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TAG
Treatment Action Group

tagline

NEWS ON THE FIGHT FOR BETTER TREATMENT, A VACCINE, AND A CURE FOR AIDS

New Hepatitis C Epidemic
Outbreaks in HIV-Positive Gay Men

Outbreaks of sexually transmitted hepatitis C infection have been reported among HIV-positive gay men. Early diagnosis and treatment can prevent serious liver disease, but too few doctors notice the warning signs.

BY TRACY SWAN

A new epidemic of hepatitis C virus (HCV) infection is on the rise. In the last few years, outbreaks of HCV have been reported among HIV-positive gay men in the United Kingdom, France, the Netherlands, Australia, Germany, and the United States. Many of these cases involve sexual transmission and are associated with group sex and recreational use of noninjection drugs such as ecstasy and cocaine. There have been no reports of an HCV epidemic among HIV-positive women.

When HCV infection is detected and treated early, during the acute phase (within six months of infection), the likelihood of successfully curing the infection is greater than when treatment is begun later. However, acute HCV infection often goes undiagnosed because there are usually no symptoms; there is no specific test to differentiate acute from chronic HCV. The rising number of acute HCV infections in HIV-positive men calls for increased vigilance among doctors and better efforts to provide information to gay men, who are most at risk.

End-stage liver disease from HCV coinfection is a leading cause of death among HIV-positive people in the United States and Western Europe. People with HIV/HCV coinfection have generally acquired both viruses from injection drug use with shared, unsterilized equipment or from contaminated blood products such as clotting factor (prior to 1987; clotting

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TAG at the Union, 2008
The Impact of Activism on TB

The Union Conference provides an important opportunity for TAG to exert its activist influence on all of the key people in the fight against TB.

BY JAVID SYED

The tuberculosis universe convenes once a year at the World Conference on TB and Lung Health, organized by the TB equivalent of the International AIDS Society: the International Union against TB and Lung Disease (IUATLD). This large meeting—also known as the Union Conference—is where data on TB research, programs, and policy are presented and discussed, and it provides an important opportunity for TAG to exert its activist influence on all of the key people in the fight against TB, a disease that continues to kill nearly two million people a year.

The initial goal of TAG's advocacy efforts was to increase activist participation at the Union, to create a wider understanding of the need for TB activism, and to infuse a greater sense of urgency into conference proceedings, especially on issues such as TB/HIV coinfection, TB diagnostics, multidrug-resistant (MDR) TB, and the

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factor has been safe to use since then). Most of what we know about HIV/HCV coinfection comes from studies of people who were infected with HCV before they became HIV-positive. Given the reports of HCV outbreaks in HIV-positive men, information about how the virus behaves in people who have contracted HCV after being infected with HIV is important.

The 2009 Conference on Retroviruses and Opportunistic Infections (CROI), held in Montreal, offered a range of information on the transmission, progression, and treatment of acute HCV infection among HIV-positive men.

Sarah Fishman and colleagues provided a snapshot of sexual activity and drug use among a handful of HIV-positive gay men with acute hepatitis C in New York (N = 21) and the United Kingdom (N = 60). Most cases were in men under 35 years old; the majority had never injected drugs, although more than 65% had used poppers, and more than 35% had used cocaine and ecstasy within the past 12 months. Group sex and anal sex were common; more than 75% reported engaging in unprotected receptive anal sex, and more than 60% in unprotected insertive anal sex. Many respondents reported fisting (receptive 23–56%; insertive 33–73%).

Daniel Fierer and colleagues at Mount Sinai Hospital in New York City fear that hepatitis C may be more aggressive in people who are already HIV-positive. They discovered unexpectedly serious liver damage in 19 of 24 HIV-positive men whose livers were biopsied within a median of 4.3 months (range: a few weeks to over four years) after being diagnosed with acute hepatitis C. It is not known if any of these men had preexisting liver damage, since liver biopsy is not—and should not become—part of the standard clinical workup for HIV-positive people.

Many factors can cause or contribute to liver damage, including HIV. Little is known about the prevalence, types, and extent of liver damage among HIV-positive people, though some information is available from a small study of HIV-positive people without underlying liver disease. Morse and colleagues performed liver biopsy and other tests on 24 people who had persistently elevated liver enzyme levels. They found serious liver disease in 35%, but no link with duration of HIV infection or length of time on antiretroviral therapy.

HCV Testing

U.S. HIV treatment guidelines recommend HCV testing for all HIV-positive people. Unfortunately, guidelines don't mention HCV risk assessment or routine and episodic testing unless triggered by elevated liver enzyme levels. Despite expert medical recommendations (from treatment and prevention guidelines), HCV screening has not been consistently incorporated into clinical practice. Karen Hoover and colleagues looked at viral hepatitis screening rates at six U.S. clinics in 2006–2007. They reported that less than 50% of 1,607 HIV-positive gay men were screened for hepatitis C during this period.

Fortunately, HCV treatment is more likely to work if it is initiated during the acute phase (within six months of HCV infection), regardless of HIV status (see table on page 4, "Response to HCV Treatment by HIV Status and in Acute versus Chronic Infection"). Fierer and colleagues reported that 8 of 15 HIV-positive men who initiated HCV treatment during acute infection were able to cure their HCV with treatment (one person remains on treatment; three others have just completed HCV treatment, and one person was lost in follow-up).

However, acute hepatitis C often goes undetected. It is rarely symptomatic and can be tricky to diagnose, since a group of tests are necessary to distinguish acute HCV from chronic HCV. An alert doctor, however, may suspect acute HCV if sudden spikes in alanine aminotransferase (a liver enzyme) are detected during routine monitoring of HIV-positive patients.

Unfortunately, HCV treatment has serious side effects, and this leads people to refuse or discontinue treatment even when offered during acute infection—when it is most likely to be effective.

Although improvements in HCV treatment are anticipated in the near future, pegylated interferon and ribavirin will still be the backbone. New drugs may shorten the course of treatment and increase response rates, but poor tolerability and significant expense will continue to limit treatment uptake. Thus, preventing new infections—or at least diagnosing them promptly and offering treatment when it is most likely to be successful—is warranted. Clearly, a public health strategy that includes messages about HCV sexual transmission and risk reduction for HIV-positive men who have sex with men is needed. Clinicians need to perform routine risk assessments, provide testing when indicated, and offer HCV treatment during acute infection until the current standard of care improves. ●

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The Virtual AIDS Conference
CROI Webcasts Reviewed

Webcasts make CROI the most accessible AIDS conference of the year.

BY BOB HUFF

The Conference on Retroviruses and Opportunistic Infections (CROI) is the most important scientific meeting on HIV and AIDS during the year. Although attendance at CROI is highly restricted, the conference is actually one of the most accessible sources of cutting-edge information about new HIV research due to the abundance of webcasts that are presented for free on the CROI website at www.retroconference.org.

To view the webcasts, open the tab for Webcasts and Podcasts, scroll down to the session you are interested in, and select the way you would like to view the webcast (I recommend Play Audio and Slides). Once the program loads, you can jump ahead to a particular speaker by selecting the Index tab at the bottom of the viewer, then clicking on the name of a specific speaker.

While most scientific sessions will be impenetrable to nonscientists, a few selected webcasts provide an accessible and informative overview of some of the emerging and persistent challenges in HIV research. Here are a few recommended webcasts from presentations made on Sunday, February 8, 2009.

Special Presentation for Young Investigators
Revisiting the Unanswered Questions
Jon Cohen, *Science* magazine

Science magazine journalist Jon Cohen offers a "perspective talk" on the state of AIDS science in a special lecture for young investigators. As a nonscientist who has closely followed HIV research for over 20 years, he speaks clearly and sensibly about the most interesting unanswered scientific questions that are ripe for new research. In 1993 Cohen contacted 150 researchers and asked them to name the top ten questions standing in the way of obtaining a cure and a vaccine for HIV. It is surprising how many remain relevant today. Cohen also notes the conflicts and controversies that swirled around AIDS in the early 1990s. With no effective treatments and the death rate rising, anger, speculation, and ignorance made headlines; a feeling of doom and gloom prevailed. Then, with the breakthrough discovery that AZT could prevent transmission of HIV from mother to infant during childbirth, the tide began to turn, and Cohen details the wave of good news that followed, including the advent of effective therapy that finally tamed the death rate in the United States and Europe.

In 1993, the epidemic in Africa had not yet exploded but the signs of the coming disaster were evident. Cohen's presentation also covers the revolution in access to therapy in Africa and elsewhere that was brought about by worldwide activism during the first few years of the new millennium. Cohen notes the contrast he observed during his travels: "I began to see activism everywhere."

Today, the drugs are better, and treatment access in poor countries has improved, but the gaps remain daunting, as prevention efforts have failed to take root and limits in funding and infrastructure prove difficult to master. And of the top questions for scientists that existed in 1993, less than half (mainly those regarding treatment) have been answered; none of the questions about the development of a vaccine have been put to rest. For young scientists, Cohen suggests, there is no shortage of important and fascinating work yet to be done in the world of HIV and AIDS, and he concludes his talk by detailing some intriguing new developments that have appeared in the scientific literature.

Workshop for New Investigators
HIV Prevention
Susan Buchbinder, San Francisco Department of Health

In part 2 of the special session for young scientists, Susan Buchbinder provides perspectives from the world of HIV prevention, focusing on what we know about the current epidemiology—who is becoming infected and why; the opportunities to be found in the failure of several recent clinical trials for prevention technologies; and lessons for moving forward in how we learn from these failures and build on our successes.

Buchbinder discusses useful and easy to understand concepts such as "attributable risk," and how sometimes the impact of a risk factor may not appear evident without having a deeper understanding of how people really behave. A spate of "negative" trials in the field of biomedical approaches to HIV prevention, Buchbinder notes, is actually an opportunity to understand new ways of thinking about prevention interventions. For example, a failed trial of using diaphragms to prevent HIV infection revealed that women who were assigned to the experimental intervention were less likely to protect themselves with consistent condom use, a finding that will help design how future trials are designed. The question of risk compensation is a problem for the implementation of all kinds of successful prevention technologies, from seat belts to sunblock: people will increase their levels of risk if they believe they have become invulnerable. The lesson is that interventions that combine technologies with behavioral change and education are essential if we are to realize the full gains that our discoveries promise.

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Workshop for New Investigators
Complications and Opportunistic Infections
Richard Chaisson, Johns Hopkins Univ.

Dr. Chaisson begins by noting that, although the Conference on Retroviruses and Opportunistic Infections has often neglected opportunistic diseases during the past decade, the 2009 meeting features several "blockbuster" presentations on these infections. He notes the dramatic decline in deaths due to the "classic" opportunistic infections of AIDS that followed the introduction of antiretroviral (ARV) treatment in 1996. Yet people with HIV are still becoming sick and dying at a faster rate than others, primarily due to tuberculosis, viral hepatitis, and other so-called non-AIDS events involving the heart, kidneys, or liver. Antiretroviral treatment reduces the impact of these diseases but does not eliminate them. It is unknown if the non-AIDS conditions are due to permanent immune damage from HIV infection, residual immune damage, ongoing inflammation, or to long-term ARV toxicity.

Chaisson then discusses the infections that can accompany HIV, first focusing on the problem of tuberculosis in Africa. TB rates have exploded among people with HIV, and TB kills more people with HIV than any other disease. Treatment with ARVs plus TB drugs is effective—if the disease is diagnosed and the drugs are available. Viral hepatitis B infection is another emerging problem that affects 400 million people worldwide, 4 million of whom are also infected with HIV. While people with both viruses respond to ARVs, they often experience greater liver toxicity from the drugs.

These are only three of the more accessible CROI webcasts, but they cover a vast amount of terrain and open up questions that viewers are encouraged to explore through the dozens of other, more technical webcast presentations from this important conference.

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Response to HCV Treatment by HIV Status and in Acute versus Chronic HCV

Source	Population	Regimen & Duration	SVR	Comments
Fried et al.; *NEJM* 2002	HIV-negative, chronic HCV; N = 453	48 weeks of peg-IFN plus weight-based ribavirin	56%	
Manns et al.; *Lancet* 2001	HIV-negative, chronic HCV; N = 511	48 weeks of peg-IFN plus ribvairin	54%	
Kamal et al.; *Gastroenterology* 2006	HIV-negative, acute HCV; N = 175	12 weeks of peg-IFN	87% overall	HCV treatment was initiated at 8, 12, or 20 weeks after onset of acute HCV; sustained virologic response (SVR) by timing of treatment initiation was 95% at week 8, 92% at week 12, and 76% at week 20
Wiegand et al.; *Hepatology* 2006	HIV-negative, acute HCV; N = 89	24 weeks of peg-IFN	71%	≥80% adherence to treatment increased SVR to 89%
Chung et al.; *NEJM* 2004	HIV-positive, chronic HCV; N = 66	48 weeks of peg-IFN plus ribavirin	27%	Low initial ribavirin dosing could have worsened response rates
Torriani et al.; *NEJM* 2004	HIV-positive, chronic HCV; N = 289	48 weeks of peg-IFN plus ribavirin	40%	
Dominguez et al.; *AIDS* 2006	HIV-positive, acute HCV N = 25	24 weeks of peg-IFN plus ribavirin	71%	14 people completed treatment and follow up at publication; 10/14 achieved SVR
Vogel et al.; *Antivir Ther* 2006	HIV-positive, acute HCV N = 36	24-48 weeks of peg-IFN	61%	Longer treatment duration increased SVR

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empowerment of people infected and affected by TB and HIV. TAG began its work at the Union in 2002 by organizing advocacy workshops that fostered a cadre of science-based TB/HIV activists who understood TB policies and could critique why treatment programs were failing people with HIV and MDR TB. To provide a platform for these activists, TAG began to organize panels at the Union that targeted TB control program implementers and grant makers and highlighted how activist efforts were strengthening TB control.

During the past two years, TAG's work at the Union has evolved. With its advocacy workshops now held at least two times a year in Africa, the Union Conference has become an opportunity for TAG to convene leaders in TB research, program implementation, grant making, and activism at satellite meetings focused on priority advocacy concerns that are also pressing challenges for TB control—from MDR TB in the context of HIV to achieving universal access for TB/HIV prevention, care, and treatment. TAG's preconference satellite meeting capitalizes on its ability to bring together diverse stakeholders who seldom talk to each other and to get them to focus on how they can and must work together to address these challenges in TB control. The presentations include concrete examples of how this collaboration has been undertaken by others, and this helps break down myths that certain interventions—such as community-based treatment for MDR TB in settings of high HIV incidence—are not possible in low-income countries. By organizing these satellite meetings and showcasing examples of effective implementation and collaboration, TAG has been able to reframe discussions to underscore what can be accomplished through political leadership and partnership—with a strong focus on the involvement of people infected and affected by TB. It is TAG's own version of President Barack Obama's motto "Yes, We Can!" The impact of this strategy can be seen when the examples and analyses generated at the satellite meetings are referred to throughout the rest of the ensuing conference, as participants push for faster scale-up and greater ingenuity in addressing the grave challenges to TB control that continue to make the disease the leading killer of people with HIV around the globe.

In light of the above goals, the 2008 Union Conference was a great success. TAG facilitated the participation of 40 activists in the conference, including its successful preconference satellite titled "TB/HIV Programs: Working Together to Achieve Universal Access to HIV and TB Prevention, Care, and Treatment." This preconference meeting provided cutting-edge information on how programs in resource-constrained settings were scaling up effective interventions to address TB/HIV coinfection. Some of the interventions highlighted in the satellite meeting include providing isoniazid to prevent TB disease among people with HIV and latent TB infection in the routine program settings of public HIV clinics in Rio de Janeiro, and scaling up MDR TB services through a community-based model of treatment support in the high-HIV-prevalence setting of Lesotho. The success and very existence of these efforts has challenged long-standing TB dogma that essentially says such interventions are impossible to scale up in poor communities. Discussions from TAG's satellite meeting echoed throughout the Union, bringing to the fore the need for greater leadership by TB and AIDS programs and underscoring how these programs must harness the power of civil society if they are to successfully improve how TB/HIV and MDR TB services are provided. (To download presentations from a symposium on activist-generated solutions: www.treamentactiongroup.org/TB_comm_activism.aspx .)

TAG underscores what can be accomplished through political leadership and partnership.

In addition to the satellite, TAG's leadership was vital in organizing a late-breaker session that, for the first time in the Union conference's history, invited the leadership from ten national AIDS programs to discuss actions that such programs should undertake to fulfill their responsibilities to implement interventions to reduce the burden of TB among people living with HIV. This session was very well attended, and stimulated a lively dialogue that not only highlighted what national AIDS programs needed to do but also provided a space in which activists could share their perspectives on what was lacking in TB and HIV programs' responses and how infected and affected communities can be engaged to help address challenges in TB/HIV program implementation. Following the success of this session, the conference organizers have committed to the inclusion of AIDS program leadership at the next Union Conference, and have already worked with TAG to organize a follow-up session at Union 2009. (For a report on the 2008 TB/HIV late-breaker session: www.treatmentactiongroup.org/union_satellite08.aspx.)

As it has for the past three years, TAG also released its latest report tracking changes in TB research and development (R&D) investment. The report is the only comprehensive TB R&D resource tracking effort and is used by scientists and research activists to advocate for increased resources to address the inadequacy of global investment in TB. (For TAG's *2008 TB R&D Resource Tracking Report*: www.treatmentactiongroup.org/TB_RD_2009.aspx.)

The Union Conference is an important opportunity for TAG to help create momentum on the global level for programs and policies that are responsive to communities' priorities. The activities detailed in this review were catalyzed by TAG's leadership and brought to fruition with the support of partners such as Medicines sans Frontieres, the World Health Organization, the Open Society Institute, Partners in Health, the Stop TB Partnership, AIDES (a French AIDS activist organization), the International Community of Women Living with HIV, and many individual activists. These partnerships have moved TB/HIV advocacy much farther than TAG could have accomplished working on its own. TAG also works with these partners to ensure that the impact of discussions that take place at the Union are also carried home to the national level so that research, science, policies, and programs addressing TB are put into service where they are needed most: among the people in greatest need.

A Delicate Balance
Accelerated Approval and Postmarketing Commitments

Research presentation poster by Tracy Swan and Lei Chou; winner of a Chairman's Choice Award at the 2008 HIV DART conference "Frontiers in Drug Development for Antiretroviral Therapies." The complete text is available online at www.treatmentactiongroup.org/HIV_DART.aspx.

Populations in Preapproval Studies and Postmarketing Commitments, 2005–2008

Aptivus (tipranavir, TPV), approved on June 22, 2005	
Women	12% female
HBV/HCV coinfection	~10% coinfected
Renal/hepatic impairment	Has not been studied in people with moderate or severe hepatic impairment or severe hepatic impairment Renal clearance is negligible, therefore difference in clearance not expected or studied in persons with renal impairment
Postmarketing commitment	Released from: methadone/buprenorphine interaction study; 48-week prospective observational diversity cohort study stratified by race and gender to assess efficacy and safety including potential risk parameters such as CD4 count and coinfection Pending: drug-drug interaction study of PEG-IFN alfa 2a and TPV/ritonavir; pharmacokinetics (PK) in HIV-negative persons with Child-Pugh class B liver disease; formal QT prolongation study
Intelence (etravirine), approved on January 18, 2008	
Women	~10%
HBV/HCV coinfection	12.4%
Renal/hepatic impairment	Studied in people with mild and moderate hepatic impairment Renal clearance is negligible, therefore difference in clearance not expected or studied in persons with renal impairment
Postmarketing commitment	48-week study of ARV-experienced females to elucidate potential differences in safety and efficacy

Ongoing Underrepresentation

The underrepresentation of women, people of color, and drug users in clinical trials for AIDS/HIV has been an ongoing concern for HIV treatment activists, who routinely push the pharmaceutical industry and the public research networks to enroll trial populations that are representative of the actual HIV demographics in the United States. According to recent Centers for Disease Control and Prevention data on U.S. HIV prevalence, women constitute approximately 25% of those with HIV infection; African Americans, a staggering 46%; Hispanics, 17%; and injection drug users, 18%. All of these populations are typically underenrolled in HIV clinical trials.

Swan and Chou's presentation focuses on the clinical trials of five recently approved antiretroviral (ARV) drugs and highlights the sharp contrast between the demographics of the trials' participants and the demographics of the U.S. epidemic. Their study notes that "insufficient enrollment of special populations—an umbrella term for women, people of color, and people with common comorbid conditions, such as renal impairment and viral hepatitis—has led FDA to request postmarketing commitments (PMCs) for five recently approved antiretroviral agents."

The authors conclude with these key points:

- Preapproval trials can address concerns usually dealt with in postmarketing commitments, through diverse enrollment and a more thorough portfolio of pharmacokinetic and drug-to-drug interaction studies.

- Regulators need larger, more tempting carrots and sharper sticks to prompt more thorough premarketing studies, and prompt initiation of postmarketing commitments.

Populations in Preapproval Studies and Postmarketing Commitments, 2005–2008 (Cont.)

Isentress (raltegravir), approved on October 12, 2007	
Women	ARV experienced: ~12%; ARV naive: 20%
HBV/HCV coinfection	ARV experienced: HBV coinfected 6%; HCV coinfected ~9%; HBV/HCV <1%; ARV naive: 7% overall
Renal/hepatic impairment	Studied in people with moderate hepatic impairment and severe renal impairment
Postmarketing commitment	48-week nonrandomized open-label, single-arm study in 200 people—at least 50% African American and at least 25% female—to characterize efficacy and safety of raltegravir in a population that closely reflects the U.S. HIV-infected population
Prezista (darunavir, DRV), approved on June 23, 2006	
Women	ARV experienced: ~11%; ARV naive: 30%
HBV/HCV coinfection	ARV experienced: Yes; number unspecified; ARV naive: ~13%
Renal/hepatic impairment	Not studied in people with hepatic impairment; studied in people with moderate renal impairment
Postmarketing commitment	Conduct study of DRV/ritonavir in treatment-experienced female patients to elucidate differences in efficacy and safety; drug-drug interaction study with buprenorphine/nalaxone
Selzentry (maraviroc, MVC), approved on August 6, 2007	
Women	ARV experienced: ~11%; ARV naive: 29%
HBV/HCV coinfection	ARV experienced: 6% HBV coinfected; 6% HCV coinfected; ARV naive: unknown
Renal/hepatic impairment	Not specifically studied in renal impairment or sufficiently studied in hepatic impairment
Postmarketing commitment	Study in coinfected people including people with Child-Pugh class C; assess effect of renal impairment on maraviroc PK at a dose of 150 mg combined with a boosted protease inhibitor (in people with mild to moderate renal impairment) and 300 mg alone (in people with severe renal impairment and on dialysis)

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TAG NEW WAYS TO CONTRIBUTE

Please join the Board of Directors of the
Treatment Action Group (TAG)
for a cocktail reception

Wednesday, April 29, 2009
7 pm – 9pm

At the home of:
David Sigal and Brad Hoylman
30 Fifth Avenue, (corner of 10th Street)
Apartment #15H
New York, NY 10011

With special guests:
Simon Doonan
Creative Director for Barney's New York,
Author, and Columnist

Jonathan Adler
Home Accessories Designer and Potter

Guests are required to make a minimum donation to TAG of $250 per individual ($500 per couple) to attend this event.

Guests will receive signed copies of the book *Beautiful People* by Mr. Doonan as a thank you gift for supporting the work of TAG.

Purchase tickets online at www.treatmentactiongroup.org. For inquiries or to purchase tickets, call the TAG office at 212.253.7922 or email tag@treatmentactiongroup.org.

TAG BE INVOLVED

About TAG

Treatment Action Group is an independent AIDS research and policy think tank fighting for better treatment, a vaccine, and a cure for AIDS. TAG works to ensure that all people with HIV receive lifesaving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions. TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end AIDS.

Program areas include antiretroviral treatments, basic science, vaccines, prevention, hepatitis, and tuberculosis.

Join TAG's Board

TAG is always seeking new board members. If you are looking for a great place to invest your time and talents, please call Barbara Hughes, TAG board president, to learn more about board opportunities with TAG.

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