Trauma Matters

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A quarterly publication dedicated to the dissemination of information on trauma and best-practices in trauma-informed care.

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A PDF version of this publication with a full list of references is available for download at : www.womensconsortium.org

Prescription Digital Therapeutics to Treat Substance Use Disorder

Audrey Kern, MD

Technology has been advancing rapidly, and mobile devices now affect many aspects of our everyday lives. Our smartphones and tablets influence the way we communicate, work, and live in many ways. What if these devices could also treat disease?

The Food and Drug Administration (FDA) has recognized that software, or Prescription Digital Therapeutics (PDTs), can be used to treat diseases and conditions. The agency has created a new category for clearance and oversight called Software as a Medical Device (SaMD), and these therapeutic products are now being integrated into standard medical care. The first two PDTs to be authorized were reSET®, cleared in 2017 for treating substance use disorder (SUD), and reSET-O®, cleared in 2019 to treat patients with opioid use disorder (OUD) who are also using buprenorphine medication-assisted therapy.

How were these treatments created?

About ten years ago, as the need for new approaches to treat substance abuse and mental health conditions became more urgent and apparent, and to help patients overcome some of the barriers to accessing much-needed therapies, the National Institute of Health sent out a solicitation for projects to digitize evidence-based behavioral therapies. One investigator who responded to this request was Dr. Lisa Marsch, PhD, from Dartmouth's Geisel School of Medicine. Using an evidence-based form of cognitive behavioral therapy called the Community Reinforcement Approach, Dr. Marsch developed clinical content, which was then studied in randomized clinical trials sponsored by the National Institute for Drug Abuse (NIDA). Pear Therapeutics, which develops many PDTs, partnered with Lisa Marsch along with many other academic researchers exploring different types of software treatments. Pear advanced development of reSET for substance use disorder and reSET-O for opioid use disorder which Pear submitted to and were cleared by the FDA.

What makes PDTs different from health or wellness apps downloaded from the internet?

Many apps are now available that aim to help with a variety of medical, behavioral, and mental health problems. Unlike these wellness apps, PDTs must meet stringent FDA regulatory requirements. Their safety and efficacy have been tested in randomized clinical trials and are backed up by peer-reviewed data as required by the FDA. PDTs provide patients with therapeutic tools to improve recognized clinical treatment outcomes. The labeled claims are authorized so clinicians and clients can be assured the software improves outcomes and are reliable. Another difference is that third-party payers such as insurance companies can make an evaluation for coverage based on the traditional pathways and therapeutic coverage mechanisms. The FDA also requires the continued monitoring of PDTs to evaluate safety. All of this gives both clinicians and patients confidence that the claims made for PDTs are reliable.

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What are some of the advantages of digital treatments?

Substance use disorder (SUD), including alcohol use disorder, opioid use disorder, stimulant use, and other substance, is common. In fact, the 2019 National Survey on Drug Use and Health reported that in the previous year, 20.4 million people, or 7.4% of the population age 12 or over, had a substance use disorder.

We know that of the many people struggling with SUD, most are not getting adequate treatments. There are many reasons for this. One is stigma and the fear of being judged negatively by family, friends, and employers for seeking treatment. Another reason is lack of access to qualified clinicians due to lack of nearby treatment providers. Many people with SUD live in rural areas and may have difficulty with transportation, or a lack of time due to the demands of working and parenting. Providing treatment on mobile devices can help overcome these barriers. The treatment can be used privately at a time and place that is convenient to the individual rather than when a clinic is open. For those in recovery, cravings and triggers can occur at any time of the day or night, so having a treatment available 24/7 is invaluable. In addition, PDTs allow clinicians to track their patients' progress during those times when they cannot be seen in clinic.

The COVID pandemic has made stressors worse overall, but particularly for those with SUD. Ongoing care is more important than ever. Remote treatments such as telemedicine and PDTs allow patients to continue to receive care during those times when it is not safe or practical for them to be present in the clinic.

How do reSET and reSET-O work?

Both reSET for SUD and reSET-O for OUD combine three evidence-based forms of therapy into one treatment. Cognitive Behavioral Therapy in the form of Community Reinforcement Approach is presented as lessons or "modules" which are completed in a specific order. This approach supports mastery of key concepts and promotes steady growth in a patient's skills and knowledge as they progress through the weeks of treatment. Each module is followed by a quiz, which is presented in a Fluency Training format. Fluency Training is the second form of evidence-based treatment in the therapeutic, a technique where timing and repetition are used to reinforce concepts. Successfully completing quiz questions allows the individual to move on and to spin a "Rewards Wheel." The immediate dispensing of Contingency Management rewards is the third form of evidence-based treatment in the device. Spinning the wheel gives the person either a non-monetary or a monetary reward. Monetary rewards are stored in the device in the form of digital gift certificates that the individual can redeem whenever they want.

The combined therapeutic approaches of Community Reinforcement Approach, Fluency Training and Contingency Management within reSET have been demonstrated to improve the key outcomes of increased abstinence and retention over the 12-week course of treatment. reSet-O, indicated specifically for treating OUD in conjunction with transmucosal buprenorphine, has also been shown to increase retention in treatment over the 12-week course of therapy.

As patients work their way through the reSET or reSET-O PDTs, they are given opportunities to report their experiences of cravings, triggers such as hunger, loneliness, or anger, and also to record instances of substance use and medication adherence. Patients can report these on their device and the information is shared with their clinician via a Clinician Dashboard. The dashboard allows clinicians to track patients progress in treatment. Clinicians can follow their patients' completion of lessons, the rewards earned, and reported triggers and cravings. Clinicians can also enter drug screen result information, and negative results (i.e., abstinence) allow the patient to spin the wheel and get the positive motivation of a reward.

Despite ongoing efforts, what our health system, public health and payers have been doing to combat the addiction epidemic is not working. As treatment providers caring for patients with substance use disorders, traditionally we have had very few tools in our "toolbox" of treatments. PDTs offer a novel and effective approach to providing patient care and can help us meet our patients where they are.

Featured Resource: The Seed Keeper

Eileen Russo, MA

Told through the eyes of Rosalie Iron Wing, The Seed Keeper is historical fiction based on the true story of a Dakhóta family. Opening in 2002, the narrator reaches back through time to learn and tell the stories of her ancestors, continually detailing their multi-generational spiritual and physical relationship to the titular seeds. The seeds offer Rosalie a spiritual connection to her ancestors who have protected and passed them on, and similarly offer the reader a glimpse into the family's past.

When Rosalie's father dies and she is placed in foster care, she hopes that her extended family will rescue her. Isolated, Rosalie struggles to find herself and the story of her ancestors. When Rosalie connects with a great-aunt as an adult, she is given a basket of seeds that were saved for her, helping her to uncover the traditions she had been deprived of.

Towards the end of the story, a friend from the reservation says to Rosalie, "One more thing before you go, sometimes women and men, can lose their minds when traumatized. Especially when they were not able to keep their children safe. That loss can be too painful to carry. Remember that about your family" (337). The trauma of isolation and loss are central to The Seed Keeper; but it is the story of generational connection and the preservation of tradition that lifts this novel.

For those with an interest in historical trauma and how this affects present day experience, The Seed Keeper will take you on an unforgettable journey.

Ask the Experts:
An Interview with Caroline Sennett

Carl Bordeaux, CPRP, CARC

Caroline Sennett is the Director of the Immigration Legal Services program at the Connecticut Institute of Refugees and Immigrants (CIRI). She is a graduate of Tulane University and Tulane Law School. Caroline began working with CIRI as a volunteer a decade ago before joining CIRI's staff. Caroline provides direct services to clients of CIRI's Immigration Legal Services program and as a Staff Attorney for Project Rescue, CIRI's anti-human-trafficking program. As Director of Immigration Legal Services, Caroline also coordinates the legal services provided in CIRI's Detained Minors Program and Survivor Services Program, which serves foreign-born victims of torture. Caroline conducts outreach and trainings on immigration law, civil rights, and CIRI's programs.

Carl: My name is Carl Bordeaux, and I am an editorial board member of Trauma Matters, a quarterly publication from the Connecticut Women's Consortium. Today, I am pleased to welcome Caroline Sennett, managing attorney and director of immigration legal services at the Connecticut Institute of Refugees and Immigration. Our interview today will be focused on immigration and trauma.

Welcome, Caroline. Once again, thank you for sharing your expertise and experiences relating to refugees, immigration, and trauma.

Caroline: Thank you for having me.

Carl: Why don't you start by telling us a little bit about yourself, how you came to work for CIRI, and your time serving refugees and immigrants.

Caroline: When I went to law school, I was not initially thinking about working in immigration; but, when I graduated and I was preparing to take the bar exam, a friend of mine — who was a volunteer at CIRI — suggested that I work as a volunteer at CIRI. The organization does valuable work and I learned especially about the work that CIRI does with survivors of domestic violence and human trafficking, both of which were areas that really interested me.

I started volunteering while I was preparing to take the bar exam. As a volunteer, I connected with other immigration attorneys. Once I passed the bar exam, I got a job offer in the immigration field from one of those attorneys that I met. Probably a year after that, I was contacted by the people I had worked with previously at CIRI and they said that they had an opening for someone to work with survivors of domestic violence, doing specialized work in order to address that population.

I started to work part time at CIRI and from there I became a site supervisor, then the managing attorney, and now I am the director of immigration and legal services. This wasn't where I planned on ending up, but I am very happy to be here.

Carl: We're happy that you landed here as well. You have several different roles at CIRI. Can you tell us about those roles?

Caroline: CIRI does a lot of different work to provide services to our immigrant population and refugees. We have an anti-human trafficking project, which also focuses on unaccompanied minors. Our legal immigration services tie into a lot of these different programs.

I first started working with survivors of domestic violence who require immigration legal services. Right now, we have funding to provide social services to help those who have been victims of crimes. With this funding, I can work hand-in-hand with a case-manager who can provide for our clients' social needs.

We're historically known for our refugee resettlement, and we are one of 3 refugee resettlement agencies in the State of Connecticut. We help resettled refugees while our immigration legal service team works to help refugees receive any documents they need, such as work authorization or the application for adjustment of status after one year of being here.

Survivor Services is our dedicated program for survivors of torture. Those are foreign born individuals who have survived torture before coming to the United States. They may have some status here already as permanent residents, but many of them are asylum seekers. We provide legal services to that population while also providing them with comprehensive social services and case management.

A lot of our legal work is a joint effort between those who are providing legal services and those who are connecting people with mental and physical health resources — something that is particularly important for survivors of torture.

When I explain our different programs, people tell me that they are confused because it seems like they all overlap. The reality is that they do overlap, because we are doing this work both in the legal arena and on the social side to make sure that our clients receive as much assistance as possible.

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Carl: That's tremendous. It looks like it does overlap in some areas, and you have your fingers in all the programs across the institute.

Can you tell us what the distinction is between refugees and immigrants?

Caroline: 'Immigrants' can be used as a broad term to refer to people who are relocating to the United States and who want to do so on a permanent basis. That could be someone who is coming through a family member or somebody who is coming through employment, but we distinguish between people who are coming here temporarily, who we refer to as a 'non-immigrant', and a person who is coming here permanently.

Our ILS program sees a lot of people coming here through family members. We also see naturalization cases for people who have come here on work programs. Additionally, we have even older cases where people participating in a previous immigration reform are able to become permanent residents because they had been in the United States for a period of time.

Refugees we would consider to be a particular type of immigrant. These are individuals who are outside of the United States, who have been displaced, and who have been identified while outside of the United States as being unable to return to their country.

They must meet the same legal qualifications as an asylee. So, they must have been a victim of persecution due to their race, religion, national origin, political opinion, or their membership in a particular social group.

Usually when we work with refugee clients they have been displaced from their country of origin for some time. Often, they will be in refugee camps. I believe the statistic is that people will spend an average of 17 years in refugee camps before they are resettled to a country like the United States.

The United States government screens these individuals, they conduct extensive background checks on them. For example, they scan their irises, which is not a process many immigrants go through. Then they are resettled by agencies like ours who help them take the steps to start a new chapter in the United States.

Carl: This is quite a service that you are providing.

Caroline: I have to give credit to our refugee team because they are the ones who are there at whatever time the plane lands. They have been working throughout the pandemic, as immigration has slowed or stopped, refugees have kept arriving. When I was behind my plastic barrier in the office, the refugee team was the one out there making sure that people had what they needed. Helping them get from the airport to their new home, set up their new home, get food, and having these in-person interactions when many of us were able to take significantly more precautions. They were frontline workers for that period and the work that they did was amazing.

Carl: Truly first responders in a sense that we don't think about. You know, they respond to the needs of immigrants. Kudos to your team.

Caroline: And when you think about it, we, my coworkers who are doing the legwork, show them how to take buses, we show them how to grocery shop, and we introduce them to the neighborhood. And if you can imagine helping people acclimate to the whole new environment of the United States while it is also the environment of COVID... I can't imagine how challenging that was.

Carl: What is immigrant trauma? And what types of traumas do immigrants and refugees have?

Caroline: I don't think there is a singular immigration experience. We see people who have come from all over the world, who have arrived in the United States in so many different ways.

By the nature of my work, I see people after they have come to the United States, and I see many people who have been in the United States for a significant period before they felt safe seeking out legal assistance. Some of the traumas that you see with the immigrants that I work with are not necessarily the things that you would expect.

When I talk to families who have an undocumented family member who has been here a long time, I hear about the amount of stress and anxiety this causes them. They worry if their loved one leaves the house they are not going to come back or that they might be detained and they ask, "what is going to happen to my life if this person is no longer here?" We have family members who must seek therapy and medication to deal with the anxiety around what might happen, what separation might mean. This is especially impactful for the children.

I think the more traditional types of traumas come through our refugee program. Many of these people are victims of torture, they have seen family members killed, they have seen widespread destruction, they have witnessed war, and more. That tends to leave people very traumatized.

We see that with our asylum seekers who are also fleeing persecution and who need to show that they have experienced persecution. Anything that you can think of that one person can do to another is something that you could see with an asylum seeker. We are talking about very negative things.

Traumas vary. When we talk to people who come to the United States, often there is re-traumatization. We have people who were harmed in their country of origin, sometimes those who were harmed as they fled, sometimes for whom the transit involves trauma.

For people who are immigrating through or waiting to immigrate through Mexico, there is a high rate of crime right at the border and sometimes people are mistreated or abused while they are attempting to cross the border. There is a great risk of human trafficking, sexual abuse, other forms of mistreatment and, because we have large numbers of minors who are crossing the border, you have children who are alone and unable to protect themselves. Not necessarily that their parents would have been

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able to protect them from what they experienced crossing alone but being unaccompanied makes them increasingly vulnerable.

And then we have people who have been victims of crime here in the United States. We see people who have been victims of sexual assault, kidnapping, people who have seen a family member murdered... we also see victims of domestic violence.

Carl: It seems like everything about being an immigrant, from the journey to trafficking, to resettling, and it doesn't stop there, can involve many aspects of trauma.

Caroline: That's one thing that surprises people...that many of the victims and survivors that we serve are victims here in Connecticut. For example, in the labor trafficking context, we see regular labor — which we may perceive as legal — and we don't realize what is happening behind the scenes.

Carl: As an attorney, what types of things do you do within the legal scope that people might not be aware of?

Caroline: As an immigration attorney providing direct legal services, a lot of my time is spent interviewing clients and filling out paperwork. A lot of people think of law as just being in the courtroom, but most of our submissions are done by paper. We are filling out paperwork and we are getting supporting documents by paper. A lot of these documents are being sent across the country to a lockbox in a totally different area where they are reviewed by an anonymous officer who our client is hoping will approve their document. We are also waiting a long time to get an answer when we are asking for a benefit. When we have clients who are looking for a T-Visa because they are survivors of trafficking, we are looking at close to a 2-year wait time.

We do have cases in immigration court as well. We like to say that they are not a 'true court' in the sense that it is an administrative court. So, the rules of evidence are different, but many of the submissions we make to that court are also on paper.

The other aspect I want to emphasize is that wait times are long and a person may be waiting for years for their status. And they are waiting for a status that allows them to get healthcare, allows them to apply for services like Medicaid.

It sounds boring but most of my day is spent talking to people, filling out documents, occasionally having interviews. Interviews are very difficult for clients because they are being sat down and asked to remember everything about every part of their life. That can be terrifying, even if it's a naturalization interview for a person who is already a permanent resident. It can be even more difficult if the basis for your case is that your U.S. citizen spouse abused you terribly and you are terrified that you might be asked questions about that.

Carl: Wow. This has been a very enlightening interview. The information you've conveyed helps to illuminate how embedded trauma is throughout the whole life cycle of an immigrant and how the trauma starts before they even begin the journey and follows even after it ends. Even new traumas — as we've discussed — like the pervasive trafficking industry.

Thank you again for taking the time to share with us. Do you have any parting thoughts?

Caroline: I would share that immigration is not what the common perception of immigration is. People come in a variety of different ways, their experiences are various and diverse.

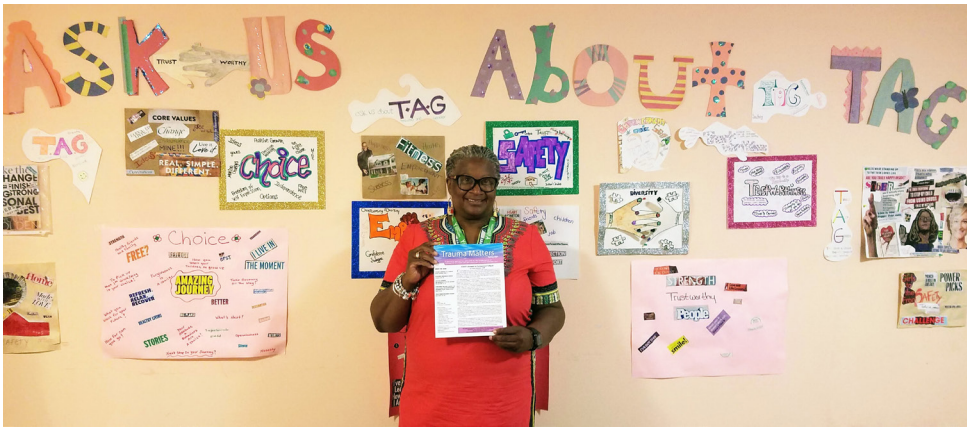
From the services we provide, one of the things that is the most striking is how common it is to encounter people who have suffered trauma, even through family-based cases. And to see how little of this we see on the surface — especially with human trafficking because this is something that we see in Connecticut homes and businesses. It's dangerous, I think, when you're working with someone, to make assumptions.

Parts of this interview have been abridged for brevity and clarity.

Listen to the full conversation at www.womensconsortium.org/podcasts-1.

Who's Been Reading Trauma Matters?

Kathleen Callahan, LMSW



Maggie Young, LADC, MSW is the Chief Recovery Officer for Liberation Programs. She has been working in addiction prevention, residential treatment, and outpatient treatment services for more than 25 years. She oversees our Inpatient Programs as well as spearheading prevention and education services which support middle and high school-aged students and their families. In addition to her local and state work, Maggie facilitated a training in Juneau and Anchorage, Alaska in 2018 for child welfare and court support services staff on the benefit of medication-assisted treatments for women with children.

Through her own personal journey, Maggie was drawn to supporting other women through the often difficult and confusing first steps of recovery. Through her efforts, she has developed collaborative relationships between the local child welfare system, local hospitals, and substance use treatment-services, which has both improved outcomes for families and increased family involvement.

Maggie has a long relationship with the Consortium, our staff, and many of our statewide initiatives. She is an active, engaged, curious, generous, and collaborative partner. The relationships are ones of mutual respect, growth, and shared commitments to the wellness of our clients and communities. She understands that trauma matters and possesses the commitment and determination to act accordingly. A highlight of her work, perhaps demonstrating the essence of Maggie and why her role as Chief Recovery Officer is so appropriate, is her work with the Women and Children's Trauma and Gender (TAG) project.

Under Maggie's persistent leadership, Liberation Programs' Families in Recovery Program (FIRP) participated in the 18-month organizational culture change project offered by the Connecticut Women's Consortium and two years after the end of the official transition from direct consultation, the program continues its evolution toward providing a trauma-informed and gender-responsive delivery of services and environment for both clients and staff. As an inpatient treatment program exclusively for pregnant and parenting women, FIRP focuses on the needs of individual women and their families and understands the heartbreaking decision of separation. Instead of barriers to treatment and recovery, the program provides a safe, nurturing ecosystem for children as well.

During two onsite consultations, we had the opportunity to tour their residence and meet with women in the program. The women were universally, and overwhelmingly, passionate about their love of Miss Maggie, "a beast, the best," and appreciative of the inclusion of examining trauma in their recovery, saying, "I'm finally learning what true recovery looks like," "I think I keep relapsing because of childhood trauma," and "This program saved my life." And the favorite meeting in the weekly schedule? In full consensus, the answer was the newly created TAG group where they talked about the five core values of a trauma-informed culture – safety, trustworthiness, choice, collaboration, and empowerment – and discuss their relationship to recovery and how they personally have, and hope to, experience them in their lives.

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