Greetings,

In this issue we focus on advocacy, and the role of community advisory boards. Our “Spotlight” this issue features Michael Louella. His dedicated work and vibrant personality are an inspiration to the many who have had the pleasure to interact with him.

In our community focus section, we hear a little more from Michael, as well as two other drivers in the HIV research field, Lynda Dee and Karine Dubé. Please also find links to past and upcoming presentations, whitepapers, and a few news items that have captured our attention. In fact, Michael, Lynda, and Karine are all authors on the first paper presented in the news section. Enjoy!

---

**News**

Here is the latest on what we are excited about:

- **Ethical and practical considerations for cell and gene therapy toward an HIV cure: findings from a qualitative in-depth interview study in the United States**

In this newly published manuscript, the authors identified preliminary considerations for a CGT (cell and gene therapy based)-based HIV cure by interviewing three key stakeholder groups: biomedical researchers, bioethicists, and community stakeholders. Qualitative research presented here is essential in determining how
we can walk the path towards cure together and highlights the need for further studies to include traditionally marginalized groups and clinical care providers.

Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products

In this landmark document, the US FDA clearly spells out points to consider in developing new CAR-T products. We were encouraged to see that the FDA clearly recognizes that local manufacturing of CAR-T cells (place-of-care) will play a significant role in moving the field forward. The agency is to be commended for creating a very clear, comprehensive, and readable document. It will serve as a reference for years to come.

BioNTech To Ship Modular MRNA Vaccine Facilities In Containers To African Countries To Jump-start Production - Health Policy Watch (healthpolicy-watch.news)

This article describes how the COVID-19 manufacturer BioNTech will fulfill the promise of global availability by creating mobile labs in which the vaccine can be produced. We likewise believe local manufacturing within similar high-quality mobile labs will play an essential role in CAR-T manufacturing in low- and middle-income countries, as well as in resource constrained settings in the US.

Bioinstructive implantable scaffolds for rapid in vivo manufacture and release of CAR-T cells

The time of direct in vivo generation of therapeutic cell populations may soon be upon us. As evidenced by the growing number of start-ups and academic labs pursuing this topic, the scientific basis and economic advantages can no longer be ignored. By introducing a gene vector into the body, as opposed to genetic engineering of cells outside the body like the current approved CAR-T products, the most expensive part of the process is removed. In this paper, an implantable scaffold is used as a locus for CAR-T generation. We anticipate the advances in the space will keep on coming.
Tell us about your background and how you came to be in your current position.

Watching a patient approach the brink of death, only to be recalled to life is what inspired me to passionately fight to transition my job as a front desk receptionist into a full-time outreach coordinator position at the University of Washington AIDS Clinical Trials Unit (UW ACTU).

I arrived in Seattle from New Orleans on January 11, 2000 without any job prospects lined up. The first place I set foot in Seattle was at the west ground floor entrance to Harborview Medical Center, because upstairs on the second floor of the west clinic worked a nurse who had the key for my new apartment. That’s when I learned about the receptionist job at the clinic. I thought to myself that as a former high school English teacher I used to control auditoriums of teenagers with
my voice alone; surely, I could staff the front desk of an HIV research clinic.

I started working for the UWACTU on January 27, 2000, which means I landed a university-level job in 16 days. I'm still surprised at the speed of that hire—it was as if it was meant to be. They begged me to stay for just one year—and I have lasted now for 22 years. I couldn't help but feel upon reflection that something wanted me to be here.

I didn't fall in love with the HIV research being conducted at the Seattle site overnight. What I paid attention to most were the patients coming and going, especially those who were not enrolling in clinical trials, in which new drugs were being tested, and who were becoming visibly ill. In many cases, patients were slowly dying before my eyes in the lobby of the clinic. Yet one man's voyage from the brink of death back to health is what motivated me to inquire about staying on at the Seattle site and in a greater capacity.

Antiretroviral therapy (ART) for HIV started to change the epidemic, but many people living with HIV were afraid of these medications, likening them to poison. Many refused the treatments because of such conspiracy theories. I saw people slowly die before my eyes. Then, there was this one man who was quite a lively, good-looking fellow who was refusing to start treatment. He grew thin and feeble, and his gait began to falter and fumble. The nurses would plead with him to start ART, yet he refused, clinging to the idea that the medicines would kill him. And then his beautiful head of hair turned white overnight. His vanity in the end helped convince him to begin ART. To my amazement, I got to witness him return to health. He put on weight. He stopped faltering and fumbling. And his hair turned back to its former luster—all in about a month's time of starting medicines. It was the closest thing to a miracle that I had ever witnessed.

Before that moment, I would give credence to every conspiracy story about HIV. It was how I mistakenly thought I was keeping an open mind. No matter what the conspiracy—that the U.S. government manufactured the virus in military labs for the purpose of wiping out gay men and black people; that there was a cure being withheld from the poor; that the AIDS epidemic may have been triggered by the mass vaccination campaign which eradicated smallpox; that recreational drug use or sexual promiscuity were responsible for the manifestations of AIDS—I'd give all ideas an equal chance. I was ignorant of the scientific method, of how human beings determined whether something was true or safe or effective. All I knew was our federal government's neglect of people like me for 20+ years, and so these beliefs seemed believable, plausible, or even likely.

But it was witnessing that miracle, which we came to call the Lazarus Effect, that changed me. That miracle—created in a lab and proven to work by thousands of people with HIV who participated in studies—is what shook me to the core and
forced me to admit I really didn’t know or understand one thing about what was happening behind the doors to our research unit. Admitting that I did not know or understand what it was that made this miracle, or how these pills helped this patient return to health, changed me. A fire was started in me to learn and to understand how the research process led to my only experience with the miraculous. It was my moment of conversion that inspires me to take my time and teach people about ACT UP or community advisory boards or about the science fueling the work towards an HIV cure. It is the moment when the teacher in me transmogrified into and HIV advocate.

Tell us what the focus of your efforts at the present time is and what motivates you.

Currently I am focused on transitioning the UW ACTU into the UW Positive Research. I am focused on starting a new community advisory board for herpes research. And I am focused on implementing community more meaningfully into the HIV research enterprise.

What is your vision for the future and how would you overcome any challenges?

I envision a time when communities and their members are treated like full partners in HIV research, that they co-own the research and guide the potential uses of that research. And I would overcome the challenges towards this goal as any person might do, I would seek collaborators. I would build allies. I would share in the ownership of these ideas. We all would be equal partners with a shared goal.

If there is one thing that would make a difference to your efforts, what would it be?

FUND ALL COMMUNITY ENGAGEMENT ACTIVITIES—FULLY—AND ESPECIALLY FOR HIV TREATMENT & CURE RESEARCH.

Our federal government seems to understand that people by and large don’t see themselves needing, for their own personal benefit, to get involved in an HIV vaccine study. They know it will take teams of people to educate and recruit other people, and it will take vast sums of money to produce advertising, create events, record videos, and disseminate study results, especially after decades without much success in reaching their goal.
HIV treatment and cure research are not funded nearly to the same level. Why not? Because people with HIV should be involved—first and foremost because they are directly affected. People with HIV deserve to be engaged—to be taught with great videos and engaging social media posts. We must ask ourselves why we don’t see equal amounts of money given to HIV treatment & cure studies. I believe it comes from the way things were done at the start. HIV treatment research didn’t need such funds because people were fighting to stay alive. Death was the real engine recruiting people into studies, or perhaps I should say survival was.

Now that people can be otherwise healthy while living with HIV, they don’t need the treatment/cure research to survive. They are like the participants contemplating joining an HIV vaccine study, and thus to not treat them similarly says more about the vestiges of HIV stigma at the federal level than about the potential recruits for cure-related study.

It is a sad shame to still see large research projects seeking to improve the health and well-being of people with HIV put little to no money towards community engagement and education. This must be considered from the very start.

When I was a teacher, I remember having to buy paperback novels for my students, if I wanted them to read a novel together as a class. To see this happen, I had to use my hard-earned and my poverty-level salary to make a broken educational system work. The same broken situation exists in HIV research when we inadequately fund our community engagement efforts.

**What is a fun fact about yourself that you would like to share?**

I have a secret desire to star as the titular character in Sondheim’s musical Sweeney Tood, the Demon Barber of Fleet Street and to direct my version of the great American opera, Porgy and Bess.

---

**Whitepapers**

Interested in learning more? Read our latest whitepapers on the Caring Cross website. Click below to access them.
Regulatory Considerations for Decentralized Manufacturing of Personalized Cell Therapies: A Path Forward for Commercialization of Decentralized Manufacturing of CAR-T Cell Therapies

Centralized vs Decentralized Manufacturing of Personalized Cell Therapies: CAR-T cell Product Manufacture, Quality and Release

Centralized vs Decentralized Manufacturing of Personalized Cell Therapies: Overview and Logistics

Introduction to Chimeric Antigen Receptor (CAR) engineered immune cells

Upcoming Events

Next month’s education tutorial will be the eighth in a series of 9 presented by Rimas Orentas, PhD, Caring Cross Scientific Director.

**CAR-T cells specific for multiple targets (series 8/9)**

Register for the event

Date: May 6, 2022  
Time: 3:00pm EST / 12:00pm PST  
Location: Zoom (link provided upon registration)

This event will last approximately 30-40 minutes and will consist of a presentation and Q&A session following.

All our events are on Fridays at 3pm EST and require registration to access the live webinar. A recorded replay will be available to Caring Cross Community members only (Membership is free).
Recent Events

If you missed these recent events, click on the links below to view them.

Armoring, Fueling, and Loading CAR-T cells: getting ready for the long haul (series 7/9)

Driving anti-HIV duoCAR-T cell therapy to the clinic: Preclinical studies toward a Phase I/IIa clinical trial

CAR-T: A deeper dive into structural and signaling domains (series 6/9)

Enabling HIV CURE Therapies in LMICs

If you are not a member, you can become a member and view all our past events.

Caring Cross Community

We are creating a membership community to connect healthcare professionals, scientists and engineers, community advocates and business leaders that are on a mission to develop new advanced medicinal cures - and help make them affordable to all who need them.

Inspired by Michael Louella’s story and experiences, we wanted to highlight the role community plays in our efforts to bring affordable genetic medicines to all who need them. When new technologies, interventions, or clinical approaches are being tested, it is essential to include the community at large, as well as those who might be directly affected by the intervention.

We asked three inspirational community leaders to educate us on community advisor boards and how their work in community engagement is impacting HIV cure research. Each of them serves in their community as well as in GGTI, the Global Gene Therapy Initiative. The GGTI is described further in the “Impact Initiatives” section of our website.
First we asked this month’s spotlight presenter, Michael Louella, “What is a CAB?”

“Engaging community in clinical research can assume a wide array of shapes and sizes. One common method is a community advisory board, or CAB, which basically consists of group of representatives from the general public, who should also be representative of the community participating in the research. The CAB meets with representatives of the research project or institution to relay information between the two groups. This bidirectional communication is the key to assuring that clinical research is conducted ethically and a prime means to establishing and cultivating trust amid communities affected by the research.

CABs benefit a research project by providing advice about the effectiveness or appropriateness of all parts of a research protocol, from the question it seeks to answer, and the methods used to get those answers, to interpretation of the data collected and dissemination and implementation of the results. Researchers who consult the CABs get valuable information about the community they are researching that they otherwise would not get. They also get guidance that can help keep the research from doing any potential harm to community members. When given a meaningful role with clearly articulated goals, CABs can build capacity in both researchers and community members to better address the aims of the research and to better translate the findings in ways that are meaningful and beneficial to the community.”

What CABs are you involved in?

“I have coordinated the University of Washington’s ACTU (AIDS clinical trial unit) site’s CAB since 2007 and the defeat-HIV CAB FROM 2013 -2020; I have been a member of the Seattle HVTU since 2013 and the UW/Fred Hutch CFAR CAB from 2013-2020. I currently am the co-chair of the DARE CAB and a member of the RID-HIV CAB. I am currently forming an HSV CAB for Dr. Anna Wald and Keith Jerome to inform their herpes vaccine and cure research.”

We then turned to Lynda Dee, best known for her work with AIDS Action Baltimore, and who is also active on our Advisory Board: What CABs are you involved in and how long?

“I have been involved in CABs for about 30 years, first locally with the Johns Hopkins ACTG and the Maryland AIDS Drug Assistance CABs. Thereafter, I have been on all HIV and many HCV Industry CABs since the beginning of HIV and HCV DAA
industry drug development. I have also been involved with government CABs, such as the NIAID ACTG CAB and NCI ECOG CABs as well as an informal FDA CAB and the CROI Community Subcommittee. Most recently I have been on the CARE, amfAR Cure Institute and DARE CABs.”

**What is your role in the CAB?**
“"I have often been a CAB co-chair. I have been responsible for accruing and retaining CAB members, acting as the point of contact for PIs, creating CAB governance documents, creating CAB policy and implementing CAB goals as well as collaborating with other related entities, including government, industry, academia and community. I have acted as a firebrand and provocateur in creating new trial designs and pre-approval drug access that have significantly shortened drug approval time and access to life-saving drugs at much more reasonable prices and the inclusion of community as part of the drug development process from Phase 2 to post-approval as well as the inclusion of women and people of color in clinical trials.”

**How does your role in the CAB help to shape & support the CAB’s mission as it relates to HIV cure research?**
“"My prior HIV experiences will help me to shape and support our CAB’s HIV related cure related mission. I sincerely hope our leadership will make a concerted effort to quickly address and embrace this concept. I’ve been requesting a call in this regard for some time. I'm still waiting...”

Finally, we asked one of the academic leaders of our field, Karine Dubé, DrPH, to share as well.

**What CABs are you involved in and how long?**
“I am a member of the Delaney AIDS Research Enterprise (DARE) CAB. I also coordinate the BEAT-HIV and RID-HIV Collaboratories Social Sciences Initiatives. I am involved with the Global Gene Therapy Initiative (GGTI).”

**What is your role in the CAB?**
“I am very passionate about giving patients, participants and communities a voice in HIV cure-related research and building community capacity to engage in this type of research. I like to help generate ethical considerations for ground-breaking areas of HIV cure science to help ensure that research remains acceptable to communities of interest.”
How does your role in the CAB help to shape & support the CAB’s mission as it relates to HIV cure research?

“I am a socio-behavioral scientist. I help research groups integrate meaningful patient/participant-centered outcomes in HIV cure trials. I am also advising the Female Rising in Education, Support and Health (FRESH) cohort in Durban, South Africa with an upcoming HIV cure (post-intervention control) trial. We hope this research can help inform the design of HIV cure-related strategies that meet the needs of patients where the need for a cure is greatest.”

We applaud Michael, Lynda, and Karine, and thank them for sharing here. They have given of their time, talent, and skills to make community advisory boards a vital part of our work together to find a cure for HIV.

Join us to collaborate in a group, learn from seminars and training, and gain access to job opportunities or internships.

What else would you like to hear about in this newsletter?
Reply to let us know.

Thank you for being here, look out for another update every other month!

- Caring Cross

P.S. Are you following along with us on social media? Be the first to know about our progress and share in the conversation!

>> Join us on LinkedIn
>> Follow us on Twitter

Caring Cross

You can click here to unsubscribe from this list. If you have made any recurring donations, you'll continue to receive receipts via email.

Caring Cross Inc.
708 Quince Orchard Road