (O_3MA and O_3MC) and female mice (O_3FA and O_3FC) showed a significant increase in goblet cell number following both acute and chronic O_3 exposure compared to AIR (AirMA, AirMC, AirFA and AirFC). Interestingly, no statistically significant differences in the females were seen following either 24hr or 6wk exposure to O_3 compared to AIR. O_3 induced a significant increase in the number of colonic goblets per crypt as follows: O_3MC > O_3MA > AIRMC > O_3FC = O_3FA = AIRFC > AIRMA > AIRFA ($p \leq 0.05$, n=9 crypts per animal, 48 male and 48 female). Taken together, these findings suggest that inhaled O_3 induced damage to colonic goblet cells more so in males compared to females. These observations following both an acute and chronic exposure to O_3 in males, suggests that mucin response in the colon is independent of sex. Further studies are needed to investigate observed sex differences, which may be important to better understanding gut defensive mechanisms against O_3.

Program Affiliations: Rutgers Honors College

Funding: NIH Grant RO1ES004738

Poster Category: Basic and Translational Science

Primary Author Title: Pharm.D. Student

Abstract 58

Impacts of estrogen gender affirming hormone therapy on gut mucosal properties

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The effects of estrogen gender affirming hormone therapy (E-GAHT) on gut homeostasis are unknown. Forty C57BL6 male mice were grouped (n=10/group) as follows: 1) intact with oil, 2) intact with estradiol benzoate (EB, 150 µg/kg) and finasteride (F, 0.25 mg/kg), 3) orchiectomized (ORX) with oil; and 4) ORX with EB (150 µg/kg), daily oral administration for 8 weeks. Ileum and colon were collected, washed with PBS, and prepared for histology and immunohistochemistry. Structural distortion of ileal and colonic crypts with inflammatory cell infiltrate was observed in all treatment groups except Intact:oil. Goblet cells were enumerated using Alcian Blue Periodic Acid Schiff (ABPAS) which binds to mucin; acidic mucins stain dark blue and acidic/neutral mucins stain purple. ORX:EB mice had significantly increased total goblet cells per colon crypt than Intact:oil, Intact:EB+F and ORX:oil ($p \leq 0.05$). Increased numbers of acidic goblet cells were observed in the ORX:EB compared to other treatment groups. Mucin-2, a gel-forming mucin, was expressed in the gut goblet cells and was increased in the Intact:oil > Intact:EB+F > ORX:EB > ORX:oil in the ileum, while in the colon Intact:EB+F > Intact:oil > ORX:EB > ORX:oil. Lysozyme, an anti-microbial protein essential for innate immunity is produced by Paneth cells of the ileum. Expression of lysozyme was as follows: Intact:EB+F > Intact:oil > ORX:EB > ORX:oil, interestingly lysozyme expression was observed in the lumen of the colon, Intact:oil > ORX:oil > Intact:EB+F > ORX:EB. Taken together these data suggest that ORX:EB induces changes in the proteins essential for the protection of the gut compared to E-GAHT. Further studies will investigate the administration of hormone therapy by injection which may bypass the digestive system and manifest with different outcomes.

Program Affiliations: Pharm.D. Honors Research Program, Rutgers Honors College

Funding: Rutgers University Faculty Funds

Poster Category: Basic and Translational Science

Primary Author Title: Pharm.D. Student

Abstract 59

The Relationship Between the Domestication of Dogs and Current Veterinary Anxiolytics

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Originating from gray wolves, dogs have undergone significant neurological and behavioral changes through centuries of human-animal interaction and selective breeding. Some consequences of domestication, in terms of behavior, include increased attention and docility towards humans and a wider range of emotional expression. These behavioral changes allow for optimized human interaction. However, these changes may also induce anxiety disorders–such as separation anxiety–in dogs. Considering the impact of domestication on neuroanatomy, these disorders may have a neurological basis. For example, the influence of domestication on canine emotional range has resulted in increased signaling of glutamate receptors compared to wolves, which may lead to increased glutamate levels. Increased glutamate is implicated in stress responses and anxiety disorders, potentially contributing towards the development of anxiety disorders in domesticated dogs. However, it is worth noting that other stimulatory neurotransmitters may carry importance when discussing anxiety; stimulatory neurotransmitters and their deficiency or abundance often share similarities in their symptomatology. Therefore, anxiolytics for dogs will often target other stimulatory neurotransmitters as well.

This study reviews the implications that neurological and behavioral changes arising from domestication have for veterinary medicine. Multiple anxiolytics that are currently marketed for dogs were evaluated. It was found that most anxiolytics enable other neurotransmitters that oppose glutamate, such as GABA (benzodiazepines), or act as GABA analogs (gabapentin). Stimulants, such as those targeting serotonin (trazodone, fluoxetine), are also used. Afterwards, we discussed adverse effects and possible methods of mitigation for these effects. It was found that, despite their intended anxiolytic properties, some of these drugs caused increased activity and agitation. There was also a general lack of clinical studies and long-term follow-ups for the use of these medications in dogs. Further research will be needed to explore the mechanisms behind these side effects and the long-term impact of current anxiolytics for dogs.

Program Affiliations: AAPP Student Journal Club

Poster Category: Basic and Translational Science

Primary Author Title: Pharm.D. Student

Abstract 60

Validating Gene Maps for Pathway and Target Discovery Using AlphaFold and Deep Learning Models

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The rise of artificial intelligence has revolutionized pharmaceutical and academic research, particularly in protein modeling. AlphaFold, a deep learning program trained on thousands of experimentally determined protein structures, predicts highly accurate tertiary structures and was awarded the 2024 Nobel Prize in Chemistry. At Rutgers University's Center of Alcohol Studies, the Genetic Analysis ("Project GEAN") Research Project leverages this technology to investigate a potential biological pathway linking SIP30 and RSEP7, genes implicated in neuropathic pain. Using Ingenuity Pathway Analysis (IPA), researchers have identified 5–7 intermediary genes and aim to evaluate their interactions with SIP30 through deep learning tools like NeuroSnap, which hosts AlphaFold and RosettaFold. Models are ranked by mean pLDDT values, ensuring accuracy through cross-validation. Preliminary findings indicate significant structural differences between known interactants and non-interactants, supporting AI-driven modeling as a powerful tool for pathway validation and therapeutic discovery. Future experiments, including wet lab validation with a Chronic Constriction Injury-Induced Neuropathic Pain Mouse Model, will further confirm these insights.

Program Affiliations: Rutgers Honors College

Funding: NeuroSnap, the online platform hosting the AI tools used in the project, sponsored our research by providing free access to their services. They also collaborated by offering guidance and expertise on utilizing these tools effectively.

Poster Category: Basic and Translational Science

Primary Author Title: Pharm.D. Student

Abstract 61

Comprehensive Review of Antiepileptic Drug Efficacy and Ethical Considerations in the Management of Refractory and Non-Refractory Epilepsy

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Background: Epilepsy affects over 50 million people worldwide, making it one of the most common neurological diseases. Patients diagnosed with epilepsy are treated by antiepileptic drugs (AEDs) as their primary treatment, but only about 60-70% of patients achieve seizure freedom. Of the patients who develop refractory epileptic seizures, formally called drug-resistant epilepsy (DRE), they are typically indicated for neurostimulation or surgical resection as follow-up treatment.

Objective: The author seeks to synthesize the available effectiveness/tolerability rates of older and newer AEDs as first-line monotherapy and adjunctive medications and provide an ethical assessment of follow-up invasive therapies (surgery or neurostimulation) for patients with DRE.

Methods: The author performed a search on PubMed, ClinicalTrials.gov, Medline, Scopus, and Web of Science databases, filtering explicitly for randomized controlled trials (RCTs), meta-analyses, systematic reviews, and observational studies for 20 pharmacological treatments for focal, generalized, syndromic, and refractory epilepsy. The outcomes measured included seizure reduction, responder rates (≥50% seizure reduction), seizure freedom rates, cognitive/mood adverse effects, and treatment tolerability.

Results: Older AEDs (valproate, carbamazepine, ethosuximide) remain excellent first-line treatments, with freedom from seizures in approximately 50-60% of new-onset epilepsy. Newer AEDs (lamotrigine, levetiracetam, oxcarbazepine) have similar efficacy but improved tolerability profiles, particularly for cognitive and mood side effects. Add-on AED treatments for drug-resistant epilepsy have small incremental efficacy (20-40% responders). New AEDs approved within the last several years, such as cenobamate, cannabidiol, and fenfluramine, demonstrate very significant reductions in seizure frequency in previously drug-resistant epileptic syndromes like Lennox–Gastaut and Dravet syndromes.

Conclusions: No newer AED is consistently better than older AEDs in attaining seizure remission, but newer medications have better safety and tolerability. Ethical practice requires early discussion of invasive options, such as surgical resection or neurostimulation, weighing efficacy against patient wishes, risks, and quality of life.

Program Affiliations: Independent Study

Funding: NA

Poster Category: Basic and Translational Science

Primary Author Title: Pharm.D. Student

Abstract 62

Exploring the Effects of Edge Activators on Liposomal Particles for Transdermal Drug Delivery

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Purpose: This study explores the interaction between diclofenac sodium and various edge activators, such as Tween 80, Tween 60, and Tween 20 in the development of deformable liposomes for transdermal drug delivery. These surfactants reduce surface tension, enhancing drug permeation, absorption, and therapeutic efficacy while minimizing side effects in transdermal formulations.

Method: Transfersomes were prepared using the thin film hydration method using Rotavapor R-100 (Buchi Corporation, Switzerland. Four formulations (F1-F4) were formulated using no surfactant, Tween 20, Tween 60, and Tween 80 respectively. Zeta potential and particle size were conducted using a Zetasizer (Malvern Instruments, Malvern, UK). An In Vitro Permeation Test was performed using dermatomed human cadaver skin on a vertical glass Franz diffusion cell (Logan, USA).

Results: The average zeta potential and particle size were as follows: F1 (-17.7 ± 0.06 mV, 115.7 ± 0.95 nm), F2 (-6.50 ± 0.24 mV, 112.7 ± 6.38 nm), F3 (-9.62 ± 0.41 mV, 77.6 ± 0.03 nm), and F4 (-6.83 ± 0.43 mV, 71.2 ± 0.33 nm). The cumulative drug release after 48 hours for F1, F2, F3 and F4 was found to be 10.07 ± 0.94 μg/cm^2, 8.13 ± 0.97 μg/cm^2, 29.78 ± 14.60 μg/cm^2, and 12.33 ± 0.70 μg/cm^2 respectively. The amount of drug found in the epidermis for F1, F2, F3, and F4 formulations was found to be 0.11± 1.31 μg/ mg of skin, 0.10 ± 0.09 μg/ mg of skin, 0.19 ± 0.07 μg/ mg of skin, 0.12 ± 0.02 μg/ mg of skin respectively. Epidermal retention was highest in F3 (0.19 ± 0.07 μg/mg), while F1 had the highest dermal retention (0.07± 0.01 μg/mg).

Conclusion: The edge activators demonstrated varying effectiveness in stabilizing diclofenac sodium, with Tween 60 exhibiting the highest potential of permeation in epidermis. By enhancing the solubilization of diclofenac sodium within the skin, Tween 60 facilitated a higher drug release into the receptor compartment of the Franz diffusion cell.

Program Affiliations: Pharm.D. Honors Research Program

Poster Category: Basic and Translational Science

Primary Author Title: Pharm.D. Student

Abstract 63

Assessing the Efficacy and Drug-Drug Interactions of Kava, Valerian, and Ashwagandha in Psychiatric Pharmacy Practice

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Anxiety disorders are common mental health conditions that disrupt emotional well-being and daily functioning. The purpose of this literature review is to evaluate the efficacy and potential use of herbal alternatives, including kava, valerian, and ashwagandha, for managing anxiety disorders. The key terms included kava, valerian, ashwagandha, anxiety, SSRIs, and benzodiazepines. Kava effectively reduces anxiety, as shown in clinical trials using the Hamilton Anxiety Rating Scale (HAM-A). Participants experiencing a moderate to severe level of DSM-IV anxiety revealed a reduction of 8.5 points (kava) with a large effect size (d = 0.82). Side effects include hepatotoxicity, headaches, and Kava dermopathy. Some countries previously banned the use of kava but have now reinstated it with warning labels added. Valerian moderately reduces psychic factors in generalized anxiety disorder (HAMA-A: T = 5.50, 3.50, 5.00). Side effects include dizziness, drowsiness, and gastrointestinal discomfort. The results of an ashwagandha study showed a statistically significant anxiety reduction (13.76 ± 2.17 to 9.09 ± 2.97) within the treatment group, as measured by the GAD-7-item scale. Ashwagandha may enhance the hypoglycemic effects of diabetic medications. Demonstrating the efficacy of herbal agents is challenging due to several factors. Patients should be aware that these remedies are not FDA-regulated, may cause side effects, carry risks of contaminants, and can interact with other medications. Since current studies remain preliminary, further research is essential to evaluate the potential of herbal alternatives in treating anxiety disorders.

Program Affiliations: None

Poster Category: Basic and Translational Science

Primary Author Title: Undergraduate Student

Abstract 64

Cocaine Exposure Alters Orexin System Function and Sleep: Pharmacological Reversal with Suvorexant

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Cocaine use disorder (CUD) represents a significant public health challenge, because of a lack of effective treatments. Cocaine abstinence is associated with severe sleep disturbances, often cited as a primary driver for relapse. Thus, interventions that normalize sleep disturbances represent a potentially novel approach to treating CUD. To this end, the brain's orexin (hypocretin) system, a key regulator of both reward and arousal, represents a potential therapeutic target, as existing medications that block orexin receptor signaling are effective sleep aids. This study examines how cocaine affects orexin function and whether orexin receptor antagonists can normalize sleep and reduce drug seeking during cocaine abstinence.

Male and female SD rats were trained to develop a conditioned place preference (CPP) for one side of a two chamber system that was paired with systemic injections of cocaine (10 mg/kg) while the other side was paired with saline (4x cocaine, 4x saline). A control group received saline in both chambers. In Experiment 1, rats were sacrificed 1d following 48h cocaine abstinence and qPCR was used to quantify pre-pro orexin levels (hypothalamus) and orexin receptor expression (ventral tegmental area, VTA; dorsal raphe, and other arousal regions). In Experiment 2, cocaine CPP was extinguished by giving rats access to both chambers for 5d without drug exposure. Across extinction, electroencephalography (EEG) and electromyography (EMG) recordings during the inactive period measured sleep. Rats were treated with the dual orexin receptor antagonist suvorexant (30mg/kg; p.o.) or vehicle 30mins before the inactive period.

Rats in Experiment 1 that developed a cocaine CPP exhibited higher orexin 1 receptor expression in VTA, but not in other brain regions, compared to saline controls. Rats in Experiment 2 exhibited sleep disturbances during cocaine abstinence (extinction), characterized by reduced time spent in non rapid eye movement (NREM) sleep and increased time spent awake; these outcomes were normalized by suvorexant administration, which was also associated with reduced cocaine seeking during daily extinction sessions.These data suggest that reducing orexin signaling during cocaine abstinence normalizes sleep and reduces drug seeking, identifying the orexin system as a promising therapeutic target in CUD.

Program Affiliations: Summer Undergraduate Research Fellowship

Poster Category: Basic and Translational Science

Primary Author Title: Undergraduate Student

Abstract 65

CO2-Induced Metabolic and Inflammatory Dysregulation in Neutrophils: Implications for Cognitive Dysfunction

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Background and Purpose: Carbon dioxide (CO2) exposure up to 5000 ppm is considered non-toxic; however, acute inhalation of CO2 has been linked to Polymorphonuclear cell (PMN) activation and cognitive decline. We have shown that CO2 exposure in humans increases neutrophil superoxide production and inhibits PMA induced-oxidative burst. We hypothesize that CO2 exposure modulates neutrophil metabolism, causing the generation of ROS and stimulating inflammatory response, contributing to cognitive dysfunction. This study is to determine the pathways impacted by CO2 in CO2-exposed subjects and investigate the effect of CO2 on neutrophil oxidative burst and metabolic functions.

Methods: Human exposure and RNA sequencing, the subjects were exposed to 600 ppm (control) or 2500 ppm CO2 in chambers for 2hrs. Peripheral blood was obtained from the subjects 4 h post-exposure. Total RNAs from peripheral blood mononuclear cells (PBMCs) were isolated and subjected to RNA sequencing analysis. Retinoic acid differentiation of HL60 cells were carried out to measure effect of CO2 on neutrophil metabolisms such as glycolysis, mitostress test and oxidative burst. HL-60 were differentiated in culture for 5 days with 1 μM all-trans retinoic acid and differentiation was confirmed using Giemsa staining to visualize multi-lobed nuclei. Metabolism in the differentiated HL-60 was assayed using the XF96 seahorse efflux analyzer. Immunocytochemistry (ICC) was performed for phospho-p47phox (Ser370) and membrane separation was also performed and western blot was performed for p47 phox to assess NADPH oxidase activation. Statistical analysis was performed using one-tailed Student's t-tests with $p< 0.05$. In addition, RNA sequencing was conducted on PBMCs collected from human participants exposed to 2500 ppm CO2 versus 600 ppm (control) [Z score, $p<0.05$)].

Results: PBMC RNA sequencing data demonstrate that CO2 exposure in humans regulates multiple pathways; stimulating neutrophil degranulation genes (ADAM10 and ATP11A), inhibiting ROS detoxification (SOD2), upregulating inflammatory signals (TNF and CCL22), enhancing kinases (MAP2K7, PIK3C2B), and mitochondrial electron transport chain (ETC) enzymes (CoQ10A) while inhibiting phosphofructokinases (PFKBP4). CO2-exposed HL60 demonstrated a significant increase in basal OCR (Air: 2.3 ± 0.7 pmol/min, CO2: 3.6 ± 1.2 pmol/min, $p < 0.05$), indicative of increased non-mitochondrial respiration. Furthermore, oxidative burst (Area under curve) in response to PMA was significantly reduced by CO2-exposure (Air : 5283 ± 626 pmol/min, CO2 : 3969 ± 701 pmol/min, $p < 0.05$). ICC showed increased p-p47phox in the membrane of CO2-exposed HL60 compared to Non-CO2 group. Membrane separation through ultracentrifugation was performed on HL60 and there was increase in presence of p47 phox in the membranous portion. These data are consistent with NADPH oxidase activation.

Conclusion: CO2 exposure in humans results in significant alterations in both inflammatory and metabolic gene expression. In particular, reduction in glycolytic (PFKBP4) and increased ETC expression (CoQ10A). Interestingly, the neutrophil cell model HL-60 upon direct exposure to CO2, where there was an apparent shift to non-mitochondrial metabolism. In conjunction, with these metabolic changes we observed an increase in membrane association and phosphorylation of p47 phox, indicating that CO2 exposure activates NADPH oxidase in the absence of stimulation. We think these bioenergetic changes are mirrored in humans upon CO2 exposure and may be a component of the loss of cognitive function.

Program Affiliations: Joint Graduate Program in Toxicology

Poster Category: Clinical Science

Primary Author Title: PhD Student

Abstract 66

A Benchmark Survey of "Impostor Syndrome" in Pharmacy Students, Post-doc PharmD Industry Fellows, and Post-doc PharmD Residents

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Purpose: To assess levels of impostor syndrome (IS) among Doctor of Pharmacy students and post-graduate trainees at different educational stages, analyzing various demographic subgroups to add data to the limited understanding of IS in pharmacy.

Methods: An anonymous survey was administered to approximately 1,500 PharmD students, industry fellows, and teaching residents at Rutgers University in April 2024. The survey included demographic questions, the 20-item Clance Impostor Phenomenon Scale (CIPS), and questions about self-identified IS types and coping behaviors. CIPS scores categorized respondents as having few (≤40), moderate (41-60), frequent (61-80), or intense (≥81) IS experiences.

Results: 227 individuals (15.1% response rate) completed the survey. Most were 18-29 years old (96.1%), female (71.8%), and Asian (44.9%) and/or Caucasian (39.6%). Key findings included: Over 75% experienced frequent or intense IS feelings (mean CIPS: 69.5). Residents had the highest mean CIPS score (75.9), followed by students (70.2) and fellows (66.7). No significant differences were found across gender, age, marital status, or employment status. African Americans showed moderate IS feelings (CIPS: 58.1), while other racial/ethnic groups showed frequent IS feelings (CIPS: 65.5-72.8). Most common IS types were expert (32.7%) and perfectionist (32.2%). Most common coping mechanisms were "holding back" (70.3%) and "over preparing" (63.5%). Higher IS familiarity correlated with higher CIPS scores

Conclusion: Frequent IS feelings were observed across pharmacy training programs and demographic subgroups, except for African Americans. The diversity in IS types and coping behaviors shaped individual experiences, highlighting the need for additional research.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Industry Fellow

Abstract 67

An Open-Label, Phase I, Single-dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Fexofenadine Topical Lotion 1% in Normal Healthy Volunteers

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Background: Atopic Dermatitis (AD), or eczema, affects ~230 million individuals worldwide annually, with up to 20% of children and up to 3% of adults affected. The current treatment for mild and moderate forms often involves topical corticosteroids, which have limitations.Fexofenadine is an FDA-approved over-the-counter antihistamine product with a 25-year safety history and the capability to modulate multiple proinflammatory cytokines involved with AD pathophysiology. This study assesses the safety, tolerability and pharmacokinetic (PK) profile of fexofenadine HCl topical lotion 1.0% (FEX).

Methods: This open-label Phase I study included 12 healthy males aged 18-45 who received a single application of 11 g of the lotion to cover 54% of their body surface area. Safety, sensorial, and tolerability assessments occurred throughout the study period. Blood sample collection occurred at (0 hours [pre-dose] and at 1, 4, 8, 12, 16, 24, 36, 48, 60 and 72-hours post-dose) after application for assessment of PK.

Results: Over 90% of participants reported no adverse reaction or tolerability issue. One participant reported mild topical discomfort involving itch, which was transient and resolved. PK parameters included mean C max at 1.841 +/- 1.180 ng/mL, T max at 12.31 +/- 6.6 hr and AUC 0-t of 12.406 +/- 18.576 ng*hr/mL.

Conclusion: The single-dose administration of FEX was safe, well-tolerated, showed limited systemic absorption, and supported once-daily dosing. These observations will serve as the basis for further clinical development.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Industry Fellow

Abstract 68

A Literature Review of the Underrepresentation Within the Hispanic Population in Clinical Trials

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Purpose: This article looked at various disease states including cancer, liver disease, diabetes and cardiovascular diseases. The Hispanic population accounts for the second largest racial group in the nation according to the 2020 US Census and is the largest minority group within the US. Social determinants also play a role when it comes to the poor outcome and increased rate of mortality within this population such as being uninsured, poverty, limited access to healthcare, health literacy, etc. Some of the underrepresentation of this population in clinical trials also constitutes for under-reporting of proper ethnicity, instead classification of participants is attributed to race. The FDA guidance document for industry focuses on Diversity Action Plans for the enrollment and retention of a clinically relevant study population, to help ensure adequate representation of study participants that reflect various age groups, sexes, and racial and ethnic demographic characteristics. The purpose of this research/review article is to discuss the various health disparities associated with the underrepresentation of the Hispanic population in clinical trial.

Methods: This review reviewed google scholar and utilized the CDC website to obtain information especially on prevalence and statistics. American Heart Association and National Institutes of Health was also used to search data, as well as the FDA guidance document for industry titled Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies.

MeSH headings used: common disease states within Hispanic population, underrepresentation of Hispanics in clinical trials

Results: Most of the articles were dated between 2016-2022, but there was a older article from 2006 and another from 2011 that was used as supplemental material. I reviewed about 6 different websites and 8 journal articles. The websites including CDC, AHA, etc showed supporting information about the common disease states seen within the Hispanic population whereas the journal articles described each disease state and its impact on the targeted population along with their underrepresentation in clinical trials.

Conclusion: Data and guidelines suggest Hispanics have the same outcome as non-Hispanics regarding current therapy for indicated disease states (cancer, liver disease – NFLD, cardiovascular disease and diabetes) despite their increased risk of developing the disease. The FDA discusses their action plans as of June 2024.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Industry Fellow

Abstract 69

Landscape of Clinical Trial Diversity in Patients with Heterozygous Familial Hypercholesterolemia (HeFH): Findings and Future Perspectives

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Purpose: Heterozygous familial hypercholesterolemia (HeFH) is a genetic disease with extremely elevated low density lipoprotein cholesterol (LDL-C) levels, increasing the risk of cardiovascular complications. The prevalence of FH is similar between the sexes at 0.4% while Blacks have the highest prevalence at 0.5%. These are similar in the pediatric population. Undiagnosed FH costs 16 years of life expectancy and females are often diagnosed four years later than males. Females and Blacks are less likely to be on guideline therapy and at goal LDL-C. This literature review aims to determine whether clinical trials in patients with HeFH represent the true HeFH population.

Methods: A literature review was performed to characterize the demographics of completed clinical trials and compare their diversity factors to the current HeFH population. The literature review was executed by examining publicly available data sources in ClinicalTrials.gov. First, the search term “familial hypercholesterolemia – heterozygous” was used to filter results by condition. In the treatment section, “statin” was entered to incorporate trials that included this first-line treatment option or as a background lipid-lowering therapy for participants with HeFH. However, trials with other types of lipid-lowering therapies were not excluded. In the study phase section, “phase 3” and “phase 4” trials were selected. Only “interventional” trials “with results” were included. Trials that met these criteria were manually screened to exclude those that did not have participants with HeFH as the primary population or include racial demographics in the results. This was completed by reviewing the “results posted” tab under the “baseline characteristics” section, or if missing, in the “results” section of the publication.

Results: An initial 79 trials populated when “familial hypercholesterolemia – heterozygous” was chosen as the condition of interest. After filtering for studies that included “statin,” 28 trials emerged. When “phase 3” and “phase 4” trials were selected, 20 trials resulted. The results were narrowed to 13 trials by including only “interventional” trials “with results.” Two trials were excluded for not having participants with HeFH as the primary population while one was excluded for lacking racial demographics. Ultimately, 10 trials were included with start dates from August 2005 to May 2018. Calculations were performed with 3,176 participants across the 10 included trials. Findings were similar when assessed by population age and lipid-lowering therapy of interest. The following lipid-lowering therapies were evaluated: five trials with proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors, three trials with statins, one trial with a cholesteryl ester transfer protein (CETP) inhibitor, and one trial with a bile acid sequestrant. Adults were included in five of the trials with 2,133 participants while the others included children with 1,043 participants. A total of 1,420 participants (45.4%) were reported as female. Only six trials reported racial categories other than White, so from those trials, 20 participants (1.4%) were reported as Black.

Conclusion: The results demonstrated that 45.4% of participants enrolled in HeFH trials are female and 1.4% are Black while real world data reveals females account for 49.5% and Blacks account for 17.8% of HeFH diagnoses. Several trials either did not include racial demographics other than White or failed to include a representative Black population. There is an unmet need in defining the HeFH burden in underrepresented groups. Future clinical trials should follow diversity plans with racial goals reflective of the HeFH population and aim to recruit an equal sex ratio. Regardless of outcomes, all sex and racial data should be reported.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Industry Fellow

Abstract 70

Characterizing Emergency Department Evaluation of Blood Culture Growth Following Patient Discharge

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Blood cultures are commonly ordered for patients in the Emergency Department (ED). Patients are often discharged prior to final culture result for various reasons including increasing competition for hospital space. This study characterizes Emergency Medicine (EM) provider decision regarding blood culture growth following patient discharge from the ED and examines consequent patient outcomes.
Blood cultures obtained for patients discharged from the ED with subsequent microbial growth between June 1st 2022 and October 28th, 2024 were reviewed for inclusion. Patients 18 years and older with microbial growth on blood culture after ED discharge were included. Patients with history of bacteremia within 30 days and patients evaluated in the pediatric ED were excluded. Patient action and outcomes based on patient action were evaluated as secondary endpoints.

Ninety eight blood cultures collected in the ED resulted with microbial growth after patient discharge during the study period. Seventy seven patients were included with the primary reason for exclusion being age less than 18 years (n = 17). The most common provider actions upon blood culture growth were: ask patient to return to the ED (n = 48, 62.3%), inform patient of result and instruct to follow-up outpatient (n = 13, 16.9%), and not contact patient for growth considered contamination (n = 3, 3.9%). A total of 54 (70.1%) patients returned to the ED for evaluation within 30 days of the index visit with a median time to return of 1.27 days (IQR 1.03 to 2.08). During return ED evaluation the following actions were performed: antimicrobial therapy changed (n = 37, 77.1%), diagnosis of bacteremia (n = 31, 64.6%), admitted inpatient (n = 33, 68.8%), blood cultures repeated (n = 41, 85.4%) and discharge from ED (n = 9, 18.8%).
Variability exists in action taken by providers following microbial growth on blood cultures after patient discharge.

Program Affiliations: Rutgers PGY2 Emergency Medicine

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Resident

Abstract 71

Description and Evaluation of Contemporary Systemic Thrombolysis for Pulmonary Embolism

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Uncertainty exists regarding the ideal role, dosing, and administration of thrombolytics in treatment of pulmonary embolism (PE). Available studies evaluating thrombolytics for PE are largely disparate in populations studied, thrombolytic regimens used, and results observed. In addition to the heterogeneity of available data, significant changes to risk stratification and available therapies for PE in recent years have further distanced current standards of evaluation and treatment from historical literature. With these significant changes contemporary use of thrombolytics for PE is not well described. This study characterizes utilization of systemic thrombolysis for pulmonary embolism and examines outcomes amongst patients treated with systemic thrombolytics.

Cases of alteplase administrations between 6/1/2022 and 10/9/2024 were reviewed. Patients receiving systemic alteplase for pulmonary embolism were included with exclusion of patients receiving alteplase during cardiac arrest. Cases were evaluated for the descriptive primary outcome of dosing strategy used and pulmonary embolism severity according to European Society of Cardiology definitions. Exploratory secondary outcomes included in-hospital and 30-day mortality, and rates of major bleeding, intracranial hemorrhage, and readmission due to venous thromboembolism.

A total of 3,015 alteplase administrations were recorded between 6/1/2022 and 10/9/2024 with 44 patients receiving alteplase for PE and 32 meeting inclusion criteria. Of patients treated with systemic alteplase for PE, severities were as follows: 2 (6.3%) intermediate-low risk, 18 (56.3%) intermediate-high risk, and 12 (37.5%) high risk. Five patients (15.6%) received 100 mg of alteplase, 19 patients (59.4%) received 50 mg, and 8 patients (25%) received 25 mg. Administration strategies were variable with a total of 13 different dosing and administration strategies utilized. In-hospital mortality occurred in 2 patients (6.3%) and 30-day mortality occurred with 3 patients (9.4%). Major bleeding occurred in 5 patients (15.6%) including 2 cases of intracranial hemorrhage (6.3%). One patient had a readmission for venous thromboembolism within one year (3.1%).

With evolving risk stratification and options for treatment of PE significant variability exists in indication for use, dosing and administration of thrombolytics.

Program Affiliations: Rutgers PGY-2 Emergency Medicine Pharmacy Residency Program - Ernest Mario School of Pharmacy

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Resident

Abstract 72

Enhancing Early Cancer Detection and Treatment through Traditional Medicine Practitioners in Kenya

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Traditional Medicine Practitioners (TMPs) are integral to healthcare delivery in Kenya, particularly in regions with limited access to Western medical services. This quality improvement project aims to assess the impact of TMPs on delays in cancer diagnosis and treatment. The project will evaluate TMPs' diagnostic methods, treatment decisions, and referral patterns to determine their influence on timely cancer care.

This project will utilize a mixed-methods approach. Primary data will be collected through structured questionnaires administered to TMPs. These questionnaires will evaluate TMPs' knowledge of cancer diagnosis, treatment, and referral processes. Secondary data analysis will be conducted on de-identified medical records of cancer patients from Kitui County Referral Hospital and Moi Teaching and Referral Hospital. The project will also analyze patterns of patient care delays and identify gaps in TMPs' understanding of cancer management.

The findings are expected to reveal whether TMPs contribute to delays in cancer treatment due to a lack of awareness or reluctance to refer patients to Western Medicine Practitioners (WMPs). Identifying these gaps will highlight critical areas for educational interventions to improve early cancer detection and referrals.

By emphasizing the role of TMPs in the cancer care continuum, this project seeks to inform public health policies and promote collaborative efforts between TMPs and WMPs. Implementing targeted educational programs for TMPs could enhance early cancer detection, reduce treatment delays, and ultimately improve patient outcomes in Kenya. The results of this project will aim to influence future healthcare strategies and guide further research in this area.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Resident

Abstract 73

Impact of Pharmacist-Led Interventions on Medication Adherence in Patients with Hypertension at a Federally Qualified Health Center

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Objectives: The primary objective of this study is to examine patients' self-reported adherence to antihypertensive medications in a pharmacist-led cohort (intervention) compared to those receiving the standard of care (control) in a Federally Qualified Health Center (FQHC). The secondary objectives are to evaluate antihypertensive medication adherence based on medication possession ratio (MPR) and to compare self-reported adherence to the MPR while managed in the intervention versus control arms.

Previous studies involving pharmacist-led home blood pressure (BP) monitoring programs have demonstrated improvements in BP control. However, the applicability of previous studies to an FQHC is limited and often omits patients with certain risk-enhancing conditions. Project HOPE is a randomized controlled crossover trial, which was initiated to provide ambulatory blood pressure cuffs to patients with resistant hypertension or hypertension with a pre-determined risk enhancing condition. Patients were enrolled in the study based on a diagnosis of hypertension in the last five years with at least two visits to the health center within the previous 12 months (November 2021- November 2022) with at least two documented in office blood pressure readings > 140/90 plus an additional pre-determined risk factor or resistant hypertension (rHTN). The risk factors include chronic kidney disease and congestive heart failure with additional disease comorbidities later added to the protocol including cerebrovascular accident, transient ischemic attack, non-ST segment elevation myocardial infarction, ST-elevation myocardial infarction, acute myocardial infarction, unspecified, and old myocardial infarction.

The purpose of this retrospective chart review is to examine the impact of pharmacist-led interventions on adherence to BP medications compared to those receiving the standard of care in an FQHC.

Methods: This project is a retrospective subanalysis of patients enrolled in Project HOPE. Patients were evaluated in a control group where they were managed by a primary care provider (PCP) for 6 months, and a treatment group where they also met with a clinical pharmacist for medication management for 6 months. Patients were screened for self-reported medication adherence using the Hill-Bone screener by a community health worker and research analyst at baseline, between treatment groups, and at the end of study. The Hill-Bone scale ranges from 14-56, while the scores are as follows: 14–28 defines poor compliance, 29–42 defines average compliance, and 43–56 defines good compliance. Adherence will also be assessed for patients filling prescriptions at the health center's retail pharmacy using the MPR for each antihypertensive prescription filled during the study period. The MPR will be collected using PioneerRx, the pharmacy's prescription claims software, and then downloaded to Excel for analysis. The primary outcome is the change in Hill-Bone score in the control group compared to the intervention group. The secondary outcomes include the difference in the MPR for each fill of an antihypertensive medication, and the difference in the number of patients who have appropriate medication adherence per the MPR (≥0.80) and Hill-Bone scale score (≥43) in the control group compared to the intervention group. The primary outcome will be evaluated using Mann-Whitney U test and secondary outcomes will be evaluated by using descriptive statistics.

Program Affiliations: N/A

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Resident

Abstract 74

Assessing healthcare costs and utilization trends in patients receiving CAR T-cell therapy

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Background: Despite encouraging outcomes of chimeric antigen receptor T-cell (CAR T) therapies against hard-to-treat cancers, significant barriers remain such as high upfront costs and ancillary costs of care. Additionally, long-term outcomes on duration of response are lacking. CAR T-cell therapies come with toxicities such as cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). Studies show CAR T-cell therapy is associated with variable healthcare costs factored by treatment-related costs and additional costs related to managing severe side effects. As CAR T-cell therapy continues to evolve, understanding the total cost of care among specific patient populations is essential.

Objectives:

(1) To compare baseline patient demographics and utilization trends among patients administered with CAR T-cell therapy in hematologic cancers.
(2) To compare total cost of care, and healthcare resource utilization post-treatment to pre-treatment among patients administered with CAR T-cell therapy in hematologic cancers.

Methods: Members were identified using authorization data from 12/1/2017 to 12/31/2024. Retrospective claims data of members enrolled in Commercial, Medicare, and Medicaid lines of business in a New Jersey health plan was collected. Members with an unidentified infusion date were excluded. Medical and pharmacy utilization data was collected from 12 months before CAR T-cell administration date and followed up until 12/31/2024.

Results: 149 members received CAR-T cell therapy. Average per member per month (PMPM) costs were 46% lower at 6 months and 66% lower at 12 months post-treatment compared to pre-treatment. Of 132 members who had IP claims, 46 had claims for a CRS (80%) or ICANS reaction (11%) or both (9%). 51 members (37%) received a subsequent treatment after CAR T-cell infusion, with median time to next intervention was 246 days. These findings highlight the need for further research on long-term clinical outcomes and cost of care following CAR T-cell therapy.

Program Affiliations: N/A

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Resident

Abstract 75

The Impact of Phototherapy in Atopic Dermatitis and Psoriasis: A Retrospective Claims Analysis

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Background: Phototherapy has historically been used in atopic dermatitis (AD) and plaque psoriasis (PsO) and is supported by guidelines. Phototherapy an effective treatment for AD and PsO that can be offered at a lower cost compared with biologics. The annual cost of biologic treatment is >10x the annual cost of phototherapy. Barriers to phototherapy include adherence to office-based regimens and the fear of malignancies. Home-based phototherapy devices may address barriers and are offered at a lower cost. There are limited studies on the real-world utilization of phototherapy and the role of phototherapy in biologic initiation rates or in combination with biologics.

Objectives:

(1) Identify the real-world utilization of phototherapy in adult members diagnosed with moderate-to-severe PsO or AD.
(2) Determine the potential benefit of phototherapy in delaying initiation of biologic therapy

Methods: Observational retrospective analysis of paid pharmacy and medical claims in a large health plan from 1/1/22 –12/31/24. Study population included adult commercial and Medicare members continuously enrolled during study period with diagnosis of AD or PsO. Phototherapy arm included ≥1 claim for home-based phototherapy OR ≥5 claims for office-based phototherapy. Non-phototherapy arm included no claims for phototherapy

Results: Of the 171 phototherapy utilizers (1.8%) received home-based phototherapy. The average annual cost of phototherapy was $1,387.44 and the average annual cost of biologic therapy was $59,103.84. The average cost of a home-based phototherapy device was $892.74. Among members who received phototherapy, 11.7% of members in the phototherapy arm initiated a biologic versus 16.0% of members in the non-phototherapy arm. Of the 20 members in the phototherapy arm who initiated a biologic, 5 (25.0%) added the biologic for concomitant use with phototherapy

Conclusion: Phototherapy utilization has the potential to delay or avoid biologic initiation, which can contribute to biologic cost-avoidance.

Program Affiliations: Rutgers Residency Program

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Resident

Abstract 76

A Cost-Effectiveness Analysis of Diagnostic Testing in Alzheimer's Disease

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Objectives: Alzheimer's disease (AD) is a form of dementia that progressively affects cognition, behavior, and functional status. Early detection and diagnosis of AD enables earlier access to treatment. Therefore, this study aimed to identify the most cost-effective diagnostic strategy (amyloid blood test [ABT], cerebral spinal fluid tap [CSF], amyloid positron emission tomography [aPET]) for AD from the US payer perspective.

Methods: A Markov model was developed to simulate three cohorts of patients with AD and receiving ABT, CSF, or aPET testing. Assuming all patients enter in mild cognitive impairment (MCI) stage, progressive states of mild AD, moderate AD, severe AD, and death were considered. The cycle length was one year with a time horizon of 25 years. Inputs for the model included rates of state transition, cost of each state, cost of the diagnostic, and specificity (i.e., effectiveness among patients with AD) of each diagnostic. The model leveraged true positive rates for each diagnostic. A cost-effectiveness analysis (CEA) was conducted to assess the incremental cost-effectiveness ratio (ICER) and net monetary benefits (NMB) of the diagnostic strategies at a willingness-to-pay (WTP) threshold of $150,000. A sensitivity analysis was conducted with a +/-10% variation in all model inputs.

Results: Without dominance, the ICER for aPET ($52,500) was higher than for CSF ($10,821) and it fell on the WTP threshold. NMB of aPET was the highest ($1,955,969) followed by CSF ($1,880,303) then ABT ($1,799,293). Thus, aPET was the most cost-effective diagnostic strategy. The time horizon and specificity were determined the most influential inputs on the NMB for all three diagnostic strategies.

Conclusions: aPET has greater effectiveness but at a higher cost compared to CSF and ABT. At the WTP threshold of $150,000, aPET was determined the most cost-effective diagnostic strategy for AD.

Program Affiliations: HOPE Program, Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 77

Addressing the Missing Link in Comprehensive Care: Advocating for Psychotherapy as an Adjunct Treatment in Cachexia

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Cancer-induced cachexia is a metabolic syndrome characterized by degradation of skeletal muscle, abnormal weight loss, and loss of appetite. These symptoms can cause psychological distress in patients. Although there is no current standard of care for treating cachexia, physicians employ varying interventions including pharmacological treatments, nutritional support, exercise programs, and psychosocial therapies. Managing psychological symptoms is often overlooked in healthcare settings as demonstrated by the lack of clinical trials involving psychotherapy as a supplemental intervention. Considering the impact of psychological symptoms on cachectic patients, it is crucial to explore the potential of supplemental psychotherapy. This study highlights the need for a multimodal approach to treating cachexia, with a focus on addressing the unmet psychological needs that often manifest as a key component of the condition. A literature search was conducted via PubMed and Google Scholar. The articles that were included in this study examined the role of psychological symptoms in cachexia and the potential for psychotherapy in treatment of cachexia. In our study, we compared multiple qualitative studies discussing the psychological impact of cancer cachexia in which patients reported experiencing negative body image, worry of inconveniencing others, and frustration towards their lack of independence. Overall, the prevalence of psychological symptoms in cachectic patients prompted a review of current interventions aimed at treating these issues. Clinical evidence linking psychotherapy to cachexia is sparse; however, its integration into comprehensive care for cachectic patients appears beneficial in the few clinical trials conducted. Future clinical trials should aim to rigorously evaluate the impact of various psychotherapeutic approaches on cachexia and provide evidence into how and when psychotherapy can be used to treat cachexia. Recognizing and advocating for psychotherapy as an adjunct treatment is essential to address the psychological aspects of cachexia and enhance overall patient care.

Program Affiliations: Independent Student Research for AMCP Conference

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 78

Advancing Alzheimer's Disease Detection: A Literature Review of Novel Plasma, Saliva, and Ocular Diagnostic Tools and Biomarkers

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Alzheimer's Disease (AD) is a neurodegenerative disorder characterized by tau proteins and amyloid-beta (Aß) plaques. A 2023 CDC report estimates 6.7 million Americans have AD, costing the healthcare system $345 billion, with projections reaching 14 million cases by 2060. The newly approved anti-amyloid drugs Leqembi and Kisunla slow early-stage disease progression, underscoring the need for accessible, early detection. Definitive AD diagnosis currently involves combining imaging and cerebrospinal fluid (CSF) testing modalities. This literature review examines the potential of additional diagnostics such as plasma, saliva, and ocular testing to advance earlier and more accessible detection of AD.

A comprehensive literature search utilizing Pubmed was conducted. The following keywords and MeSH terms were included: “Alzheimer's Disease,” “diagnostic markers,” “Alzheimer's Disease biomarkers,” “amyloid beta,” “p-tau,” “blood-based biomarkers,” “plasma biomarkers,". 150 abstracts were evaluated; 9 studies selected; inclusion criteria at least two MeSH terms: AD or AD-dementia (AD-D), control and/or mild cognitive impairment. This review highlights the potential of innovative diagnostic tools in AD detection. Studies support the use of plasma signaling proteins, ocular scanning, and saliva testing to detect AD. Combining standard diagnostic methods such as PET imaging and CSF testing with these novel modalities may enhance the accuracy of early disease detection. Results of ongoing studies evaluating inflammatory biomarkers and tear analysis may lead to the development of additional definitive, non-invasive tests. Incorporating these novel diagnostic tools into future clinical trials could advance their validation as earlier predictive biomarkers and further characterize the efficacy of anti-amyloid beta therapies in early-stage AD.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 79

Appropriateness of Pharmacologic Sedation for the Duration of Paralysis during Rapid Sequence Intubation in the Emergency Department and Intensive Care Unit

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Rapid sequence intubation (RSI) is a technique performed to maintain airway protection and involves an induction agent to induce unconsciousness, followed by a neuromuscular blocker. Etomidate and rocuronium are commonly used. Rocuronium has a longer half-life (120 min) than etomidate (5 min), increasing the risk of patient awareness while paralyzed. Maintaining deep sedation and analgesia post-intubation is critical. This study evaluates sedation practices after RSI paralysis in emergency and intensive care settings. This was a single-center, retrospective chart review examined patients who received RSI paralysis with rocuronium in the emergency department or ICU between October 29, 2023, and June 30, 2024, at a large teaching hospital. Only patients aged ≥ 18 with documented rocuronium administration were included. Exclusion criteria were pre-arrival intubation, intubation before ICU admission, use for ventilator synchrony, pregnancy, and myasthenic syndromes. Primary endpoints assessed mean sedative and analgesic doses at 0-2 and 2-4 hours post-paralysis. Opioid and benzodiazepine use were measured in fentanyl and midazolam equivalents. Secondary endpoints evaluated sedation scale monitoring, blood pressure, heart rate, and induction sedation. Of 247 patients screened, 131 were included. The average rocuronium dose was 1.22 ± 0.48 mg/kg. Average analgesic and sedation requirements in the 0-2 hour and 2-4 hour period, respectively, were fentanyl (67.0 ± 45.5 and 85.2 ± 50.8 mcg/hour), midazolam (2.45 ± 1.5 and 2.8 ± 1.7 mg/hour), propofol (18.1 ± 17.9 and 19.7 ± 17.4 mcg/kg/minute), and dexmedetomidine (0.65 ± 0.4 and 0.58 ± 0.3 mcg/kg/hour). Median GCS score was 11. Average sedation/analgesic doses increased from 0-2 to 2-4 hours. Within three hours, many patients had inadequate sedation or pain. Mean time to sedation after the first order was 43 ± 0.06 minutes; 38 patients received sedation >30 minutes post-rocuronium. Delays in sedation and analgesia suggest improvement is needed in education and electronic medical record optimization.

Program Affiliations: KNIGHT ScholaRx

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 80

Assessing the Use of Augmented Reality and Virtual Reality in Managing Symptoms of Alzheimer's Disease and Dementia, a Literature Review

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Alzheimer's Disease (AD) and dementia affect millions of people globally, impairing memory, cognition, and behavior, leading to reduced quality of life (QoL). While pharmacologic treatments aim to slow disease progression and manage symptoms, nonpharmacologic interventions focus on enhancing QoL, which addresses behavioral and psychological symptoms. Nonpharmacologic interventions, including Augmented or Virtual Reality (AR/VR), are emerging tools for managing cognitive, behavioral, and emotional symptoms associated with these conditions.

This study evaluates current literature on the use of AR/VR technologies in managing cognitive function, mood, daily living activities, physical fitness, and social engagement related to Alzheimer's Disease and dementia. Seven clinical studies published between 2019 and 2023 were identified and reviewed from a comprehensive PubMed and Google Scholar search, including a total of almost 400 patients throughout. Studies that assessed the impact of AR/VR technologies on mild cognitive impairment (MCI) were included, along with those that assessed a broad range of outcomes, including cognitive performance, physical health, emotional well-being, and functional abilities in activities of daily living (ADLs).

VR interventions, including exercise and cognitive training programs, using a headset-based technology system, demonstrated significant improvements in cognitive function, emotion regulation, physical fitness, and memory enhancement. AR interventions, particularly those supporting ADLs, showed enhanced functional independence and cognitive performance. Additionally, personalized VR and social robot AR experiences improved emotional well-being and social engagement in patients with MCI and dementia. Despite positive findings, cost, comfort, disorientation, and distress limitations were noted, especially in patients with moderate to severe cognitive impairment. Findings support the growing potential of AR/VR as nonpharmacologic models for assistance in managing cognitive impairment shown in early Alzheimer's or dementia patients. Future research should address optimal intervention durations, frequencies, and settings, as well as the tools used to assess the long-term impact of AR/VR on cognitive dysfunction.

Program Affiliations: iPhO Scholarly Activities

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 81

Comparative Evaluation of Loading and Not Loading Clopidogrel in Patients with Minor Stroke or Transient Ischemic Attacks

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Purpose: Clopidogrel-containing dual antiplatelet therapy (DAPT) is recommended for secondary stroke prevention in patients with minor stroke or high-risk transient ischemic attacks (TIA). Landmark clinical trials employed a loading dose of clopidogrel 300 mg or 600 mg prior to initiation of maintenance daily dose of 75 mg. Superfluous concerns of bleeding and errors of omission may contribute to frequent exclusions of loading doses in initial management. The goal of this evaluation is to compare the effectiveness and safety of loading and not loading clopidogrel in patients newly initiated on clopidogrel-containing DAPT for minor stroke or TIA.

Methods: The institutional review board approved this retrospective chart review of adult patients admitted to the emergency department (ED) or hospital at Princeton Medical Center (PMC) who were newly initiated on clopidogrel-containing DAPT for management of minor stroke with National Institutes of Health Stroke Scale (NIHSS) < 4 or TIA for at least 21 days from January to December 2023. Key exclusion criteria included documented use of clopidogrel or any anticoagulation prior to index event. Data collection included age, sex, weight, diagnosis of minor stroke or TIA, select comorbidities of interest, neurology consultation status, documented NIHSS for minor stroke and ABCD2 for TIA, hospital length of stay, discharge disposition, loading dose if administered, and intended or prescribed duration of DAPT. The primary objective of this evaluation was to compare the 90-day composite incidences of rehospitalization/ED visit for stroke/TIA and any bleeding events in patients who were loaded with clopidogrel compared to those who were not following index event. The secondary objectives of this evaluation were to compare individual incidences of readmissions for all causes, stroke, TIA, and bleeding events at 30-days and 90-days following index event. Descriptive statistics were used to analyze the results.

Results: There were 424-patients screened for inclusion. After exclusion criteria were applied, 74-patients (17%) were included in the final analysis. Of those, 15-patients (20%) received a loading dose of clopidogrel (300mg [67%] and 600mg [33%]). Comparing patients who were loaded with clopidogrel to those who were not, there were similar diagnoses of minor stroke (73% vs. 78%) and similar severity of stroke symptoms (median NIHSS 2 [IQR 1-3]). For patients who presented with TIA, there was similar risk for stroke after suspected event (median ABCD2 4 [IQR 2-5] vs. 4 [IQR 3-5]). Hospital length of stay, neurology consults, DAPT duration < 30 days, and home discharges were similar. Those loaded with clopidogrel tended to be younger (median 63-years [IQR 5-72] vs. 74-years [IQR 66-86]), male (53% vs. 44%), and reported lower incidences of previous stroke (13% vs. 29%) and ischemic heart disease (7% vs. 15%) when compared to those who were not loaded. The incidence of 90-day rehospitalization/ED visit for stroke/TIA or bleeding event was observed for one patient (7%) in the loaded group and two patients (3%) in the not loaded group. Events within 30-days were consistent with these findings, and clinically similar between the two cohorts.

Conclusion: The findings from this preliminary evaluation suggests that loading clopidogrel for patients newly initiated on clopidogrel-containing DAPT for minor stroke/TIA does not increase risk for bleeding events compared to initiating maintenance doses of clopidogrel without loading. Clinically similar events of minor stroke/TIA may be explained by a small sample size and inclusion of patients with nonhigh-risk TIA (defined as ABCD2 < 4). Further research is warranted to evaluate the effectiveness of loading clopidogrel for minor stroke/TIA on readmissions for new vascular events.

Program Affiliations: KNIGHT ScholaRx

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 82

Comparing the Efficacy of Ceftriaxone 1 Gram Versus 2 Gram Dosing in Various Bacterial Infections

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Ceftriaxone, a third-generation cephalosporin, is commonly used to treat bacterial infections. Its time-dependent, bactericidal activity may lead to subtherapeutic concentrations, especially in critically ill patients with hypoalbuminemia, due to its high protein binding. Limited data exists on how ceftriaxone dosing affects patient outcomes. This study aimed to compare clinical outcomes between ceftriaxone 1 gram and 2 grams daily, hypothesizing that 2 grams would result in lower treatment failure rates.

This single-center, retrospective cohort study was conducted at Robert Wood Johnson University Hospital Somerset from June 2021 to July 2024. Inclusion criteria were patients aged 18 or older who received either ceftriaxone 1 gram or 2 grams daily for at least three consecutive days for a bacterial infection. Exclusion criteria included interruptions in therapy, concomitant antibiotics, surgical prophylaxis, or infections like central nervous system infection or endocarditis. The primary outcome was treatment failure, defined as therapy escalation, 30-day mortality, or hospital readmission. Secondary outcomes included hospital length of stay (LOS), Intensive Care Unit LOS, and duration of ceftriaxone use. Data were analyzed using descriptive statistics and linear regression.

Of 1039 patients screened, 194 met inclusion criteria. The cohort had 148 patients (76.3%) on ceftriaxone 1 gram and 46 (23.7%) on 2 grams. There were no significant differences in treatment failure rates, including therapy escalation (4.1% vs. 4.3%), 30-day readmission (5.4% vs. 4.3%), or mortality (5.4% vs. 10.9%). Median hospital LOS (6.0 vs. 6.5 days) and ICU LOS (2.0 vs. 3.0 days) were also similar. However, duration of ceftriaxone use was significantly different (3.0 vs. 4.0 days). After adjusting for albumin levels, the primary outcome remained nonsignificant (p=0.66). These findings suggest no difference in treatment outcomes based on ceftriaxone dose, although further research is needed.

Program Affiliations: KNIGHT ScholaRx

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 83

Comprehensive review of utilizing resistin as a biomarker to insulin resistance in Type 2 Diabetes Mellitus

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In the U.S., over 38 million people have diabetes, with 90% diagnosed with Type 2 Diabetes Mellitus (T2DM), a condition marked by insulin resistance. Approximately 30% of diabetics experience anxiety over blood glucose finger pricks, which cost an average of $800 annually—posing a financial burden for many. Resistin, an adipocyte hormone linked to insulin resistance, presents potential for non-invasive salivary diagnostics, offering a cost-effective alternative to blood testing. This review examines the correlation between plasma and salivary resistin levels to assess its reliability for T2DM screening.

A systematic search of PubMed was conducted using terms like “diabetes,” “monitor,” “screening,” “diagnosis,” and “resistin.” Reference lists from selected studies were manually reviewed. Data from January 2004 to January 2024 were analyzed without time restrictions. Inclusion criteria encompassed studies measuring serum and/or salivary resistin in T2DM and non-diabetic individuals or animals. Exclusion criteria included studies without a T2DM group or those using diabetics as controls. Studies also examined resistin’s relationship with biomarkers such as HbA1c, blood glucose, BMI, and weight.

Seventeen studies, involving 70 to 3,000 human participants and 20 to 500 mice, assessed resistin’s association with insulin resistance. Resistin positively correlated with HbA1c ($r=0.78$, $p=0.0001$), obesity, and T2DM severity. Higher salivary resistin was noted in gestational diabetes mellitus (GDM) ($P<0.01$), with elevated fetal cord levels ($P<0.02$). Salivary superoxide dismutase (SOD) correlated with plasma resistin, while reduced glutathione (GSH) showed an inverse relationship. Resistin levels decreased post-metformin treatment, linking lower levels to improved glycemic control. Overall, findings suggest salivary resistin is a promising non-invasive biomarker for insulin resistance. However, further research is necessary to establish diagnostic thresholds and enhance T2DM management strategies.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 84

Effects of Implementing a Pneumonia Care Bundle on Hospital Mortality Rates Utilizing Pneumonia Severity Scoring: A Retrospective, Multi-Center Analysis

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Mortality from pneumonia remains a critical performance indicator of healthcare quality. While the CURB-65 score helps predict pneumonia severity and associated mortality, a standardized Pneumonia Care Bundle may improve outcomes by ensuring consistent, evidence-based interventions for high-risk patients. This study seeks to evaluate the effect of the care bundle on one year mortality rates stratified by pneumonia severity.

This multi-center, retrospective study included patients admitted with pneumonia and pulmonary infiltrates between June 2020–May 2021 (pre-intervention) and June 2021–May 2022 (post-intervention). Baseline demographics, comorbidities, and smoking history were collected. CURB-65 scores were calculated at emergency room presentation or hospitalization. The care bundle interventions included timely antibiotic administration, early mobility, pulmonary consults, spirometry, aspiration risk assessment, pneumonia action plan development, pharmacist consultation, and follow-up within five days of discharge. The primary outcome was one-year mortality while secondary outcomes included readmission rates.

A total of 941 pre-intervention and 1,182 post-intervention subjects were included. Baseline demographics were similar between groups. No significant differences were observed in 30-day ($p=0.223$), 60-day ($p=0.426$), and 90-day ($p=0.955$) readmission rates. Length of stay remained unchanged at 6.6 days ($p=0.989$). However, 30-day mortality significantly decreased from 24.7% (pre-intervention) to 16.6% (post-intervention) ($p<0.001$), particularly among patients with severe pneumonia.

The interdisciplinary Pneumonia Care Bundle significantly reduced mortality in hospitalized pneumonia patients despite no impact on readmission rates or length of stay. These findings highlight the value of standardized care pathways in improving survival, especially in high-risk populations. Future efforts should explore strategies to further reduce readmission rates while maintaining improvements in mortality.

Program Affiliations: N/A

Poster Category: Clinical Science

Primary Author Title: PharmD Student

Abstract 85

Efficacy and Safety of Seltorexant for Insomnia and Major Depressive Disorder

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Introduction: Insomnia is a sleep disorder characterized by persistent difficulty in initiating and maintaining sleep, affecting overall quality of life. About 10% of the population struggles with insomnia, while another 20% experiences occasional sleep issues. Despite the availability of traditional sleep aids and antidepressants, many patients continue to experience sleep disturbances that worsen their overall well-being. Research of Dual Orexin Receptor Antagonists (DORAs) like Seltorexant, a selective orexin-2 receptor antagonist, exhibits positive improvements in sleep quality and antidepressant effects. Recent studies highlight its potential as an adjunctive therapy for patients with Major Depressive Disorder (MDD), who continue to experience persistent insomnia despite using antidepressants.

Methods: For the literature search keywords and MeSH terms used on Pubmed included: “Seltorexant,” “Insomnia” “Major Depression Disorder,” “Dual Orexin Receptor Antagonist,” “Traditional Hypnotics”. Key filters included “Clinical trials,” “Randomized control trials,” “Review”, “Systematic Review” and “years 2019-2025.”

Results: Randomized controlled trials and double-blind studies evaluated the safety and efficacy of Seltorexant compared to placebo. A double blind study showed Seltorexant 40 mg improved both sleep onset and mood. A Phase 2b study reported that a 20 mg dose effectively reduced depression scores, particularly in patients with insomnia. A10-day study on MDD showed that 20 mg alleviated depressive symptoms and induced changes in brain activity during stage 2 sleep. Another systematic review confirmed that a 20 mg dose significantly reduced depression scores in patients who had not responded to traditional antidepressants. Common side effects included somnolence, headache, and nausea, with no new major safety concerns identified.

Conclusion: Ongoing phase studies show Seltorexant effectively improves sleep and depression by modulating arousal and wakefulness, with a favorable safety profile. More studies are needed to explore the potential benefits of combining Seltorexant with antidepressants to improve remission rates. Further research with larger sample sizes and long-term studies is needed.

Program Affiliations: N/A

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 86

Evaluating Sugammadex Usage and Dosing in Postoperative Neuromuscular Blockade Reversal

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Purpose: Sugammadex selectively reverses non-depolarizing neuromuscular blocking agents (e.g., rocuronium, vecuronium). Due to its high cost and growing use at our institution, we evaluated the dosing patterns of sugammadex for post-operative neuromuscular blockade reversal to optimize cost-effectiveness and clinical outcomes.

Methods: This IRB-approved retrospective chart review included adult patients who received sugammadex in June 2024. Patients without a documented weight were excluded. The primary outcome of this study was to correlate the depth of neuromuscular blockade (using train-of-four (TOF) scores) with the sugammadex dose utilized. Secondary outcomes included the incidence of adverse events and instances of treatment failures requiring repeat dosing.

Results: This study included 154 patients of which, 60.4% were female and the mean (SD) age was 54 (16.8) years. For deep neuromuscular blockade (TOF 0/4), the mean (SD) sugammadex dose (mg/kg) administered was 2.9 (1.0). Of these, 72.2% were dosed based on vial size (200 mg), and 16.7% received the guideline-recommended dose. For moderate blocks (TOF ¼-3/4), the mean (SD) dose was 2.7 (0.7), with 77.8% of doses being based on vial size. For shallow blocks (TOF 4/4), the mean (SD) dose was 2.5 (0.9), with 76.6% of doses being based on vial size. Patients without a specified block depth received a mean (SD) dose of 2.7 (0.9), with 77.3% of doses based on vial size. Treatment failures requiring repeat dosing occurred in 5 patients (3.3%). Adverse events occurred in 12.9% of patients (bradycardia 7.7%, hypotension 4.5%).

Conclusion: Sugammadex was predominately dosed based on vial size rather than guideline-recommended dosing across various depths of neuromuscular blockade. There was a low incidence of patients requiring repeat dosing and most patients did not experience adverse events related to sugammadex use. These findings highlight opportunities to improve adherence to guideline-recommended dosing, which may enhance cost-effective usage and clinical outcomes.

Program Affiliations: KNIGHT ScholaRx

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 87

Evaluating the Appropriate Use of Hydralazine in a Community Teaching Hospital: A Retrospective Analysis

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This retrospective chart review was performed to evaluate the appropriateness of hydralazine utilization at a community teaching hospital and identify any potential areas for improvement in pharmacy intervention. Data was collected from April 2024 to July 2024. Inclusion criteria: 18 years of age or older and admitted to an inpatient unit with at least 1 administration of hydralazine. Exclusion criteria: less than 18 years of age, hydralazine being continued from home medications without any changes and no administrations on as needed orders, and patients admitted outside of the general inpatient units.

The primary endpoint assessed the appropriateness of hydralazine usage based on set criteria which included patients that had a diagnosis for hypertensive emergency, subsequent treatment parameters of systolic blood pressure greater than 160 and/or diastolic blood pressure greater than 110 mmHg, or patients that had at least three other anti-hypertensive medications during their hospital stay. Secondary outcomes included each criteria individually, order specific breakdown, and potential adverse events.

In this study, 129 out of the 258 patients were included. The primary outcome analysis resulted in about 48% of patients with appropriately prescribed hydralazine. Results for secondary outcomes were as follows: 73 (56.59%) patients had diagnoses for either hypertensive emergency or urgency. Forty-four (34.11%) had diagnoses for hypertension. The remaining 12 (9.30%) patients had no indication for hypertension. There were a total of seven patients with possible reflex tachycardia, four with hypotension and one with a possible incidence of both events.

Based on the pre-defined criteria, this study identified 48% of patients as having appropriately prescribed hydralazine. Potential safety events occurred in 12 patients. These findings suggest that there may be room for improvement when managing acute hypertensive elevations in the inpatient setting, helping guide pharmacy-led education opportunities to help ensure patient safety and therapeutic efficacy.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 88

Evaluating the Effects of Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists on Substance Use Disorders

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GLP-1 receptor agonists were originally developed for the treatment of type 2 diabetes mellitus, and many are also FDA-approved for weight loss. Studies suggest that GLP-1 receptor agonists may reduce the rewarding properties of cocaine, amphetamine, and nicotine, and may also be a potential treatment target for alcohol use disorder.

This study aims to review the effects of GLP-1 receptor agonists on SUDs through analysis of clinical trials.

A literature search was conducted through PubMed, using the terms “glp-1” and “substance use disorder.” Only clinical trials and randomized controlled trials were included. Studies that did not utilize GLP-1 receptor agonists for treatment groups were excluded. The search term initially yielded a total of 99 results. After filtering and title and abstract screening by two reviewers, only four articles fulfilled the inclusion criteria. A total of 375 participants were studied in the placebo-controlled trials with dulaglutide (n =1) and exenatide (n = 3) utilized as the GLP-1 receptor agonists.

The primary outcome assessed is the effect of GLP-1 receptor agonists on the consumption and/or craving of the drug associated with the SUD (dulaglutide for alcohol; exenatide for nicotine, cocaine, and alcohol). The secondary outcome was GLP-1 receptor agonists' adverse events.

Dulaglutide showed statistically significant reduction in alcohol intake ($p = 0.04$). The combination of exenatide and nicotine replacement therapy (NRT) demonstrated a higher rate of abstinence compared to the combination of placebo and NRT. No significant differences were found in heavy drinking days, total alcohol intake, and cocaine craving when comparing exenatide to placebo.

The results indicate GLP-1 receptor agonists have the potential in decreasing consumption or cravings of alcohol and nicotine. However, further research is necessary to demonstrate the long-term effects of GLP-1 receptor agonists in a variety of SUDs, as well as efficacy of individual agents and dose optimization.

Program Affiliations: American Association of Psychiatric Pharmacists Research Committee & Journal Club

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 89

Evaluating the Impact of Deep Brain Stimulation on Tremor Reduction and Quality of Life in Parkinson's Disease Adult Patients: A Literature Review

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Purpose: Deep brain stimulation (DBS), a neurosurgical intervention that delivers electrical impulses to targeted brain regions, has emerged as a significant therapeutic approach for the management of Parkinson's disease (PD), particularly in patients whose symptoms are inadequately controlled with pharmacotherapy. As PD progresses, patients often experience symptoms including tremors that significantly impact quality of life. This review evaluates findings on the efficacy, safety, and patient outcomes associated with DBS.

Methods: A literature review was conducted to assess the effects of DBS on tremor reduction and quality of life in patients with Parkinson's Disease. The review utilized databases including PubMed, EMBASE, Google Scholar, and ClinicalTrials.gov. The search strategy included peer-reviewed articles published between 1986 when DBS was first used and 2024, utilizing Boolean operators (AND, OR) to refine results and exclude irrelevant studies. Ultimately, 21 articles were selected for detailed analysis.

Results: The analysis of 21 peer-reviewed articles encompassing 678 patients revealed varying outcomes regarding the effectiveness of deep brain stimulation (DBS) for tremor reduction and quality of life in Parkinson's Disease (PD) patients. Of the studies reviewed, 57.1% (12/21) indicated that DBS targeting the subthalamic nucleus improved severe motor fluctuations or tremor in advanced stages of the disease. Conversely, 14.3% (3/21) of the studies reported negative outcomes, indicating that axial symptoms either worsened or showed no significant change in tremor reduction or quality of life.

Conclusion: DBS has shown considerable promise in enhancing patients' quality of life by significantly reducing tremors, particularly when combined with medication. However, current research on DBS has notable limitations with many studies focusing on stimulating only specific regions of the brain. Further research and technological advancements in electrode design or programming methods are needed to address such challenges and improve outcomes for DBS use as treatment for PD.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 90

Evaluation of the Use of Droperidol: A Single-Center Retrospective Analysis

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Droperidol is a first-generation antipsychotic used to treat postoperative nausea and vomiting, with off-label uses for anxiety and agitation. Although initially withdrawn due to QT prolongation and torsade de pointes, it was reintroduced with a black box warning recommending ECG monitoring. The American College of Emergency Physicians advises ECG monitoring only for higher doses, leading institutions to establish their own monitoring policies.

This study aimed to investigate adherence to droperidol monitoring protocols and prescribing patterns. A retrospective medication use evaluation was conducted at a community teaching hospital. Patients who received parenteral droperidol from May 20th to August 31st, 2024, were identified via an Epic SlicerDicer report. Data collected included demographics, indications, doses, ECGs, adverse events, and comorbidities like sepsis and heart failure. The primary endpoint was the percentage of droperidol administrations with appropriate monitoring, defined as baseline and follow-up ECGs for higher doses and patients at risk for QTc prolongation. Secondary endpoints included the incidence of QTc prolongation and adverse events like hypotension.

Of 183 patients identified, 124 received droperidol. The mean age was 36.9 years, with a mean droperidol dose of 1.21 mg IV and 2.82 mg IM. The primary outcome showed 96% adherence to monitoring protocols. Four of five cases requiring ECGs did not follow protocol. There were 6 instances (4.8%) of prolonged QTc and 18 adverse events (14.5%), all hypotension. No cases of torsades de pointes or extrapyramidal symptoms were reported. Droperidol is a safe medication with a low risk of QTc prolongation or torsades de pointes. Although monitoring adherence was high, further education on identifying patients at risk for QTc prolongation and utilizing the Tisdale risk score is needed.

Program Affiliations: KNIGHT ScholaRx

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 91

Evaluation of Weight-Based Diltiazem Boluses on Critical Care Admissions for Patients with Atrial Fibrillation with Rapid Ventricular Response

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Atrial fibrillation with rapid ventricular response (AF-RVR) treatment includes an intravenous diltiazem bolus of 0.25 mg/kg (actual body weight) over two minutes. Variability in provider dosing practices may result in reduced efficacy and subsequent gaps in patient care. The purpose of this research is to assess whether initial intravenous diltiazem doses of less than 0.25 mg/kg for AF-RVR increase critical care unit admission rates. This was an Institutional Review Board-approved retrospective chart review of patients presenting to the emergency department at a large community teaching hospital receiving an intravenous diltiazem bolus after an initial EKG impression reading of AF-RVR from November 1st, 2023, to June 30th, 2024. The study's primary outcome was the number of critical care unit admissions for patients receiving an initial diltiazem bolus of <0.225 mg/kg in comparison to those who received >0.225 mg/kg (maximum dose of 30 mg). Descriptive and inferential statistics at a significance level of 0.05 were used as appropriate for the collected data. In total, 152 subjects were screened, and after data collection, 85 subjects were included with 44 subjects in the <0.225 mg/kg group and 41 subjects in the >0.225 mg/kg group. A total of 53 patients were female, an average age of 72.5 years old and an average weight of 76.6 kg. It was found that a diltiazem dose of <0.225 mg/kg did not significantly affect critical care unit admission rates (4/44 versus 2/41; P=0.677). The secondary and safety outcomes were also not significantly different between groups. The use of weight-based dosing for the initial intravenous diltiazem bolus for atrial fibrillation with rapid ventricular response was not associated with an increased rate of critical care admissions. It also did not indicate any significant safety concerns to use the higher dosing strategy with comparable rates of adverse events.

Program Affiliations: KNIGHT ScholaRx

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 92

Examining an Emerging Global Threat and its Implications: A Historical Perspective on Ceftriaxone Resistance in Gonorrhea

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Antimicrobial stewardship programs have been reporting increasing ceftriaxone resistance rates in East Asia and Europe since 2017. For instance, ceftriaxone-resistant isolates were surveilled in Cambodia, increasing from 26.2% in the first quarter of 2022 to 61% in the second quarter of 2023. Additionally, resistance in China was 2.9% in 2017 and grew to 8.1% in 2022. Our intent is to evaluate the growing body of literature addressing the emerging global resistance to the current gold standard. We assessed how treatment of gonorrhea has evolved, roles of antimicrobial stewardship programs in mitigating resistance, and alternative treatment options through evaluation of over 50 articles encompassing treatment guidelines, journals, and clinical trials.

Predominantly, decreased susceptibility and resistance rates are on the rise in China, Japan, Thailand, the United Kingdom, Austria, and Cambodia. Subsequently, in 2015, the WHO created a subsect to GASP, their global surveillance program, called EGASP. In collaboration with the CDC and STD testing centers, EGASP is enrolling more high-risk countries every year. Specifically for the U.S., while the CDC states that there have not been any complete treatment failures for gonorrhea as of February 2024, its Gonococcal Isolate Surveillance Program (GISP) found that from 2018 to 2022 up to 0.2% of the annually collected isolates required higher than standard levels of ceftriaxone for treatment. Also, there were isolates discovered with the same mosaic penA60 allele seen in the aforementioned countries. This illustrates an issue that will become more prevalent in the U.S. in the future if left unaddressed globally. In fact, in 2017, a CDC-developed model predicted emerging ceftriaxone resistance will lead to 1.2 million additional gonorrhea infections in the next 10 years, costing $378.2 million to treat. Thus, consideration of alternative treatment options including ertapenem and zoliflodacin is warranted.

Program Affiliations: N/A

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 93

Gender and Medical Comorbidity Differences in 30 Day Readmission Rates of Bipolar Disorder Patients

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Psychiatric readmission rates of Bipolar Disorder (BPD) have long been considered significant indicators for hospitalization outcomes. In 2022, a retrospective study conducted by Everett et al. reported a readmission rate of 21.6% within 30 days of a primary diagnosis of BPD. In the U.S., males are more likely to experience externalizing symptoms including aggressiveness and substance abuse leading to a change in disease prognosis. Left untreated, uncontrolled BPD presents with various medical comorbidities like hypertension and diabetes. Our study evaluates gender differences in psychiatric readmission rates within 30 days of primary BPD diagnosis and incidence of medical comorbidities.

The institutional review board approved this retrospective study. This is a single-center chart review of 30 day patient readmission rates from a large, academic medical center between August 1, 2019 and June 30, 2024 with a primary BPD diagnosis. We will analyze data from electronic medical records stored on a password protected hospital network drive. As this is a retrospective study, all data was de-identified so no additional informed consent was required. Inclusion criteria include a primary diagnosis of BPD, patients > 18 years old and the patient must have been readmitted within 3 months of initial admission with or without the use of psychotropic medications. Exclusion criteria include no previous diagnosis of BPD, hospitalization for a non-psychiatric reason, psychiatric comorbidities (schizophrenia, schizoaffective disorder, PTSD), patients > 65 years old, pregnancy and prisoners. The study's primary outcome is to evaluate gender differences in psychiatric readmission rates with a primary diagnosis of BPD within 30 days of discharge from SJUMC. The secondary outcome is to identify prevalent medical comorbidities in BPD patients readmitted from SJUMC. Inferential statistics including a simple linear regression model and F test to check for variances based on gender will be implemented to analyze results.

Program Affiliations: EMSOP Faculty

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 94

Identifying Sexually Transmitted Infections (STIs): The Added Value of Extragenital Gonorrhea and Chlamydia Testing Beyond Urogenital Screening in Sexual Minority Men (SMM) with HIV

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Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) are the most common curable sexually transmitted bacterial infections. Urogenital nucleic acid amplification tests (NAATs) are the gold standard for detection. However, they may miss infections at other anatomical sites (e.g., rectal, pharyngeal). In sexual minority men (SMM), rectal and pharyngeal infections are often asymptomatic. The CDC recommends testing at exposed anatomical sites (urogenital, rectal, and pharyngeal). The retrospective cohort study examined patient records from an HIV clinic within an academic health system, covering the period from January 1, 2023, to July 1, 2024. Inclusion criteria for this analysis were: at least 18 years of age, male by self-identification and birth assignment, reported sexual contact with male partners, and CT and NG NAAT performed. Exclusion criteria were: only CT/NG urine testing performed, cisgender women, and individuals prescribed medication active against CT or NG at the time of testing.The primary endpoint was to compare urogenital and extragenital (defined as rectal and pharyngeal) testing sites in detecting gonorrhea or chlamydia in sexual minority men at our clinic. Variables analyzed will include the impact of age, race/ethnicity, sex assigned at birth, sexual orientation, STI PEP/PrEP use, condom use, and number of partners on test outcome. We evaluated 672 specimen samples from 112 individual visits where urogenital, rectal, and pharyngeal sites were tested for CT and NG. The mean age of subjects was 34.8+/-8.98. Hispanic individuals represented the majority of the SMM demographic, accounting for 79% of the study population. Among the 39 positive NG tests, 84.7% were identified through extragenital screening, with 38.5% detected at rectal sites and 46.1% at pharyngeal sites. Similarly, of the 28 positive CT tests, 92.9% were diagnosed via extragenital testing, with rectal sites accounting for 78.6% and pharyngeal sites contributing 14.3%.

Program Affiliations: N/A

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 95

Impact of Cannabinoids for the Management of Chemotherapy-induced Nausea and Vomiting in Oncology Patients: A Literature Review

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Purpose: Chemotherapy-induced nausea and vomiting (CINV) is a distressing side effect of cancer treatment, impacting patients' quality of life and treatment adherence. Current treatments include antiemetic agents, such as 5-HT3 receptor antagonists, but may not provide adequate relief for all patients. This literature review investigates existing evidence on the efficacy of cannabinoids for CINV treatment, the limitations of their widespread use, and future directions for integration into clinical practice.

Methods: A literature review was conducted using the following databases: PubMed, EMBASE, Google Scholar, and ClinicalTrials.gov. The search strategy included peer-reviewed articles published between 1996 and 2024 when California first legalized the use of medical marijuana. A total of 149 studies were initially identified and 26 articles were chosen for an in-depth analysis.

Results: Based on our analysis, we found a range of outcomes regarding the effectiveness of cannabinoids as an antiemetic for CINV. 30.77% (8/26) of the studies reported a positive outcome, indicating that CBD was more effective than a placebo. However, 7.69% (2/26) of the studies showed no significant difference between CBD and existing antiemetics, suggesting that its effects might be comparable to those already in use. 23.08% (6/26) presented negative findings, stating that other antiemetic medications outperformed CBD in terms of efficacy. 46.15% (12/26) of the articles underscored the need for additional research, emphasizing that current data is limited.

Conclusion: The current research available for cannabinoid usage for CINV is limited but shows promising results as an adjunctive treatment. Limitations exist in the current research, including lack of head-to-head studies between cannabinoid products and current antiemetic drug therapies as well as differences between ingested or inhaled cannabinoid products. Therefore, further research is needed to understand the efficacy and safety of cannabinoid products when used as a treatment therapy.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 96

Investigating the Mechanisms by which SARS-CoV-2 Manifests an Autoimmune-like Phenomena to Rationalize the Implication of Immunomodulators in Infected Patients Receiving Supplemental Oxygen or Ventilatory Support

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Severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) emerged in 2019, rapidly escalating into a global pandemic. The absence of standardized treatment protocols prompted the repurposing of immunomodulators, traditionally used for autoimmune and rheumatologic disorders, in patients requiring oxygen supplementation or mechanical ventilation. This study examines SARS-CoV-2's potential to induce nonclassical autoimmunity and the mechanisms by which pharmacotherapies mitigate these effects, advancing understanding of its pathology and therapeutic approaches.

A systematic review was conducted using PubMed, ClinicalTrials.gov, and reference lists from relevant studies. Clinical trials evaluating immunomodulators in COVID-19 patients requiring respiratory support were analyzed, with a focus on their mechanisms in counteracting inflammatory responses. Studies lacking results or focusing solely on specific organ systems were excluded. The second phase of the review explored the molecular pathways underlying SARS-CoV-2-induced immune dysregulation. Abstracts were screened for relevance, prioritizing studies that investigated SARS-CoV-2's "mechanism of action" alongside MeSH terms such as "molecular mimicry," "bystander activation," "protein homology," "cytokine storm," "tocilizumab," "baricitinib," and "dexamethasone."

Findings indicate that SARS-CoV-2 proteins exhibit homology with human proteins, leading to cross-reactivity, disruption of peripheral tolerance, and subsequent organ damage. This process triggers epitope spreading, further amplifying the immune response. Additionally, the virus's interaction with angiotensin-converting enzyme-2 receptors exacerbates cytokine release, fueling systemic inflammation. Current therapeutic interventions, including dexamethasone (glucocorticoid), tocilizumab (IL-6 inhibitor), and baricitinib (JAK inhibitor), target inflammatory pathways, improving pulmonary function and reducing mortality. The ability of SARS-CoV-2 to induce autoimmune-like responses through molecular mimicry, cytokine dysregulation, and bystander activation underscores the rationale for immunomodulatory treatments.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 97

Leveraging Albuterol's anti-inflammatory properties to address immune activation induced by inhalation of microplastics and nanoplastics

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Recent decades have seen a surge in airborne microplastics in metropolitan regions, exacerbated by the formation of nanoplastics—smaller fragments capable of penetrating cells and triggering cytotoxicity. Traces of synthetic polymer particles, such as polypropylene and polyethylene, have been detected in lung tissues. The increasing presence of these microplastics correlates with rising asthma cases, leading to widespread prescription of Albuterol, a Beta-2 agonist with broad pulmonary effects. This study aims to determine the interactions between inhaled microplastics and pulmonary-administered Albuterol.

A literature review was conducted using PubMed, Google Scholar, and Rutgers Library, covering the years 2015–2023. MESH terms included “microplastics,” “nanoplastics,” “inhalation,” “Albuterol,” and “immune activation.” Additionally, members of the Environmental and Occupational Health Sciences Institute at Rutgers University were consulted for reviewing findings. Results suggest that Albuterol may mitigate the inflammatory effects of microplastic and nanoplastic inhalation through a shared pathway. Polypropylene nanoplastics act as agonists for the NF-κB signaling pathway in immune cells, leading to the release of interleukins 6 and 7, which cause inflammation in human type II alveolar epithelial cells. These cells play a critical role in gas exchange by producing lung surfactant, and their inflammation can impair surfactant production. However, (R)-albuterol suppresses cytokine secretion, acting as an NF-κB antagonist and preserving lung surfactant production despite nanoplastic exposure. While Albuterol addresses respiratory conditions, further research using A549 cell models is necessary to confirm its efficacy in counteracting microplastic-induced inflammation. Understanding the biological interplay between plastic particulates and medications is essential for community pharmacists, as microplastic-related adverse drug reactions remain an emerging concern. Given Albuterol’s widespread use in treating lung diseases, investigating its interactions with microplastics offers critical insights into this patient population.

Program Affiliations: Independent Student Research for AMCP Conference

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 98

Metformin-Induced Vitamin B12 Deficiency and its Role in Diabetic Neuropathy: A Comprehensive Review

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Purpose: Diabetic neuropathy is a complication of type 2 diabetes mellitus (T2DM) characterized by nerve damage and chronic pain. Metformin is commonly prescribed for individuals with T2DM; while effective, chronic use is associated with vitamin B12 deficiency, a factor implicated in neurological complications. This study evaluates the relationship between metformin-induced B12 deficiency and the development of neuropathy.

Methods: Literature review utilized PubMed, ClinicalTrials.gov, and reference lists from articles identified in the search. Medical Subject Headings (MeSH) terms such as “metformin,” “diabetic neuropathy,” and “vitamin B12 deficiency” were employed. Inclusion criteria encompassed studies investigating metformin-induced B12 deficiency and its association with diabetic neuropathy. Studies were excluded if they failed to present results. A results table featuring study titles, authors, publication years, study methodologies, and key findings was constructed.

Results: In line with inclusion criteria, eight studies were selected for comparative analysis, comprising three cross-sectional studies, three systematic reviews with meta-analyses, one comparative study, and one observational study. Each reported a potential association between metformin and B12 deficiency, though association strength varied. In five of the studies, B12 deficiency was primarily linked to cumulative and/or average daily dose of metformin; higher doses correlated with increased deficiency prevalence. However, the connection between deficiency and duration of metformin therapy remained inconclusive, with two studies finding no significant relationship. Four studies identified an association between metformin-induced B12 deficiency and neuropathy, though prevalences varied. One study found no significant link between deficiency and neuropathy.

Conclusion: While several studies suggest a link between metformin-related B12 deficiency and neuropathy, the relationship remains inconsistent. Future investigations should focus on clarifying underlying mechanisms linking metformin, B12 deficiency, and neuropathy through longitudinal studies. Exploring efficacy of routine monitoring and B12 supplementation in metformin users could mitigate neuropathy risks. Such research could inform clinical guidelines, enhancing patient care and outcomes.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 99

Narrative Review of Comparative Efficacy of Prazosin and Cognitive Behavioral Therapy for Post-Traumatic Stress Disorder Nightmares

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Post-traumatic stress disorder (PTSD) may lead to frequent recurrent trauma nightmares, resulting in deteriorated quality of life, suicidal thoughts and behaviors. Despite treatment with first-line options for PTSD, trauma nightmares may persist with a lack of compelling treatment recommendations. This narrative review's purpose is to compare the efficacy of prazosin to cognitive behavioral therapy (CBT) for management of PTSD-related nightmares. Prazosin is an alpha-1-adrenergic-receptor-antagonist used off-label for trauma nightmares. By counteracting central nervous system noradrenergic stimulation, prazosin reduces startle and primitive fear responses during nightmares and reverses REM sleep disruption. Several types of CBT exist, including Image Rehearsal Therapy (IRT) and CBT-Insomnia (CBT-I). IRT reduces nightmares by rewriting them into safer neutral versions, while CBT-I improves sleep quality through structured behavioral strategies.

This narrative review was conducted using PubMed. Peer-reviewed studies (randomized controlled trials, meta-analyses, systematic reviews, and other reviews) were included if they analyzed the efficacy of prazosin and/or CBT for treating PTSD-related nightmares in human participants with confirmed PTSD diagnosis. Full-text English articles published after 2008 were included. Monotherapy prazosin was well-tolerated, improved sleep-time, and resulted in significant change towards normal dream content. Prazosin reduced distressing dreams on the Clinician-Administered PTSD Scale, non-nightmare distressed awakenings, and total PTSD civilian checklist. However, Prazosin did not improve sleep quality and increased risk of sleep apnea. Efficacy of IRT monotherapy and CBT-I monotherapy appear comparable to prazosin. IRT and prazosin showed statistically significant effects of moderate magnitude favoring the treatment group. Combined IRT with CBT-I therapy proved more effective than prazosin monotherapy in improving sleep quality. Prazosin, IRT, CBT-I, and combined IRT with CBT-I did not differ in improving nightmare frequencies. IRT combined with CBT-I seems more efficacious than either prazosin or IRT monotherapy. Additional research encompassing long-term studies, therapy combinations, alternative alpha-1-adrenergic-agonists, and extended-release formulations is needed

Program Affiliations: N/A

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 100

Psilocybin for TRD: Addressing Unblinding in Randomized Control Trials

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Purpose: This research investigates the success of blinding methods in previously conducted randomized-controlled and open-label trials revolving around the administration of psilocybin for various mental health disorders, namely, treatment-resistant depression (TRD). It proposes a novel means of dosage obfuscation that potentially reduces issues associated with unblinding, preventing unwanted biases from affecting results.

Background: Treatment-resistant depression (TRD) is defined as a major depressive disorder that fails to achieve remission after at least two adequate trials of different antidepressant classes. Psilocybin is a 5-HT2A receptor agonist, believed to exhibit long-lasting antidepressant effects by increasing neuroplasticity, providing a unique option for depression treatment. Despite these positive results, psilocybin produces strong subjective (hallucinogenic) effects that make blinding difficult to achieve due to lack of effective placebo.

Methodology: This journal club literature review employs a narrative approach, utilizing peer-reviewed sources from databases such as PubMed. Studies used were limited to randomized, double-blinded and open-label trials. Inclusion criteria included patients with MDD, large sample size, primary sources, English language, human studies, and clinical cases from the past. A major constraint was the limited research available on this topic, research on psilocybin is still developing.

Results: Studies referenced included two RCTs, two open-label trials, and a systematic review regarding psychedelic blinding trials and trial designs. Despite multiple studies showing depressive symptom reduction with psilocybin administration, ensuring adequate blinding remains challenging, skewing results and diminishing trial validity. Researchers have suggested using deception to obfuscate their true treatment assignments (psilocybin vs. placebo), potentially addressing unblinding issues.

Discussion/Conclusions: The findings highlight psilocybin's potential as a novel treatment for TRD, offering through enhancing neuroplasticity. Based on these insights, our project improves upon current blinding conditions and proposes a hypothetical clinical trial for psilocybin and TRD that incorporates deception to more effectively blind patients to obtain less biased results.

Program Affiliations: American Association of Psychiatric Pharmacists Student Journal Club

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 101

Psilocybin Therapy in End-of-Life Care: A Literature Review on Addressing Psychological and Existential Distress in Terminally Ill Patients

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Purpose: This literature review examines the potential benefits of psilocybin-assisted therapy for alleviating anxiety, depression, and existential distress in patients facing terminal illnesses. Psilocybin, a Schedule I substance naturally found in “magic mushrooms,” causes hallucinatory effects, leading to its antidepressant and anti-anxiety properties. With current pharmacotherapies often falling short in addressing the full spectrum of emotional and spiritual suffering in palliative care, this review seeks to provide an overview of existing research that supports psilocybin as a novel therapeutic option. The focus is on synthesizing findings from key studies to highlight psilocybin’s efficacy, safety, and possible integration into end-of-life care.

Methods: A comprehensive literature search was conducted across multiple databases, including PubMed, Embase, and ClinicalTrials.gov, to identify relevant studies on the use of psilocybin in end-of-life care. The search terms included 'psilocybin,' 'existential distress,' 'palliative therapy' and 'terminal care'. Inclusion criteria focused on systemic reviews, randomized controlled trials (RCTs), and pilot studies involving psilocybin for patients with life-threatening conditions. Articles published between 2010 and 2024 were prioritized to capture the most recent advancements. The search yielded studies from mainly the United States, with few from other countries. Studies that assessed psychological outcomes, quality of life, and spiritual well-being in terminally ill patients were included. These studies were critically appraised for methodological rigor and relevance to palliative care. Palliative care clinical guidelines focus on improving the quality of life for patients facing life-limiting illnesses. These guidelines emphasize holistic, patient-centered care that addresses not only physical symptoms but also emotional, psychological, and spiritual suffering. This philosophy aligns closely with the emerging interest in using psilocybin for end-of-life care.

Results: The literature consistently demonstrates psilocybin’s effectiveness in alleviating psychological distress among terminally ill patients, with various surveys employed to assess overall patient outcomes. After excluding irrelevant sources, a total of 59 articles were evaluated, of which three studies were included: two pilot studies and one Early Phase 1 randomized controlled trial. The findings revealed that patients frequently reported enhanced existential well-being and enriched spiritual experiences. Across the studies, psilocybin's impact on down regulating 5HT2A receptors and altering the brain's default mode network was associated with reduced ruminative thinking and improved emotional regulation. There was a shared recognition of the need for further trials to explore psilocybin's long-term benefits and its potential integration into standard palliative care practices.

Conclusion: Our results indicate the growing body of literature highlights psilocybin as a promising intervention for addressing the unmet psychological and existential needs of terminally ill patients. Its rapid and sustained therapeutic effects, combined with a favorable safety profile, make it a compelling option for palliative care. However, regulatory barriers and the need for further clinical research remain significant challenges. Future studies should aim to expand the evidence base and explore pathways for making psilocybin-assisted therapy more accessible in end-of-life care settings.

Program Affiliations: Rutgers Institute for Pharmaceutical Industry Fellowships (RPIF)

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 102

Quantifying Oxidative Stress and Inflammation in Postmenopausal Sleep Apnea Patients

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Background and Purpose: Obstructive sleep apnea is characterized by arousals from intermittent airway blockage and is linked to cardiovascular disease. Even though post-menopausal women have a higher incidence of sleep apnea and report excess sleepiness, little is known about the effects of sex or menopause upon the mechanisms of disease. Postmenopausal women are an understudied group in the context of sleep apnea and cardiovascular disease. Estrogen protects against cardiovascular disease, but issues arise following menopause, whilst replacement therapy can lower cardiovascular risk. We reasoned that the loss of estrogen in postmenopausal women created a significant increase in oxidative stress because of sleep apnea.

Methods: We investigated oxidative and inflammatory markers in postmenopausal female patients with sleep apnea. Blood samples were drawn before and after a sleep assessment and pre and post a 12-week continuous positive airway pressure treatment regimen. Plasma samples underwent ELISA for inflammatory markers; TNF R1/2, IL-6 and the oxidative stress markers 8-isoprostane in the plasma and reduced/oxidized glutathione within the red cell. Plasma values were normalized to total protein, while red blood cell parameters were normalized to hemoglobin.

Results: 8-isoprostane was observed in several patients (range 3-754 pg/mL plasma; median 340 pg/mL), which is indicative of oxidative stress. Reduced and total glutathione levels were correlated but were not related to oxidized glutathione or 8-isoprostane (reduced mean ±SEM 260±42uM; total mean ±SEM 508±52uM). TNF R2 was high relative to historical controls but was not significantly altered by sleep (mean ±SEM 3.25±0.15 ng/mL). IL-6 levels fell within expected values (mean ±SEM 5.77±0.15pg/mL).

Conclusions: These studies highlight the capability to assess oxidation and inflammation in sleep apnea patients.

Program Affiliations: Pharm.D. Honors Research Program, Summer Undergraduate Research Fellowship

Funding: NIH, NYU

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 103

Renoprotective Effects of Sodium-Glucose Cotransporter 2 Inhibitors Against Vancomycin-Induced Acute Kidney Injury

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Vancomycin is a widely used antibiotic which can cause acute kidney injury (AKI). A preclinical study showed that the concomitant use of a sodium-glucose cotransporter 2 inhibitor (SGLT2i) with vancomycin therapy may reduce AKI. In this study, we compared patients who received vancomycin concomitantly with an SGLT2i to evaluate the association between SGLT2i use and AKI development.

We performed a single-center, retrospective, IRB-approved cohort study using data from electronic patient medical records. All adult patients who received at least two vancomycin doses alone or concomitantly with an SGLT2i during a thirty-two-month period were eligible. We excluded patients on hemodialysis, peritoneal dialysis, or with severe kidney dysfunction. All eligible patients were included in the vancomycin with concomitant SGLT2i group, and a random sample of patients on vancomycin alone served as the control. The primary endpoint was KDIGO/AKIN AKI development, and the secondary endpoint was RIFLE AKI development. Baseline renal function values were collected and compared to values during and up to 24 hours after vancomycin discontinuation. Data were analyzed using descriptive statistics, and a multivariable logistic regression analysis was performed.

We identified 30 patients on both therapies who met inclusion/exclusion criteria and a random sample of 90 patients on vancomycin alone. Baseline characteristics were similar. Concomitant SGLT2i use versus vancomycin alone was associated with a nonsignificant decrease in the incidence of KDIGO/AKIN AKI (10% vs. 15.6%; p=0.45) and RIFLE AKI (10% vs. 12.2%; p=0.743). After adjusting for chronic kidney disease (CKD) and type 2 diabetes mellitus (T2DM), concomitant SGLT2i use was associated with a reduction in the primary endpoint of KDIGO/AKIN AKI (odds ratio=0.164; 95% confidence interval [0.030, 0.900]; p=0.037). When adjusted for CKD and T2DM, SGLT2i use was associated with a reduction in the development of vancomycin-induced AKI. Larger studies are needed to confirm this finding.

Program Affiliations: KNIGHT ScholaRx

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 104

Restoration of the Antibiotic-Impacted Microbiome in Children: A Case Study

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Antibiotics effectively control bacterial infections but collaterally perturb the microbiome, usually with slow and incomplete spontaneous recovery. Early-life gut microbiome disturbances correlate with an increased risk of developing immune and metabolic diseases. As young children are often prescribed antibiotic courses, addressing gut dysbiosis correction is critical. Fecal microbiota transplant (FMT) has successfully restored the microbiota in patients with Clostridioides difficile infection. We hypothesize that oral autologous FMT (aFMT) after antibiotics can accelerate gut microbiome restoration to the child's pre-antibiotic state.

Our study aims to determine safety and impact of aFMT post-antibiotics on the child's gut microbiota trajectory. To accomplish this aim, our pilot observational case-control study will compare the gut microbiomes of healthy children between 1 month and 4 years of age from post-antibiotics exposure to spontaneous recovery versus aFMT intervention. Monthly fecal samples from healthy children are collected and stored frozen. When the child is prescribed antibiotics by their pediatrician for non-gastrointestinal infections, children in the intervention arm will receive oral aFMT the day after the end of their antibiotics course. The inoculum, used from their previous healthy sample prior to antibiotics, is screened for pathogens, then mixed with milk and fed to the child. Children in both groups will be prospectively followed for 6 months after the antibiotics course to determine their microbiome recovery trajectory. Fecal samples from intervention and control groups will be analyzed using QIIME2 software. Of infants who took antibiotics, those receiving aFMT will have their bacterial microbiome composition compared with spontaneous recovery. Additionally, they will be matched to reference babies' samples in the study not yet exposed to antibiotics to control for age-, sex-, and breastmilk usage-related changes. This study has potential implications as a sound ecological approach in preventing early antibiotic-exposure associated perturbations by restoring the impacted microbiome via pre-antibiotic microbial diversity supplementation.

Program Affiliations: Pharm.D. Honors Research Program

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 105

Retrospective Evaluation of Droperidol Use in the Emergency Department

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Droperidol has previously been absent from the United States drug market for many years following an increase in the incidence of reported cardiac adverse effects, specifically QTc prolongation. There has been renewed interest in using droperidol in the emergency department (ED) for the indications of nausea, vomiting, headache, and acute agitation, which has led to its reintroduction into the United States drug market. The goal of this evaluation is to determine the indications and place in therapy of droperidol in the ED, as well as its safety and efficacy following its reintroduction. This retrospective chart review was conducted on adult patients (ages 18 and older) who received droperidol in the ED at Princeton Medical Center between March 2023 and March 2024. Patients who were pregnant, incarcerated, or received droperidol within the behavioral health section of the ED were excluded. Data collected from the patient's electronic medical record included age, sex, indication of droperidol use, dose, other medications administered in the ED, vital signs, QTcB and QTcF intervals, ED length of stay, and any reported side effects such as hypersensitivity, extrapyramidal syndrome symptoms, drowsiness, hypotension, tachycardia, or QTc prolongation. The primary objective of this study was to characterize droperidol use based on its indications, while the secondary objectives were to assess the safety of droperidol and the incidence of adverse drug effects. Results showed that droperidol was primarily administered for gastrointestinal complaints and headaches or migraines. While some adverse effects, including prolonged QTc from baseline, were noted, further electrocardiogram (EKG) data is needed to assess the current monitoring protocol for use of droperidol in ED patients. Overall, droperidol remains a therapeutic option in the ED and its reintroduction has provided clinicians with an additional treatment modality, though continued evaluation is necessary to optimize monitoring strategies and ensure patient safety.

Program Affiliations: KNIGHT ScholaRx

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 106

Review of Management of Hemophagocytic Lymphohistiocytosis-like Syndrome Following Chimeric Antigen Receptor T-cell Therapy: Diagnosis, Treatment, and Differentiation from Cytokine Release Syndrome

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Purpose: Chimeric Antigen Receptor T-cell (CAR-T) therapy, a second-line treatment for hematologic malignancies, is commonly associated with toxicities like Cytokine Release Syndrome (CRS) and Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS), both with established guidelines. However, Immune Effector Cell Associated HLH-like Syndrome (IEC-HS) remains a rare, life-threatening complication with limited treatment protocols. This review analyzes IEC-HS symptoms, differentiates it from CRS, and evaluates current and emerging treatment approaches.

Methods: A literature search was conducted using PubMed, Google Scholar, and ScienceDirect, focusing on studies from 2017 to 2024, with one foundational 2006 study included. Search terms included “CAR-T,” “HLH,” “HLH-like,” and “treatment.” ClinicalTrials.gov, package inserts, and additional sources on HLH management were reviewed. Fifteen studies were analyzed to assess IEC-HS treatment strategies and investigational therapies.

Results: IEC-HS frequently follows CRS, with differentiation relying on a prior CRS event and markedly elevated ferritin levels. Diagnosis follows HLH-2004 and Hscore criteria, emphasizing fever, splenomegaly, cytopenia, and hyperferritinemia. Current IEC-HS management adapts from secondary HLH protocols, with etoposide as first-line therapy, either alone or with dexamethasone. Anakinra, an IL-1 receptor antagonist, is a key alternative. Corticosteroids remain integral to treatment, while ruxolitinib shows promise for refractory cases. Though research on IEC-HS treatment is ongoing, early intervention is critical. Emerging therapies like emapalumab and the investigational monoclonal antibody ELA026 are in clinical trials and may improve treatment outcomes.

Conclusions: IEC-HS is a severe CAR-T-related complication requiring prompt diagnosis and intervention. While current treatment mirrors secondary HLH protocols, distinguishing IEC-HS from CRS remains challenging. Continued research into novel therapies may enhance management and patient outcomes.

Program Affiliations: Lambda Kappa Sigma, EMSOP

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 107

Risk-Benefit Analysis on the use of Complex Innovative Trial Design (CID) in Clinical Studies

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Purpose: In the past decade, complex innovative design (CID) trials have emerged as variations in clinical trials. CID trials often refer to Bayesian analysis and strategic randomization which accelerate drug development and enhance treatment efficacy for test subjects when compared to traditional design. However, CID trials have risks which may yield flawed data and cause subject harm. The objective is to evaluate CID case studies to determine their effectiveness compared to traditional trial design.

Methods: A comprehensive literature review involving five published case studies from the FDA's Complex Innovative Trial Design (CID) Paired Meeting Program, intends to increase interactions between sponsors and the FDA regarding CID. Each case study focuses on the single clinical trial design that was the subject of the submission, and does not include any plans to conduct other trial types or establish evidence of effectiveness.

Results: Each case study implements borrowed data for its own intent to maximize efficiency. Study 1 and 3 use historical data and apply it to a new population. Study 1 uses data from the same drug to support new indications and Study 3 uses data from previous substudies for different types of chronic pain. Study 2 extrapolates adult and pediatric data for a more feasible pediatric trial. Each case carries the risk of inappropriate data for the present study rendering the results uninterpretable.

Conclusion: Potential benefits of CID include improvements in efficiency and feasibility of conducting trials using borrowed data to improve statistical power, especially for studies facing challenges in patient recruitment. However, risks to CID include potential for increased bias, further Type I and Type II error, and implausibility of study results. While CID promises new, innovative ways to facilitate clinical trial design, further research is necessary to weigh the benefits against the risks when compared to traditional study design.

Program Affiliations: IPhO Scholarly Activities

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 108

Safety and Efficacy of Vitamin K in Pediatric Patients

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Phytonadione (Vitamin K) plays an essential role in the regulation of clotting. It is primarily used in the setting of coagulopathy in which one's INR reaches a value above therapeutic range (INR < 1.2). In some disease states, fat soluble vitamin absorption is impaired and in these cases Vitamin K can be given as a dietary supplement. Current recommendations may not be practical which provides a challenge for providers and leads to a large variation in treatment for these patients.

Pediatric patients at Cooperman Barnabas Medical Center who received at least one dose of Vitamin K administered either orally or intravenously (IV) during their admission between January 1, 2022, and July 31, 2024, were enrolled in this study. Exclusion criteria were patients who received subcutaneous Vitamin K, patients not receiving labs before and after Vitamin K administration, and patients who had a normalized INR prior to Vitamin K administration. The primary objective was to determine the number of patients who achieved a normalized INR, defined as 1.2 or less after Vitamin K administration.

25 patients met inclusion criteria, and 5 patients were excluded. After administration of Vitamin K, 12 patients (48%) were able to achieve a normal INR. Within 24 hours after administration of Vitamin K, the mean INR change was -0.293. IV administration of Vitamin K resulted in greater reductions to INR compared to oral use. The mean INR change was -0.436 for IV administration and -0.193 INR for oral administration.

The use of Vitamin K in pediatric patients at its current dosing of 0.5mg/kg (max 10mg) was safe and effective in our study as it resulted in a noticeable decrease in INR, PT, and PTT. It can also be determined that in our study IV administration resulted in a greater reduction in INR.

Program Affiliations: N/A

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 109

Sodium Zirconium Cyclosilicate Use in the Management of Patients with Hyperkalemia

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Purpose: Sodium zirconium cyclosilicate (SZC) and sodium polystyrene sulfonate (SPS) are medications used to manage hyperkalemia by binding potassium in the gastrointestinal lumen and facilitating its excretion. SPS use may be limited by severe gastrointestinal adverse effects, while SZC may be better tolerated. This study aims to understand the safety profile of SZC and its usage at a regional community hospital system, since it is a newer agent to prescribers.

Methods: This retrospective chart review included adult patients with hyperkalemia (potassium level 5.2 mmol/L or greater) who received at least one dose of SZC between April 1, 2024 and June 30, 2024. Key exclusion criteria included patients receiving dialysis, missing a potassium level prior to or after the initial dose of SZC, withdrawal from care, or expiration prior to regimen completion. The primary analysis described SZC prescribing patterns, including dosing regimens utilized and change in serum potassium levels. The secondary analysis described the safety profile of SZC and use of concomitant medications affecting potassium levels.

Results: A total of 98 patients were included. Mean baseline serum potassium level was 5.7 mmol/L and 45% of patients received insulin. SZC was administered as a one-time dose for 66 (67%) patients. The mean serum potassium reduction from baseline was 0.7 mmol/L at 11.3 hours. Of the 75 patients with follow-up levels by 48 hours, 58 (77%) achieved normokalemia, 72% of whom received one-time doses. Constipation and edema occurred in 10% and 19% of patients, respectively, while hypokalemia occurred in 3 patients.

Conclusion: SZC, as a one-time dose, may provide urgent reduction in potassium levels. Further prospective studies are needed to confirm the efficacy of this regimen. Provider education may also be warranted for primary use of adjunctive agents, such as insulin.

Program Affiliations: KNIGHT ScholaRx

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 110

Systematic Review of Montelukast's Potential for Drug Repurposing and Management of Neurodegenerative Disorders

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Background: Montelukast (MTK) is a leukotriene receptor antagonist historically used for asthma and allergic rhinitis. Given the neuropsychiatric events associated with MTK, research has been conducted to better understand MTK diverse biological effects, with an emphasis on neuromodulation. Recent studies suggest that MTK may have a role as a neurodegenerative disorder (NDD) modulator and has potential to be repurposed for NDD management. Recent studies suggest that MTK reduces neuroinflammation and may have direct antioxidant properties, providing a neuroprotective effect. This study aims to review existing literature and report on the potential role of MTK in the management of NDDs.

Objectives: 1. Assess the neuroprotective effects of MTK in mitigating the progression of NDDs. 2. Evaluate MTK's potential to be repurposed for the management of NDDs and identify disorders with the strongest evidence for repurposing.

Methods: A systematic search will be conducted using MEDLINE, PubMed, and Embase with the following MeSH keywords: "Montelukast," AND "Neurodegenerative Disorders," OR "Alzheimer Disease," OR "Parkinson Disease," OR "ALS - Amyotrophic Lateral Sclerosis" OR "Multiple Sclerosis." References of identified publications will be reviewed for additional relevant studies. Preclinical (animal) and clinical (human) observational studies will be included. Only full-text primary literature published in English will be included. Studies published prior to 2015 will not be included in the results to maintain relevance from the search. Results will follow the PRISMA 2020 reporting guidelines.

Outcomes: The study will report findings from both preclinical and clinical observational studies that detail the effects of MTK on neurodegenerative and neuroinflammatory markers, neuronal activity, and neural processing. These outcomes will be evaluated to support the research objectives. Comparisons will be made across the various types of NDDs and may provide valuable insights for future research and potential clinical applications, particularly in identifying novel therapeutic avenues for managing NDDs.

Program Affiliations: Rutgers American Association of Psychiatric Pharmacists (AAPP) Journal Club

Poster Category: Clinical Science

Primary Author Title: Pharm.D. Student

Abstract 111

The Evolution of Mycophenolate Mofetil (MMF): A 30-Year Journey in Clinical Practice

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Purpose: The purpose of this paper is to examine the 30-year journey of Mycophenolate Mofetil (MMF) in clinical practice, where it has evolved and expanded its therapeutic use as an immunosuppressant. Originally introduced for transplant patients, MMF subsequently has since been adapted to additional therapeutic areas such as Autoimmune Hepatitis and Systemic Sclerosis, improving clinical outcomes across diverse populations. Our research highlights major clinical trials that have demonstrated the broader efficacy and safety of MMF. Despite its long-standing presence, MMF continues to evolve, remaining a critical component in modern immunosuppressive therapy.

Methods: Our literature search on MMF utilized PubMed, Embase, Google Scholar, and Clinicaltrials.gov. We also used the MeSH terms “Mycophenolate,” “Solid Organ Transplant,” “Autoimmune Hepatitis,” “Systemic Sclerosis,” “Systemic Lupus Erythematosus,” “Lupus Glomerulonephritis,” “Bullous Pemphigoid”, “Dermatomyositis,” “Myasthenia Gravis,” and “Immune Thrombocytopenia.” A total of 22 studies were included, focusing on the significance of clinical trials supporting the off-label indications of mycophenolate in terms of efficacy and safety. These studies consisted of retrospective analyses, systematic reviews, meta-analyses, cohort studies, clinical trials, and cross-sectional studies. We excluded studies published before 1994, those without control groups, and ongoing clinical trials without available results, as they fell outside the scope of our research.

Result: A total of twenty-two studies were found studying Mycophenolate in a series of off-label disease states. For hepatitis, autoimmune refractory (AIH), six studies showed MMF as a possible alternate route for patients failing azathioprine therapy. In patients with early diffuse systemic sclerosis (dcSSC), three studies reported a significant improvement of MMF therapy in patients compared to those on cyclophosphamide. Furthermore, two studies were found reporting MMF use in Lupus erythematosus (SLE), indicating possible MMF improvement in lowering incidences of lupus nephritis, while one study was found demonstrating long term efficacy in MMF for patients with lupus glomerulonephritis. In the off-label use for bullous pemphigoid, four relevant studies were identified that demonstrated a superior hepatotoxicity profile versus azathioprine in patients with this rare skin condition, suggesting improvements in adverse effects. In patients with dermatomyositis, three studies were found administering MMF post-treatment, showing some gastrointestinal side effects but overall a positive trajectory. Finally, in patients with myasthenia gravis, three studies were found that did not show a significant difference between MMF monotherapy and adjunctive therapy.

Conclusion: Throughout MMF’s 30-year clinical journey, its immunosuppressive impact has expanded and ensured. For example, retrospective trials with MMF in hard-to-treat rare diseases such as Bullous pemphigoid and Lupus glomerulonephritis signal superior safety and efficacy versus the current standard of care. As a result, MMF merits further investigation, especially given the high unmet medical need in rarer immunosuppressive diseases. In addition, while the often lengthy regulatory process is requisite for labeling, MMF can still make a wider mark in the clinical world with a future that has much potential and a concurrent lens on health equity.

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Abstract 112

The Financialization of Depression: Studying SSRIs on Creativity

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This paper examines the intersection of pharmaceutical marketing, mental health treatment, and creative cognition in young adults, with a focus on the impact of selective serotonin reuptake inhibitors (SSRIs). As pharmaceutical companies aggressively market SSRIs to 18–25-year-olds, many individuals are drawn to these medications by promises of relief from depression and anxiety. However, direct-to-consumer advertising often presents misleading claims that oversimplify the science behind depression, contributing to increased medication dependence. The research explores how marketing strategies, including the illusory truth effect, shape public perception and influence young adults' reliance on antidepressants. Furthermore, this paper investigates the neurological effects of SSRIs on creativity, analyzing how supplementing changes in neurotransmitter function impact cognitive flexibility, emotional depth, and artistic expression. While some individuals experience therapeutic benefits, others report a diminished sense of creativity and self-identity. The study ultimately critiques the pharmaceutical industry's role in shaping mental health narratives and questions whether the commodification of antidepressants fosters long-term well-being or reinforces learned helplessness. By integrating psychological, neurological, and sociological perspectives, this paper argues for a more critical evaluation of SSRIs' effects on creativity and calls for increased transparency in pharmaceutical marketing.

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Abstract 113

Therapeutic Use of Cannabidiol (CBD) in Autism Spectrum Disorder: A Comprehensive Review of Mechanisms of Action and Clinical Applications

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Autism spectrum disorder (ASD) is a neurodevelopmental disorder marked by impaired social interaction, communication challenges, and repetitive and stereotyped behaviors, with global prevalence on the rise. Current pharmacological treatments include antipsychotics such as risperidone and aripiprazole, which primarily target aggression and irritability, leaving core symptoms largely unaddressed. Cannabidiol (CBD), a non-psychotropic cannabis derivative, exhibits anti-inflammatory, neuroprotective, and anxiolytic properties, suggesting potential as an adjunct therapy for ASD. This literature review will evaluate CBD's potential mechanisms of action, clinical efficacy, safety, and drug-drug interactions in the context of ASD treatment with a focus on its effects on the endocannabinoid system, gut-brain axis, and neurotransmitter modulation, synthesizing data from preclinical and clinical trials. This literature review will systematically analyze preclinical and clinical studies on CBD use in ASD by utilizing PubMed with MeSH terms, including "Cannabidiol" and "Autism Spectrum Disorder." Studies were selected based on inclusion criteria focusing on CBD's molecular mechanisms, behavioral outcomes in ASD patients, and pharmacokinetic interactions, then categorized by safety, efficacy, and tolerability, with strengths and limitations assessed for translational relevance and clinical implications. The scope also included cross-comparison studies of drug-drug interaction implications as a secondary outcome. Exclusion criteria eliminated anecdotal reports and articles lacking quantitative or measurable clinical outcomes. Additionally, studies focusing solely on THC or unrelated cannabinoids, such as cannabidivarin (CBDv), were excluded to ensure relevance to CBD. Evidence indicates that CBD modulates endocannabinoid signaling through two receptor subtypes, Cannabinoid Receptor Type 1 and 2, and reduces neuroinflammation. Unlike tetrahydrocannabinol (THC), CBD is not a direct agonist of CB1 or CB2 receptors but influences endocannabinoid signaling by inhibiting fatty acid amide hydrolase (FAAH), increasing anandamide levels. Clinical trials in ASD report statistically significant behavioral improvements in social deficits, anxiety, and sleep disturbances, although adverse effects such as irritability, appetite changes, and somnolence were noted. Drug-drug interaction analysis revealed increased serum levels of anxiolytic medications, especially selective serotonin reuptake inhibitors (SSRIs), and elevated liver function tests with antiepileptics like valproate and clobazam, underscoring the significance of therapeutic monitoring. Gaps remain in understanding long-term safety, optimal dosing, and mechanisms of adverse effects.

Program Affiliations: American Association of Psychiatric Pharmacists (AAPP) Journal Club

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Abstract 114

Evaluation of readability of educational materials for coronary artery disease and the impact of health literacy and behavioral psychology on medication adherence and health outcomes

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Title: Evaluation of readability of educational materials for coronary artery disease and the impact of health literacy and behavioral psychology on medication adherence and health outcomes.

Purpose: According to the CDC, 1 in 20 American adults over the age of 20 are impacted by coronary artery disease (CAD), costing the healthcare system over $200 billion annually. While the NIH recommends a reading level of 6.5-8 for patient education materials, it appears that most materials are written at a higher level. With improved readability (grade level) of patient education materials (PEMs) and health care provider (HCP) understanding of patients' health motivations, much of this burden can be resolved. This poster examines the impact of health literacy (HL) and behavioral psychology on patient medication adherence and health outcomes.

Methods: This effort involved reviewing primary literature relevant to the objectives. Sources were found through PubMed and Google Scholar. Mesh headings used included health literacy, medication adherence, medication management, readability, coronary artery disease, locus of control, health belief model, and health and patient outcomes. Journals published outside the United States, not relevant to CAD, and before 2009 were excluded from this review. Microsoft Word was used to determine the Flesch-Kincaid reading level of 17 current patient education materials, including nine sources referencing cholesterol-lowering medications and eight patient websites explaining the disease state. After the initial research on health literacy, confounders were considered and further explored. Various methods to improve patient medication adherence and the readability of PEMs were evaluated, which led to the investigation of the psychological explanation behind patient behavior.

Results: This analysis reviewed 26 articles. A correlation has been identified between low HL and poor health outcomes. HCPs attempted to overcome this concern by providing PEMs and encouraging different techniques for medication adherence. Based on the assessment of PEMs, we found that the readability of information written on various articles explaining CAD and multiple cholesterol lowering medication websites ranged from 7.6 to 14.1, averaging at 10.2. Additionally, a randomized controlled trial found that none of the predetermined approaches used for managing medication refills improved adherence. Because patients have not demonstrated improved health outcomes utilizing high-level PEMs or assigned adherence strategies, it's clear that there's a psychological underlay preventing their willingness to adhere. A study showed that medication beliefs are more influential to medication adherence (7%) than understanding the disease state (2%). This further confirms that education is not sufficient alone, favoring the use of the locus of control and health belief model. Focusing on the patients' internal locus of control has proven to motivate the patient and encourage them to follow their treatment regimen rather than feeling isolated from the HCP decision making process. Patients believing they have informed ownership over their health can promote favorable outcomes.

Conclusions: Improving medication adherence and health outcomes requires patient education, lowering readability, and recommending adherence techniques. Patients' health beliefs also need to be considered. There is limited data on the impact of direct patient education provided; therefore, pinpointing the cause of poor outcomes is difficult. Future research is needed to encourage healthcare organizations and pharmaceutical manufacturers to aspire to lower reading levels on PEMs while establishing comprehension and reinforcement of information. HCPs must use behavioral psychology techniques to motivate their patients to expand their education and feel involved in the decision-making of their medication regimens to improve overall health outcomes."

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