team leader effectiveness correlated with patient care ($p<0.05$) as predicted by team leadership conceptual models. DISCUSSION/SIGNIFICANCE OF IMPACT: This work represents a critical step in advancing translational simulation-based research (TSR). While there are several examples of high quality translational research programs, they primarily focus on procedural tasks and do not evaluate highly complex skills such as leadership. Complex skills present significant measurement challenges because individuals and processes are interrelated, with multiple components and emergent nature of tasks and related behaviors. We provide evidence that simulation-based training of a complex skill (team leadership behavior) transfers to a complex clinical setting (emergency department) with highly variable clinical tasks (trauma resuscitations). Our novel team leadership training significantly improved overall leadership performance and partially mediated the positive effect between leadership and patient care. This represents the first rigorous, randomized, controlled trial of a leadership or teamwork-focused training that systematically evaluates the impact on process (leadership) and performance (patient care).

## Commercialization/Entrepreneurship/Regulatory Science

**3466**

### Innovative 3D Printed Intravaginal Rings: Developing AnelleO PRO, the First Intravaginal Ring for Infertility

Rima Janusziewicz[1] and Janus, S. Rahima Benhabbour
[1]University of North Carolina School of Medicine

OBJECTIVES/SPECIFIC AIMS: The study aims to develop and test a biocompatible 3D-printed IVRs for the mechanical and release properties of a model drug, β-estradiol, then translate these methods to the target drug, progesterone. The goals include demonstrating decoupling of mechanical and release properties of the rings, release profiles driven by geometry and efficacy in sheep animal models to evaluate device safety. METHODS/STUDY POPULATION: A novel 3D-printing platform, continuous liquid interface production (CLIP), pioneered by Carbon, enables the fabrication of complex designs on a timescale that is amenable to manufacturing. The process utilizes computational-aided design (CAD), specifying shape and geometry, which is recreated via a photopolymerization process. IVRs are fabricated with CLIP using a biocompatible resin at a rate of approximately 15 min. per ring. Rings were fabricated and assessed for the release of a model drug, β-estradiol. The process was then translated to the target drug, progesterone. Rings were evaluated for radial compression and in vitro release in simulated vaginal fluid (SVF). RESULTS/ANTICIPATED RESULTS: Intravaginal rings (IVRs) were designed and fabricated to be geometrically complex in an effort to control release. Ring geometry and subsequent pore size was achieved through the use of unit cells. Several design parameters were explored including unit cell type, size, and band presence in two resins of differing mechanical properties. Through design, a wide range of radial compressive properties were achieved which spanned values covered by commercially available rings. The release of β-estradiol in SVF was found to span 57 – 115 days and resulted in near or complete release of the total loaded drug. Changing the internal geometric design of the ring was found to have minimal influence on the compression properties, thus the mechanical and release characteristics of the rings were largely decoupled. DISCUSSION/SIGNIFICANCE OF IMPACT: This is a novel approach to the design and fabrication of intravaginal rings for the treatment of infertility. The use of CAD and the decoupling of release from mechanical properties allows for us to move away from the one-size one-dose fits all approach to IVRs.

**3570**

### The Regulatory Landscape of Products to Treat Opioid Overdose

Pooja Singh[1], Kaylene Okada[1], Amelia Spinrad[1], Nancy Pire-Smerkanich[1] and Eunjoo Pacifici[1]
[1]University of Southern California

OBJECTIVES/SPECIFIC AIMS: Since 1971, Naloxone has been the only FDA approved opioid antagonist indicated for use after opioid overdose. New formulations of Naloxone have been introduced into the market, including an injectable, auto-injector, and nasal spray. However, Naloxone is short-acting and as such often requires multiple doses and may induce severe withdrawal symptoms. This study examines the regulatory framework to understand the evolution of products indicated to treat opioid overdose and the landscape of therapies in development. Furthermore, this study examines how the Food and Drug Administration (FDA) and other government agencies have approached the opioid crisis. METHODS/STUDY POPULATION: A PubMed search of "naloxone AND opioid overdose" with the filter "humans" was conducted to understand Naloxone's regulatory framework. The term "naloxone" was searched on the Drugs@FDA: Approved Drug Products database. Additionally, "nalmefene" was searched on ClinicalTrials.gov. To examine the opioid antagonist market landscape, a PubMed search of "opioid antagonist AND opioid overdose" with the filters "humans" and "clinical trial," and a ClinicalTrials.gov search of "opioid antagonist and opioid overdose," were conducted. Government agency reports were reviewed and cataloged. RESULTS/ANTICIPATED RESULTS: Preliminary findings suggest a lack of innovation in the development of novel opioid antagonists. Most literature review findings focused on already-marketed Naloxone products, including the original injectable approved in 1971, the 2014 Evzio Auto-Injector, and the 2015 Narcan Nasal Spray (Figure 1). For example, there were 14 results yielded from the FDA approvals database, but none of these results represented a new opioid antagonist molecule. A longer-acting opioid antagonist, Nalmefene injectable, was approved in 1995 but has since been removed from the market due to low sales. Our initial ClinicalTrials.gov search using condition "opioid overdose" and other terms "opioid antagonist",revealed no new studies being conducted on alternative opioid antagonist treatments for opioid overdose. Findings only focused on the distribution, co-dispensing, intervention, pharmacokinetics/pharmacodynamics (PK/PD) of Naloxone (Figure 2). However, a Google search yielded one new trial with an opioid antagonist by Opiant Pharmaceuticals, almost fifty years after FDA's approval of Naloxone. A ClinicalTrials.gov search was then performed using the search term "nalmefene" to find whether Opiant Pharmaceuticals' trial was in the ClinicalTrials.gov database. However, the Opiant trial is phase I, and as such does not require reporting on ClinicalTrials.gov. In 2017, the National Institutes of Health (NIH) launched an initiative for longer-acting opioid antagonist formulations. In 2018, Opiant Pharmaceuticals announced positive phase I results for intranasal Nalmefene. The potential return of Nalmefene in intranasal form

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may play a significant role in reducing overdoses, especially in cases where a longer-acting opioid antagonist is necessary. Opiant Pharmaceuticals' trial commenced after the NIH announced their initiative; furthermore, the NIH's National Institute on Drug Abuse granted the company $7.4 million to further the investigation of this drug. We will continue to research drugs that have previously been studied for the indication of treating opioid overdose in the United States and abroad and catalog them. DISCUSSION/SIGNIFICANCE OF IMPACT: The abuse and misuse of opioids in the United States has caused an epidemic accounting for over 115 opioid-overdose deaths each day, devastating our nation, both socially and economically. The United States spends $78.5 billion annually to combat the misuse of these drugs. Due to the severity of the opioid crisis, efforts to better understand approved therapies and investigational products in development to treat opioid overdose will be of significance moving forward. This research can inform agencies who are developing strategies to reduce opioid overdoses and pharmaceutical product developers about the current opioid antagonist landscape.

## Digital Health, Social Media, and AI

3220

### Can you read me now? Clinician variations in managing and responding to secure messages from patients

Joy Li-Yueh Lee[1], Michael Weiner and Marianne Matthias
[1]Indiana University School of Medicine

OBJECTIVES/SPECIFIC AIMS: To identify areas of variation in primary care clinician responses to secure messaging and to assess the quality of secure messages by clinicians. METHODS/STUDY POPULATION: This mixed-methods study included twenty one primary care clinicians from a Midwestern safety net hospital and Veterans Affairs medical center. Participants were presented with five short clinical vignettes and corresponding secure messages from hypothetical patients and asked to compose responses. Participants were interviewed about their cognitive approach to the responses as well as perspectives on quality of care as related to electronic communications. RESULTS/ANTICIPATED RESULTS: Every participant recalled having patients who misused secure messaging for urgent issues, suggesting the need for more patient education and the possible adverse consequences of overlooked messages. The study also uncovered key differences in several areas, include clinician timeliness, message management, the circumstances in which they would use messaging, and the content of the messages (including patient-centeredness). While participants agreed that messages about clinical issues should not be resolved via secure messaging, there was a lack of consensus regarding emotionally charged messages and messages dealing with medication adjustments. Some participants spoke of the need for more guidance in knowing when best to use secure messaging. "Sometimes," one physician said, "it feels like we're just making up [rules for secure messaging]." Although clinician responses were uniformly respectful, the patient-centeredness varied in the use of jargon and social talk, as well as clarity for patients. DISCUSSION/SIGNIFICANCE OF IMPACT: This study revealed variations in provider approaches to secure messaging, and the content of responses. These variations reflect lack of consensus about how care is delivered via secure messaging, and reveal the need for clinician guidance. They also suggest possible negative patient consequences if secure messaging is used ineffectively. The extent to which variations are undesirable remains unknown. Future work will explore the consequences of such variations.

3098

### Combined Eating Disorder and Weight Loss Online Guided-Self Help Intervention: A Pilot Study

Grace Elise Monterubio[1], Denise E. Wilfley and Ellen E. Fitzsimmons-Craft
[1]Washington University in St. Louis, Institute of Clinical and Translational Sciences; Washington University in St. Louis

OBJECTIVES/SPECIFIC AIMS: Among college students with binge-type eating disorders who are overweight (BMI >25), does use of an online, guided self-help program for EDs combined with healthy weight-loss (WL) methods lead to reductions in ED symptoms and weight loss compared to controls referred to standard in-person treatment (Student Health Services)? Aim 1: Develop online, guided self-help program for intervention of ED psychopathology and weight reduction. Aim 2: Implement online, guided self-help program for intervention of ED psychopathology and weight reduction. Aim 3: Follow-up to track remission of ED psychopathology and symptoms and WL maintenance. METHODS/STUDY POPULATION: Up to N=60 college students who meet the criteria (clinical or sub-clinical binge-type ED and have a BMI > 25) and elect to participate will complete a baseline survey to enroll in the study, then will be randomized into a condition. Students in the intervention group (n=30) will be offered 8 weeks of online, guided self-help intervention for ED and WL. Students in the control group (n=30) will receive an email message encouraging them to seek support from Student Health Services for their WL and eating behavior concerns, along with appropriate contact information. All participants will receive follow-up 9 weeks after completing initial baseline, and a final follow-up survey 6-months after completing their baseline. RESULTS/ANTICIPATED RESULTS: Analysis of intervention and control groups will compare average Eating Disorder Examination Questionnaire (EDEQ) scores and WL (change in BMI) at the end of the intervention (9 weeks) and at 6-month follow-up. Group comparisons will be assessed via two-way mixed model ANOVA. DISCUSSION/SIGNIFICANCE OF IMPACT: Online, guided self-help interventions have been used for WL, as well as for treatment of EDs separately, but no program exists to manage these conditions together. Thus, the use of online intervention for ED psychopathology and WL in individuals with clinical and sub-clinical EDs is the next step. The goal of this study is to implement a program to reduce weight and shape concerns, reduce disordered eating symptoms, such as bingeing, and compensatory behaviors associated with binge-type EDs, while also reducing weight for individuals with EDs and comorbid overweight/obesity. This project will pilot an online, guided self-help ED intervention that offers cognitive behavioral based tools to improve ED symptoms in college students, while also teaching the healthy methods of behavioral WL, for students with clinical/sub-clinical binge-type EDs with comorbid overweight/obesity in order to examine effectiveness of the program compared to referral to Student Health Services for ED and WL concerns. Furthermore, the use of an online, guided self-help intervention is more scalable and can circumvent many of the barriers to traditional in-person treatment.

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