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## Transdermal delivery of Selected Therapeutic Agents used for the Management of Migrane / Dr. Kevin Ita

Migraine is the most prevalent neurological disease, affecting 38 million people in the U.S. and 1 billion worldwide. It is characterized by recurring headache of unilateral onset, photophobia, phonophobia and autonomic disturbances. Migraine pathophysiology is associated with disturbances in many parts of the brain including the hypothalamus, thalamus and brainstem.

Tryptans are commonly utilized for the management of migraine. These include almotriptan (ATN) malate and naratriptan (NTN). In this research project, the *in vitro* transdermal flux values for almotriptan malate and naratriptan hydrochloride across microneedle-treated pig skin will be investigated. However, only few medications can cross the human skin in therapeutic quantities. The outermost layer of the epidermis (stratum corneum), hinders the quantity of medications which can enter the systemic circulation through the skin. Microneedles can be used to overcome this obstacle. Microneedles(MNs) are micron-sized needles (less than 1000μm) which can pierce the stratum corneum and facilitate transdermal drug delivery.

Franz diffusion cells will be used to study the percutaneous penetration of ATN and NTN across pig ear skin. Microneedles will be used to increase transdermal drug delivery. Steady-state transdermal flux values will be calculated from the linear portion of the mean cumulative amount versus time curves. Mann-Whitney Rank sum test will be used for statistical analysis. Graphpad Prism software will be utilized for this purpose. Results will be expressed as mean ± standard deviation (SD) and considered significant at the 95% confidence interval ($p < 0.05$).

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  Sattar M , Hadgraft J, Lane ME Preparation, characterization and buccal permeation of naratriptan (2015 ) Int J Pharm. 493(1-2):146-51
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## Roles of Autophagy and Cellular Senescence in Tumor Suppression / Drs. Daniel Keppler & Athena W. Lin

Dr. Daniel Keppler is an expert on the role of lysosomal cysteine proteases (cathepsins) and their endogenous inhibitors (cystatins) in normal cellular homeostasis and in proliferative diseases such as neoplasia.

Dr. Athena W. Lin is an expert on signaling mechanisms leading to cellular senescence and tumor suppression.

Jointly, their efforts are aimed at identifying novel tumor suppression mechanisms using a combination of cell biology, molecular biology and biochemical approaches. Currently, they are elucidating the roles of senescence and autophagy in tumor suppression.

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## Design, synthesis and pharmacologically evaluation of SHetA2 analogs as anti-cancer agents / Dr. Shengquan Liu

The MS research project involves the design and synthesis of SHetA2 analogs as novel anti-cancer agents. Previously, we synthesized SHetA2 which have been shown to induce the apoptosis of cancer cells while sparing normal cells. The preclinical study on SHetA2 in National Cancer Institute (NCI) showed that it is effective and much less toxic than traditional anti-cancer drugs and thus is now in Phase 0 human clinic trial. Our goal is to design, synthesize and pharmacologically evaluate more potent and less toxic SHetA2 analogs as anti-cancer agents. The MS students will learn how to design, synthesis drug molecules and the whole process of drug discovery. Background and knowledge in organic chemistry and organic synthesis are important for this research. The research experience will benefit students in the employment in pharmaceutical industries.

2 specific aims

1. Design and synthesis of SHetA2 analogs which target cancer cells without harming normal cell.
2. Design and synthesis of anticancer codrugs which conjugate the traditional cytotoxic anticancer drug with SHetA2 (cancer-recognition moiety)

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## Gedunin suppresses amyloid beta (Aβ)-induced inflammatory and pro-oxidant responses in astrocytes and microglia: Implications for Alzheimer's disease / Dr. Shankar Chinta

Alzheimer's disease (AD) is an age-related irreversible, progressive brain disorder that slowly destroys memory and thinking skills, and eventually the ability to carry out the simplest tasks. Classically, AD has been viewed as a neurodegenerative disease of the elderly, characterized by extracellular deposition of misfolded amyloid beta (Aβ) peptides and intracellular formation of neurofibrillary tangles.

Recently, neuroinflammation has emerged as an important component of AD pathology. The sustained formation and deposition of Aβ aggregates are proposed to be the cause of chronic activation of the immune system and disturbance of microglial clearance functions. The activated microglia cells, which compose the majority of this inflammatory response, contribute to the neurodegenerative process. Suppression of microglia activation may provide an effective therapeutic intervention that alleviates the progression of the neurodegenerative diseases. Recently, the natural products and their components have received considerable attention as alternative candidates for therapeutic purposes. They have a reputation for being safe, inexpensive, and readily available.

In this study, we propose to evaluate the anti-inflammatory and neuroprotective role of natural product gedunin in the inflammatory response induced by Aβ deposition. For this purpose, we will analyze the role of gedunin in the expression of proinflammatory cytokines such as IL-6 and TNF-α from microglia and astrocytes activated by Aβ in vitro. We will further evaluate the effect of Aβ-treated microglia-conditioned media on hippocampal neurons. For this study, we propose to utilize various molecular biology and biochemical techniques such as primary microglial and neuronal culture, western blot, qPCR and immunocytochemical techniques.

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## Development of an anti-cancer Epstein-Barr virus vaccine/ Dr. Alison McCormick

Lymphomas of all types have been associated with Epstein-Barr virus (EBV) coinfection. As such, EBV is considered an oncovirus that promotes B cell proliferation and transformation. Though it is an important mediator of B cell tumorigenesis, there is currently no vaccine for EBV, for prevention or for treatment. Our hypothesis is that the latent membrane proteins LMP1 and LMP2 represent EBV antigens that are expressed after B cell transformation, and are excellent candidate vaccine targets. An EBV vaccine could be combined with standard B cell lymphoma treatments like Rituximab to improve tumor eradication, and limit tumor escape during therapy. One key problem with EBV studies is that there is no mouse model of EBV B cell lymphoma. Our goal will be to develop mouse B cell lines (A20 and/or 38C13) that express EBV antigens LMP1 and LMP2 and use those cell line to study vaccine efficacy in a mouse model of EBV disease. We will vaccinate with LMP1 and LMP2 antigens and then challenge mice with the mouse B cell-EBV tumor cells and measure tumor progression over time. Efficacy will be evaluated as a stand-alone vaccine, or combined with Rituximab or other potentially synergistic anti-tumor antibodies.

Research goals:
1. Transform mouse A20 or 38C13 B cell lines with EBV LMP1 and LMP2 plasmids
2. Develop stable cell lines and confirm surface expression of LMP1 and LMP2 by western blot and immunocytochemistry
3. Characterize tumor cell growth in mice compared to the parent cell lines
4. Vaccinate mice and challenge with tumor cells and monitory tumor volume compared to unvaccinated controls
5. Compare efficacy with Rituximab addition, or other antibody treatments

This is a well-defined project with achievable goals in the time frame of a master's thesis project. Skills gained will be broadly applicable to clinical and biotechnology methods, including molecular biology, cell biology, and animal study protocols, with a cancer biology study emphasis.

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## Energy metabolism in health and disease / Dr. Shona Mookerjee

All life depends on the flow of energy. In biological systems, one of the major ways that energy flow occurs is through the synthesis and turnover of ATP. Despite decades of research on metabolism, ATP production and consumption in cells is not well understood, though it is clearly vital to cell survival and proliferation. My research program is focused on how ATP homeostasis is maintained in cells, and whether it is important for maintaining proper cellular behavior. Conversely, we are interested in whether dysregulation of ATP production promotes disease, including cancer progression. Current projects in my lab include:

1. Understanding ATP turnover during muscle cell differentiation
2. Understanding ATP turnover during breast cancer progression
3. Understanding ATP turnover and mitochondrial DNA maintenance

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## Novel Flexible Heteroarotinoids as Targeted Therapeutics for Prostate Cancer/ Dr. Vanishree Rajagopalan

In our laboratory, we are involved in screening and testing the growth inhibitory effects of novel anti-cancer agents in human prostate cancer cell lines. These agents have been designed and synthesized as diarylthiourea analogs of SHetA2 by our colleague and collaborator, Dr. Shengquan Liu. Thus far, our screening has resulted in lead compounds, SL-01-18, SL-01-30 and SL-01-39 that have shown potent growth inhibition in both breast and prostate cancer cell lines (Liu, Louie et al. 2015 and Liu, Louie et al. manuscript in preparation). We are now investigating the mechanism of action of these agents. We will be using various cellular and molecular biology techniques such as western blot analysis, RT-PCR, fluorescence microscopy, and other cellular and biochemical assays during this investigation. Specifically, we will be studying cell cycle markers, senescence markers and apoptotic markers that may be involved growth inhibitory effects of these agents on prostate cancer cells.

Liu, S., M. C. Louie, et al. (2015). "Synthesis and evaluation of the diarylthiourea analogs as novel anti-cancer agents." Bioorg Med Chem Lett **25**(6): 1301-1305.

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# Lesson Learned from Reaching Out to the Community: From Knowing Prediabetes/Diabetes Status to Behavioral Changes (tentatively) / Drs. Clipper Young, Jay Shubrook, Gordon McCarter & Mark Gloudeman

**Research Team:** Clipper Young, PharmD; Gordon McCarter, PhD; Mark Gloudeman, PharmD; Jay Shubrook, DO

**Student Investigators**: Monica Rhee, PharmD Candidate 2018; Sena Shin, PharmD Candidate 2018

**Objectives:** (1) To capture the differences in Solano County residents' behaviors responding to prediabetes and diabetes community outreach efforts and (2) to identify the missing components in regard to social determinants of health (SDOH) while reaching out to those who might need the services the most

**Introduction**: The Diabetes Prevention Program (DPP) has been shown effective in weight loss and reducing diabetes incidence in high-risk individuals through lifestyle interventions. Although the program has shown successes, there are many socioeconomic barriers that stop the people with prediabetes from seeking, accepting, and maintaining care.

**Methodology**: This study consists of two study arms: the "passive" mechanism (partnering with Solano County Partnership Health Care Plan to receive clinical data on potential participants) and the "proactive" mechanism [utilizing Touro University's Mobile Diabetes Education Center (MOBEC) outreach efforts].

In the "passive" mechanism, Partnership patients will be contacted to inform about their elevated hemoglobin A1c's (ranging between 5.7% and 6.4%), to inquire whether they knew about their elevated blood glucose levels, as well as to inform them about options to take and to assess their interests on taking further actions in addressing this issue [e.g., urge them to see their primary care providers (PCPs) if a medication to prevent diabetes is desired by the patient vs. offer/enroll them in diabetes prevention program (DPP)]. A follow-up phone call will be made in a month to inquire about their progression in addressing prediabetes, aiming to identify barriers relating to SDOH (if no progression has been made in the past month).

In the "proactive" mechanism, MOBEC will reach out to Solano County residents, but only those who have Partnership Health Care Plan will be included in this study. Data from participants will be collected at every outing (e.g., results from CDC prediabetes screening questionnaire, fingerstick glucose levels, and hemoglobin A1c levels). Based on participants' A1c results, they will be advised to take actions accordingly. For those whose A1c levels are between 5.7% and 6.4%, the same procedure will be followed as in the "passive" mechanism. For those whose A1c levels are at 6.5% or above, they will be urged to see their PCPs for further evaluation and treatment. A follow-up phone call will be made in a month to inquire about their progression in addressing prediabetes or diabetes, aiming to identify barriers relating to SDOH (if no progression has been made in the past month).

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**Implications**: The findings can be used to reveal how different socioeconomic backgrounds relating to SDOH can affect/determine Solano County residents' behaviors responding to the two outreach efforts. With these results, efforts will be made to inform prediabetes and diabetes outreach programs in regard to residents' preferences on outreach methods, attitudes about their elevated hemoglobin A1c, and extent of following through on addressing their elevated blood glucose levels.

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## Motivational Interviewing: Understanding Training Modalities for Skill Acquisition / Dr. Patricia Shane

Introduction:

If patients are not able to fully participate in self-management and medication adherence, especially for those with chronic conditions, the brief interaction with health care providers will be insufficient to create better treatment outcomes. Improving medication adherence requires reframing the events surrounding the communication interface with patients during diagnosis, prescribing and treatment. Ideally, these would be opportunities for collaborative discussion between the patient and his/her providers. While the U.S. healthcare system is moving towards a more patient=centered delivery of medical care, pharmacists have a vital role to play in shaping the ways patient care becomes functionally more patient-centered. Motivational Interviewing (MI) focuses on patients' "current interests and concerns," and requires the healthcare provider to assess the patient for their readiness to change health related behaviors, limitations (e.g. low health literacy) in their ability to follow a treatment plan, and the provider's skillfulness in guiding an exchange on achieving the *patient's treatment goals.*

Methodology:

The research involves developing and evaluating a Motivational Interviewing Training module in the PharmD curriculum, using several training formats. Students will receive 6 to 8 hours of training, including mixed modalities that combine didactic materials, role playing, assessing patient cases, and working as a team through a motivational interviewing skills learning lab with trained standardized patients. The evaluation materials are constructed to capture both individual and team based reviews of the learning lab exercises. Linked to skill acquisition are the following domains: reflective listening, normalizing, expressing empathy, utilizing cognitive dissonance, avoiding power based discourse and conflict, understanding stages of change and readiness to change; and strategizing ways to support patients' autonomy and self-efficacy. Subsequently, an interview guide will be developed that reflects current research and questions about MI. The interview guide will be used in a focus group of participating students during the following semester to collect qualitative data. This will be analyzed for insights and opportunities to expand the experiment and build the capacity to initiate interdisciplinary trainings.

Motivational Interviewing is increasingly used by healthcare professionals to improve patient-centered communication and patient's health outcomes by motivating changes in their health related behaviors. However, substantial time and training are needed before clinicians are sufficiently skilled to adopt MI and implement its techniques. Multi-modality training and technologies show promise as methods to achieve skill acquisition. The American College of Clinical Pharmacology (ACCP) encourages clinicians to utilize motivational interviewing.

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