THE CURE CHRONICLES

October 2022 ISSUE

Enabling affordable and accessible advanced medicines

Greetings, we are pleased to welcome you to our latest issue – and introduce **Dr. Karine Dubé** – a researcher, patient advocate, and tireless warrior for inclusion. She just moved to San Diego to start a new position in Infectious Disease and Global Public Health. We have some great photos and insights from recent travels – but first.

News

Here is the latest on what we are excited about:

At Caring Cross, we know that a key to lowering cost and increasing access to curative cell and gene therapies for sickle cell, malignancy, and HIV will depend on local manufacturing. As it turns out drug manufacturing is following a similar path.

Please see a recent article describing current needs in drug manufacturing and proposed advances by Rachel Chikwamba et al., 2022, “Equitable drug access: small-scale manufacturing units can help,” in Nature:

➡ **https://www.nature.com/articles/d41586-022-02803-8**

Regulators are also recognizing that local manufacturing is coming soon. Please see the request for comment from the US FDA-CDER (Center for Drug Evaluation and Research), “Distributed Manufacturing and Point-of-Care Manufacturing for Drugs – Discussion Paper,” October 17, 2022.

➡ **https://www.fda.gov/drugs/distributed-manufacturing-and-point-care-manufacturing-drugs-discussion-paper**

Our colleagues at the University Hospital's Seidman Cancer Center in Cleveland were featured in a local news story wherein Dr. Koen van Biesen describes the opening of CAR-T trial in which CAR-T cells are produced locally in 24-48 hours, a major advance!

➡️ **https://www.news5cleveland.com/news/local-news/oh-cuyahoga/researchers-at-university-hospitals-create-a-breakthrough-in-car-t-cell-therapy-for-cancer-patients**

Much awaited results for a second CAR target for Multiple Myeloma were recently reported by researchers at Memorial Sloan Kettering Cancer Center in New York. High response rates were seen with CAR-T specific for GPRC5D, even in patients who had failed BCMA-specific CAR-T therapy. Please see, "GPRC5D-Targeted CAR T Cells for Myeloma," by Sham Mailankody, et al.:

➡️ **https://www.nejm.org/doi/10.1056/NEJMoa2209900?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed**

➡️ **https://www.nature.com/articles/s41571-022-00701-6**

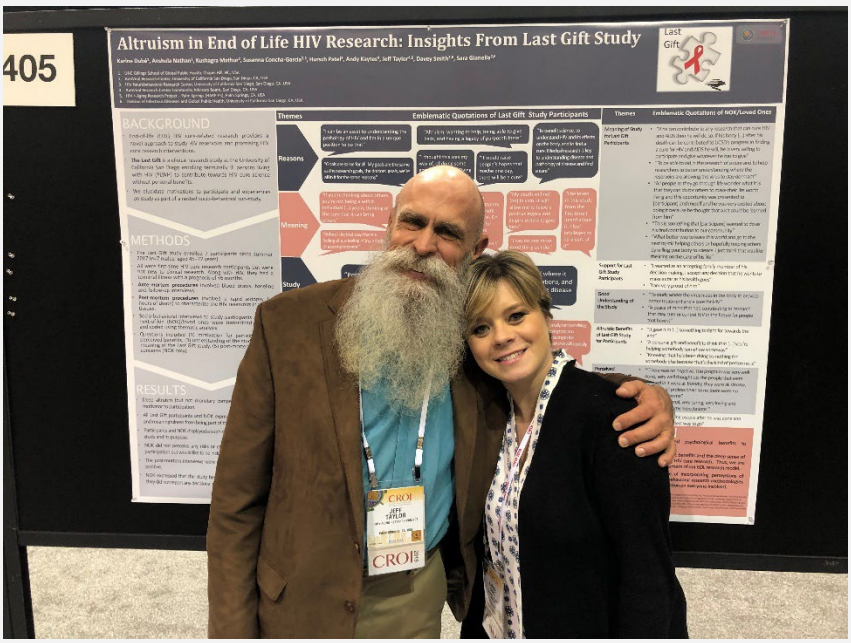
A comprehensive review of the long-term outcomes of bone marrow transplant for children with sickle cell disease was recently published. While the data is very positive, severe toxicities were noted and graft-vs-host disease remains a concern. Please see "Long-term organ function after HCT for SCD: a report from the Sickle cell Transplant Advocacy and Research alliance," by Elizabeth Stenger, et al.:

➡️ **https://www.sciencedirect.com/science/article/abs/pii/S2666636722017080?via%3Dihub**

Community Spotlight

Karine Dubé, DrPH

Associate Professor, University of California San Diego, Division of Infectious Diseases and Global Public Health



Tell us about your background and how you came to be in your current position.

I am a socio-behavioral scientist and research program manager who integrates biomedical, social sciences, ethics, and patient/community engagement in HIV cure-related research in the United States and South Africa. I completed a master's degree in Development Studies/International Health at Oxford University (England) (2003 – 2005), and a Doctor of Public Health from the UNC Gillings School of Global Public Health (2013 – 2016).

As part of my research journey, I wore several different hats to get to my current position – from clinical monitor, research analyst, clinical research manager, epidemiologist, research site developer, research program manager, teacher, and now socio-behavioral scientist. Prior to joining academia and the HIV cure research field, I led a vaccine cohort development program, prospective incidence studies

and a clinical research site capacity development effort in Mozambique with the United States Military HIV Research Program (MHRP)/Walter Reed Army Institute of Research/Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF) and FHI 360 (2008 – 2013). I am also worked with amfAR, the Foundation for AIDS Research, in the policy office in Washington D.C., (2007 – 2008).

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

- I am concluding an ethics supplement which allowed me to examine ethical and practical considerations for cell and gene therapy towards an HIV-1 cure (https://pubmed.ncbi.nlm.nih.gov/35397551/). I would like to continue expanding on this work as part of actual cell and gene therapy clinical trials in the United States and Africa.
- I am multi-Principal Investigator (MPI) of an R01 grant from the National Institute of Mental Health (NIMH) to investigate the psychosocial experiences of people with HIV who interrupt treatment in cure research (with Dr. John Sauceda, UCSF). I serve as socio-behavioral scientist on several protocols in the AIDS Clinical Trials Group (ACTG) and at UCSF. We will soon implement a series of surveys to help resolve critical challenges in HIV cure research, such as the underrepresentation of specific groups.
- I am leading the socio-behavioral and ethics component of the UCSD Last Gift program (http://lastgift.ucsd.edu/), which enrolls extremely altruistic people with HIV in HIV cure research at the end-of-life.
- I am integrating socio-behavioral sciences with the Females Rising through Education, Support and Health (FRESH) cohort in Durban, South Africa (https://ragoninstitute.org/community/fresh/). The program is implementing a study on post-intervention control of HIV with young woman, paired with a structural intervention.
- I am leading socio-behavioral sciences with some of the Martin Delaney Collaboratories towards an HIV-1 Cure, including the Delaney AIDS Research Enterprise (DARE), BEAT-HIV and RID-HIV.
- With Dr. Michael Peluso (UCSF), I am co-leading the AIDS Partner Protection Working Group to mitigate risk of HIV transmission to partners of ATI trial participants.
- I will be completing an ethics residency at the Brocher Foundation in Geneva in early 2023. The goal of this residency will be to help advance ethical considerations for infectious diseases research at the end of life. One research frontier would be to introduce interventions at the end of life (like cell and gene therapy). This work would require robust ethical and patient/participant-centered considerations.

- I will endeavor to remain a student of the Global Gene Therapy Initiative (GGTI) for as long I possibly can.

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

I envision a transdisciplinary comprehensive support program around HIV cure trials involving analytical treatment interruptions that would place the voice of community activists and HIV cure trial participants (present and former) at the very center of the research. This support program would be funded with a U-type grant mechanism and would support people with HIV undergoing ATIs or cure before, during and after they interrupt HIV treatment and undergo curative interventions.

I also envision a world where more transdisciplinary collaborations will be enabled by funders (e.g., HIV cure, sickle cell, hepatitis B and cancer cure research).

I envision a world where curative cell and gene therapy interventions will be available in resource-limited settings.

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

I am grateful to have started a position at UCSD on October 1, 2022, which will allow me to have more research support.

I would also like to have more hours in the day (which would also mean more time to take walks around beaches near San Diego).

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

I am learning to become a Californian. I also love to travel to beautiful places on planet Earth at least once per year with my husband, Shadi. Destinations I highly recommend are Iceland, New Zealand, and Montenegro.

Whitepapers

Interested in learning more? Read our latest whitepapers on the Caring Cross website. Click below to access them.

➡ **Global Access to Human Gene Therapy: Lessons Learned from HIV**

➡ **Centralized vs Decentralized Manufacturing of Personalized Cell Therapies: How to Implement Local Manufacturing of CAR T-Cells**

➡ **Regulatory Considerations for Decentralized Manufacturing of Personalized Cell Therapies: A Path Forward for Commercialization of Decentralized Manufacturing of CAR-T Cell Therapies**

Upcoming Events

We feature a Technology Education seminar series on the first Friday of every month.

We just completed a 9-part series describing in-depth the current concepts and the development of new approaches for CAR-T therapy.

We now present a multi-part series on how to manufacture CAR-T cells and other gene therapy products in a place-of-care setting. You will see a step-by-step series with direct hands-on demonstrations of how they did it.

Place-of-Care Manufacturing of CAR-T Cells – Practical Application (Part 4)

➡ **Register for the event**

Date: Nov 4, 2022
Time: 3:00pm EST / 12:00pm PT
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.

On the third Friday of every month, we feature an international expert in cell and gene therapy. This November please register to hear Dominic Kemps, DrPH present,

Accelerating Progress towards and HIV Cure for Africa

➡ **Register for the event**

Date: Nov 18, 2022
Time: 3:00pm EST / 12:00pm PT
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.

➡ **HIV cure research: implementation challenges and participant engagement in cutting-edge therapeutic studies**

➡ **Place-of-Care Manufacturing of CAR-T Cells – Practical Application (Part 3)**

➡ **Environmental Social and Governance (ESG) goals for addressing disease on a global scale**

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

Caring Cross Community

Please follow the link below to be enrolled for an in-depth seminar series designed to educate our community about cell and gene therapy. This series was designed by patient advocates, with a general audience in mind. Don't miss this unique opportunity to hear from international leaders in the field, designed just for you.

the DARE Community Cell and Gene Therapy webinar series

➡️ **Register: https://bit.ly/3kapavg**

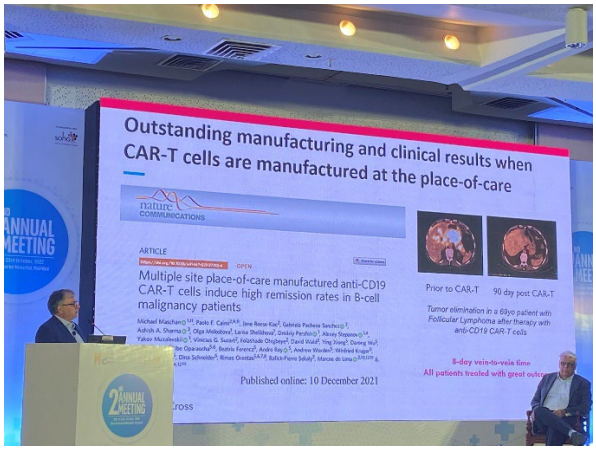
We are creating a membership community to connect healthcare professionals, scientists and engineers, community advocates and business leaders that are on a mission to develop new advanced medicinal cures - and help make them affordable to all who need them.

Sickle Cell Disease Community: the FDA is holding a patient-focused listening meeting on 11/15/22.

The Office of Tissues and Advanced Therapies (OTAT, FDA, CBER) is hosting a virtual patient-focused drug development listening meeting on November 15, 2022, from 12:00pm-4:30pm ET. This virtual listening meeting is an opportunity for patients, caregivers, patient advocates, and other important stakeholders to share their perspectives regarding gene therapy products, including cell-mediated gene therapies. To sign up to speak at the meeting, please register by November 7, 2022. Register to attend here: https://web.cvent.com/event/032e3502-07eb-4f98-b8fa-f15fe3f19972/summary

Here are Some of Our Recent Travels:

Dr. Boro Dropulić visited the team at ImmunoACT and presented our model to enable affordable access of advanced medicines like CAR-T cell therapy at the HCC meeting in Mumbai, India. Pictured below with Dr. Geeta Jotwani, Prof Vikram Matthews, and colleagues



Dr. Dopulić also participated in the ABTCel-Gen Scientific Meeting in Rio De Janeiro. Great conversations were had about improving access of advanced therapies in Brazil. Pictured here with Drs. Marcos de Lima, Jordana Ramires and Martin Bonamino.

Meanwhile, Dr.Rimas Orentas visited Uganda, where he helped inaugurate a new auditorium in the AIDS education center being created by Moses Supercharger (more info is on our web site under Impact Initiatives). Pictured below with Dr. Cissy Kityo and Moses Supercharger

Dr. Orentas also visited the JCRC, and participated in the organizational board meeting, and visited the facilities with Dr. Francis Ssali

The second leg of the journey was a visited to Tanzania and the sickle cell research team led by Dr. Julie Makani at MUHAS.

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

➡ **Become a member**

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!

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

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