DECEMBER 2019| ISSUE 2

THE CAB GAB

THE OFFICIAL NEWSLETTER OF THE CVVR COMMUNITY ADVISORY BOARD

DID YOU KNOW...

The CTU is on Social Media!

This past summer, our team received approval from BIDMC to pilot a Facebook page and Twitter page for our research group. We plan to use these platforms to provide information about upcoming clinical trials, recruitment opportunities, trial results, and group events. We also will use these platforms as a way to disseminate general education and counseling to our followers.

Follow us!

BIDMC_CVVRTrial **BIDMC.CVVRTrial**

WHAT'S INSIDE THIS ISSUE:

RECRUITMENT & EVENTS

By Tatenda Makoni

Boston Latino Family Festival
August 4th, 2019

The CTU team and BIDMC staff closed off summer 2019 with a bang! The team participated in the Boston Latino Family Festival at Fenway Park on August 4th. With over 10,000 attendees, interactive family games, and a full concert, our team got the privilege to exhibit and provide educational resources on infectious diseases such as HIV and Zika Virus.

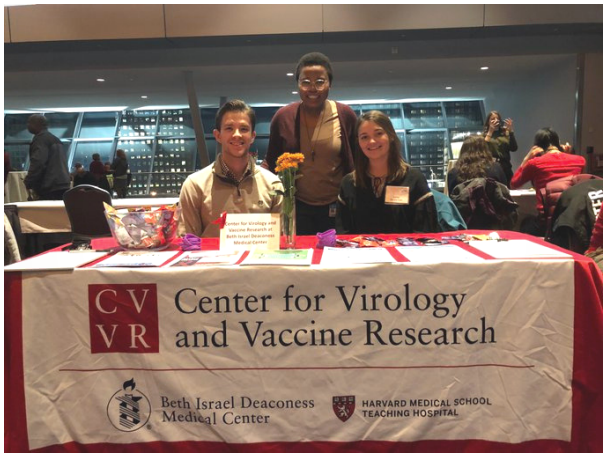
Emmanuel Wellness Fest,
October 8th, 2019

The CTU research assistants (RAs) helped Emmanuel College's Health Center kick off the fall semester by participating at the school's biannual Wellness Fest Program. The goal of the program is to provide resources that will assist students to be well during their time at Emmanuel College. The RAs enjoyed being back on a college campus and educating others on the importance of safer sex practices.

RECRUITMENT & EVENTS CONTINUED

Whittier Street Health Center, October 18th, 2019

The CTU team had the opportunity to meet with staff from the Whittier Street Health Center in Roxbury. The Center works to provide accessible health care for Boston neighborhoods. The CTU and Whittier Health staff engaged in enriching conversations tacking issues surrounding challenges associated with research participation and also the importance of an HIV vaccine.



Celebration of Life, November 6th, 2019

The 30th anniversary of the Victory Programs' service to community members living with HIV/AIDS kicked off Wednesday, November 6th, 2019 at the Boston Convention & Exhibition Center. Our CTU team was excited to be back at the Celebration of Life to commemorate this momentous event with our dear friends at the Victory Programs.

Trans Day of Remembrance, November 18th, 2019

Since 1999, November 20th is observed annually as the Transgender Day of Remembrance. Every year, the transgender community and its allies seek to honor the memories of transgender individuals who lost their lives to acts of violence and discrimination. This year, the CTU team participated in an educational training hosted by Fenway Health. CTU staff participated in writing letters of encouragement to incarcerated transgender individuals.

STUDY UPDATES

IPCAVD010: A Phase 1 Study of Two HIV Vaccine Candidates in HIV-uninfected Adults:
IPCAVD010 opened in March 2016 and is now complete. The study looked at different vaccine schedules using two experimental HIV vaccines. The study manuscript was submitted to *The Lancet Infectious Diseases.* It was accepted and is awaiting publication.

Z001: A Phase 1 study of a Zika Virus Vaccine Candidate:
Z001 opened in October 2016. The study looked at different vaccine schedules using a Zika Purified Inactivated vaccine (ZPIV) in healthy adults. The study manuscript was submitted to the *The Lancet Infectious Diseases* in November 2019 and is under review for publication.

IPCAVD012: A Phase 1/2a Study of Three HIV Vaccine Candidates in HIV-uninfected Adults:
IPCAVD012 opened in March 2017. The study looked at two different vaccine regimens using three different experimental HIV vaccines. Study participants are currently in the long term extension phase where researchers are looking at the effects of the vaccines on the body's immune system over a long period of time.

T001: A Phase 1 Study of PGT121 Monoclonal Antibody (mAb):
T001 opened in December 2016. The study looked at different dosages of PGT121 mAb given both intravenously and subcutaneously to HIV-uninfected and HIV-infected adults. The study is now complete and data analysis is underway.

T002: A Phase 1 Study of PGDM1400, PGT121, and VRC07-523LS Monoclonal Antibodies (mAbs):
T002 opened in October 2017. The study looked at different dosages of PDGM1400 alone and in combination with PGT121 given intravenously to HIV-uninfected and HIV-infected adults. In spring 2019, the study added an additional mAb called VRC07-523LS to be studied in HIV-infected adults. The study is now complete at BIDMC but is still ongoing at outside sites. It is expected that outside sites will complete the study by Summer 2020.

HTX1002: A Phase 1 Study of Two Different Vaccine Regimens in HIV-Infected Adults:
HTX1002 opened in March 2018. The study aims to look at different vaccine schedules of four experimental HIV vaccine candidates. Currently, we have vaccinated 23 out of 26 needed participants. **This study is actively enrolling at BIDMC.**

T003: A Phase 1/2a study of PGT121, VRC07-523LS, and PGDM1400 Monoclonal Antibodies (mAbs):
T003 opened in December 2018. The study looks at different dosages of each mAb given in combination together intravenously. HIV-infected adults will undergo an ART treatment interruption as part of this study. **This study is actively enrolling at BIDMC.**

Do you know someone who would be interested in participating in a clinical trial?

Have them contact us!

(617) 735-4610 **cvvrtrials@bidmc.harvard.edu**

WALKING INTO YOUR TRUTH

By Diane Kanjilal

> ***"You are not transitioning to another gender, but you are simply walking into your truth."***

I recently had the opportunity to attend a Transgender Healthcare conference hosted by Harvard Medical School and The Fenway Institute, titled, "*Advancing Excellence in Transgender Care.*" The purpose of this conference was to promote the development of new practices for a gender diverse community in healthcare. Attendees included physicians, nurses, nurse practitioners, physician assistants, lawyers, social workers, community advocates, parents, and any general LGBTQI+ ally. Some individuals were Boston natives, while others traveled from across the world to join in on this important conversation.

The conference was conducted over three days and included topics such as the epidemiology of common health issues within the transgender community, hormone and surgical therapies, trauma-informed care, transgender legal concerns, and pediatrics. A group of panelists from the transgender or gender diverse community discussed their experiences interacting with our healthcare system. I wanted to share some of the highlights from this conference that showcase the progress being made to develop a more inclusive healthcare system for the transgender and gender-diverse community.

In the culture I grew up in, the sex organ you were born with created your gender identity. If you had a vagina you were a female. If you had a penis, you were a male. I was raised to think girls looked and acted one way, while boys another. For myself, the disassociation of gender identity from sex organ was not something I really thought about until after college. The term "cisgender" was something I first observed when working for our clinical trials group at the CVVR four years ago. Even despite working 10 years as a nurse at a major academic hospital in New York City. Even inside one of the most progressive urban centers in the world, it wasn't common practice to use the terms binary and non-binary in the clinic. The act of thinking outside of these deeply routed cultural norms can be intimidating for some individuals. And this may explain why seemingly educated people may be unaware of these terms outside of the gender diverse community. However, the time has come for a change in that respect. This conference did an excellent job of opening up a conversation around the common concerns that healthcare staff at all levels may have when it comes to addressing transgender health issues. We received training videos on how to discuss one's gender identity and extensive reading materials. These are critical tools to be able to engage the community and develop evidence-based practices that promote LGBTQI+ health. I found these tools to be one the most valuable aims of this conference, as they pass along the message of acceptance.

Much of the conference was focused on the epidemiology of health disparities and conditions prevalent within the transgender community. Depression, anxiety, and post-traumatic stress disorder are extremely common. The data made an impact on conference attendees, including myself. Hormone therapy was another hot topic. A particular concern with hormone therapy is that it may elevate the risk for cardiovascular events and exacerbate co-existing metabolic diseases such as high cholesterol and diabetes.

Clinicians were given advice about how to improve their connections with transgender and gender diverse patients, and how to approach discussions on the informed consent process for patients moving forward with gender-conforming therapies and procedures. Having an open conversation about all possible options promotes a positive experience and reduces the risk of future medical or mental harm. Interestingly, one presenter argued that cardiovascular risk could decrease in individuals who are in a better mental state as this may increase their level of daily exercise and activity.

I left the conference feeling inspired and wanting to have this conversation with members of our BIDMC community. I was not alone in this sentiment, there was a real energy among all attendees. Many packed their bags, energized and ready to make a change within their own medical centers. With our current political environment and the well-documented history of unacceptance in many corners of our society, the need to take a stand is more urgent than ever. I hope we can learn to move forward together and build a new paradigm of care for our patients. As one of the panelists declared, you are solely, "walking into your truth." I couldn't agree more.

MEASLES VIRUS INFECTION DIMINISHES PREEXISTING ANTIBODIES THAT OFFER PROTECTION FROM OTHER PATHOGENS

Article Review by Connor Bradshaw

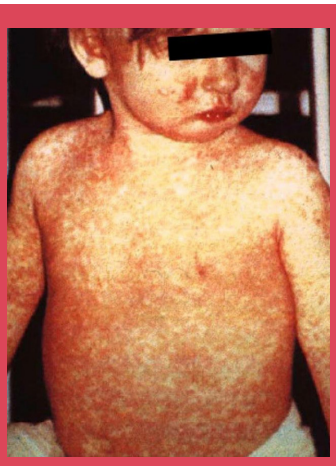


Photo courtesy of CDC.gov

Affecting more than 7 million people annually, and killing more than 100,000, the measles virus (MV) is rearing its ugly head once again. The number of confirmed global cases of MV has increased by a staggering amount over the past year, rising nearly 300% since 2018. Scientists now believe that MV may have been associated with almost 50% of childhood deaths by infection in the pre-vaccine era, so naturally this spike in infection rate has doctors and public health officials worried.

Recently, researchers at Harvard Medical School (HMS) and Brigham and Women's Hospital conducted a study to investigate this association, under the impression that these high mortality rates may be the result of "immune amnesia" caused by a MV infection. The term is quite simply that- your body forgetting how to fight off infections. As we grow up, we encounter numerous pathogens throughout our lives, and develop a number of antibodies to not only clear the infection, but to also "remember what they look like," and ensure that we will not be susceptible to those pathogens again. Dr. Stephen Elledge, a geneticist at HMS and BWH, and his team were able to show than a MV infection can potentially eliminate a significant amount of these antibodies from the host's immune system, leaving them susceptible to other infections.

The study, titled "Measles virus infection diminishes preexisting antibodies that offer protection from other pathogens," looked at 77 unimmunized children in the Netherlands during a recent measles outbreak, and collected blood samples before and after confirmed MV infection in these individuals. Of the 77 children, 34 contracted mild measles infections and 43 contracted severe infections. Using a technology known as a VirScan, an instrument developed by Dr. Elledge that can detect antibodies to hundreds of different viruses in a very small sample of blood, the researchers were able to see the presence of antibodies to common viruses before infection, and were thus able to determine the amount of antibodies that were wiped out after infection. On average, it was found that MV infection eliminated approximately 20% of the individual's antibody repertoire. Specifically, those children with "severe" infections lost about 40% (ranging from 11-62%) of their preexisting antibodies, and those with mild infections lost roughly 33% (ranging from 12-73%) of their antibodies. What this data shows is that measles infections are not only bad in their own capacity, but can leave the body defenseless against many of the common pathogens that it has encountered through life. Furthermore, the more severe the MV infection is, the worse off a person is immunologically when it comes to fighting off potential future infections.

The control group referenced above was made up of children from the same population, but who had received their MMR vaccine, the vaccine that is administered for measles, mumps, and rubella (also known as German measles). This cohort retained approximately 90% of their antibody repertoire over the same or longer period of time, which is consistent with the long held belief that the MMR vaccine will not leave the body vulnerable to infection.

This study by Dr. Elledge and his team confirmed their assumptions about the associated immune amnesia caused by MV. In addition, it highlights not only the importance of proper vaccination, but also the future, long lasting impacts that will affect the lives of these unvaccinated children for years to come. With the body's immune memory gone, the only way to build it back is through revaccination or reinfection, a process that could take years to accomplish. With reservations about vaccines on the rise, studies like this are crucial in showing that vaccines, such as the MMR vaccine, are not only safe, but also necessary in preventing future suffering. The WHO estimates that about 21 million deaths were prevented between 2000-2017, but these researchers anticipate that number to be much higher based on their findings. That being said, they stress the massive value that the MMR vaccine has to offer not only individuals, but the world.

Reference: Mina, M., Kula, T., Lena, Y., Li, M., Vries, R.D.D., Knip, M...Elledge, S.J. (2019). Measles virus infection diminishes preexisting antibodies that offer protection from other pathogens. *Science*, *366*(6465), 599-606. doi: 10.1126/science.aay6485

ARTICLE REVIEW

By Jessica Ansel

Recently, while monitoring our teams Twittter account, I stumbled across an interesting article discussing the latest advances in HIV prevention and treatment. Since the start of the HIV epidemic, scientific advancements have led to innovative approaches that have helped decrease the overall incidence and mortality of HIV. However, while these interventions have provided some success, the HIV epidemic remains.

This intrigued me. Over the past 4 decades, there have been a swarm of new technologies and approaches developed for HIV. It is curious to me that despite all this, the challenge of eradication remains. So, when I stumbled across this article, I had to read it. The authors provide an outline for how they think society can overcome the HIV epidemic. I have summarized the highlights but you can also read the article **here.**

Over the years, science has allowed for the development of HIV "toolkits," to help with both treatment and prevention. These toolkits include interventions such as ART, PrEP, HIV testing and campaigns such as "U=U." However, even with all these impressive tools, there were still 1.7 million new HIV infections in 2018. The authors believe this is because we are not optimizing the use of these toolkits.

A huge barrier to ending the HIV epidemic is that many of the tools we have available to us are not being used to their full potential. This is known as the "implementation gap." For example, we know that ART can lead to viral suppression and a near normal life expectancy, yet there are almost 15 million people living with HIV who are not receiving this medication. One common barrier to effectively using tools such as ART or PreP, is obtaining access to hard to reach, at risk individuals (i.e. those with housing instability, ongoing substance abuse and mental illness). HIV stigma and discrimination can also be a barrier.

In order to end the HIV epidemic, we must optimize the tools we have for both treatment and prevention of HIV. This means finding ways to overcome the challenges that are standing in the way of full toolkit implementation. To help optimize treatment, the authors suggest that we must develop new HIV treatments that are easy to administer and can reach diverse populations. There are currently several approaches being studied to help with this. The first approach would be to create a long acting ART that would only need to be administered intermittently. For example, a monoclonal antibody infusion or a long acting injection may only need to be administered every few months. Advancements like this would help decrease the burden and stigma associated with taking a daily HIV pill. The less demanding regimen may also help increase treatment adherence, which in turn may increase the population of those living with HIV who are virally suppressed.

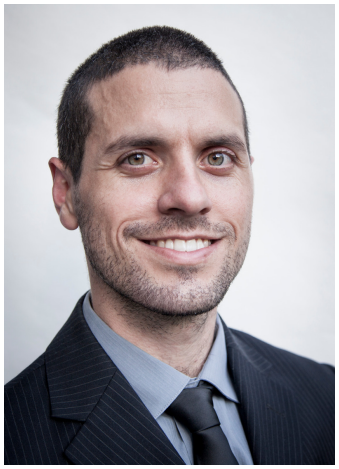
In order to optimize HIV prevention, we must improve the use and accessibility of PrEP. Once way to achieve this would be the creation of long-acting PrEP options, similar to those being used for HIV treatment (i.e. antibody infusion or long-acting injectable). A second strategy would be the development of a safe and effective HIV vaccine. While there are many studies underway testing potential HIV vaccine candidates, there is not yet a licensed vaccine.

The ideas the authors present in this article are relevant to the HIV community as a whole, but are especially relevant to the work being done here at the CVVR. It is articles like this one that help me put into perspective how important the work we do is. The eradication of HIV will be a team effort. With the help of scientists, clinicians, study participants and dedicated community advocates, I believe we can close the implementation gap and develop an HIV toolkit that will effectively make the HIV epidemic a thing of the past.

Reference: Eisinger, R., Folkers, G., & Fauci, A. (2019). *E*nding the Human Immunodeficiency Virus Pandemic: Optimizing the Prevention and Treatment Toolkits. *Clinical Infectious Diseases*

RESEARCHER SPOTLIGHT: AN INTERVIEW WITH MICHAEL MINA, M.D., PH.D

Interviewed by Connor Bradshaw & Anna Tyler



Michael Mina, M.D., Ph.D., first author of the measles paper highlighted in this issue, answered some of our questions regarding his life and interests.

Connor & Anna: Could you briefly tell us about your background? What have your career/research interests looked like over the years?

Michael: I'm currently an Assistant Professor of Epidemiology and of Immunology & Infectious Diseases at Harvard School of Public Health and a physician at Brigham & Women's Hospital. My research focuses on vaccines, child infectious diseases and development of immunity. My interest in public health began as an undergraduate at Dartmouth College where I studied engineering and public health. Soon after beginning college, I spent time in Belarus helping to rebuild Jewish cemeteries; it piqued my interest in international work. Later, I went to an extremely rural area of Nicaragua, where we set up small clinics and provided medicine. I went to Nicaragua a few additional times with the intention to figure out better lasting interventions that could help improve health. I eventually started a not-for-profit NGO in Nicaragua that taught communities how to produce chlorine for water purification using solar panels and table salt. I moved to Nicaragua for a year on a fellowship. While there, I applied to an MD/PhD program. I eventually joined Emory's MD/PhD program where I focused my PhD on looking at infectious diseases through mathematical and immunological lenses. Before completing medical school I did a post-doc at Princeton University, which led to much of the work I currently work on. We discovered that measles infections predispose children to numerous years of heightened susceptibility to other infectious diseases. After Princeton, I finished up medical school at Emory and went to Harvard Medical School and Brigham & Women's Hospital for residency. During those years I worked with Steve Elledge (Professor of Genetics at Harvard) and his lab working on figuring out if measles really does erase a person's immunological history. With our technology, we found that after measles, some kids had lost over 70% of their pre-existing immunological protective memory. This led to our paper recently published in Science. This was a startling discovery and one that suggests that measles vaccines are much more important than we gave them credit for.

Connor & Anna: What are you currently working on here in Boston?

Michael: I suppose I started to answer this question in the last bit of the above question. Besides measles, I'm currently working on furthering our understanding of how childhood vaccines and infections get stored as immunological memories and how these same infections or vaccines can perturb or prevent perturbation of immune memory formation and retention. Ultimately, the questions address the non-specific effects of vaccines- do vaccines have impacts on pathogens that are not directly targeted by the vaccine itself? It's somewhat of a new area of research but one that I find tremendously interesting and that leads to all sort of interesting fundamental questions about how immune memory is stored, how it is regulated, and how it has evolved and how we evolve to use it.

RESEARCHER SPOTLIGHT CONTINUED

Connor & Anna: Could you explain the basic mechanism of how a vaccine works, and more importantly, how to effectively vaccinate a community against a pathogen?

Michael: At their basic level, vaccines use all of the natural biological resources that we have evolved with and provide the immune system with a small glimpse of a pathogen. Once the immune system sees this glimpse, it forms a biological memory of the pathogen and, upon re-exposure with the same or similar pathogen, it can mount a rapid defense against it. This "glimpse" of a pathogen I am referring to is either a whole killed pathogen, part of a pathogen, or a weakened but live pathogen. Collectively, I'll call these the "vaccine pathogen." Once the body sees the vaccine pathogen, it shuttles it to the lymph system where immune memory cells learn to recognize the features of the pathogen using different type of cell receptors and proteins called antibodies. Then, if an actual virus or bacteria enters the body, the immune memory system can sense it as a foreign invader very quickly and can neutralize it before it has a chance to make you sick. Think of the immune memory as human warfare. For example, the vaccine is like showing a picture of a bad guy to a sniper. If the sniper has never seen what the bad guy looks like, she won't know who to shoot. But, if she has already seen what the bad guy looks like, the sniper can act the moment she sees him, preventing him from causing any harm.

Connor & Anna: What would you say to the "anti-vaxxers" to try and educate them on the importance of proper vaccination/ease their worries about vaccines?

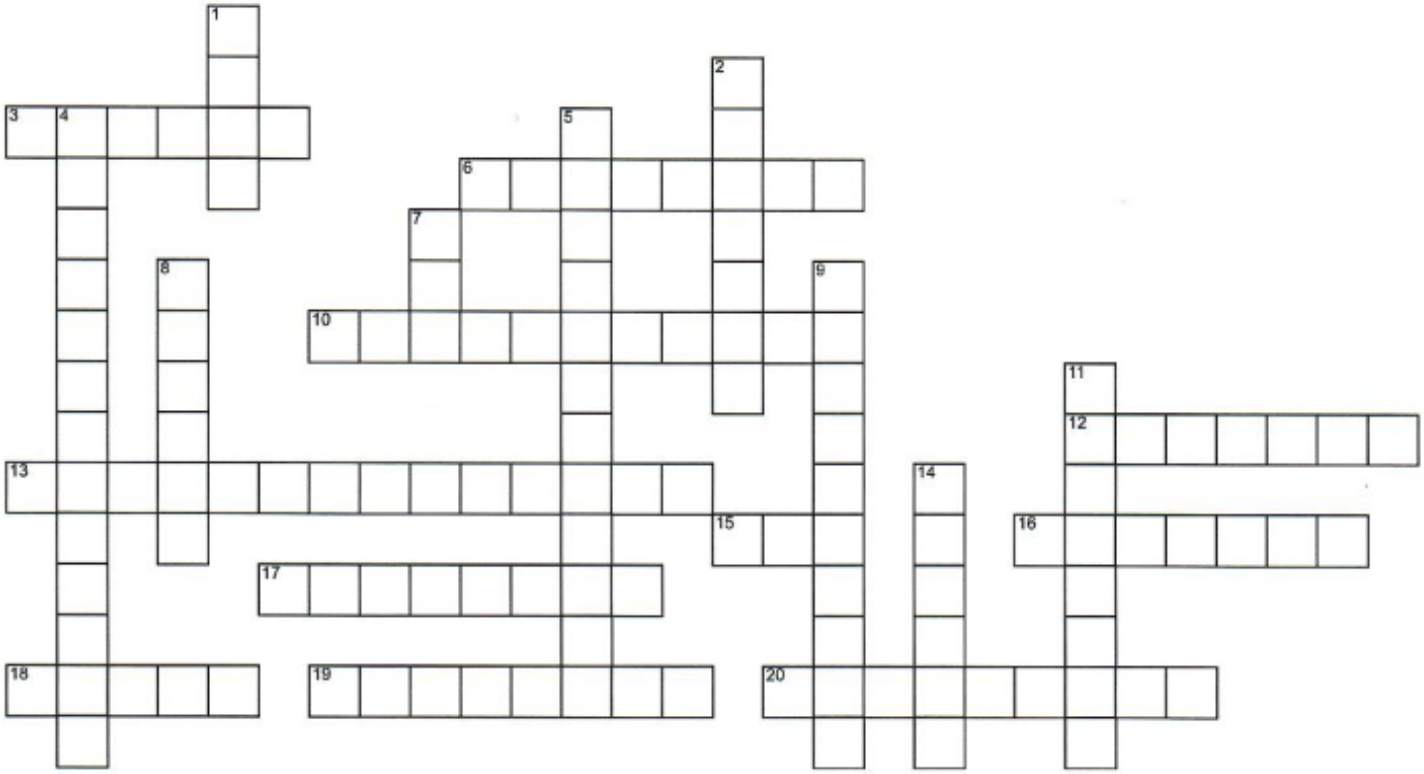
Michael: First, I try hard to make a distinction between "anti-vaxxers" and "vaccine hesitant." In an era of social media, there is so much misinformation. Because of the echo chamber of social media, all of the information that many parents are sometimes getting exists completely within a bubble of misinformation. We can say things like, "they should use reputable sources" to make their decisions but the average person doesn't have the experience to know what is and what is not reputable. To an untrained eye, a blog looks not too much different than a formal informational website. So, try to come from the assumption that most people only want what is best for their child. With that approach, I find that people are more willing to start asking questions and it gives me something to talk with them about that isn't directly a vaccine question. I start by talking to them about what sorts of information they read and how they choose the information. I also try to give them simple descriptions of how vaccines work and how we study and assess them. Most importantly, I let them know that there are in fact risks associated with vaccines, and that the risks while minimal and rare, are there. I think this helps to break down a huge wall that sometimes exists between healthcare practitioners and others. By making it clear that there are some risks, it provides the opportunity to discuss risk versus benefit. I find that people are actually quite able to think about risk versus benefit when provided with the right information and they can make their own informed and rational decisions at that point. I think we, as a vaccine and medical community, would do well by trying to "show our hand." If we know there is a small risk, then by saying it we gain a bit of trust, and that little bit of trust can go miles.

Connor & Anna: In the next five years, what do you hope to see in regards to the measles epidemic?

Michael: In the next five years... honestly I just hope to see no change from today. I am concerned that the true anti-vaccine rhetoric is growing and causing more and more parents to become vaccine hesitant. Eventually, in a place like the US where outbreaks have managed to remain small pockets of unvaccinated individuals will begin to grow in size and merge into each other. Once this happens, a small measles epidemic can quickly grow large, spanning states or even the whole country. This is what happened in Europe in the recent years. Measles was well controlled in much of Europe and reductions in vaccinations in small pockets eventually coalesced and have caused enormous outbreaks. This has led to infection in hundreds of thousands of children, send 20% of children to the hospital and killing 1 in every 100 children infected. Across the globe, there continue to be over 7 million cases of measles a year, killing over a hundred thousand children each year. So, for the next five years, I hope that we can keep outbreaks small and contained and we can figure out, as a medical and scientific community and as a society, how to best reinforce the need for preventative healthcare through immunization practices.

FUN AND GAMES

Crossword Puzzle



ACROSS
3 One way that HIV is transmitted is from a _____ to her baby
6 This document describes a clinical trial and how it will be performed
10 Our next CAB meeting is on January _____
12 Sharing _____ is one way that HIV is spread
13 _____ therapy is a combination of drugs used to treat HIV infection
15 Federal agency that reviews clinical trial applications to ensure safety
16 Approximately 38 _____ people are living with HIV globally
17 World AIDS Day is celebrated in this month
18 Boston hospital that the CTU is affiliated with
19 Street name of the CTU headquarters
20 Day of the week that CAB meetings are usually held on

DOWN
1 Medication taken by individuals who are at high risk of acquiring HIV infection
2 This type of trial in the CTU involves an injection into the muscle
4 Infections that occur more frequently and are more severe in people with weakened immune systems are called _____ infections
5 Name of the event the CTU hosted with Fenway Health last February
7 Clinical trial phase that assesses the safety of a drug or device
8 The _____ patient was the first person considered to be "cured" from HIV/AIDS
9 Scientists believe that this animal is the source of HIV infections in humans
11 Infusion studies in the CTU involve a monoclonal _____
14 Body system affected by HIV

FUN AND GAMES

Holiday Word Search

Find all the hidden words!

U	F	K	A	X	U	M	B	R	O	H	V	N	X	O	G	I	F	B	Q
M	R	S	Y	Z	S	S	F	R	S	D	E	C	E	M	B	E	R	M	K
G	N	I	I	K	S	B	F	T	T	M	E	N	O	R	A	H	R	Z	B
R	U	Q	S	R	J	A	N	U	A	R	Y	E	G	X	T	S	O	R	F
D	N	S	H	W	U	E	E	K	A	L	F	W	O	N	S	D	B	V	O
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WINTER
DECEMBER
FEBRUARY
GLOVES
MENORAH
CHRISTMAS
ICESKATING
PRESENTS
HANUKKAH
FROST
BOOTS
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SNOWBALLS
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SANTACLAUS
JANUARY
SNOWFLAKE
SCARF
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NEWYEARSEVE

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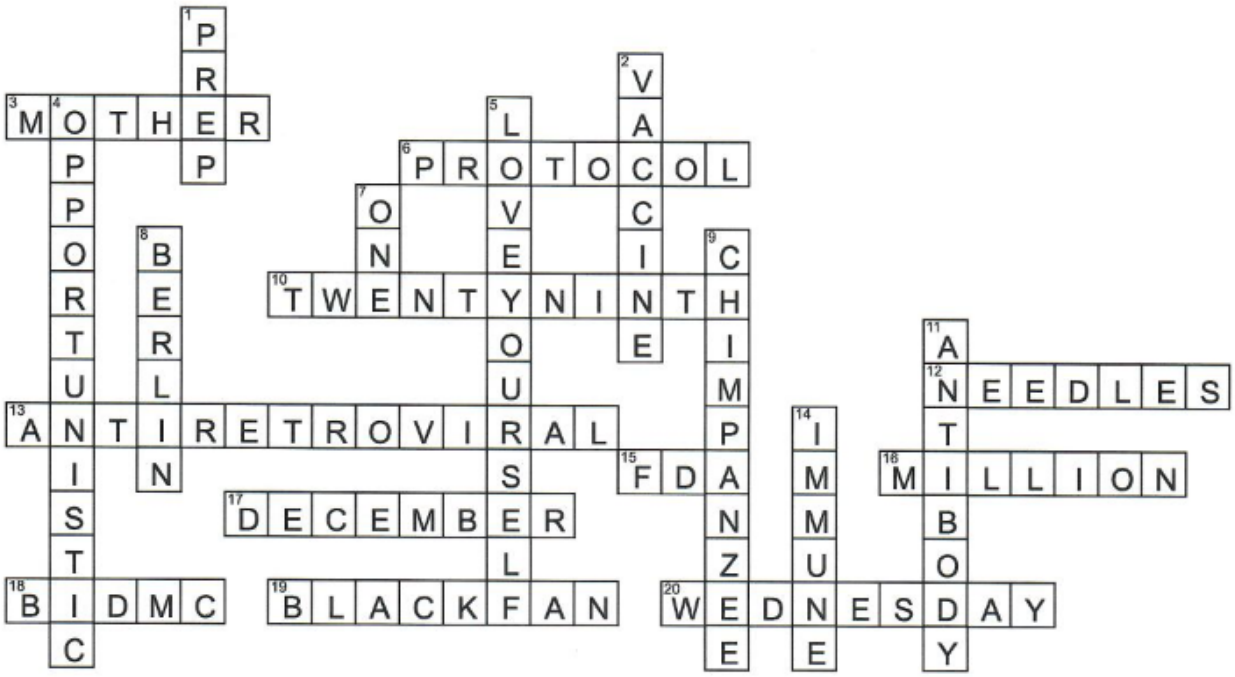
I	R	V	W	S	F	W	Y	Q	S	L	S	G	N	F	H	R	E	B	L
K	H	Z	F	H	A	N	U	K	K	A	H	Q	S	U	L	P	R	Z	L
N	C	O	O	O	E	H	X	N	H	S	H	J	C	Y	E	G	G	Y	S
R	G	N	I	T	A	K	S	E	C	I	U	E	C	A	N	D	L	E	S
V	W	B	R	M	E	N	T	D	L	V	E	Y	T	Q	B	T	F	J	O



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