BIOGRAPHICAL SKETCH

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NAME: Anne J. Gonzales-Luna

eRA COMMONS USER NAME (credential, e.g., agency login): GONZALESLUNA

POSITION TITLE: Assistant Professor - Research

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
The University of Texas, Austin, TX	BA	05/2012	Biology
The University of Texas College of Pharmacy, Austin, TX	PharmD	05/2016	Pharmacy
Michael E. DeBakey Veterans Affairs Medical Center, Houston, TX	Residency	06/2017	Internal Medicine
University of Houston College of Pharmacy, Houston, TX	Fellowship	08/2019	Infectious Diseases

A. Personal Statement

My career goal is to become an expert on antimicrobial resistance in *Clostridioides difficile* infection (CDI), including resistance to both the antimicrobials that cause CDI *and* the antimicrobials that are used to treat CDI. The continuing paradigm guiding CDI treatment is that colonic concentrations of any given antibiotic exceed the minimum inhibitory concentration (MIC) needed to sufficiently eradicate *C. difficile*, thereby deeming susceptibility testing unnecessary. As a board-certified infectious diseases pharmacist, I serve as the clinical expert for a large translational research lab focusing on *C. difficile*. This lab, where I completed my post-doctoral training and have spent the past two years as a faculty member under the mentorship of international CDI expert Dr. Kevin Garey, has a biobank of > 10,000 clinical *C. difficile* isolates with paired strain typing and clinical data. I have used this biobank over the past four years to study antimicrobial resistance and associated outcomes in CDI to begin to close the knowledge gap linking MICs with clinical outcomes. My collaborators and I have been able to demonstrate decreasing clinical success rates associated with increasing metronidazole MICs through use of two different and novel susceptibility testing methods. I aim to apply the clinical and laboratory skills I have developed to continue this work in my transition as a junior, research-intensive faculty member.

1. **Gonzales-Luna AJ**, Olaitan AO, Shen WJ, Deshpande A, Carlson TJ, Dotson KM, Lancaster C, Begum K, Alam MJ, Hurdle JG, Garey KW. Reduced susceptibility to metronidazole is associated with initial clinical failure in *Clostridioides difficile* infection. *Open Forum Infect Dis*. 2021; 8(8):ofab365.
2. Johnson S, Lavergne V, Skinner AM, **Gonzales-Luna AJ**, Garey KW, Kelly CP, Wilcox MH. Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of *Clostridioides difficile* Infection in Adults. *Clin Infect Dis.* 2021; 73(5):755-7.
3. Bassères E, Begum, K, Lancaster C, **Gonzales-Luna AJ**, Carlson TJ, Miranda J, Rashid T, Alam MJ, Eyre DW, Wilcox MH, Garey KW. *In vitro* activity of eravacycline against common ribotypes of *Clostridioides difficile*. *J Antimicrob Chemother*. 2020; 75(10):2879–84.
4. Begum K, Bassères E, Miranda J, Lancaster C, **Gonzales-Luna AJ**, Carlson TJ, Rashid T, Eyre DW, Wilcox MH, Alam MJ, Garey KW. *In vitro* Activity of Omadacycline, a New Tetracycline Analog, and Comparators Against *Clostridioides difficile*. *Antimicrob Agents Chemother.* 2020; 64(8):e00522-20.

B. Positions, Scientific Appointments, and Honors

Positions and Employment

06/2016-06/2017	Clinical, Inpatient, and Outpatient Pharmacy Weekend Staffing
08/2019-present	Research Assistant Professor (Infectious Diseases)
08/2019-present	Infectious Diseases Pharmacotherapy Fellowship Program Coordinator

Other Experience and Professional Memberships

2017- Present	Member, American College of Clinical Pharmacy (ACCP)
2017- Present	Member, Society of Infectious Disease Pharmacists (SIDP)
2017- Present	Member, Infectious Diseases Society of America (IDSA)
2017- Present	Member, European Society of Clinical Microbiology and Infectious Diseases (ESCMID)

Honors

2011	Phi Beta Kappa society
2012	Big 12 Conference Student Athlete Spotlight
2013-2015	UT College of Pharmacy Honor's Day
2015	Texas Pharmacy Association Member Spotlight
2015	Texas Pharmacy Association Magazine Cover Feature

C. Contributions to Science

1. Through my involvement in a Texas statewide *C. difficile* surveillance program based out of the University of Houston College of Pharmacy, I have had the opportunity to coordinate several epidemiologic and translational projects in addition to playing a hands-on role in the associated sample processing and clinical data collection. This effort has been instrumental in educating clinicians of local epidemiology and in complimenting national epidemiology informed by ongoing *C. difficile* surveillance systems that exclude Texas, such as the CDC Emerging Infections Program. Through this experience, I was able to identify and describe an emerging strain 255 in Texas (*Emerg Microbes Infec* 2020, *Microbiol Resour Announc* 2019), contribute to knowledge of strain 027 evolution (*Open Forum Infect Dis* 2019), and utilize a systems approach to identify strain and host traits underlying multiply recurrent CDI (*Anaerobe* 2021).

a. **Gonzales-Luna AJ**, Carlson TJ, Dotson KM, Poblete K, Costa G, Miranda J, Lancaster C, Walk ST, Tupy S, Begum K, Alam MJ, Garey KW. PCR ribotypes of *Clostridioides difficile* across Texas from 2011 to 2018 including emergence of ribotype 255. *Emerg Microbes Infec*. 2020; 9(1):341-7
b. **Gonzales-Luna AJ**, Spinler JK, Oezguen N, Khan Md AW, Danhof HA, Endres BT, Alam MJ, Begum K, Lancaster C, Costa GPD, Savidge TC, Hurdle JG, Britton R, Garey KW. Systems biology evaluation of refractory *Clostridioides difficile* infection including multiple failures of fecal microbiota transplantation. *Anaerobe*. 2021; 70:102387.
c. Spinler JK, **Gonzales-Luna AJ**, Raza S, Runge JK, Luna RA, Savidge TC, Garey KW. Complete genome sequence of *Clostridioides difficile* ribotype 255 strain Mta-79, assembled using Oxford Nanopore and Illumina sequencing. *Microbiol Resour Announc*. 2019; 8(42):e00935-19.
d. Endres BT, Begum K, Sun H, Walk ST, Memariani A, Lancaster C, **Gonzales-Luna AJ**, Dotson KM, Bassères K, Offiong C, Tupy S, Kuper K, Septimus E, Arafat R, Alam MJ, Zhao Z, Hurdle JH, Savidge TC, Garey, KW. Early emergence of epidemic *Clostridioides difficile* ribotype 027 lineages in the US: implications for fluoroquinolone use. *Open Forum Infect Dis*. 2019; 6(2): ofz013

2. CDI continues to be the most common healthcare-acquired infection in the United States and carries with it an enormous burden on morbidity and mortality despite a decades-long focus on the disease. As a postdoctoral fellow, I concentrated on outcomes research in a translational lab focused on infections caused by multidrug resistant organisms, and specifically *C. difficile*. I have worked on a variety of translational research projects to elucidate both host and bacterial factors contributing to poor outcomes associated with CDI, including the impacts of acute kidney injury (*Open Forum Infect Dis* 2020), glucocorticoid use (*Open Forum Infect Dis* 2021), and strain type (*Anaerobe* 2021). I also worked with collaborators to demonstrate that

hospitalized patients diagnosed with CDI are more likely to require a higher level of care following discharge (*Clin Infect Dis* 2018).

a. Almutairi MS, **Gonzales-Luna AJ**, Alnezary FS, Fallatah S, Alam MJ, Begum K, Garey KW. Comparative clinical outcomes evaluation of hospitalized patients infected with *Clostridioides difficile* ribotype 106 vs. other toxigenic strains. *Anaerobe*. 2021; [Online ahead of print].
b. Carlson TJ, **Gonzales-Luna AJ**, Wilcox MF, Theriault SG, Alnezary FS, Patel P, Ahn BK, Zasowski EJ, Garey KW. Corticosteroids Do Not Increase the Likelihood of Primary *Clostridioides difficile* Infection in the Setting of Broad-spectrum Antibiotic Use. *Open Forum Infect Dis.* 2021; [Online ahead of print].
c. Carlson TJ, **Gonzales-Luna AJ**, Nebo K, Chan HY, Tran N-L T, Antony S, Lancaster C, Alam MJ, Begum K, Garey KW. Assessment of Kidney Injury as a Severity Criteria for *Clostridioides difficile* Infection. *Open Forum Infect Dis*. 2020; 7(11):ofaa476.
d. Reveles KR, Dotson KM**, Gonzales-Luna A**, Surati D, Endres BT, Alam MJ, Garey KW. *Clostridioides* (formerly *Clostridium*) *difficile* infection during hospitalization increases the likelihood of non-home patient discharge. *Clin Infect Dis.* 2018; 68(11):1887-93.

3. Our lab, which has existing relationships with two large tertiary care hospitals in the Texas Medical Center, has served as an enrollment site for multiple clinical trials, including an R01 NIH-funded clinical trial. As a postdoctoral fellow, I served as the regional clinical lead for this project focused on improving *C. difficile* diagnosis through use of a single molecule array (Simoa) technology to quantitatively detect toxins with high sensitivity. In addition to overseeing the day-to-day logistics, I was responsible for patient consent, data aggregation, and sample collection, processing, and transport to our collaborators. This project has produced high-impact research in a variety of populations, including immunocompromised (*Open Forum Infect Dis* 2021) and pediatric (*J Pediatric Infect Dis Soc* 2022) patients. Continued analysis is ongoing and higher toxin concentrations have already been described as associated with worse CDI outcomes (*Clin Infect Dis* 2021) and in the epidemic 027 strain (*Clin Infect Dis* 2022).

a. Sandora TJ, Williams DN, Daugherty K, Geer C, Cuddemi C, Kociolek LK, Chen X, Xu H, Savage TJ, Banz A, Garey KW, **Gonzales-Luna AJ**, Kelly C, Pollock NR. Stool Toxin Concentration Does Not Distinguish *Clostridioides difficile* Infection from Colonization in Children Less than 3 Years of Age. *J Pediatric Infect Dis Soc*. 2022; [Online ahead of print].
b. Alonso CD, Pollock NR, Garey KW, **Gonzales-Luna AJ**, Williams D, Daugherty K, Cuddemi C, Villafuerte-Gálvez J, White NC, Chen X, Xu H, Sprague R, Barrett C, Miller M, Foussadier A, Lantz A, Banz Al, Kelly CP. Higher *in vivo* fecal concentrations of *Clostridioides difficile* toxins A and B measured by ultrasensitive toxin assay in patients with NAP-1/027 strain infection. *Clin Infect Dis.* 2022; [Online ahead of print].
c. Alonso CD, Kelly CP, Garey KW, **Gonzales-Luna AJ**, Williams D, Daugherty K, Cuddemi C, Villafuerte-Gálvez J, White NC, Chen X, Xu H, Sprague R, Barrett C, Miller M, Foussadier A, Lantz A, Banz A, Pollock NR. Ultrasensitive and quantitative toxin measurement correlates with baseline severity, severe outcomes, and recurrence among hospitalized patients with *Clostridioides difficile* infection. *Clin Infect Dis*. 2021; [Online ahead of print].
d. Alonso CD, Papamichael K, Sprague R, Barrett C, **Gonzales-Luna AJ**, Daugherty K, Garey KW, Villafuerte-Gálvez J, Xu H, Lin Q, Wang L, Chen X, Pollock NR, Kelly CP. Humoral Immune Response to Clostridioides difficile Toxins A and B in Hospitalized Immunocompromised Patients With *C. difficile* Infection. *Open Forum Infect Dis*. 2021; 8(7):ofab286.

4. As one of the largest research labs specialized in *C. difficile* in the country, I have hands-on experience and have served in supervisory roles in clinical trial execution and drug discovery. Our lab, which has existing relationships with two large tertiary care hospitals in the Texas Medical Center, has served as an enrollment site for multiple clinical trials and I have been a part of the downstream clinical, microbiome, and susceptibility analyses for phase I (*J Antimicrob Chemother* 2020), phase II (*Clin Infect Dis* 2022, *Antimicrob Agents Chemother* 2022), and post-approval (*Antimicrob Agents Chemother* 2020) trials. In addition to serving as a critical part of the drug approval process, our focus on microbiome-focused analyses are paving the way as a novel approach to understanding collateral damage and antimicrobial spectrum.

a. Garey KW, McPherson J, Dinh AQ, Hu C, Jo J, Wang W, Lancaster CK, **Gonzales-Luna AJ**, Loveall C, Begum K, Alam MJ, Silverman MH, Hanson B. Efficacy, Safety, Pharmacokinetics, and Microbiome Changes of Ibezapolstat in Adults with *Clostridioides difficile* Infection: A Phase 2a Multicenter Clinical Trial. *Clin Infect Dis*. 2022; [Online ahead of print].

b. McPherson J, Hu C, Begum K, Wang W, Lancaster C, **Gonzales-Luna AJ**, Loveall C, Silverman MH, Alam MJ, Garey KW. Functional and Metagenomic Evaluation of Ibezapolstat for Early Evaluation of Anti-recurrence Effects in *Clostridioides difficile* Infection. *Antimicrob Agents Chemother.* 2022; 66(8):e0224421.
c. Garey KW, Begum K, Lancaster C, **Gonzales-Luna AJ**, Bui D, Mercier J, Corinne, SY, Ducharme MP, Hu M, Vince B, Silverman MH, Alam MJ, Kankam M. Randomized, Double blind, Placebo controlled, Single and Multiple Ascending Dose Phase 1 Study to Determine the Safety, Pharmacokinetics, Food, and Fecal Microbiome Effects of Ibezapolstat Administered Orally to Healthy Subjects. *J Antimicrob Chemother.* 2020; 75(12):3635–43.
d. Begum K, Bassères E, Miranda J, Lancaster C, **Gonzales-Luna AJ**, Carlson TJ, Rashid T, Eyre DW, Wilcox MH, Alam MJ, Garey KW. *In vitro* Activity of Omadacycline, a New Tetracycline Analog, and Comparators Against *Clostridioides difficile*. *Antimicrob Agents Chemother.* 2020; 64(8):e00522-20.

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