

COTT *Washington Update* -- November, 2012

VOLUME 14 NUMBER 4



The ***COTT Washington Update*** is posted on the hemophilia-support listserv and on our website, www.cott1.org. To receive the Update directly, send an e-mail to COTT at cott-dc@earthlink.net.

> PATHOGEN PREVALENCE

Hepatitis C Virus

On August 17 of this year, the Centers for Disease Control and Prevention issued a recommendation that all US residents born between 1945 and 1965, essentially the 'Baby Boomer' generation, get a test for Hepatitis C. The vastness of this public health alert was startling, especially in light of our community's frustration with the years of silence by the federal government regarding the HCV epidemic in our society. Given the hemophilia community's specific history with HCV, the widespread infection of a significant number of community members with HCV, we question what changed leading to the federal government's widespread alert. We were asking for a more robust HCV testing structure and initiative from the mid 1990s when the magnitude of the problem became more apparent in the hemophilia community. By 1975, HCV had become the leading cause of death for men with hemophilia. This is a startling fact given that no alarms were sounded in the federal regulatory system for blood and blood products. The Summary of CDC's announcement is presented as Attachment #1 of this ***Update***.

Hepatitis E Virus

More recently, the FDA presented at its regular Blood Products Advisory Committee meeting September 20-21, a review of the safety implications of another hepatic infection, not previously believed to be prevalent in the US: Hepatitis E. Like Hep C (HCV) this virus has a long incubation period; many of the studies done to date (worldwide) have surveyed various groups to identify latent infections, seeking to reveal groups with a higher incidence. Although in most infections the virus never becomes strongly symptomatic, studies confirmed in blood donor surveys, indicate potential implications in the US: two conditions may predispose persons to the rarer but "fulminant" (CDC's wording) development of the disease, with serious implications. Those groups are, those with underlying liver disease, and, those with compromised immune systems -- due to pregnancy, mild illnesses in general, or HIV -- and according to recently discovered literature from the 1980s, persons with hemophilia. Those with hemophilia who have HIV, of course, are more at risk; the two conditions combined with HCV even more so.

When this information was presented to the BPAC, COTT President Corey Dubin, the Committee's current Consumer Representative, asked if there had been any discussion of seroprevalence testing of older men with hemophilia for exposure to HEV since this subset of the hemophilia community utilized human-derived factor in the years before the advent of recombinant; it would be critical to learn if there was any significant exposure to HEV in this population. We were surprised to hear that this had ***not*** been discussed at CDC or FDA, which

certainly is a point of concern for our community for a number of reasons. HEV is prevalent in Latin America; US firms continue to collect source plasma in the region along the US side of the border with Mexico. It is also important to note that HEV, unlike HIV or HCV, is a non-lipid envelope virus, which is significant given that our viral inactivation technologies are tied to removing the lipid envelope and rendering HIV, and HCV inactive. However, we were informed at the meeting that as HEV is a large-molecule virus, current filtration processes should trap it successfully. We will look for confirmation of this and to being relieved if this is, in fact, the situation. We might say we "dodged another bullet" in the end user communities who depend or have depended on human plasma derivatives. For the end users of plasma derivatives (blood products produced from pooled human plasma), our greatest concern is a blood transmissible, non-lipid envelope virus such as Parvo B-19 or hepatitis E that has the lethality of HIV and is not susceptible to our current viral inactivation technologies.

A review of some of the findings and discussion on Hepatitis E at the BPAC meeting is presented as Attachment #2 of this **Update**. Other topics discussed at the meeting are described below in the section on **AGENCIES**.

> **INDUSTRY**

NHF has entered into an agreement with Biogen Idec, manufacturers of therapies for Multiple Sclerosis and non-Hodgkins Lymphoma with long-lasting Factor VIII and IX in the pipeline, to support genotype testing at Hemophilia Treatment Centers nationwide. Patient education materials have gone out to the Centers, along with a survey of knowledge and expectations, and processes are being set up to encourage clients to agree to the procedure, and systems for collecting the results. Data entry for results will be conducted by Puget Sound HTC; the specifics of how the genotype results will be meshed with other patient record data for submission to ATHN, the Coordinating Contractor for the Hemophilia Treatment Center program, are under development. The project is to be operated under a Steering Committee comprised of ATHN, NHF and Biogen Idec representatives. As it was explained to COTT and to HFA, this committee would "own" the data, making any decisions as to its further use.

COTT was surprised to be briefed on this project, not otherwise announced by NHF, and despite brief assurances verbally, has questions about the consumer role, the process, and the ownership issue:

> Will patients be pressured to agree to the test? Will it be put before them for approval along with other routine items, so that it does not get the attention or explanation it deserves? Will consumers have a fair, objective chance to learn about the test and its implications for their treatment, and to accept or decline without prejudice.

> We also have been assured that the consumers will have a fair, objective chance to decide whether to request a copy of their own test results, apart from their medical record, or to agree to have the results entered into their medical record and submitted to the system. What is the **proof** that these decisions will be presented to the consumer in a fair and non-pressured way?

> Through the years we have been told that if the hemophilia care community wants to be fairly treated by insurers, under ACA, and in Managed Care settings, it will have to provide data

showing its true cost of care. The ATHN CDC (UDC) and separate HRSA (HTC) grants would seem to make ATHN the single most comprehensive database on hemophilia, or at least the 2/3 of the community seen at HTCs. How will the Biogen/NHF/ATHN Steering Committee entertain requests by others -- insurers mostly, it is expected -- to purchase some or all of the hemophilia care dataset? In this or other ATHN work, are there plans for analysis and reporting on the data, as information on the hemophilia community presented to insurers and others from within the community itself (rather than just sold for later analysis by others)?

> When ATHN was formed some ten years ago, the concept of a central database for information on all HTC users was disturbing to COTT, largely because these same issues arose. How are consumers 'invited' to participate, with education or not; who has access to the data at interim points and in final configurations ... and the greatest concern, can it be sold, and is it likely to be sold. In the case of the current genotyping project, with its three-organization steering committee, these last concerns are of extreme interest to COTT.

We expect much information on this project to be shared with participants at Orlando in November; this will also be a topic at the COTT Town Meeting (scheduled for 6:30 to 9:00 pm Friday November 9 in the Crystal A & B Rooms at the Marriott).

> INTERNATIONAL

COTT attended the XIX World AIDS Conference in Washington ("AIDS 2012") in July. Held in Washington, this Conference was the first World AIDS Conference held in the United States since a prohibition on travel from abroad to the United States for anyone testing positive for HIV was declared in 1990 -- 22 years ago. In 1990 there were no effective HIV medications; some Conference participants needed emergency medical assistance; some died. The face of the battle against HIV is now strong. The Conference and its sessions are reviewed in Attachment #3 to this Update.

> CONGRESS

By the end of September, with a six-month Continuing Resolution (funding the government at current levels through March of next year), Congress wrapped up its year, and in fact the two-year 112th Congress, as one which passed less legislation than any other Congress in 50 years. This year we heard less of the loud vitriol from deficit-cutters borne out of the Tea Party extremism formed last year, but the result was in its way just as devastating. The Democratically-controlled Senate and the Republican-controlled House each passed substantial amounts of legislation, including the necessary annual appropriations bills to keep the government running -- but, particularly obvious and painful with regard to these money bills, **neither chamber seriously entertained merging or compromising** its own language on any of them with the very different language from the other side of the Hill -- so no bills were finalized, sent to the President, and signed into law. Hence, while apparently busy, Congress accomplished almost nothing.

The six-month extension of level funding was negotiated at the beginning of August, as leadership looked at the schedule for the rest of the year: a five-week recess for August vacations and the

election-year party conventions, returning September 10th, but then four days out of that abbreviated month for religious holiday observance, and only one week in October before adjournment for election campaigning.

The 'lame duck' session -- when Congress reconvenes after the elections are over, some members having lost and merely running out the clock until the end of the year -- only sits for four more weeks, punctuated by Thanksgiving and ending before the Christmas adjournment. Given the difficulty of passing legislation when Congress was in session for weeks on end, such as in the late spring, observers and members alike look at this fall schedule and despair of ANY legislation of importance being debated, voted on, conferenced (House-Senate reconciliation) and sent to 1600 Pennsylvania Avenue for signature.

If the outcomes of the election are as expected, Democrats will retain the majority in the Senate, and Republicans will do so in the House. If the Democrats retain control of the White House, the Republican majority in the House will likely be a far less receptive body to Democratic proposals in the weeks after election day. Too, the House will have 60 new faces and will have fewer centrists, increasing the guarantee that House bills won't survive the Senate, and Senate bills will die in the House, with little if anything being enacted into law.

While not shutting the government down, as was threatened so many times last year, this year of inaction threatens crises in a number of areas, outside of as well as within government funding bills. For example, negotiations broke down this summer over re-authorization (every-so-often renewal) of the Farm Bill. This is not just a bill providing price supports for farmers. It is that, and much more. Eighty percent of the funds authorized in a draft version of the bill this year was to fund the federal Food Stamps program! an \$800 *Billion* dollar item! Now the Continuing Resolution mentioned above will assure that funds keep flowing for this program, so important as the national recession continues, but there are other parts of the bill that may cause serious disruption shortly: milk prices may skyrocket after the first of the year when subsidies for American dairy farmers and tariffs against foreign dairy imports both expire.

The Fiscal Cliff

Closer to home, the Fiscal Cliff looms. The term refers to the multiple budget-threatening actions scheduled to occur shortly after the first of the year. The specifics of this threatening multi-part fiscal dilemma facing the country are described more fully in Attachment #4 to this **Update**.

> **AGENCIES**

In reporting on the implementation of the Affordable Care Act (ACA), we will hereafter include both Federal-level developments such as new regulations, and state-level activities, under this **AGENCIES** heading. FDA and meetings reports follow the ACA discussion.

ACA was signed into law March 18, 2010, calling for states to establish 'exchanges' through which to both oversee insurer business practices, and provide access to a variety of health coverage plans to consumers. The target date by which states are to establish exchanges, including all of the supporting authorizing legislation and/or executive orders, computer systems, and

criteria for reviewing and accepting insurance plans, is January 1, 2014, but the deadline for submitting plans for the design and creation of them is this month.

Few states are well along in their progress. The chart on the next page indicates progress in this effort for 16 states (plus the District of Columbia) which have passed state laws or executive orders authorizing the creation of Exchanges -- these are the states furthest along.

The data was prepared by the Commonwealth Fund, and reflects aspects of these development actions as of June, 2012. COTT highlights key components of each state's work, to focus on some aspects that may be of importance to the hemophilia community.

Over half of the states in the US are not in this list, including seven on record as refusing to develop exchanges. The remaining 26 have much to do in the time remaining: if the states do not have an Exchange operational by the deadline, the federal government will come into the state to operate one -- something those objecting to developing their own programs will want even less. The full dataset is available at

<http://www.commonwealthfund.org/Maps-and-Data/State-Exchange-Map.aspx>.

There is a large amount of information in this chart; many entries use abbreviations. To better understand entries for these categories in your state or any other, consulting the report on-line is the best resource. The key findings of the chart, however, is the large number of these *leading* states that have:

- Board Membership: Two have not appointed a Board. Five of those that have made appointments, have representatives of insurers on the Board.
- Board Conflict of Interest Provisions: In six of these states -- over one-third -- no provisions against this have been developed.
- Active or Passive Health Plan Purchase: How insurance plans will be sought out for possible inclusion in the Exchange has not been determined in five of these states -- nearly one-third. Specific criteria to be developed/used for considering plans already being considered, however, may be under way even at these states without the 'outreach' component finalized.
- Tools to Reduce Adverse Selection: Nine -- over half -- of these 17 Exchange planning efforts have as yet not provided consumer protections against favoring healthier patients.
- Coordination with Medicaid / CHIP: Seven states have not developed plans for coordination with Medicaid and its Child Health program to permit joint enrollment directly through the Exchange.

LEAD STATE PROGRESS ON DEVELOPMENT OF HEALTH CARE EXCHANGES -- AREAS OF INTEREST TO OUR COMMUNITY

State	Board Membership	Board Conflict of Interest Provisions	Active or Passive Health Plan Purchase	Tools to REDUCE ADVERSE SELECTION	Coordination with Medicaid / CHIP
CA	2 govt, 2 finance, 1 advocate	No employees/ reps of insurer/hlth prov.	Active	Insurers have plans at all benefit levels	Board must coord enr. w/all agencies
CO	3 govt, 5 providers, 2 advoc, 2 hlth admin	cannot benefit	Passive	Federal protections only	Not addressed
CT	6 govt, 7 "experts," 1 advocate	May pose an obvious conflict of interest	Active	Same plan price in or out of Exchange	Tell/enroll in all plans for which elig
DC	7: not yet named	No employees/ reps of insurer/hlth prov.	Active	Same plan price in or out of Exchange	ID/offer all plans for which eligible
HI	4 govt, 6 providers, 2 advoc, 2 others	"will" adopt policies re financial interest	Comm'r determines eligibility	Not addressed	State responsibility
IL	Undetermined	Undetermined	Undetermined	Undetermined	Undetermined
KY	3 govt, 1 ins rep, 2 provider reps, 2 advoc	Per state laws	Undetermined	Undetermined	Undetermined
MD	3 govt, 2 acad, 1 fdn, 1 legal aid, 1 PH assn	No employees/ reps of insurer/hlth prov.	Active	Same plan price in or out of Exchange	ID/offer all plans for which eligible
MA	4 govt, 2 insur, 2 acad, 1 union, 2 others	No empls of licensed insurers	State plan selects, certifies	Max: 1 gold, 3 silver, 3 bronze plans	State responsibility
NV	3 govt, 3 provider, 2 advoc, 2 others	No employees/ reps of insurers	Not addressed	Not addressed	coord w/state for single entry point
NY	Not addressed	Not addressed	Not addressed	Not addressed	ACA requirements
OR	2 govt, 1 provider, 4 business, 1 union	no vote if benefit, max of 2 affil w/ins.	Active	bronze & silver plans in ea mkt in or out	ID/offer all plans for which eligible
RI	5 govt, 3 business, 1 advoc, 1 union	No employees/ reps of insurer/hlth prov.	Active	Not addressed	Not addressed
UT	13 mbrs: 5 govt, 4 providers, 3-4 brkrs	Not addressed	Passive	Not addressed	Not addressed
VT	6 govt, 2 insur, 2 hlth prov, 3 advoc	Not addressed	Active	Same plan price in or out of Exchange	ID/offer all plans for which eligible
WA	2 govt, 2 insur, 2 acad, 2 bus, 1 advoc	No appt; removal if benefit identified	Bd, Authority, Leg coord to recd stds to Gov	Not addressed	Not addressed
WV	4 govt, 1 empl, 1 ins, 1 provider, 2 advoc	Govt ethics training @ 2 years	Not addressed	Not addressed	Not addressed

In each of the five categories in the chart, the entries where nothing has been done include not only "Undetermined," which may mean 'still being developed,' giving hope that the state will be taking the matter up, but also "Not Addressed," -- which may mean there are no plans to provide these safeguards, or simply that this aspect, as many others, has not yet been tackled.

If you live in a state listed here as showing less than full patient protections and soundness of design, please get in touch with others in the chronic condition community and together contact the agency which will operate the Exchange (start with the State Health Department) to convey your concerns. If you live in another state, attempt to research progress on these aspects through the Exchange's website, and proceed with the coordination and contact suggestions here. Please keep COTT informed of your efforts, and the results you see. We must work to assure that these upcoming health care access plans are not being developed solely for the benefit of the provider corporations, not the consumers.

Blood Products Advisory Committee

As mentioned on the first page of this Update, the FDA Blood Products Advisory Committee met in September. In addition to the Hepatitis E risk presentation and discussion, other topics included Platelet Contamination Risk Reduction, and Octapharma's application for production of solvent-detergent treated Pooled Plasma. After a discussion of the underreporting of adverse outcomes traceable to platelet contamination offset by several striking case studies, the committee concurred with the conventional wisdom that length of storage time correlates with presence of contamination, but not always. The committee suggested that a schedule of testing be implemented, with the retention of units for seven days only permitted for those testing negative for contamination on Day Four, and urged the FDA to propose greater attention to reporting requirements concerning adverse transfusion outcomes. The committee also endorsed the Octapharma application, after an intense questioning of the applicant and substantial discussion among themselves.

Of note was a presentation during the Public Hearing section of the meeting by Mr. Michael Allen, a young man with a physically painful and emotionally draining disease: Sickle Cell Disease. The presentation was a powerful reminder to the committee that concern for all at risk for blood and blood product contamination was in its charter; this was a good opportunity (too rare in the past) to apprise a notable circle of experts about the trials of access to care for the estimated 100,000 with the disease. Many more, estimated at 1 in 12 African-Americans or some 3/4 million, are born with the Sickle Cell Trait, which may evolve into disease. It is a painful and chronic condition for a community with economic challenges, racial barriers and medical access problems nationwide.

In addition to FDA's BPAC, COTT's President Corey Dubin and Government Relations staff Dave Cavanaugh also made use of Corey's time in Washington that week for appointments with Dr. Hani Atrash, Dr. Michael Lu, and CDR Richard Henry. Dr. Atrash was until recently the Director of the Division of Blood Disorders at CDC for three years, but now Director of Perinatal Health Programs (Dr. Atrash is an obstetrician-gynecologist by training) in the Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA). Although less well known than many in the Department, it is of equal organizational stature to the National Institutes of Health or FDA. HRSA is known for its funding for the many state and local

operations of the Ryan White Care Act helped with its \$2.2 Billion program, for its funding of now over 1,200 Community, Migrant, Homeless and other Federally Qualified health centers, serving over 17 million consumers annually, and of course for its funding and support for the national Hemophilia Treatment Centers network. (Dr. Atrash's work is not expected to include specific work on hemophilia.) In addition to our meeting with Dr. Atrash, we briefly met and chatted about the characteristics and history of the hemophilia community with Dr. Michael Lu, new Director of MCHB.

One additional and most helpful meeting was with CDR Richard Henry, Deputy Secretary of the Advisory Committee on Blood Safety and Availability, operated by the Office of the Assistant Secretary for Public Health. Possible topics for future meetings of the committee were discussed, and we were apprised of new developments in biovigilance -- identifying threats of contamination and disease at the earliest possible point, and the national data collection and notification needed.

> COALITIONS

Ann Marie Benzinger - by Dave Cavanaugh

The co-founder and leader of the Alpha-1 Advocacy Alliance (A1AA) since its establishment in 2004, Ann Marie Benzinger, passed away on September 22 after a two-year long fight with infectious viruses which plagued her nearly constantly after a double-lung transplant, succumbing finally to pancreatic cancer. Alpha-1 Antitrypsin Deficiency (AAT) is a blood product treated disease. The Alliance, the newer of two organizations representing the Alpha-1 community, was a participating member of the APlus (American Plasma Users Coalition) to the extent possible. Ann Marie served as a member of the federal Advisory Committee on Blood Safety and Availability from March 2007 through March 2010.

I participated in the Alliance's growth and issues development, twice presenting the Legislative Update session at its Conferences. Ms. Benzinger, based in rural Virginia, who for a year and more before her double lung transplant required oxygen full-time, stayed often at my home -- sometimes needing to bring to Washington up to 16 oxygen bottles (6 pounds each, carried everywhere, one at a time, on a dolly) to last her through travel, a two-day Committee meeting, and visits to the hospital where she eventually had the transplant.

Alpha-1 is one of the most common life-shortening genetic disorders in the world, exceeded only by Down's Syndrome and Cystic Fibrosis. Easily misdiagnosed, many patients are told they have asthma, bronchitis, Chronic Obstructive Pulmonary Disease (COPD) or emphysema caused by smoking or cirrhosis of the liver, even though the patient neither smoked or drank. Alpha-1 is a liver disease which often manifests as lung deterioration, or asthma. Treatment can retard this deterioration to an extent, but it is not unusual to find person with 60%, 40%, 30% of oxygen capacity -- or less. Unlike hemophilia, it is a progressive disease, usually leading to unfortunate outcomes.

The better-known COPD is caused by AAT. While very few people know they have AAT deficiency, it is estimated that as many as 100,000 Americans have it. It can, like hemophilia, be

cured by a liver transplant. If one family member is diagnosed, it is important that siblings be tested as well; some are reluctant to do so given the dark prognosis.

Ms. Benzinger's work leaves the Alliance in good hands, with hundreds of members, a solid Committee structure, a strong and unique financial assistance program, a website offering disease and industry updates, diet and other health tips, an entertainment coroner for the kids (starring their mascot, Alphapotamus), and contacts for shopping, at www.alpha1advocacy.org. The monthly newsletter the A1AA Register contains much of these, plus special features and columns from the leadership.

The Alliance's substantial work in serving the Alpha-1 community continues, under its Interim Director, Ms. Carole Morton, an A1AA Board Member since 2005.

>COTT Operations

COTT is saddened to announce the departure of long-time National Advocate John Rider. Unfortunately for us all, a combination of funding reductions at COTT and changes in John's life left us no other avenues but to make some very difficult decisions. We had hoped to find a way to bring John back but the combination of factors has made that even more difficult and we felt it was time to announce the change while honoring the incredible work and commitment of this unique human being, John Rider.

Simply put, for fifteen years John Rider was a resource, a voice of justice and reason, and an individual psychosocial pillar of support for so many members of our community, especially the HIV/AIDS and or/HCV infected hemophilia community. John stood by individuals and families devastated by HIV/AIDS and hepatitis C. He was a wealth of psychosocial and treatment information whose commitment to our community was unwavering and tireless. He undertook important advocacy initiatives on behalf of individuals and families in New England and across our nation. He worked closely with COTT Co-Vice-Presidents Mary Lou Murphy and Terry MacNeill to ensure an ongoing COTT presence in the New England region. He was also instrumental in developing and implementing strategies for addressing Trauma and its aftermath in the hemophilia community. In many instances John also undertook the most difficult task of helping to work individual families through the loss of a loved one to HIV/AIDS or hepatitis C.

John will be sorely missed as he had a profound impact on the psychosocial component of our organization. He too suffered through the loss of so many of our brothers, sisters and loved ones. We are forever thankful to John for a job done way beyond a job description or directive. He put his heart and soul into this work each and every day he worked for the Committee of Ten Thousand. We wish John and his family all the best and look forward to hearing about his accomplishments in his new endeavors. John, from our entire board of directions, and a grateful community, we want to express our heartfelt thanks and wishes for a good future.

COTT acknowledges the assistance of Hemophilia Health Services and Factor Support Network in publication of this issue of the COTT Washington Update.

Attachment #1: CDC Recommendation for General Hepatitis C Screening

[Morbidity and Mortality Weekly Report \(MMWR\)](#)

Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965

Recommendations and Reports , August 17, 2012 / 61(RR04);1-18

Summary

Hepatitis C virus (HCV) is an increasing cause of morbidity and mortality in the United States. Many of the 2.7–3.9 million persons living with HCV infection are unaware they are infected and do not receive care (e.g., education, counseling, and medical monitoring) and treatment. CDC estimates that although persons born during 1945–1965 comprise an estimated 27% of the other HCV-related liver disease. With the advent of new therapies that can halt disease progression and provide a virologic cure (i.e., sustained viral clearance following completion of treatment) in most persons, targeted testing and linkage to care for infected persons in this birth cohort is /expected to reduce HCV-related morbidity and mortality.

CDC is augmenting previous recommendations for HCV testing (CDC. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. MMWR 1998;47[No. RR–19]) to recommend ***one-time testing without prior ascertainment of HCV risk for persons born during 1945–1965***, a population with a disproportionately high prevalence of HCV infection and related disease. Persons identified as having HCV infection should receive a brief screening for alcohol use and intervention as clinically indicated, followed by referral to appropriate care for HCV infection and related conditions.

These recommendations do not replace previous guidelines for HCV testing that are based on known risk factors and clinical indications. Rather, they define an additional target population for testing: persons born during 1945–1965. CDC developed these recommendations with the assistance of a work group representing diverse expertise and perspectives. The recommendations are informed by the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework, an approach that provides guidance and tools to define the research questions, conduct the systematic review, assess the overall quality of the evidence, and determine strength of the recommendations.

This report is intended to serve as a resource for health-care professionals, public health officials, and organizations involved in the development, implementation, and evaluation of prevention and clinical services. These recommendations will be reviewed every 5 years and updated to include advances in the published evidence.

The full announcement (34 pp.) can be viewed at

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6104a1.htm>

Attachment #2: Summary of Facts and Issues on Hepatitis E

from the September 2012 BPAC Meeting

Facts

"Hepatitis E virus (HEV) has been recognized since 2004 as a transfusion transmissible infectious agent and recent epidemiological data suggest that it may pose a safety threat to the U.S. blood supply. Although there have been no cases of transfusion transmitted infection reported in the U.S., there are documented cases from Japan, the United Kingdom, Saudi Arabia and France. Although documented cases of HEV infection are uncommon in the U.S., some studies have detected a high prevalence of antibodies to HEV in blood donors suggesting the possibility of transmission by blood transfusion." (emphasis added)

-- FDA Background Paper prepared for the Meeting

No cases of HEV disease have been found in the US. Like Hepatitis A, HEV is transmitted by fecal-oral contact, usually from unsanitary conditions such as slums in third world countries.

HEV antibodies have been found in as high as 80% of animals on pig farms, with those farmers and pig veterinarians studied showing higher rates of antibodies than expected. Human studies of antibody prevalence in the US have revealed surprisingly high rates:

Hepatitis E usually causes mild symptoms and runs its course in a matter of weeks, but like some other diseases can in a few individuals cause serious disease -- particularly in the immunocompromised. Data from cases in developing countries show mortality rates of 20% among pregnant women but zero in pregnant women in developed countries to date.

Implications for the hemophilia population are presented in this paper so gradually they can be missed. But they are there, and they are strong. First, studies from the 1970s and 79s indicate that even clotting factor is an immunosuppressive, so all persons with hemophilia except a few milds have suffered this effect. Added to that, HIV is of course immunosuppressive as is Hepatitis C to some extent.

Issues

The issue arose at the BPAC meeting that already-recognized immuno-compromised patients have nevertheless not been tested as a group for HEV. Corey Dubin, COTT President and the current Consumer Representative on the Committee, asked FDA, CDC representatives and the entire Committee membership:

Why aren't we communicating with the Division of Bleeding Disorders to do some seroprevalence testing in the hemophilia community?

The CDC Representative responded, saying they have discussed Hepatitis A and Hepatitis C with the Division of Bleeding Disorders, "Of course, there's a lot of work before testing can be done."

After this answer, the very next speaker asked the Committee how many blood donors would be lost if HEV testing were begun. Blood Center supply politics, unmindful of the presence and recent vocal statement of need, of the blood *recipient* population.

The Committee answered the FDA's question about the appropriateness of beginning testing with a unanimous Yes vote:

Do the available scientific data indicate a need to determine the risk of HEV transmission by transfusions in the U.S.?

Discussion then turned to types of test to be considered. Mr. Dubin:

That then gets us to the beginning of characterizing the risk. And we're not asking lightly. I want to be clear about that. I don't want to be difficult about it, but I want to be clear. This is a strong request.

if we could characterize this risk, then we talk about it, we air it out, and we make progress. That's really important to people's security. We're dealing with human beings, which is what we bring to the table. You all are the science and tech, but we have to assess the risk with our MDs. They don't have enough information at this point and they depend on you all.

The input this review provided to the Office of Blood Resources and Research at FDA was of major importance, especially since, after hearing the evidence, not one member of this expert panel doubted that action is needed to control it, first by assessing the risk, and targeted testing.

HEV is a type of virus that cannot be eradicated in blood product fractionation by use of a solvent detergent process, or a heating process. Therefore it is vital to keep it out of the blood collection process from the outset, for our community at least. Again, the question was put before both FDA and CDC at this meeting, to work with the CDC Division of Blood Disorders toward an earliest-possible program of blood testing for persons with hemophilia.

Attachment #3: The XIX International AIDS Conference

COTT attended the XIX World AIDS Conference in Washington ("AIDS 2012") in July. Participation was estimated at 22,000 or more -- with fewer than 9,000 from the US -- over the four days of the Conference. Plenary session presenters included, from the international perspective, Ban Ki-Moon, Secretary-General of the United Nations and Michel Sidibé UNAIDS Executive Director, Jim Yong Kim, President of the World Bank, and Kgalema Motlanthe, Deputy President of South Africa; from the US government, Senator John Kerry, Representative Barbara Lee, Eric Goosby, Global AIDS Coordinator, Secretary of State Hillary Clinton, HHS Secretary Kathleen Sebelius, CDC Director Tom Frieden and Dr. Anthony Fauci, of the National Institutes of Health. Other notable speakers included Bill Gates, Whoopi Goldberg, Sharon Stone, Elton John and Sean Penn, and many national and regional US AIDS associations such as Phill Wilson, Director of the National Black AIDS Institute.

Unlike past conferences, there was no evidence of a flagging of the energies devoted to handling and researching a cure for the epidemic, despite there being no concrete evidence of a vaccine developed or even in the pipeline. Rather, the tone was one of strong determination, with much of this strength coming from the opportunity provided by the conference to meet other AIDS workers (and researchers), describe each others' work, and compare notes on successes and challenges.

One theme supporting this sense of successes was conveyed by a number of presenters: in the US, vertical transmission -- from mother to baby before birth -- has been essentially eliminated through availability of the appropriate medications. It was also pointed out that there has been substantial success in limiting this vertical transmission worldwide.

HIV medications in place in recent years have helped thousands avoid the progression of their HIV to AIDS. The successful development of medications by 1996 changed HIV/AIDS from a death sentence, and instead gave those with HIV and proper use of medications every expectation of a full and near-normal life expectancy.

In short, as US Secretary of State Clinton pointed out very powerfully, we can look for a day when in the US there will be no AIDS. HIV, yes, but its progression to AIDS is destined for curtailment to zero. This was a subtheme heard often around the conference: "Getting to Zero."

Proof of the new outlook on what 'a lifelong infection with HIV' means, one very popular session, moderated by journalist Laurie Garrett, author of the 1995 book The Coming Plague, concerned living with HIV for those over 50 years of age. For one thing, universal precautions are seldom observed in this sexually active age group -- with multiple partners. Many of the expected problems of aging can be exacerbated by HIV, it was learned. Other issues concerned drug compliance -- persons of this age taking a number of daily medications for many health problems, increased with the addition of HIV medications, are at risk for compliance errors, and should note that the risk of an adverse event increases 10% with each additional drug to be taken regularly.

The conference participants were diverse to say the least, with all points of the globe represented. However one characteristic noted was that roughly speaking, the average *age* of participants was such that most had never known a world before HIV. Yet the zeal present in their participation in

all aspects of the conference showed the strongest determination to care for those in need and to fight the epidemic and as soon as possible see it vanquished.

There were sessions on TB and HIV coordinated care, on antiretroviral (ARV) medication use in limited settings (e.g. without refrigeration), on pricing of ARVs around the world, including barriers and successes, on confronting the stigma of HIV / AIDS, and stigma toward groups without adequate access to HIV medications, such as sex workers. Perhaps the most disturbing finding presented at the Conference was by the Centers for Disease Control documenting that, in a study of 800 men who have sex with men in a major southern city, a measure of viral load showed that the chance of transmission of the virus in a given encounter in the African American community was six times greater than the corresponding risk among whites.

Sixty of the sessions from the Conference are available for viewing at www.kff.org/aids2012

Attachment #4: The 'Fiscal Cliff' and its Impact

The term refers to the multiple budget-threatening actions scheduled to occur shortly after the first of the year. They include:

- 1) Expiration of substantial tax reductions which have been retained since the Bush years
- 2) Expiration of a payroll tax cut in place created in 2009 as part of the stimulus response to the recession
- 3) Implementation of federal program cuts made last year during preparation of next year's federal budget
- 4) The need to raise the national debt limit again
- 5) A required \$1 Trillion Dollar reduction in the federal budget over the next ten years (\$100 Billion each year), cuts to be taken equally from domestic and defense budgets under terms of last year's Budget Control Act

The national debt is the engine driving most of these strident attempts to curtail spending, and to some extent increase revenues if not by adding new taxes, then at least by bringing to a close some tax **reductions** that have been in place for years. The debt first exceeded \$1 Trillion only by 1981. Then it rose steeply through 1995, at that point exceeding \$5 Trillion. That may seem small compared to the size of the debt today (over \$16 Trillion), but it meant increases averaging over \$300 Billion each year. This period coincides with the Reagan and Bush years.

The rate of growth continued, slowing somewhat during the Clinton years; the slowdown ended in 2001 when, with several military actions in Iraq expanding to Afghanistan, the costs thereof were kept out of annual budget planning, and the growth of the deficit accelerated to \$2 Trillion **per year** by 2009 and essentially has been in runaway condition as a result. With a \$16,500,000,000 national debt at present, the total amount is now increasing by \$6 Trillion **per year**, even without any deficit increases from annual budgets. No state government can run a deficit; while many first world countries are in a financial crisis now, their ratings, and ours, are facing reduction to higher-cost loans. The interest on this debt is already a huge component of federal spending each year. This Bullet Train of debt can hardly be slowed by eliminating funding for individual programs.

Many of the funding bills developed this year but not passed contained substantial if not shocking cuts in domestic programs. While the sense of these cuts is similar to the Deficit Reduction themes heard these last two years, and which was the basis for the Trillion-dollar cut language, the pressure of these combined crises on Congress, which has already shown than even before these crises they are willing to dig in their heels and do nothing, could increase ten-fold. Bottom line: early 2013 is likely to be such a federal debt / program cut / government freeze arena that it will be perhaps the hardest trial ever faced by the American government. Certainly it will massively impact recovery from the recession.