ADVISORY COMMITTEE ON

BLOOD SAFETY AND AVAILABILITY

Crystal Gateway Marriott

Salon 1 & 2

1700 Jefferson Davis Highway

Arlington, VA

Thursday, August 31, 2006

The meeting, was held pursuant to notice, on Thursday, August 31, 2006 at 9:00 a.m., Arthur W.. Bracey, M.D., Chair, presiding.

MEMBERS:

JUDY ANGELBECK, Ph.D.

JULIE BIRKOFER

M. GREGG BLOCHE, M.D., J.D.

WILLIAM DUFFELL, JR., Ph.D.

KAREN SHOOS LIPTON, J.D.

DAVID E. MATYAS, J.D.

JACK McGUIRE

GARGI PAHUJA, M.P.H., J.D.

GLENN PIERCE, M.D., Ph.D.

GLENN RAMSEY, M.D.

SUSAN D. ROSEFF, M.D.

S. GERALD SANDLER, M.D.

MERLYN H. SAYERS., M.B., B.Ch., Ph.D.

LINDA THOMAS

PEARL TOY, M.D.

JOHN W. WALSH

WING YEN WONG, M.D.

NON-VOTING EX OFFICIO MEMBERS:

MATTHEW J. KUEHNERT, M.D.

JAY S. EPSTEIN, M.D.

NON-VOTING EX OFFICIO MEMBERS: (CONTINUED)

HARVEY KLEIN, M.D.

CDR MICHAEL LIBBY

JAMES S. BOWMAN, III, M.D.

P R O C E E D I N G S

(9:00 a.m.)

DR. HOLMBERG: If we could have all the Committee members at the table, please?

Welcome back to the second day of our meeting. I hope everyone had an enjoyable night and is rested.

We'll go through and do the roll call today.

Dr. Bracey?

DR. BRACEY: Present.

DR. HOLMBERG: Dr. Angelbeck?

DR. ANGELBECK: Present.

DR. HOLMBERG: Ms. Birkofer.

MS. BIRKOFER: Present.

DR. HOLMBERG: Dr. Bloche?

(No response.)

DR. HOLMBERG: Dr. Duffell?

DR. DUFFELL: Present.

DR. HOLMBERG: Ms. Lipton?

MS. LIPTON: Present.

DR. HOLMBERG: Mr. Matyas?

MR. MATYAS: Present.

DR. HOLMBERG: Mr. McGuire?

(No response.)

DR. HOLMBERG: Ms. Pahuja?

(No response.)

DR. HOLMBERG: Dr. Pierce?

(No response.)

DR. HOLMBERG: Dr. Ramsey?

DR. RAMSEY: Here.

DR. HOLMBERG: Dr. Roseff?

(No response.)

DR. HOLMBERG: Dr. Sandler?

DR. SANDLER: Here.

DR. HOLMBERG: Dr. Sayers was here yesterday, and had to go back on a plane to Dallas to go to South Africa, so he won't be with us.

Ms. Thomas?

MS. THOMAS: Present.

DR. HOLMBERG: Dr. Toy is again absent. Mr. Walsh?

MR. WALSH: Present.

DR. HOLMBERG: Dr. Wong is absent. Dr.

Kuehnert?

DR. KUEHNERT: Here.

DR. HOLMBERG: Dr. Epstein?

DR. EPSTEIN: Here.

DR. HOLMBERG: Dr. Klein is absent.

Commander Libby?

COMMANDER LIBBY: Here.

DR. HOLMBERG: Dr. Bowman.

DR. BOWMAN: Here.

DR. HOLMBERG: Mr. Chairman, we have a quorum, with ten people, exactly, so we can do business.

DR. BRACEY: Yesterday was a day full of lots of good discussion, and we also have a number of presentations today. As you know, we did have to move some of the afternoon session to this morning.

I will ask the speakers to really try to make their presentations within the time framework that's been allotted, because we do need to have more time for discussion, in consideration of recommendations for the Assistant Secretary later today.

Also of note is that we will have the Assistant Secretary visiting this morning, but I'd like to go ahead and proceed with our first presenter for this morning, who will be Barbee Whitaker.

Dr. Whitaker is the Director of Data and Special Projects for the American Association of Blood Banks. She is very active right now in terms of the efforts of the American Association of Blood Banks, to address the important issue of biovigilance.

She'll discuss the use of biovigilance from within the U.S. blood community, as seen by the AABB.

DR. WHITAKER: I apologize that yesterday I put the wrong data on my slide, and that's what got us behind time.

(Laughter.)

DR. WHITAKER: I'll try to go through my slides quickly, and I'll try also not to repeat some of the things that we discussed yesterday, in the interest of time.

But what I'd like to start with, is a

definition of what we see as biovigilance.

(Slide.)

DR. WHITAKER: It is the detection, gathering, and analysis of information regarding the untoward and unexpected events of transfusion and transplantation of cells, tissues, and organs.

That includes quite a few possible events.

(Slide.)

DR. WHITAKER: The objectives of this process, this collection of information, is having some early warning system of safety issues; the exchange of important information; the application of evidence for practice improvement, so that we can actually take the information we get from this system and apply it to the hospitals and the blood centers, so they have a chance to improve their practice and use the information that we have gleaned, and the promotion of educational activities.

The outcome that we're interested in seeing, is safer and more efficacious transfusion.

(Slide.)

DR. WHITAKER: What we saw yesterday, that

Matt Kuehnert talked about, were several categories that we saw coming together for biovigilance.

The one that I'm going to talk about the most today, is adverse transfusion events, but there are other categories that are important for biovigilance. These include: Infectious disease monitoring; emerging infectious disease; and hazards of donation.

Two of these categories -- adverse transfusion events and hazards of donation -- right now, we get certain information about them, and the information that we gather in the United States, is only fatalities. That pretty much just comes up through the FDA's monitoring system.

Infectious disease monitoring, we do a pretty good job through the CDC and through the FDA, and also through the state and territorial epidemiological system.

Matt talked a lot yesterday about the emerging infectious diseases. There are systems in place, but there's not an overall system of biovigilance to bring it altogether.

ABC will be talking after me and will be talking about the hazards of donation and some of the ways we can look at that and put that into a system of biovigilance.

(Slide.)

DR. WHITAKER: Other countries have hemovigilance networks. Here's a partial listing of many of the hemovigilance networks.

One of the things that's interesting here, is that many of these countries are from the European Union, because the European Union instituted the requirement last year, in November of 2005, that there be a hemovigilance system in place.

Almost every European country, like every European country, has a hemovigilance network or system or some sort. I'll talk a little bit about that in a minute.

You'll see also that there are other countries like Brazil, Japan, South Africa, and New Zealand, that have systems, so we are, as we discussed yesterday, one of the few westernized countries that does not have a system.

(Slide.)

DR. WHITAKER: So, what can be learned from some of these other countries? For example, in Denmark, there's been a study published or a review of the literature published just recently, in Vox -- I believe that was in your package of materials -- from many of these countries.

Denmark's review of 124 severe risk reports is about six years of data, 450,000 components transfused. Overall, most of the risk reports were associated with incorrect blood component transfusion.

Transfusion-transmitted infection was a very small amount of the risk reports. Clearly, that area is not a problem anymore; that's been managed by our infectious disease testing and our infectious disease surveillance programs.

Still, we do have this issue of incorrect blood component transfusion, so we have, through this review, transfusion reaction, hemolytic reactions, anaphylactic reaction, TRALI, and then delayed reactions, after the release of the patient.

Of these incorrect blood component transfusions, over half of them were from the sample that occurred during collection. When they traced it back, it was an error that happened at collection, and when they looked at it even further, 80 percent of them happened outside of routine procedures.

So, something was going on that made them not follow their normal process.

(Slide.)

DR. WHITAKER: This isn't a great replication of the slide. It is in your package, but what I wanted to just point out here, is that it's the same issue, the higher -- they're collecting the same kind of data that we like to see collected -- hemolytic reactions; incorrect blood components transfused; A-B-O incompatibility, TRALI.

We're looking here at Poland. This is just a comparison of two different years, but, looking at red cell concentrate and FFP, some of the things being captured in other systems, are the components that are being transfused and the types of reactions.

(Slide.)

DR. WHITAKER: In the United Kingdom, we've got the various reports being analyzed from 2004, from the SHOT system, with primarily incorrect blood components transfused; acute transfusion reaction; delayed transfusion reaction; TRALI.

Then you get further down, and this is transfusion-transmitted infection, and so on, down to just very low numbers of reports.

(Slide.)

DR. WHITAKER: When you break down the 2000 reports of incompatible red cell transfusions, incorrect blood component transfused, you'll see the bottom line here. This is the ABO compatibility. These are quite few in occurrence; in 2004, about 19.

(Slide.)

DR. WHITAKER: The question is, do we have any information from our system? In the last nationwide blood collection and utilization report funded by HHS and performed by the American Association of Blood Banks, we did ask a couple of questions about adverse reactions.

For 2004, we got reports of 32,128 transfusion-related adverse reactions. This was reported by 1,322 medical treatment facilities.

Of this list of, 1,680 hospitals reported, so we didn't get reports from everyone of the hospitals, of their adverse reactions, so, clearly, this is not the whole sample.

However, of those, we have reported 160 TRALIs. If you run that out with a denominator of the amount of FFP, it's about four per 100,000.

Then, 52 ABO incompatibilities were reported, and if you use the denominator of total units transfused, that's about .4 per 100,000, so we do have some data, and we're interested in collecting more data in future surveys. I think there are lots of opportunities to expand on this and to look to other countries for what the particular data are to be collected.

(Slide.)

DR. WHITAKER: What should we do, moving forward with biovigilance? Based on what we've seen of the strategic plan from the Secretary, as was

discussed in the May 2006 meeting, biovigilance -- and Matt talked about this yesterday, and it came up under transforming the healthcare system -- we are definitely very supportive of that, of bringing biovigilance into the discussion.

Since the May 2006 meeting of this Committee, we have had discussions with the Department of Health and Human Services, particularly with this group, and also with the FDA, to look at definitions and purpose and vision.

I think this might be why Jerry suggested that it might have been helpful to the panel, to have had this talk before your discussions yesterday. So, over the last three months, we've been looking into further elaboration of definitions and looking into defining that vision and purpose for biovigilance.

(Slide.)

DR. WHITAKER: We did have a meeting in July where we talked about how we can move forward with public and private participation in the process. This meeting was held with representation from the government, Health and Human Services, CDC, and

NHLBI, and the FDA, and also from the blood collection and transfusion medicine community, AABB, ABC, and the American Red Cross.

(Slide.)

DR. WHITAKER: We discussed a vision for a task force that would come together and work toward defining biovigilance. The vision for this task force, is to design and implement a comprehensive biovigilance system for the United States, that will improve the outcomes of collection and transfusion, and/or transplantation of blood components and derivatives, cells, tissues, and organs.

The task force would work together and bring together the important stakeholders, to put together the concept, not leave anyone out, and define it, so it wouldn't be a system where it would be defined at a committee level; it would be a real working group.

(Slide.)

DR. WHITAKER: The purpose of this task force is to collect, analyze, and report on the outcomes of collection and transfusion and

transplantation of components and derivatives, cells, tissues, and organs, to provide an early warning system for adverse events, and to continuously improve donor and recipient safety.

(Slide.)

DR. WHITAKER: We also discussed some charges for the task force. There are quite a few of them here: To establish goals and directives; to determine essential characteristics of the system; establish the necessary data elements; system specifications; a timeline with the potential for a pilot next year; and an operational system within two years -- well, actually three years.

Have standardized terminology and definition; a workflow process; to figure out costs and develop a budget; develop the pilot system; develop a marketing and communications plan, which is very important; a system for analysis and recommendations; and to oversee implementation.

(Slide.)

DR. WHITAKER: The way that we discussed this, is shown in this slide. The Task Force would

bring together this larger group of stakeholders, which include AABB, AATB, ABC, AdvaMed, AHA, ARC, ASA -- it's pretty much a smorgasbord of acronyms up here, but we believe that everyone in this group has an interest and will be invited to participate in this task force, as an overseeing group.

There's a steering committee that will be involved in Phase I of bringing together the information, and, particularly this group that met in July, which was the AABB, ABC, and ARC, and then from the government, HHS, CDC, FDA, and NHLBI.

We're bringing together a working group to work on some of the charges that were discussed on the previous slide. We have a group of international consultants that are coming from different countries, who already have mature, robust hemovigilance systems that we believe can advise us on the advantages and pitfalls of the current system, and different approaches to developing a hemovigilance and biovigilance system.

This group would not actually be meeting with us, necessarily, but working through electronic

communications.

(Slide.)

DR. WHITAKER: So, as far as what elements of biovigilance network do we believe are important to moving forward, we think that a public/private partnership is essential. It essential in the process of developing the system, and it's essential in the implementation, and I think we had some discussion yesterday about why that's the case.

It's very important that the reporting into the system, is non-punitive, is confidential, it's non-burdensome to the participants; it has to be an easy process or it won't be done. I think Jay's point that every reporting system is essentially voluntary, is really true.

Predetermined common definitions for data elements, is really, really important. As we've seen with the initial collection and utilization system, if people don't have a common definition for something, it doesn't really matter if they all report something, and if it's not the same understanding of what they are reporting, then the

data doesn't mean anything.

Funding is still going to be a big question.

(Slide.)

DR. WHITAKER: Confidentiality is very important. You had a question yesterday about whether we should integrate with international systems, and I think it's important for us to have data elements that are consistent with other systems.

We should be seeing what other countries are reporting, but I think it's also very important that we standardize on the U.S. practice of transfusion medicine.

We have to be true to our own system, and we need to map to what the international system is, so, as long as our definitions are really clear, then I think we will be integrated with an international system, but also true to the U.S. practice of medicine.

Then, lastly, it's very important for our analysis to have a clear plan. We have to be able to benefit our hospitals and patients, but we also have

to make sure that the data doesn't go into a black hole.

Not only do we have to know how we're going to analyze the data, but we also have to know who's going to analyze data. Setting up a system where we don't have a place, a venue, a partner, or a group that's going to be set up to receive the data and bring it back to the users at the hospital, I think, will be a problem.

One of the very important things that we have to have, going in, is a marketing plan. If we can tell the hospitals, whether it's the sentinel group hospitals, or the country, as a whole, they need to report into it, and we'll have to be able to get the data back and to use it for prediction.

Lastly, I think there should be an opportunity for peer-to-peer exchange, so that there can be -- if a community of group of -- a particular group, has a problem, they should be able to ask a question, like, we have a problem with labeling; how do we solve this? And this is a way to find that answer.

(Slide.)

DR. WHITAKER: AABB is committed to working with this interorganizational task force. We definitely would like to see a public/private joint effort.

It's very important to see both hospitals and blood centers represented in this process, and we'd like to see a beneficial outcome to patients and donors alike. Thank you.

DR. BRACEY: Thank you. Questions or comments from the Committee? Dr. Epstein?

DR. EPSTEIN: I'm struck by the fact that the organizational task force is doing the thing that we just asked ourselves to do, and that it's more likely that the task force will be able to do it, over time, than we would be able to do it at our meetings at less frequent intervals.

I'm also struck by the fact that Barbee's first slide -- there is a vision statement. If we could contribute our input to the vision statement, and then, I think, sort of step back and get periodic reports, that would help the evolution of what is

developed by the organization.

DR. BRACEY: Ms. Lipton?

MS. LIPTON: I also think, going back to the slide about organization, that we should have some discussion on the role of the Federal Government. There are some things that aren't quite what we were working on yesterday, that we could define those and get those into the working system.

We were talking earlier, I think, yesterday -- at least it could be an oversight function.

DR. BRACEY: Given our charge of ensuring the safety of the blood supply, we really are obligated to have an oversight function for an important activity like this, recognizing, I think, that we'll need to have partnerships, because, again, in terms of the frequency of our meetings, it would be very hard for us to actually implement a system.

I think we have a huge role to play, as far as partnerships. Ms. Thomas, did you have a comment?

MS. THOMAS: I really enjoyed your

presentation, and I wish you would have been able to present yesterday. It would have saved a whole lot of confusion.

But I did have a question. Early in your presentation, you mentioned incorrect blood component transfusion, and you had mentioned that there were errors in sampling collection. I would just like to know, what is an example of a not-normal process that you mentioned, where errors were occurring?

DR. WHITAKER: That would be an example -- for example, if somebody came in for an emergency surgery, I mean, normally, you might have somebody who would come in and -- actually, Karen?

DR. BRACEY: There are a number of examples in terms of misadministration. You're talking specifically in terms of where the unit has been administered.

DR. WHITAKER: I think she was talking about the sample collection.

DR. BRACEY: Well, we do know, factually -- there was a report in the Wall Street Journal, of a study from UCLA, looking at a period of about two

years or so. There were about 12,000 errors identified in specimen processing within a sample of about four million.

I don't know the figures, exactly, but we do know that there are errors that occur in terms of specimen collection. There are systems that can be designed to try to minimize those errors, and, again, what we're talking about here is having a system that will be able to present data to analyze it, and then give feedback to both sides, so they will be able to improve their practice.

Dr. Sandler?

DR. SANDLER: I have a comment. I was really going to save it for later, but it's pertinent.

Our experience at Georgetown University Hospital, matches the Danish experience that you showed, which is that more than half of the problems that we see with the blood banks, are really problems on the nursing side.

That's an extremely important part of the discussion that I think we're going to have coming

forward. That is to say, we find that a person today has Group A blood, and was in the hospital a year ago, and had Group O.

Obviously, we go to the bedside, we check the wristband, we look and we see that we've identified the wrong person. The key point that I want to put on the table -- and we're going to get back to this -- is, this isn't a blood bank problem; it's a problem of the sample that was drawn for infectious diseases testing, at the same time the same tube was mislabeled when it went to hematology; the same tube was mislabeled in chemistry.

When I started to approach this problem as a blood bank problem, five or six years ago, it drifted away. People got very interested in it, and it really became a nursing service problem and a hospital-wide problem.

As it evolved, I'm small potatoes in the issue. It's a hospital-recognized problem, so as we look for the geocenter of this problem, we're going to be a bit of the tail wagging the dog.

You want to think about, do they draw more

samples, and draw it as they did in Denmark? That's the biggest part of the Danish problem.

This is much, much bigger than the blood transfusion service.

DR. BRACEY: Ms. Lipton?

MS. LIPTON: It's interesting that you say that, because that was a large part of the discussion that the group had about that data, but I think there are two things: We have to draw attention to the issue, and if we just sit back and say nothing's going to happen unless we address, the question, we talked about how to involve nursing as a profession in this whole issue and ways to bring them in, but we also looked to bring in the hospital administration.

This may ultimately, if you will, pass to a different group, and the time to identify the specific problem and collect data around it, it's really our job at this point.

Whatever fixes come out of this thing, maybe they're in parts of the hospital that have nothing to do with blood. We have, I think, the mindset and the will to solve it and shed light on

the problem.

DR. BRACEY: Ms. Birkofer?

MS. BIRKOFER: I can't give a medical example, but I can give a real-world example. In June, my father had open heart surgery. He was very out of it in his bed.

The person came in to draw blood, had the wrong last name. I was in the room, and I said, wait, wait, that's Mr. Birkofer.

She had her needle out, ready to go, and my father was in no position, if hadn't been there to stop her. It's just errors.

And then she said, oh, you know, it happens.

DR. BRACEY: Commander Libby?

CDR LIBBY: Blood bankers have to take the initiative. In our experience in DOD, our office is not the one that oversees the transfusions. In DOD, it's generally the clinical laboratory's responsibility, and they are held responsible for it.

But you see this awareness going on in the press, that DOD oversees the transfusion safety

of our troops and our folks overseas. We have to -- me, personally -- we put a committee together for risk management, to kind of deal with this issue.

We all agreed it had to be done, and we had a group chartered, but there's a group that is already together, a patient safety group, and the transfusion safety piece, played a very small part of the overall big picture.

In the last few years, the Patient Safety Committee has been very active. They find issues that need to be corrected, so there's this big oversight of transfusion.

We're still small and are in the background, but it's a big issue for patient safety. I've been working at it for about a year, and one of the things we're really trying to do, is trying to get the system reporting what we do best for transfusions.

And even that is fairly difficult. Each Service's facilities is different. We just want to get it reported the same way, so that it means something when we gather the data. It's a long row,

and it's difficult.

DR. BRACEY: In the interest of time, we'll move on, but I have one last question of our guest, and that is, the AABB represents thousands of hospitals, but certainly not the entire network of hospitals.

Would this system be open to only AABB members? What is the extent of the involvement?

DR. WHITAKER: It would certainly be open to everyone. We represent most of the transfusing hospitals, and I think we would keep it open to everyone.

DR. BRACEY: Thank you.

DR. RAMSEY: We talked about -- obviously, doing this right the first time -- phlebotomy is a lot more streamlined than saving time for the patient, and healthcare professionals going back and correcting frequent errors that delay testing and delay transfusions.

One of the silver linings of this process is to improve everybody's capacity in the hospital.

DR. BRACEY: With that, let's move on to

the next speaker. We will have Dr. Susan Rossmann, who represents the ABC's view of biovigilance.

Dr. Rossmann is the Chief Medical Officer with the Gulf Coast Regional Blood Center in Houston. She's also currently the Chair of the Scientific, Medical and Technical Committee.

DR. ROSSMANN: Thank you. I will make a few remarks while they get my slides up. Thank you for the opportunity to come. I will try to be brief and not repeat much of what you have heard, and, instead, emphasize some small points of difference, for emphasis.

(Slide.)

DR. ROSSMANN: America's Blood Centers, for those of you who are not familiar with us, is a large network of community-based, not-for-profit blood programs. We are very horizontally organized. We have 78 blood programs serving 180 million people in 45 states and all of Canada, with more than 9 million donations annually -- about half the U.S. blood supply and all of Canada's volunteer blood supply. Many of our members provide other services

such as therapeutic services, and we recruit marrow, cord, stem cell, and tissue donors.

I'm not going to talk at all today about the tissue aspects of our members' work. We're just going to be discussing the blood work.

I'm also not going to discuss any further, the Canadian efforts, although our members are in Canada, as well.

(Slide.)

DR. ROSSMANN: These are our locations around the country.

(Slide.)

DR. ROSSMANN: I think it's important to realize, as several people have said, that we're really not talking about completely reinventing the wheel here.

We have in our regulations, a number of aspects of a hemovigilance center. We've been carrying these out for years, particularly cradle-to-grave traceability; fatality reports; the blood product deviation reports, which are a vast trove of information.

They certainly contain all sorts of information about the kinds of issues we're talking about in hemovigilance: Product retrievals; donor and recipient notification, and look-back.

(Slide.)

DR. ROSSMANN: For a variety of reasons, I think the focus here that is a little different, is that we are talking more about the entire process.

The notion of hemovigilance, as you know, was created in France, and there is a large European network that is ongoing. In particular, we've been following SHOT, which is, of course, a voluntary program in the UK.

(Slide.)

DR. ROSSMANN: And we have other areas that have covered hemovigilance, including the EU, which we discuss here.

(Slide.)

DR. ROSSMANN: I think it's important that the U.S. issues -- the FDA is now centered on product. The hemovigilance efforts, in general, seem to be centered more on the entire process, vein-to-

vein, as some people like to say.

Transfusion of blood and blood products, from the collection, through the outcomes for the recipient, this requires a lot more hospital and clinical involvement, I think, than our current system, which is limited more to reporting serious problems, and, of course, dealing with any notifications they get from blood samples.

We need to address, I believe, hemovigilance that should address donors and adverse reactions.

These are not included in many of the European initiatives. If you look at that survey that was in Vox, only a few of the programs deal with donor adverse reaction, more than just infectious disease testing.

We feel, as blood collection agencies, that it's important for us to advocate for donors and represent donors and make sure that we do everything we can to make them safe, as well as transfusion for the recipient.

Of course, we have blood center

activities, many of which we already do; hospitals' patient outcome data. I think it's worth emphasizing that hospitals now are not the only places where transfusions are received.

I don't know the numbers, but certainly they are the vast majority, but we issue an ever-increasing amount of blood to surgical centers, dialysis centers, home healthcare agencies, all in keeping with the decentralization of healthcare.

And these aspects of transfusion, will be much harder to capture, even than the events that happen in the hospitals. Again, it's not a tremendous number, but it is an ever-growing number, and they will be much harder to track.

(Slide.)

DR. ROSSMANN: The success of this program depends on definitions, and, as we have discussed, active participation is very important.

(Slide.)

DR. ROSSMANN: Of all these various groups, most of which have already been mentioned, I would include ASH and other professionals, both

physicians and nursing groups that may be involved, and representatives of hospitals and surgery centers, who are not always involved with JCAHO, but have their own professional organizations.

(Slide.)

DR. ROSSMANN: We would like to see a voluntary system focused on donors and patients, which address utilization, as well as adverse events, data analysis, and development data, and policies based on the data.

(Slide.)

DR. ROSSMANN: We do have concerns that this is going to be a data dump. A lot of people have an academic interest; I have an academic interest, but we really need to look at the return on the investment and the kind of actions we can get out of the data that we can collect at minimal cost and difficulty.

We need to refine these measurements and collect more measurements as we move on, but we really don't want to overwhelm ourselves at the beginning and not be able to take action on these.

I mean, for years, we've known now that specimens -- the difficulty of specimen draw and identification, has been a big problem. It's taking us a long time to really find effective solutions for it, so we really have to work on the action part, as well as collecting more information.

The addition of regulatory layers, is a concern for our members, and also the unfunded mandates is part of this.

Where this is going to come in the overall scheme of health care costs, which, as we all know, is a tremendous problem now.

(Slide.)

DR. ROSSMANN: What we plan to do in the near future, is support the interorganizational efforts through the AABB, and participating in the analysis of data and the development of policies, as appropriate.

We are also planning to organize volunteer systems for collections, with our own members.

(Slide.)

DR. ROSSMANN: We are working at this

point in terms of definitions, particularly standardizing them beyond the ones that we already use, such as, for example, for the FDA reports.

I thank you for your attention. I'll be glad to answer any questions.

DR. BRACEY: Thank you. Questions for Dr. Rossmann from the Committee? Dr. Duffell?

DR. DUFFELL: Thank you for your presentation. Just to speak plainly about this, do you guys support this initiative or not?

DR. ROSSMANN: Yes.

DR. DUFFELL: The way you were talking, you were raising a lot of concerns about it, rather than endorsing it and saying you're willing to participate, but, you know, it sounds like it may be more of an observer role, possibly, than someone who's advocating that there is real need for this.

DR. ROSSMANN: No, we believe that there is -- and perhaps the phrasing was bad -- we feel that the AABB is the appropriate group to do this. They have a large group of stakeholders already involved.

So, we are definitely committed to doing that. As I said, we are a volunteer organization, so it's not a top-down kind of decision we can make, but we feel that all of our members will be willing to participate, in a voluntary way.

DR. DUFFELL: Thank you.

DR. ROSSMANN: I didn't mean to be waffling on that.

DR. BRACEY: Dr. Kuehnert?

DR. KUEHNERT: Thank you for the presentation. I had a similar question about the slide after the pledge of support for the AABB effort.

It looks like there is an effort to develop standard definitions and collect data, and I just wondered, is there a plan to feed that into a larger system, or are the definitions for things that haven't been defined by the Biovigilance Task Force, or if the Task Force doesn't end up doing the work that it seems to be setting out, what's the ABC plan for that?

DR. ROSSMANN: We are in a pretty

preliminary stage at this end. We didn't want to recreate what the AABB Task Force will be involved with.

We are not -- we do not see ourselves as at quite the same level of involvement as the Red Cross, which you will hear about next. Perhaps we should have reversed these, because we're a different kind of organization.

So, we are going to collect data that we feel that we can influence or that the AABB wants us to collect. We'll certainly be participating in that.

DR. BRACEY: Question: Is there currently any sharing of data between the two systems, the ARC and ABC, regarding these sorts of activities?

DR. ROSSMANN: No. And Dr. Eder may address this, but we have a lot of informal sharing. For example, we've been recently working very hard on the uniform donor issue questionnaire.

We've shared that over the years, but, in terms of actual information, other than published stuff, we don't have a lot of informal communication.

DR. BRACEY: Okay.

DR. ROSSMANN: I think that is actually on our agenda for both organizations. As I say, I'm not going to speak for the Red Cross, but I think it's on our agenda to work more together, particularly on these kinds of initiatives.

DR. BRACEY: Dr. Kuehnert, did you have a followup?

DR. KUEHNERT: I was just going to say that West Nile sort was the model for collaboration. We figured out that we can aggregate data, and so using that model, probably is helpful.

DR. BRACEY: We'll move on to the next speaker. Thank you, Dr. Rossmann.

The next speaker is Dr. Anne Eder. Dr. Eder is the Executive Medical Officer for the American Red Cross. She's very busy with biovigilance, hemovigilance, and certainly is the National Director of Donor and Recipient Complication Surveillance Program for the Agency.

DR. EDER: Thank you for that introduction and for the opportunity to address this Committee.

(Slide.)

DR. EDER: Dr. Richard Benjamin certainly wanted to attend this meeting, but is currently in South Africa at the ISET meeting.

I do want to share with you, findings from our monitoring program, as well as to showcase some examples of how the data has been used.

(Slide.)

DR. EDER: The American Red Cross is shown schematically on this map. We have 11 divisions across the country.

(Slide.)

DR. EDER: These are further divided into 36 regional blood centers. We collect approximately six million donations per year, and we distribute more than nine million blood components per year to about 3,000 hospitals across the country.

(Slide.)

DR. EDER: These 36 regional blood centers, all of them investigate reported reactions. This is an overview of the Donor and Recipient Complications Surveillance Program, which starts in a

region when they receive a report of an adverse reaction.

We monitor -- I would very much like to echo and emphasize what Dr. Rossmann has said, that donor safety should also be addressed by a biovigilance program, because at blood centers, we have an obligation to our donors, as well as to our recipients.

Our regional blood centers, the regional medical director and the donor center staff, investigate all reported reactions, and take immediate action, when necessary.

For example, if action needs to be taken on blood components, all of the information is compiled at the national level, at our headquarters in Washington, under the umbrella of the Donor and Recipient Complication Surveillance Program, where we analyze the data and make recommendations.

As I said, I'm going to give you three examples of the kind of data that we do collect.

(Slide.)

DR. EDER: Overall, our program goal is to

improve blood safety for recipients, minimize procedure risk for donors, and detect significant trends that emerge from analysis of reports of rare events.

To say again what has been said previously, this is very much at the national level, sort of a sentinel event model, where we look at rare events or focus on the rarer and more serious reactions.

(Slide.)

DR. EDER: From the data analysis, we identify possible interventions to reduce the risk of complications in susceptible patient and donor groups, and we monitor this data monthly as part of our quality program.

Again, the scope of the program encompasses, if I haven't already emphasized this enough, donor reactions and injuries, and recipient complications.

But we are a blood center and we are focused on those reactions that are related to manufacturing or donor selection, and we do not

receive reports of transfusion errors or mistranfusion related to errors.

We also investigate transfusion-related infections and fatalities.

(Slide.)

DR. EDER: The overview of the recipient complications is shown on this slide. They can be broken into two broad categories: Infectious and noninfectious.

I will be talking in more detail about TRALI and septic reactions, which you can already see on the infection side. In my mind, it's only the acute-type reactions, and, reactions from bacteria, are, in my mind, different from the product infections that result from viruses and parasites.

But, again, just to emphasize, we're focused on those complications possibly related to component manufacturing or donor selection.

(Slide.)

DR. EDER: As the regional blood center investigates the reaction and as they complete their investigation using standard procedures and terminology, at the close of the investigation they indicate a probability code ranging from low probability that the reaction was caused by the transfusion to high probability where the transfusion, not only as the transfusion suspected of having caused the reaction, but a donor is implication and the transfusion source is confirmed.

(Slide.)

DR. EDER: This gives you a snapshot of a year's worth of data.

(Slide.)

(Pause.)

DR. EDER: This is a snapshot of complications reported in 2005. It encompasses 600 reports found in blue on the low probability cases, which I showed you on the previous scheme where transfusions and adverse events were reported to us that we investigation. But at the completion of the

investigation it's unlikely that the transfusion was responsible for the reaction. Focus on the high probability cases where a transfusion source is suspected or confirmed. You can see that on the non-infectious side TRALI accounts for most reports. Septic reactions account for the second highest number of adverse reaction reports and I'll comment only briefly on infectious complications with this type of surveillance only a few cases of transfusion transmitted infections have been identified. Those cases have been linked to a transfusion in the '80s or '90s, so it was realized many years later. It was not identified through this mechanism, but we have not identified any infections related to transfusions certainly since implementation of testing the thing now on septic and TRALI complications.

(Slide.)

DR. EDER: If you analyze these by component transfused what you see for TRALI that most TRALI reports are with FFP transfusions. Most septic reports are linked to transfusions of apheresis platelets. Even though we implemented back to real

testing on March 1, 2004, this slide show schematically our current approach to bacterial testings, which is that we inoculate culture bottles 24 hours after collection of the component, release the component after an additional 12 hours then monitor through outdate.

(Slide.)

DR. EDER: This shows you what we're able to detect with this testing where about 1 in 5000 donations is found to be contaminated with bacteria. These are the units that we intercept. So we intercept about 85 confirmed bacterially contaminated units a year. What this doesn't tell you is what gets through and the strain of the DRCP isn't analyzed in the rare event. We received 17 cases of the septic reaction after transfusion of apheresis platelets that remains negative during the incubation period. Fifteen of the 17 cases were due to contamination with staphylococcus suggesting skin contamination. Fifteen of those 17 were linked to a two-arm procedure. The DRCP was able identify that the residual bacterial risk that we're seeing was

linked to a two-arm procedure and that was deemed statistically significant.

What's the difference between a two-arm and a one-arm procedure. One arm, right, one needle. The difference is that the two-arm procedure places the return line first, collects the samples for viral testing, but when the inlet line is placed the tests that were used did not divert to the initial sample, which is the suggestive of the importance of diversion of the initial sample from the inlet draw line.

(Slide.)

DR. EDER: So as a result of this analysis, we implemented and we have now fully implemented collection sets that have inlet line sample diversion. There are other ways to improve platelet safety and we have also increased the volume of culture that's inoculated into the bottle.

(Slide.)

DR. EDER: TRALI -- these are the number of reports of TRALI that we've received, and again, the low probability cases are the lighter cases. The

high probability are the dark tips. This just shows that reports have been increasing over the three years. This represents about 550 reports of TRALI, which adds up to more than 60 per year of just the high probability cases. If you look at it across our division, you see a general relationship with the size of the division, number of units they collect with just a few outliers. But in general, the more units you collect the more reports you receive, the more units you distribute.

(Slide.)

DR. EDER: If we focus one of the challenges of the surveillance system it's extremely important to have not only common definitions, but a common approach to investigations to make sure we collect all the information. We've focused analysis on reports of possible fatalities, TRALI-related fatalities. The investigation was usually the most complete and the reporting was usually the most complete as well.

Both cases were linked to plasma transfusions. Furthermore, the donor investigation

identified a donor with HLA or anti-leukocyte antibodies. We have information from SHOT from the United Kingdom based on a similar trend.

(Slide.)

DR. EDER: There's an increased risk with high-volume plasma components. Of course, the United Kingdom went to male-only plasma in 2004. That is using plasma collected from male donors for transfusion.

(Slide.)

DR. EDER: The next slide shows this would be a feasible approach in the Red Cross when you consider that most of our plasma in manufactured through fractionation. It is possible to divert plasma from male donors for transfusion while really only having a minor impact on the distribution of the NESF fractionation as further plasma component.

(Slide.)

DR. EDER: The plasma components are responsible for the majority of TRALI and are frequently linked to antibody positive donors. I personally look forward to participating actively in

the ABB's biovigilance taskforce to advocate for prudent measures to reduce patient exposure to leukocyte antibodies and I would also comment that the first step needs to be advocating for appropriate utilization of blood components. We've seen too many cases of TRALI where the document is indicated as intended to correct I&R. There are efforts within the Red Cross to collect plasma predominately from male donors for transfusion.

(Slide.)

DR. EDER: My final two slides are to address donor complications. We, again, have common terminology that we use to describe donor complications and compile donor complications and analyze serious reactions. That classification scheme is shown on this slide. Each category is further divided.

(Slide.)

DR. EDER: The complication rate by age of the donor is shown on this slide. The majority of reactions, the biggest category are the vasovagal type reactions. Clearly, the most common and less

severe reaction. The very tip, which you can't see very well on this slide, at the very tip are the more serious major reactions. I show you this overview only to demonstrate that our youngest donors are most susceptible to complications and that our efforts are focused on reducing the reaction rate among our youngest donors, among our high school donors.

(Slide.)

DR. EDER: This is, of course, because we have an obligation to minimize the risk to our donors. It's very clear and others have shown that if a donor experiences even a minor reaction they're less likely to return to donate blood again. No surprise. If they have a major reaction, they're much less likely to return.

(Slide.)

DR. EDER: I'd like to just acknowledge the individuals who have -- without whom the DRCP would not be possible. Beth Dy is our program manager. Jean Kennedy our case coordinator, Linda Chambers was medical director. I'd also like to recognize the Holland Laboratory and all the regional

physicians at our Red Cross regional blood centers. Thank you for your attention.

DR. BRACEY: Thank you for that great presentation. It really shows how collection analysis can improve outcomes.

I have a question that's related to your sense of your facilities willingness or activity or involvement in reporting. What is your capture rate? What do you know about it?

DR. EDER: I'm sorry. What sense do we have of how many?

DR. BRACEY: How full do you believe your reporting mechanism is from your hospital facilities? Again, the feedback into your system. Do you feel it's the majority of cases.

DR. EDER: My sense is no. That any passive surveillance system is going to under capture, is going to be an under representation. That's my opinion. A passive surveillance system will have significant under reporting.

DR. BRACEY: There's been no system where you've been able to go and validate the number of

reports? In other words, working with your facility to assess, perhaps working with the transfusion committees on how many reactions actually occurred? Or was this poor reporting?

DR. EDER: That's been done in a spotty fashion. With donor complications there's definitely been efforts to call donors afterwards. If you actively investigate, you identify reactions that were not reported.

DR. BRACEY: Dr. Kuehnert?

DR. KUEHNERT: The only data I'm aware of on that was done in the '90s where CDC investigated. I think it was Rosyln Yapovi who showed that the under reporting was on the order of 10 fold. I'm sure it's very variable. But that's where you go into a hospital and review for validation.

DR. BRACEY: Thanks.

Dr. Ramsey?

DR. RAMSEY: Just to point out blood drawing procedures usually call for reports to the blood center about problems that might be related to the donor. I know that's the case for the Red Cross.

They do not call for reporting all allergic reactions that are not related to the donor necessarily. This is a very important piece of the reaction issue, but not by any stretch --

DR. BRACEY: One point that is very important that related to our discussion yesterday that related to the scope of the biovigilance program it seems also your reports of are of the non-infectious variety.

DR. EDER: Right. We do not capture hemolytic transfusion reactions. We receive reports of allergic reactions, but certainly not -- usually just the very severe ones, certainly not -- just the tip of the iceberg. That's absolutely true. We are focused on the event possibly related to manufacturing or donor selection.

DR. BRACEY: Dr. Holmberg?

DR. HOLMBERG: You mentioned about having the follow through on detection. When did you start doing that?

DR. EDER: We have not. It was a strategy for --

DR. HOLMBERG: Sorry. Okay. Will you be adding that?

(Laughter.)

DR. EDER: We have doubled the sampling volume.

DR. HOLMBERG: Also, you mentioned about the younger donors. There are some blood centers that are pushing for young donors to give. Is this a strategy that the Red Cross is going to? What are you doing to mitigate some of those reactions in the younger donors?

DR. EDER: We are currently, through a working group lead by Dr. Bruce Newman, a working group involving many regional medical directors. We're now at the stage of identifying what interventions would likely be most effective to roll them out more systematically. But those interventions include distraction, water prior to donation, looking at things that are more difficult to implement like muscle tension. The group right now is in the stage of considering what could be done, what's most likely to have the most benefit and

what would be the best way to implement in a more systematic way.

DR. BRACEY: Dr. Epstein?

DR. EPSTEIN: I was also puzzled about your finding of bacterial infection -- you said between 15 and 17 for Staph. If you've got a 12-hour culture, you'd expect to see the result for Staph aureus. Also, do you know when, in relation to collection -- in other words, when your cultures turn positive, do you transfuse the unit?

DR. EDER: None of the 17 cultures turned positive. The 17 cases that were associated with negative quality control cultures, the average turned positive. The cases were at least two Staph aureus and some Staph epi.

DR. EPSTEIN: And these were confirmed cases that were cultured and found positive?

DR. EDER: It was a reaction consistent with the septic reaction and the same organism grew from the residual unit in the hospital and the patient. It wasn't gel electrophoresis in every case, just a convincing clinical picture in every

case, just an individual bag in the culture from the patient.

DR. EPSTEIN: It's just peculiar not to have been able to ultimately -- you hold the bottle. Right?

DR. EDER: We hold the bottle for 24 hours and release it after 12 hours. The cultures do not come out of there during the culture period.

DR. EPSTEIN: When do you discard the culture? At the time of transfusion?

DR. BRACEY: It's odd the cultures never turn positive.

DR. KUEHNERT: I'm not sure it's entirely odd.

DR. EDER: I would also agree that I don't think it's odd. Any contaminate at low amounts -- why I think diversion is considerably more important than an anaerobic problem.

DR. BRACEY: Thank you.

In the interest of time, we will move on with our next topic. We've heard reference to this particular topic, that is the utilization of blood

products. The presenter will be Sharon Vernon. Sharon is representing HemoConcepts, a corporate entity that has engaged hospitals, a number of hospitals in the U.S. for blood conservation.

MS. VERNON: The subject we're really going to focus on is the initial effort on blood conservation today. Our objective to discuss their impetus toward proper utilization of blood and blood components.

(Slide.)

MS. VERNON: List some of the challenges facing today's healthcare in the United States, describe universal tools available for effective education in blood utilization and to review the results of institution hospital-wide blood utilization, education and processes.

(Slide.)

MS. VERNON: I don't think I have to ask the question what is there a growing need for blood conservation. I think that's been answered. But we're going to talk about the supply/demand gap and how it's escalating through the reports that we're

receiving. The increased awareness of the clinical impact in transfusion therapy, the inconsistent standard of care that we're seeing across the United States and the disaster emergency preparedness, which we're also seeing.

(Slide.)

MS. VERNON: Starting with the blood supply, blood shortages exist all over America. This is a quote from the American Blood Center. This was testimony that was given on our nation's blood supply. They also reported there's a wastage of organs and it's increasing that each day necessary surgeries are canceled or postponed for a lack of an adequate supply in the hospital. Today there is less than a three-day supply of blood nationwide. Never in modern times have our reserves been lower. I can personally testify to that. I'm from Ohio. We have blood emergencies almost on a monthly basis. You can drive by a hospital in any area in Cleveland and see big signs up front asking for donations because of blood emergencies. Some of our donor requirements have been modified simply because we need more blood.

Our blood supply is inadequate to deal with a major disaster. That may be true today.

(Slide.)

MS. VERNON: The blood demand is another issue. The current U.S. blood demand annually is 14 million units collected, 27 million blood components are transfused to 4.5 million patients. This is increasing by 27 percent between the years of 1994 and 2001. Now it's increasing by 3 to 5 percent per year. Why is this? Obviously, we have an expanding elderly population. They need more orthopaedic procedures and they need more cardiac procedures, so they're using half of the blood supply and 47 percent of the blood transfusions are to Medicare beneficiaries. More complex and aggressive procedures are certainly being performed in our hospitals today demanding more blood.

(Slide.)

MS. VERNON: One thing I wanted to mention today is something that hasn't been mentioned so far the growing interest in the medical community that's transfusion related immunomodulation or TRIM. We're

actually talking about the fact that the more blood you give the more there's an effect on the immune system. We've known this for years in the transplant field that if we gave blood the patient had a better opportunity of accepting the organ. Now we're looking at this in the sense of what are some of the effects. This is still new information. There's a lot of research that needs to go into this. However, some of the articles and studies that are going on are compelling. For instance, there's a 7 to 10 fold increase in post-operative infection rates that leading to increased length of stay, obviously, a higher resource consumption and this leads to total hospital costs. We're also beginning to see a relationship between cancer reoccurrence in transfused patients and also increased mortality rates in CABG. I know this has also been published in the colon/rectal area.

(Slide.)

MS. VERNON: Duke and Columbia Universities did a very interesting study on heart surgery patient outcomes following a transfusion and

a time. Of stored blood of 321 patients the mortality rate for patients receiving the freshest blood was 4 percent as opposed to a 25 percent mortality rate for those who received the oldest blood. The former spent 3.5 days in the ICU compared to 17 days for the latter. So again, this is information coming out that definitely we need more to validate these small studies.

(Slide.)

MS. VERNON: I mentioned the inconsistent standard of care and this is something that I experience as I go across the country and speak with physicians and analyze the standards of practices in hospitals in the area for instance in CABGs in some hospitals their transfusion rate across the board is 76 percent of all patients receive blood. Yet, in other areas of the country it's 50 percent. I know a hospital on the East Coast their transfusion rate across the board is 17 percent. So we do have some inconsistency. The ASH published some information on RBC transfusions are being given unnecessarily, maybe that's the case considering what we are observing

across our country. Nearly 20 percent of the stable uncomplicated CABGs in this article highlighted they were receiving unnecessary transfusions. Of 14 million RBCs transfused annually in the United States, an estimated 30 percent are given to CABG patients. You can see the domino effect that's taking place. In this study they suggested at least 170,000 units of red blood cells are administered annually in the U.S. that maybe shouldn't be.

(Slide.)

MS. VERNON: Again, we can't talk about medicine today without talking about disaster preparedness. I just took a quote from the AABB Taskforce, and by the way, they've done a very good job of addressing disaster operations. The single greatest risk of domestic disasters and acts of terrorism is not the lack of supply, but the disruption of the blood supply.

(Slide.)

MS. VERNON: Here's the first key to our presentation this morning -- the proactive rather than reactive. The diversity of disaster

preparedness plans throughout the United States are primarily focused on what is being done after a disaster or an event occurs. We look at blood conservation as a multi-disciplinary, hospital-wide initiative in education that focuses on best practices so as to be prepared prior to a disaster or an event.

(Slide.)

MS. VERNON: Yet, there's challenges. Hospitals are seeking to reduce donor transfusions, but they're having difficulty doing so in a timely and cost-effective manner. Some of the reasons are listed here -- the lack of subject-matter expertise; the inconsistent training and education of staff; the absence of standardized policies and the inability to consistently track, analyze and report outcomes.

(Slide.)

MS. VERNON: Yet, with blood conservation we're seeing that with proper blood utilization the implementation of blood conservation processes and proven best practice techniques can be obtained through training and education. This is done by a

comprehensive, multi-disciplinary process that's designed to promote a universal standard of care in transfusion therapy. Subject-matter expertise in the delivery of education is essential so that we can provide hospital with the ability to create a success program in a relatively short time period.

(Slide.)

MS. VERNON: Put another way is that education and training leads to the application of best practices, which leads to good collection of evidence based-practices and data recording and analysis, which in turn, goes back to further education and training, which again goes back to the application of best practices.

(Slide.)

MS. VERNON: What are some of the tools in blood conservation? We recognize the program manager who is a dedicated, licensed clinician who's generally been an RN in most of the programs across the United States who are properly trained in blood conservation processes. We developed standardized policies and procedures. This assures a consistent

standard of care, if I can borrow a term that was used yesterday. This takes fragmentation and creates integration. We eliminate the gaps that we have today within departments. Of course, education of clinical and administrative staff is also important.

(Slide.)

MS. VERNON: Our goals are to implement a process that's effective and conducted in a timely manner. Generally, we can develop these programs within a six-month period of time. We focus on a pre-event education and training in disaster preparedness. Our evidence-based data collection, analysis and reporting system, again, is based on the circle that I showed you before. It's a relational database that can track blood utilization, analyze and report outcomes.

(Slide.)

MS. VERNON: What are the expected results in blood conservation education and processes? I'm going to highlight three hospitals, but I wanted to mentioned that in the Military they have a saying that if you want to win a war you have to create a

beach head. And that's exactly what these hospitals have done in regard to the conservation of blood and blood utilization. They established a beach head.

(Slide.)

MS. VERNON: I think you'll be impressed with some of their results. First of all, Fairview Hospital back in 2002 is a hospital part of the Cleveland Clinic system. In their first year they reduced their total transfused RBCs by 16.5 percent. Within three years, they had reduced their transfusions in cardiac surgery by 50 percent and in orthopaedic surgery within three years they reduced it by 48 percent. They have a 66 reduction in post-operative infections and 8.8 reduction in the length of stay. And as you noticed, they have an increase in their patient census as well.

MS. VERNON: This is hot off the press. You're not going to see this in your handouts. I apologize. But this hospital was so excited to be able to share the data that they've been acquiring since they started their program. We were at 11 o'clock last night putting this into the slide

presentation for you today. They mentioned to me they would be happy to speak with any member that may have questions about their program. The Geisinger Health System is located in northern Pennsylvania. It serves almost two million people.

(Slide.)

MS. VERNON: They have two facilities in which they implemented blood conservation programs. One is a Level One trauma center in Danville, Pennsylvania.

(Slide.)

MS. VERNON: The other one is a community hospital about an hour east of Danville in the Wyoming Valley, their Wilkes-Barre facility. The Danville facility incorporated their program in April 2005 and Wyoming did theirs in November 2005. What were the results?

(Slide.)

MS. VERNON: O.R. cases increased by 14.3 percent. At the same time, transfused red blood cells decreased by 3.7 percent. Total blood products transfused decreased by 14.7 percent and discarded

blood products decreased by 53.7 percent. So there are spin off effects of this soft science. We call them transfusion reactions decreased by 20.6 percent. This was at their main campus.

(Slide.)

MS. VERNON: At their community hospital, their O.R. cases increased by 7.2 percent. Their transfused red blood cells decreased by 18.2 percent. I might add that this is a hospital that does a lot of cardiac surgery and orthopaedic surgery. Their blood transfusions decreased by 16.8 percent. Discarded blood products decreased by 4.2 percent. And again, their transfusion reactions decreased by 7.1 percent. So whether you're in a large Level One trauma center hospital or you're in a community hospital, you can see the effects they've had in decreasing or improving their blood utilization by decreasing unnecessary transfusions.

(Slide.)

MS. VERNON: In their ICU, I thought this was another interesting group of statistics, admissions increased by 19.8 percent. Again, this is

at their Danville facility. Their transfusions decreased by 7.7 percent. The reason we're giving you this is because as they begin implementing their blood conservation program and seeing the effect it was having on cardiac patients and orthopaedic patients, they decided that they needed to pilot this program in their ICU for all patients. Within three months they made a standard of care within that unit. Their total blood products transfused decreased by 20.4 percent. There's an estimated blood usage per calendar year. That's decreased by 5 percent. Again, if you have any further questions about Geisinger, I'd be happy to entertain any discussion.

(Slide.)

MS. VERNON: Finally, Virginia Commonwealth University Medical Center -- I'm highlighting this because some hospitals are just incorporating conservation efforts within a specialty. This highlights their cardiac blood conservation program in which, again, through extensive education and training in the methodologies, procedures and policies they were

quoted as saying that despite the decrease in transfusion and the lower hematocrit it appeared that not only were patient outcomes not adversely affected. They were, in fact, improved.

(Slide.)

MS. VERNON: In medicine we have a term called the "golden hour." I submit to you today that in my humble opinion we are in the golden hour of blood conservation. We know what this concept means. It means that from the time of the trauma to the time of medical intervention there's a statistical evidence that the sooner the intervention takes place the better the outcome. We understand in blood conservation today the sooner we act on some of the proposals that we'll give you the better the outcome will be for not only blood conservation, but all of the initiatives that you've been discussing yesterday and today.

So what is needed is to gain the upper hand on blood utilization will require rapid and sustained expansion of blood conservation, education. The time to act is now. We need the endorsement of a

national blood conservation campaign. There just isn't enough awareness out there of what we're talking about of techniques, of technology, of standards of practice that are improving our patient outcomes. We also need resources for additional education, not only to our physicians and our staff, but our hospitals across the United States. We need data collection and analysis from groups as have been presented for the last two days and we need an increased national awareness on the part of the public. Blood is our most precious resource. We need to be sharing with them that we understand the sacrifices they're making in donating their blood and we need to be showing them that we're using that resource in a responsible manner. So I thank you for the opportunity to speak to you today and I'll entertain any questions you may have.

DR. BRACEY: Thank you. That's a very interesting presentation. One of the things that's a real challenge is to collect all of the pertinent data in terms of patient outcomes related to transfusion. It seems that in your system you have

access to that. I guess what I'm really trying to get at is, as we discussed yesterday, it's very important to have a simple way to gather data so that you will be effective in gathering that data. What is the current structure of most hospital systems who are gathering such data? Is that a formidable challenge or are there rather easy pieces to be obtained?

MS. VERNON: Staples says it's an "Easy Button." As I mentioned before, you know, we have a clinician that is heading the whole effort toward blood conservation in the hospital. That clinician is responsible for collecting the data, but we made it simple. Through 12 years of my own experience, we were able to sit down and say what is really needed today? What is easy for hospitals to obtain on their own without a lot of additional resources and how can we supplement that? So we designed a very robust system that is able to identify what they can collect and then merge what we can collect with what they can collect. However, ours is a stand-alone system, so we're not dependent on the IT technology of any

hospital because we stand alone. So as you're probably aware, in our hospital systems across the United States today, we have some tremendous challenges with computers talking to computers. We don't need that with this. So we can collect the data on these patients independently.

DR. BRACEY: Dr. Epstein?

DR. EPSTEIN: Thank you very much. I have a question. The implication of the findings you presented are profound for patient outcomes. The concern that I have is are these data prospectively controlled or in each case were they retrospective?

MS. VERNON: I'm sorry I lost the last part of the question.

DR. EPSTEIN: What I'm saying is whether the improved patient outcomes that were found are conclusions solely from the retrospective comparisons or whether there have been any prospective cohort contemporaneous studies that could be controlled. You always have the problem when you come into the system you bring in the transfusion and you improve many, many things. All other factors may not be

equal and I think that given the importance of these presumptive findings, it's very important that they be confirmed prospectively and in a controlled fashion. So my question to you is, of the outcome findings that you've given us, is any of it prospectively controlled? Or are all the comparisons retrospective?

MS. VERNON: Let me answer the question this way, if I've understood you correctly, when we go into a hospital setting, we're analyzing what is the current standard of practice and what are their transfusion statistics. Anything that we can gather that the hospital has already been collecting becomes the benchmark against statistics such as we've showed you.

Now obviously, we are implementing new policies, new procedures. We're implementing the things that we are aware of that work in blood conservation. So we're comparing what they were doing to the results of what they're now doing. Now there are some hospitals that are actually comparing and doing pilot studies where they're dividing

patients into the traditional way of caring for patients as well as implementing blood conservation techniques. Some of this has been published in the journals. Some of it I'm just aware of because of the hospitals I've worked with that has never published. However, they're looking at this data from a variety of viewpoints. So I guess the long and short of it is, yes, that's being done and definitely with Geisinger and Fairview, they both did that, and they continue to do that.

DR. BRACEY: Looking through the literature, the majority of these data points are, in fact, not controlled studies. But the one thing that is compelling is the savings in terms of the blood supply. It would suggest there have been a number of earlier reports which suggest that there are a lot of fat, in terms of blood utilization. I think that a not so controversial piece of it may be the ability to use a more efficient approach to blood transfusion with still questions that are open regarding outcome measures.

Dr. Duffell?

DR. DUFFELL: Can you comment, maybe briefly, on some of the criteria that were used to decrease the utilization, the methodologies?

MS. VERNON: Yes. First of all, we analyzed exactly how procedures are being done at the present time. We benchmarked that against known blood conservation techniques. We look at things preoperatively, interoperative and postoperatively. So we're dividing our standards of care, our standing orders, our policies by what the hospital is doing today. Preoperatively, we're looking at how quickly are patients getting to surgery. Is there any concern around anemia and are doctors focusing on anemia at all pre-operatively? If it's an elective surgery, we have a luxury of building these patients up preoperatively so that we reduce the need or the risk of them receiving blood. Interoperatively, we incorporate a lot of techniques. The AABB is doing some very perioperative efforts in that area. So we can use blood conservation techniques interoperatively to hopefully put the patient in the best optimal condition postoperatively. But I think

the key in all of this is it has to be integrated. We have pieces and parts of blood conservation in every hospital across the United States, but it's not integrated. There's no consistent standard. So it's so dependent on physician practice or an initiative within an department or a unit that we have no consistency. We need integration and integration is really the key. It moves the whole institution into a new mind set so that everybody begins thinking about blood conservation.

DR. BRACEY: Thank you.

If there are no more questions or comments -- Dr. Angelbeck?

DR. ANGELBECK: Who do you approach at the hospital to initiate this program?

MS. VERNON: That is the million dollar question. That's why I said education and awareness is such an important issue. These programs are being instituted and initiated by a number of different people within the hospital. It's usually the person who either has had some personal experience or conversational awareness with somebody at another

hospital that has a conservation program or the Blood Bank. Obviously, the Blood Bank is impacted the most by all of the issues we've talked about in the last two days, including cost. Billions of dollars are going out to the Blood Bank and I don't think I'm answering your question.

DR. ANGELBECK: Somewhere in the process there has to be buy-in from the executive administration of the hospital. Where does that come?

MS. VERNON: That comes through showing them that from a patient outcome perspective that by reducing our blood utilization they can improve patient outcomes and at the same time do it in a cost effective manner so they realize resources that can be allocated to other areas of a hospital. They're interested in patient outcomes. They're interested in incorporating things that will allow them to reallocate resources. So administration look at it from that point of view. Physicians look at it from another point of view. They're not going to do anything that's going to jeopardize their patients.

So basically, if you can show them enough data and have them talk to enough other expertise in the area, you can convince them that this something that they're going to look into. As they see the results, it's very easy to bring them on board. But I think you see the beauty of this is that there's no punitive action in this. With physicians today, and I hear this all the time, you can't create a transfusion guideline when you have a hemoglobin of 7 and tell physicians that they have to abide by that transfusion trigger. You've got to provide education and hopefully make sure we never get our patients down to 7 in most elective cases so they never have to deal with that. Education is the key. We need education. We need more of it and we need the studies that go along with education.

DR. BRACEY: Thank you.

I think one of the real potential gains is that if one can develop a more efficient system buy-in maybe selling it to hospitals would be something that would be made much more easy. Thank you.

We now have a special guest, Assistant

Secretary Agwendoi. He will make comments for the Committee and also a presentation.

Executive Secretary Holmberg?

DR. HOLMBERG: I just have to say that it's been a real honor the last couple of months to really work with Dr. Agwendoi and share some of his thoughts with the Committee. Thank you for joining us today.

DR. AGWUNOBI: Mr. Chairman, thank you very much for this opportunity. Your leadership has inspired the Committee to great things. I've been looking at some of the work you've been working on and I expect to be fully appraised of the work of today's committee and at future committees.

My name is John Agwendoi. Some of you I know very well. Others I hope to get to know. I'm a pediatrician. I serve as the Assistant Secretary for Health in the Department of Health and Human Services. The function is such that it allows me unique access to policy makers and to scientists. I don't have power and authority. I have a beautiful uniform. I serve proudly in the U.S. Public Health

Service Commission Corps and for all of you wearing that uniform in the room, the men and women of the Commission Corps, I salute you with great pride. Your work is inspirational. In my role as Assistant Secretary for Health, I do have the opportunity to advise. This is the main function of the role. I advise the Secretary, the Deputy Secretary and many others across the Department on things that I gathered in the course of my day, the things I hear from advisory committees, the things I hear from the public, the things that I hear from advocates who come in, the things I hear from Mrs. Smith on the corner. My job is to try and constantly serve as a summarizer of the notions, the thoughts, the priorities, the values, the recommendations that are out there to make sure that they're on the table when decisions are being made by decision makers. On occasion, they use me to help coordinate the activities that might be occurring across different agencies within the Department of Health and Human Services. You might be surprised to hear that they don't always talk to each other when we first start

with initiatives, but they get together quickly and my job is just to make sure that everyone's voice is heard as we develop policies. I also have the unique privilege to be the Department's blood safety officer. I've been briefed in great detail by Jerry as to what that entails, but I've come to realize that this system that our wonderful nation has built over the years, starting as far back as the second World War, this blood safety tapestry has been brought together incrementally over the years with the gradual addition, the gradual modification of steps.

Every once and a while, a leader comes along or and advisory group comes along and decides it's time to make the next big step. And as I look at the history and the timeline of the development of the system I begin to realize that it's one that's still in formation. It's far from complete. It's beautiful to behold and it seems to work for the most part, but it's far from complete. By design, it's suppose to get better with the passage of time. Some of the work that you're doing as it relates to

disaster preparedness, for example, the notion that we might develop a national reserve, some of the work that you're doing with regards to utilization, the work that you're doing today talking about biovigiliance. Hopefully, all of this work translates into the next big step in this tapestry in our blood supply at our blood safety system.

I've come to realize that my job in this effort is to try to inspire you and others to embrace those recommendations and to recognize that it's our obligation to leave behind us a system that is better than the one we found when we arrived. My job is to make sure that your recommendations result in action.

Now I am liberated by the fact that I have a tenure. My job ends as of a certain date. It means that I have nothing to lose by trying hardest and my darnest to get things done. I don't have to worry about what will happen 10 years from now. I have to worry about how much I can get done in the time I have left. It pumps me with a certain amount of urgency. I don't mean to push or to pass this urgency on to you, but if there's anything that you

think is critically important and you're looking for a champion to help get that done now, I would urge you to let me know the sooner the better. I hope to look back on my role as Assistant Secretary of Health and be able to point to how I helped add, just even only a little bit to that tapestry. I don't want to be the creator or the designer. That's your job. I want to help be the implementor. I recognize that many more effective and greater leaders than I have come before. And indeed, we have a wonderful chairman and each of you has served. A number of you, I know, live this every day and you've see upstarts like me come around a hundred times. But I do want to help and I would urge you to give tasks. Through Jay, give me tasks. Jerry will pass things on to me and he will advise me. Give me some tasks that you know that I can get done in a period of time. As I look in front of me, I realize that there's great things happening already. Jerry spent -- is it two or three hours yesterday -- this week briefing me in great detail as to the history of how we got to where we are today, I think in large part,

so I don't make the mistakes of the past. But I think it was also to inspire me. He was trying to show me that if I do actively engage it can make a difference and he kind of pointed to the fact that there are other people over the years, whether they be in the private sector, audience or in the government -- he pointed to people who actively, over the years, made a difference. They may not have known they were making a difference at the time, but as you look back on how the system has changes you can actually point to their intervention, their energy, their enthusiasm at that point in time and how it inspired the next step up for the system. So I stand ready to serve you in that respect and I recognize today I get to honor others who have served. I know I can never hope to do what they've done in terms of their commitment and their energy and their addition to the system, but I do hope in offering a meager thanks in the form of a plaque that they will recognize that we're deeply grateful for the service that they have provided to the nation.

Sometimes we forget when we sit around

these tables that it's not a collegial group of experts talking and sharing experiences. It's not just papers and documents that get shuffled and things that get written in our resumes. It's actually really about saving lives. I have three children and I imagine a number of you have children. I have no doubt that statistically that one of them or all of them or some of them or their children will at some point rely on the system that you are building and influencing.

On occasion, I think we forget that this is about people and I'm young enough to realize that at some point I may well be the beneficiary of the work that you do today or the next meeting or the meeting after that. I urge you to get it right.

(Laughter.)

DR. AGWUNOBI: When I'm on that gurney, I urge you to get it right.

(Laughter.)

DR. AGWUNOBI: Not one of us that serve today might not have the benefit of the work that you're all doing. It helps you put things in

perspective when I describe it in those terms. I thank you.

Before we get to the plaques, I wonder, Mr. Chairman, if I might ask a few questions?

DR. BRACEY: This is a great opportunity. Questions or comments for the Secretary?

DR. SANDLER: My name is Jerry Sandler. I'm here to represent the American Hospital Association.

I want to thank you very much for taking the time to come and address the group. I asked the question yesterday, and the Executive Secretary said do you want to answer that now? Tomorrow is the Assistant Secretary.

DR. AGWUNOBI: I don't know about that, but bring it up.

(Laughter.)

DR. SANDLER: We had the AIDS epidemic, and, in retrospect, people looked at the blood program, and they said, you know, there's a lot of fragmentation; there's no one leader. Some people are saying, do this; some people are saying, do that.

In retrospect, there was a lot of criticism of that. The hope was that the Assistant Secretary of Health was going to come along and become sort of a blood czar and have that oversight.

We got up to 9/11, and that hadn't quite happened. Some of the blood centers in the country were saying to the populous, we need you to donate blood, because we don't know what's going to happen on 9/12, 13, and 14.

Other blood collectors were saying, you know, the danger of this is that there are injuries, and we want not to overburden the collection system.

That is to say, on 9/11, there was no blood czar, no umbrella. I couldn't, as a blood director in my hospital, give guidance to people who were asking me, should I give or shouldn't I give?

I wanted to go to a website, and I wanted to see the Assistant Secretary of Health or some designated person, speak with one voice about how the United States Public Health Service, saw the best coordination of information one could do.

You have introduced yourself as a mentor, advisor, helper. Are you going to have a website, when, if we do unfortunately have a pandemic, and if we have a national blood shortage, and my hospital wants to know how to use blood, the limited supply in

the nation's capital, so that I use it equitably with my partners across the community and at other hospitals, who want to know what to do themselves, where are we going to get leadership, if, when the next disaster comes, which we think might be a pandemic, and reduce blood donors, reduce personnel in the healthcare system, and take care of people, where will the initiative come from on that end? Thank you for your attention.

DR. AGWUNOBI: When Jerry and I were speaking, I remember, during the course of the conversation, I brought in a number of my staff, because, how often do you get one of the foremost experts in the country to give you a two-hour lecture on the blood safety system and the blood supply system of the nation?

I brought in all the young MPH fellows, all the young mid-level officers in my office, I brought them in and I sat them, almost classroom style, and said, listen, you're about to hear a wonderful lecture.

Midway through the lecture, I spoke to

Jerry and I said, let me ask you question. If a major disaster occurred tomorrow, and there was an acute shortage of blood supply, people were severely injured, not like 9/11, where, unfortunately, we lost people altogether, pretty quickly, but a tragedy that either on an ongoing basis, generated the need for blood, or a tragedy that was so dramatic that it impacted the blood supply, the blood donor pool, or a tragedy that was so big and acute, and there were just so many acute injuries, that we were dramatically impacted by our inability to supply blood?

And all the heads turned to Jerry, and he looked at me and he pointed at me and said, sir, that's your job; you would be the one they would hold responsible.

I have begun to realize that what you say, is true; there needs to be a single voice that speaks to this issue, whenever an emergency occurs. I'm not sure it should be a dictatorial voice.

I'm not 100 percent sure that I'm persuaded that it needs to be an emperor that says

this is what we're going to do. It needs to be a voice that starts by asking quickly, a few key people, what do you see, what do you think, and how should we proceed?

It needs to be a person -- me -- that gathers quickly, a consensus position from you and translates that to the rest of the world.

Now, Jerry is doing a lot of work today with our Office of Public Health Emergency Preparedness, to assure that the Office of Emergency Public Health Preparedness has within its structure, not just some paper on the shelf or some three-ring binder, but within its infrastructure, a person responsible for making sure that when something happens, there's a conference call, a quick bringing together of experts that assess the event, assess what the needs might be.

I'd be the voice, but I urge you to recognize that the issue is all of us. What I need to do is make sure that we always have on call, two or three people that can be brought together quickly to help advise.

They could be people within the department. I would urge, given the reality of our system, that it also needs to include people outside the Department, quickly brought together to advise on what that message should be and how those messages should evolve over time.

Be comforted by the fact that we recognize that we didn't do it the way -- we didn't respond in terms of blood, to September 11th, the way we intend to respond to the next big emergency.

That's not to criticize our response to September 11th or the spirit of our nation that resulted in blood donations and in people rushing forward to help in any way they could.

If we said give your fingers, people would have given their fingers to respond to that event. That's pretty clear in my mind.

But you'll be proud of what we're building, and I would urge you to help us build it. As we talk about the national blood reserves, I would also ask you to think about, given that no two emergencies will ever be exactly the same, the

rolling pandemic type of need and type of challenge, is going to be completely different than the triple train bombing that we saw in Spain, that could very well occur here.

It's going to be very different than the blood needs we might see following a major nuclear event, the slow impact that might come out of something like that.

I would just urge us to begin to engage this. Your points are well taken.

DR. BRACEY: I have a question related to your vision of the role of the Government in the process of designing the development of a blood safety system.

As we look across the globe, there are many countries where, in fact, it is a governmental enterprise, dictated, if you will, solely by the Government. We have strong private partners throughout the United States.

They have the ability to lead, but I would like to know specifically, whether you think that really the Government should be considered

responsible for providing the resources and the leadership that we need to get the safest blood system available.

DR. AGWUNOBI: The reason I asked Jerry to give me all the details and the timelines about this, about how the system has gotten to where it is today, is because I wanted to see, what have we tried? What have we excelled at? What have we failed at? How have things changed over time?

It's pretty clear to me that as we evolved through the Second World War, Vietnam, Korea, and the changes of the '70s, to where we are today, that a reality of our blood system, is that it truly reflects, in my opinion, one of the strengths of our nation. In fact, it kind of reflects the way we do a lot of things.

We're a nation of individual sovereign states -- and I recognize that's an overstatement of the authority of the states, but we recognize that states have different laws, states have different priorities and values. No two states are the same.

We're a nation that's always tried to

inspire, nurture, support, our private sector, the not-for-profit and the for-profit. We're nation that our history is such that it drives us into the future.

It's one thing to say I believe government should be in charge, but then you have to deal with the reality. It's never been that way, and you, therefore, would be trashing everything that you have, in order to acquire everything that you want, and the transition would be intensely painful.

The cost of the transition might well outweigh what you hope to gain at the end of such a major shift. I'll answer your question now.

(Laughter.)

DR. AGWUNOBI: I believe that the way to improve our system is to build upon the base that we have. I believe we should continue to strengthen our partnership with the private sector, both for-profit and not-for-profit.

I believe we should continue to build upon those relationships that we have with hospitals, blood banks, with advocacy groups, and others.

I think the role of government should be to inspire excellence. We should set standards and goals to inspire excellence at all times, into policies and decisions, to force standardization across that system, but I believe we should never do so at the expense of that system.

I think it's who we are; it's a reality. It's one thing to sit with pieces of paper and to design nirvana, but the reality of getting there, is a practical job. It's a trade; it's a task; it requires that you roll up your sleeves and engage your partners in every aspect that you find, and that you move forward.

I'm reminded -- and I hate to sound a little philosophical here -- but I'm reminded that our nation grew out of not a national army, but a collaboration of militias, farmers and tradesmen who laid down their tools in order to pick up their muskets.

I know I sound a little fluffy here, but it's a spirit that I'm trying to describe. I do think we can get better. It's pretty clear to me

from the presentations, that there's much work that we need to do.

I worry about the divergence that I see in terms of blood safety and organ safety and tissue safety. I worry about what appear to be different standards applied to the same or very similar risks.

And I worry that I think the role of government should always be to assure that science is what drives the system.

I'm not sure I can add much more to that.

DR. BRACEY: Thank you. Other questions? Dr. Duffell?

DR. DUFFELL: Dr. Agwunobi, I'm Bill Duffell. I represent at the table, the industry, the scientists and engineers that supply the tools, the disposable sets, the diagnostic equipment that's used to produce the products.

I've had the fortunate opportunity to hear you speak more than once. I've always been inspired by your words, and I really appreciate your presence here today, and would encourage you to come back to this Committee in the future, because, while I'm not

a long-term member of this Committee, I have sat on a few of them, and, at times, you do wonder if what we're doing is adding value, if it's being heard, if it's being acted upon, and whether or not, ultimately --

When I see your presence here today, as it was when I heard you speak before, it's very inspiring.

My question for you today is, our industry, the blood suppliers out there, as part of the foundation you mentioned earlier, has had some serious compliance issues that have been brought forth by the Food and Drug Administration.

They are impacting in some areas, supply and availability. These are not new events; they've been going on for some time.

They've been dragging, in some cases, for years. I'm curious about your level of knowledge about those things, and involvement in trying to get some resolution of some of those things, between the parts of the government and the suppliers themselves.

DR. AGWUNOBI: I have to be careful,

because these issues relate to the regulatory authority of specific agencies, and I don't want to pretend that I represent those agencies, so I won't get into the specifics.

I can tell you this: As much as I am a supporter of this tapestry and of our continued movement in seeking excellence and pushing us towards ever-better systems, in time, I am deeply troubled that it would appear that two of the largest or larger pieces of that tapestry, don't seem to inspire all of the smaller pieces of that tapestry.

That is, it would appear that they're not the models for the smaller pieces that I would hope they would be over time. Because they are large and are in the room, I'll stop right there.

(Laughter.)

DR. AGWUNOBI: FDA, did I cross some line I shouldn't have crossed?

DR. EPSTEIN: Not yet.

(Laughter.)

DR. BRACEY: Ms. Thomas?

MS. THOMAS: Actually, I don't have a

question, but just a comment I'd like to make. I'm Linda Thomas, Executive Director of the Sickle Cell Association. My husband of 28 years passed away last year, due to complications of sickle cell disease, so I am a fairly strong advocate for all persons that receive blood and blood products.

I just really wanted to say that I appreciated your comment when you said that it is all about people. In serving on this Committee, that's something that I would like for us never to forget, the people we are serving, to make the United States a better place for all of us.

I was really encouraged by your presence this morning. Thank you.

DR. AGWUNOBI: I thank you for your willingness to serve and I thank you for your willingness to share.

DR. BRACEY: Mr. Walsh?

MR. WALSH: As another consumer representative on the Committee, Dr. Agwunobi, I would like to thank you for being here today.

The Committee certainly hopes you will be

back.

One of the parts of the charter of the Committee, since its inception, has been availability, which can be defined in many ways. Unfortunately, those of us on plasma derivatives, know there are some shortage issues on products, as well as reimbursement challenges.

We get stuck in between the legislative process and the regulatory authority, CMS. We would like to ask you for your leadership and involvement in the reimbursement issues that affect access to derivatives for tens of thousands of Americans.

DR. AGWUNOBI: I am very much involved, although I will share with you that the extent of my involvement today is to learn. I've begun to realize that there a lot of variables involved in the availability and in the ups and downs of the supply for derivatives and IV/IG.

I have begun to realize that I need to become better educated on what all those variables are and how they interact with each other and how those things change over time.

I understand that there are a lot of people in the Department right now, trying to get a handle on all of those issues and their implications.

Jay, how did I do on that one?

(Laughter.)

DR. EPSTEIN: Just about right.

DR. BRACEY: We thank you so much for coming. I guess now is the time to hand out the plaques to those hardworking Committee members.

DR. HOLMBERG: Dr. Agwunobi, there are actually three people that we want to recognize, that are not here: Dr. Wong, Dr. Sayers, and Ms. Pahuja. They could not be here today.

I have to say that all three of them have been real contributors. Dr. Sayers is Medical Director at Carter Blood Care in Texas. He was here yesterday, and he's on his way to South Africa to a meeting. He is a strong supporter of what we're trying to do here.

Dr. Wong is Director of hemostasis at Children's Hospital in L.A. She could not be here today. Ms. Rahuja is a J.D. and MPH. She works in

the Palestinian community. She could not be here, but she has spent many, many years on the Committee.

DR. AGWUNOBI: Perhaps we should express our gratitude to them in a round of applause.

(Applause.)

DR. HOLMBERG: The first person I want to recognize today, is Dr. Judy Angelbeck. Judy, would you come over here, please?

Judy is Vice President of Research and Development and Cell Therapy for Paul Industries. Paul Industries is a leukoreduction company. Judy actually has spent four years on the Committee.

What we found out last year, was that we did not have an adequate replacement for her.

DR. AGWUNOBI: You will never have an adequate replacement for her.

(Laughter.)

DR. HOLMBERG: Absolutely. One of the things I've really appreciated about Judy, is that she has really looked beyond a manufacturer's point of view, and also to the patient's point of view.

I truly appreciate your service on the

Committee.

DR. AGWUNOBI: Dr. Angelbeck, for your outstanding contributions to the Advisory Committee on Blood Safety and Availability, for the term September 03, 2002, to September 30, 2006, I thank you.

(Applause.)

DR. HOLMBERG: Karen, would you come up, please. This is Karen Lipton, the CEO of AABB, formerly the American Association of Blood Banks. Karen has served on this Committee for many years, more years than is really noted here.

This only represents the last three years of her term, which has been seven years on the Committee. Thank you.

DR. AGWUNOBI: For your outstanding contributions to the Advisory Committee on Blood Safety and Availability for the last seven years, I thank you.

(Applause.)

MS. LIPTON: I just wanted to say that I have been on the Committee for seven years, and leave

behind a lot of good friends whom I will still continue to work with, but I specifically want to state that it's not about me on this Committee. I'm supported by 7,000 to 8,000 members all over the world, who really do support what I do here today, and I want to thank them.

(Applause.)

DR. HOLMBERG: One more. This is a very special person. This is Mr. John Walsh. John has been on the Committee, and, again, the dates on here are not correct, because they only recognize the last three years.

John has been on the Committee since its inception. He was initially appointed by Secretary Shalala.

DR. AGWUNOBI: Well, Mr. Walsh, for your outstanding contributions to the Advisory Committee on Blood Safety and Availability for an awfully long time --

(Laughter.)

DR. AGWUNOBI: -- I thank you.

(Applause.)

MR. WALSH: I said my piece yesterday. I'd just like to reinforce the importance of the consumer representatives on the Committee, those plasma users like myself, and those requiring blood products in the general public, who need to be at this table.

I commend the Assistant Secretary for his support, and the Department, and the Executive Secretary and Chair, for making certain that the consumer voice is heard, and is always welcome here. Thank you.

(Applause.)

DR. BRACEY: I guess it's time for a bio-break.

(Laughter.)

DR. BRACEY: Why don't we take ten minutes and then reconvene.

(Recess.)

DR. BRACEY: We do have other presentations to hear. Our next speaker will be a person that we have heard from already this morning. But it's a very important topic, and that is the West Nile reporting system. Barbee Whitaker will be presenting that. She has been introduced. So, we know who she is. Thank you. This is the AABB West Nile Virus Reporting System.

(Slide.)

DR. WHITAKER: Good morning again. I would like to tell you today about AABB's West Nile Virus Biovigilance Network, which we developed in response to a request from the West Nile Task Force. They are an organizational task force that includes quite a few representatives from this group, and a few representatives from this group, and some others that I will tell you about.

(Slide.)

DR. WHITAKER: It was initiated this West Nile virus season that includes -- the West Nile virus Task Force includes the AABB, ABC, ARC, the Canadian Blood Services, representatives from the

CDC, the FDA and the U.S. Department of Defense. The Task Force asked for AABB to develop this system to replace what had been a weekly conference call among these organizations to talk about the status of the West Nile epidemic. And this has been going on, I guess, for three or four years now during the West Nile virus peak. It was taking up a bit of time. We thought there might be a better was of addressing the issues related to blood donors and West Nile virus.

(Slide.)

DR. WHITAKER: It was intended to support and enhance the tracking initiative that started with the FDA and CDC, and particularly to support public health agencies with blood collection and transfusion services. It was not intended in any way to replace what is normally the process of reporting West Nile virus or to report to public health agencies so the normal process of positive donations to the local public health department is still operative. We have made this quite clear to all of our testing laboratories that they ought to be reporting through the regular reporting process.

(Slide.)

DR. WHITAKER: The system, which we will call the West Nile Virus biovigilance network colleagues data on blood donors with suspected West Nile virus infection for the United States and Canada. The data are collected from the screening performed by nucleic acid testing is reported to the AABB site by the facilities responsible for testing. In the beginning there was a little confusion about whether this was to be reported by the test sites, or the collection sites. But it is ultimately from the testing labs. Therefore, we are able to get a response that is really quick. It was quicker during the beginning than it is right now because there is quite a few West Nile virus presumed to be viremic donations right now. We are probably at the peak this week and probably next week.

In our reporting we have the geographic and temporal distribution of West Nile virus infection for this season. One of the things that is unique about this program is that we put a restriction on that is being reported to the system.

With a cut-off ratio of greater than 17, we expect that we are getting very, very few false positives reported into our system. We think we have a pretty good handle on what is going on. It's a web-based system. It's on AABB's web site. I'll show you a little bit more about it.

There are 45 laboratories reporting into the system at this time. Two of those are in Canada. We have Hema-Quebec and the Canadian Blood Service.

(Slide.)

DR. WHITAKER: Right now, with a mid-August -- or actually late August update of Monday of this week, we have approximately 171 confirmed positive PVDs or presumed viremic donations. There were 105 pending confirmations. As I said, we have few reported false positives right now. There are two. There may be a couple of other ones in the pending column that have low S/COs. But we will identify and sort of ferret out which ones are false positives at the end of the analysis process.

Because this is the first year we are doing this, we are collecting a list of improvements

we anticipate running this for future mosquito seasons. And improving the system as we go along.

(Slide.)

DR. WHITAKER: We have three modules, and since I haven't run this on an overhead, you can't see our web site, but I can tell you about it. We have a public section of our web site. It's the AABB.org web site. It gives you programs and services on the web site, and the model of that is West Nile virus. It's the bottom choice, and if you pick that, you can go to the public part of our web site. You will see a map of the United States and Canada, also a bar graph of PVDs by date collected. We have a data collection part of the site, which is password-only for our laboratory sites.

We also have a data reporting portion of it, which is also password-protected. I'll tell you a little bit more about those after I talk about the public site.

(Slide.)

DR. WHITAKER: This is our map, as you can see, of the United States and Canada. Each one of

the dots is presumed viremic donation. Confirmed positives are red. Yellow dots are pending interpretations. We added Canada and Alaska. You can see they take up a lot space.

Next, we'll see if we can blow up the United States a little bit more.

(Laughter.)

DR. WHITAKER: So, we can give a little bit more importance to ourselves. But, in the interests of getting something up this year, we wanted to make it available. We have also given darkness by number or shading by number of PVDs at each state. You can see that Texas, Idaho, that's Utah, California, the Dakotas, Nebraska, and Illinois, all have five to 25 PVDs and they are shaded accordingly.

One of the things to note is that these are not reports of incidents. This is just by number. Clearly, the epidemic is more severe in a state like Idaho, which has very few people living there than it is in, like California, which is more thickly populated.

One of the things we look to improve is to look more at the population and also at blood donors for the denominator. This is just strictly numerator data. Matt worked on that yesterday and presented a very nice map that the CDC has done with numerator and denominator data.

(Slide.)

DR. WHITAKER: This is how a graph of the epidemic, which looks at week of donation. We have the lighter color on the bottom, which is the confirmed deposit, and as you can see, at the beginning of the year, in May, it is very acute and the epidemic ramps up a little bit in June and July. And in August, we are looking at quite a few confirmed positives.

These are pending in red. This is last week. I updated this Tuesday morning, so you can see here, August, was pretty much a peek of what we've got. We are still waiting on confirmation reports from quite a few of the laboratories. Both the map and this chart are on the public web site.

(Slide.)

DR. WHITAKER: On the password-protected section, you get taken to the data entry portion of the web site. This is the first data entry screen, which is here you would enter the information about presumed viremic donations. This is what the data entry screen looks like.

(Slide.)

DR. WHITAKER: The data we are collecting is donation-based. Blood donation unit number, date of collection, state of residence, zip code. Then particular information about the testing platform, S/CO ratio, pool size, whether the donation was tested under conditions where the lab had triggered single donation testing protocol, final test interpretation, incidence information about antibody testing, repeat testing, and if the lab has it, we have information about follow-up samples.

Our system is pretty accommodating on a lot of data we have.

(Slide.)

DR. WHITAKER: This is the screen for reports. We have about nine reports that you can

generate. This is also in the password-protected section, on the left side.

(Slide.)

DR. WHITAKER: We have two types of reports. A very specific lab report, which is data. You would be able to access only in your own data, which, if you were a lab, you could put in your own lab's entry about specific PVDs, and then system or aggregate data.

This would be number of cases by state, zip code, and week and analysis by pool size. And there's a variety of output options. You can get it by an Excel chart, or a TIF file.

(Slide.)

DR. WHITAKER: We have quickly listed the web sites of CDC now and they are frequently asked FAQ file.

(Slide.)

DR. WHITAKER: Looking back on it, two-thirds of the way through the mosquito season, we consider that our network was a success. We are asked to develop it very quickly, by the inter-

organizational task force who came to us in March and asked us to have it out by June 1st. We were able to put it together.

One of the things they asked us to do was to be able to look at it as a biovigilance experiment. We put together something that could be used by entities throughout the country on that basis and we put it together in a flexible way. We right now have a platform that is on our web site that we can modify, not the West Nile virus one, but we can develop something that is very similar to this that could be used as a prototype or a pilot for data that we could decide to collect, perhaps on biovigilance.

We have some things we could modify for other data. If you like what you saw, we have a tool that we could use that could be used by the industry or the community to collect information about other aspects of biovigilance. And I think we are very interested in using something like this, if it could be useful to the community.

I think that by putting it on a web site, it allows you to work with the membership to

communicate your information. It's available to people right up front. You can provide the information in a place where they would be obtaining it regularly.

So, we look forward to offering both the West Nile virus biovigilance center in the future, and we would like to offer the flexible tool in support of biovigilance activities at this point.

Thank you.

DR. BRACEY: Thank you. Questions from the committee? Dr. Kuehnert?

DR. KUEHNERT: Very nice presentation. I wonder what your plans are to evaluate it at the end of the season? Just to see exactly how successful it was on a number of parameters, including the time lag. Back in the early task force days, we would be asked, the CDC would be asked, what's happening right now with the epidemic. My response was you could tell us what's happening. The blood banks, because your information is a lot more timely than what we have. Our time lag is over a month and I just wonder what sort of -- what you are looking at, perhaps, to

evaluate the data.

DR. WHITAKER: The West Nile virus organizational task force has been kind of working with us to provide -- there are two answers, actually. One is the system itself, which we are collecting information about. But the data, which is, I think, what you are addressing, we would like to work with you to talk about the time lag, and ultimately sort of -- I don't know whether there is ever any exact answer as to the number, but we are very much interested in working with the CDC, trying to figure this out.

DR. KUEHNERT: We would love to evaluate this as a surveillance system. It would be very useful for us.

DR. BRACEY: Dr. Ramsey?

DR. RAMSEY: Is this decision used in the decision-making for going to individual testing?

DR. WHITAKER: No.

DR. KUEHNERT: Would you consider having that as a parameter that is displayed in some form? You know, what areas are actively being screened by

pool?

DR. WHITAKER: It could be. It's entered into the system right now. It's not a part of the NAT. It's not a part of what is available to other people to see, but that could very easily be something that we could add to that.

DR. BRACEY: Dr. Duffell?

DR. DUFFELL: The AABB would be willing to share access to the system to the committee members just so they could explore the utility of it? I know you said part of it is passworded?

DR. WHITAKER: I would like to share our test site, rather than our live site, if you wouldn't mind. It's exactly the same, except the data is not live.

DR. BRACEY: Question from the audience?

CAP. WISE: Bob Wise. You mentioned the denominator plans. I was wondering if you were thinking in terms of having the contributing labs report their weekly total of tests done as the denominator?

DR. WHITAKER: We have talked about adding

denominator data. Not this year, but for next year. That is one of the things we have considered. What we want to do is cause the least burden as possible for this process. So, it will be a discussion. Clearly that would a good denominator.

DR. BRACEY: Thank you.

DR. KUEHNERT: Just let me go on record that I didn't make that suggestion.

(Laughter.)

DR. KUEHNERT: I believe the denominator is important, but I think we need to consider the burden of supplying data as timely as weekly, when you could use a proxy. That is an approximation.

DR. WHITAKER: Mat and I have talked about that a little bit. One of the things we have considered, just for ease of use, is population, because population is just an estimate of what your donor base is.

DR. BRACEY: Thank you. If there are no more questions from the committee, we will move on to the next talk, given by Dr. Michael Soucie, of the CDC. Dr. Soucie is an epidemiologist with the

Division of Blood Disorders of the CDC. He will speak on the surveillance system. He is in the Division of Hereditary Blood Disorders, is what he said.

DR. SOUCIE: Thank you. I would like to thank Dr. Holmberg for providing me the opportunity to inform the committee about the public health surveillance system in the Division of Hereditary Blood Disorders at the CDC, to monitor the end users of certain blood and blood products.

(Slide.)

DR. SOUCIE: CDC has established a public health surveillance system for product safety among persons with bleeding disorders. The eligibility for enrollment in this program is to receive care at a federally supported comprehensive care clinic, which we will talk about a little bit more in just a minute, to have a congenital deficiency of any of the clotting factor proteins below 50 percent of normal or a diagnosis of von Willebrand's disease.

(Slide.)

DR. SOUCIE: This is implemented through a cooperative agreement with a national network of 135 specialized hemophilia treatment centers, which are clinics set up with major educational institutions throughout the United States.

Part of the cooperative agreement is to participate in blood safety monitoring and surveillance efforts to collaborate with us and lay organizations to deliver consistent prevention messages having to do with not only the infectious disease complications for these disorders, but other complications which have been identified by the consuming groups.

We also have, as far as the agreement, to maintain a prevention evaluation network that helps us to assess the efficacy of prevention services that are provided to this population through this center network.

(Slide.)

DR. SOUCIE: This is a map. The little stars represent the distribution of the treatment

centers, which pretty much follows the distribution of the U.S. population.

(Slide.)

DR. SOUCIE: This surveillance project is referred to as the Universal Data Collection Project. The design of the study is that it is a national protocol. It is approved by the CDC, by RB, and the IRBs of each of the participating institutions. Every one of the IRBs at all of these treatment centers has reviewed the protocol and the consent forms. Enrollment involves issuing of data on a standardized data collection form on an annual basis.

The data collection tools are designed with input from experts on a working group consisting of physicians, nurses, physical therapists and other health care providers in these clinics.

We collect a blood specimen, which is tested and also a portion of which is stored in the CDC specimen bank for future studies.

(Slide.)

DR. SOUCIE: The blood specimen is tested in the CDC laboratories for known infectious disease

agents, including hepatitis ABC and HIV because the patients come back and are tested on an annual basis. We compare current and previous results in order to identify new infections that occur in the population. Any new infections that are discovered are investigated with the help of state health departments and the FDA for any link with blood product exposure.

(Slide.)

DR. SOUCIE: We have heard about some issues having to do with privacy. All patients ore parents of minor children involved in this project give informed consent. Data and specimens are sent to CDC with an identification code that cannot be laid to CDC. The link is maintained at the treatment center because the results of the testing we perform need to be given back to the patient that is there now.

In the institutions, some of the institutional IRBs have requested a certificate of confidentiality which can be submitted. We are in the process of looking into getting the certificate

of confidentiality for the whole project all across the United States, so that each participant does not have to do that on their own. This does provide some legal protection from FOIA and those kinds of issues.

(Slide.)

DR. SOUCIE: Just a little bit in terms of enrollment. Since May of '98, when this project began, more than 19,000 people with bleeding disorders have been enrolled. The overall national refusal rate is extremely low, 7.5 percent.

We attribute this to the fact that this community was the impetus for developing this system. They went to Congress and asked for a blood safety monitoring system to address concerns raised, that have already been raised in this meeting.

We have collected and stored more than 50,000 blood specimens from these patients. And of the CDC specimen bank for future blood safety testing. Ninety-one percent of the patients give consent at the time the blood is drawn.

For an investigation related to blood safety tissues, they are specifically told that there

will be no genetic testing done on the specimen other than any genetic testing related to infectious disease agents.

(Slide.)

DR. SOUCIE: A similar system has been set up called the thalassemia surveillance system. Six centers providing comprehensive care to people with thalassemia. About 200 to 300 patients using these clinics receive frequent transfusions. Since 2004, more than 400 specimens from this patient population have been collected, tested and stored.

This provides, as you all know, the patients in the universe of data collection, including hemophilia and other factor deficiencies receive products that have been virally inactivated.

This group receives products more like what we have been talking about for transfusions.

(Slide.)

DR. SOUCIE: The CDC specimen bank was created to provide a secure environment for specimens collected by CDC. It's a state-of-the-art facility located outside Atlanta. It is protected by a guard

force, and freezers are electronically monitored 24 hours a day.

The serum bank provides the service for all groups at CDC that are collecting specimens for various projects. They receive and process the specimens, then distribute the specimens either to CDC labs or other labs as specified by protocol.

(Slide.)

DR. SOUCIE: The testing and investigation -- we use testing algorithms to minimize false negative tests. This a little bit different than what you do in a clinical setting. For example, a person who would test HCV positive in general in the clinical setting would then get an RNA test. In the clinical, we like to know what the viral load is, so you can adequately treat the patient.

In the surveillance context, we do the RNA testing on the specimens that are HCV negative. We want to make sure that we have a possible false negative test, and don't miss someone who has a new infection. And we also want to provide what we show is a negative baseline, which subsequently might

become positive in the future.

All of these new infections that are discovered as part of this are confirmed with repeat testing of new specimens. Complete information on all blood and blood product exposures is obtained as part of the investigation.

The epidemiologic investigations are conducted generally by state health department. If these are reportable diseases, we work with the state health department as requested, if any assistance is requested.

(Slide.)

DR. SOUCIE: In terms of monitoring the results, there have been no new infections of Hep A, B or C or HIV that have been attributed to blood or blood product exposure during the periods since the inception of controls through 2005.

The vaccination rates for hepatitis, especially for hepatitis A, among bleeding disorder patients have been improved. As part of our prevention efforts in this community, we feel that patients who receive these products should be

vaccinated, certainly, for all viruses that are vaccinatable. We have been monitoring that as part of our testing of the blood specimens. We feel that this system has provided reassurance of product safety to the community, and we made a report of the results now to date, including a routine surveillance report, also, in the MMWR in January 2003.

We have also done a couple of special studies. Just to give you a idea, we did a study of markers of parvo virus, B19 exposure prevalence among 2-7 year old children. We found as part of that, the prevalence was higher among hemophilic boys who use plasma-derived versus recombinant factors. This has been found to be the case for some time. And it is now used in testing plasma pools of plasma-derived versus recombinant factors.

We have also done a study of the prevalence of antibodies of the West Nile among bleeding disorder patients. It was initially thought that the virus associated with West Nile virus is susceptible to viral reactivation and that patients using these products should not have an increased

risk, but we used specimens that we collected during the mosquito seasons of 2002 and 2003.

We did West Nile virus testing on those, and what we were looking for were cases of our evidence of antibodies to West Nile virus in patients who lived in areas which the virus had not reached yet.

At that time, it had not reached the West Coast. We found no cases of that. We found very few people who had evidence of having been exposed, and those patients that we did find were in areas that had large epidemics.

So, it is probably most likely from that.

(Slide.)

DR. SOUCIE: In terms of emerging infections, this group has talked about, to touch on this a little bit, how do you set up a system to look for something that you don't know exactly what you are looking for.

You have got to sort of address the same issue. The comprehensive care system that I mentioned to you at these centers monitor the health

of the patients with bleeding disorder and thalassemia. This is a relatively small community, the centers take care of probably 70 percent of hemophilia patients in the United States. And it is a small community of physicians who take care of these patients. They are very well connected with each other.

So, we monitor this community quite closely. Mortality is being tracked over time. Other issues with looking at mortality -- we certainly want to look at mortality rates and do try to collect information as much as we can, about causes of death.

The difficulties with that, as all of you know, is that there are very few autopsies performed. People die outside of the hospitals. But this community is attuned to the population, and unusual illnesses or changes in death rates may signal an emerging infection.

Just to give you an example, that's not an infectious disease example, but there have recently been reported in the past two or three years, a

couple of cases of childhood leukemia in hemophilia patients who received a radioactive dose injection for their joints, which has raised the possible fear that perhaps this exposure might be leading to childhood leukemia.

This, again, is two cases. So, I just give you that as an example. This is a very closely monitored population, and unusual things, as has already been mentioned at this meeting, clinical observation of patients is really almost always a source of new things that come along.

Once tests are available, if a new infection is discovered and tests are available, the serum bank has been generated in this population, it allows quick testing to evaluate the scope of the problem in this community.

(Slide.)

DR. SOUCIE: The potential for expansion -- we certainly could expand it to monitor other populations at risk. The example is the sickle cell population, who are also intensively transfused in certain conditions.

What I feel to be the necessary elements for the system would be we certainly need some kind of mechanism to be able to get serial sample collection. That's the comprehensive care system that allows this to occur. We need to have a reporting mechanism.

We have talked about at this meeting patient follow-up for investigation is critically important, and we all know about the issue of resources, not only for testing, but also for setting up monitoring of these other populations.

(Slide.)

DR. SOUCIE: In conclusion, CDC has established a surveillance system to monitor the health and infectious disease status of certain populations using blood and blood components. This system could be expanded to include other patient groups and I think that a system of care that provides regular access to the population is crucial, in terms of monitoring, I think, rare events such as what we are talking about that occur with blood. It might be useful to think about monitoring the

populations that have higher exposure levels to these products as a possible adjunct to any system that we would propose.

Thank you.

DR. BRACEY: Thank you. Question? Ms. Lipton?

MS. LIPTON: I have known about the system, but never in this kind of detail. I guess two questions.

How is this paid for right now? And do you know what the cost is?

DR. SOUCIE: The way this is funded is that this cooperative agreement actually is the result of a Congressional mandate. That essentially is to monitor, to prevent complications, of hemophilia and other bleeding disorders, funding in the amount of about $6 million to $7 million per year, comes into our group, that then goes out in a cooperative agreement, to this comprehensive care system, to provide not only some infrastructure support, but also to be able to collect these data, to be able to collect the specimens and some of the

money also is used to be able to establish testing and so on.

DR. BRACEY: Dr. Epstein?

DR. EPSTEIN: This is really a comment more than a question, but I am saving for later discussion. One of the difficult issues we are trying to wrestle with is whether we need to engineer a comprehensive reporting system as part of the biovigilance.

What is interesting about the CDC effort is this a targeted population that is trying to be both comprehensive and sentinel surveillance. I think this offers us a possible alternative model of biovigilance, which is intensive monitoring of selected target groups, instead of comprehensive monitoring of all donors and all recipients, in its own right.

It is a very successful and well-engineered and well-run program, but it is also, I think, a model we might want to think about as an alternative.

DR. BRACEY: Dr. Sandler?

DR. SANDLER: One of the problems I have as a transfusion service director, are patients with thalassemia and patients with hemophilia. The two populations that you are addressing, they often don't know exactly what their problem is.

A thalassemia person transfused all their life doesn't know that they have a record of ABC and GWA in their blood bank. A hemophiliac doesn't know the level of their factor 8 or factor 9.

I would like to be able to access that in my community, in my hospital. It's sometimes not easy to get it. Could I call you and say, I have John Smith. John Smith would love for me to know his antibodies without me testing him. In fact, even if I tested him, I couldn't get him.

Is there a way to access the information you have?

DR. SOUCIE: Really, one of the key features here, the reasons patients are so willing to work with us on this, is we don't know who they are. You couldn't call me and ask about John Smith because I don't know John Smith.

If you had his identification number, perhaps. But one of things that we wrestle with all the time is this issue of really balancing confidentiality issues with need to know issues.

You have pointed out sort of the weakness here. And also I know some of the people were talking about yesterday in the committee, how to get patients and to get places to give you information that they might not perhaps want you to have.

So, it's a balancing act between not wanting to know but needing to know for other reasons. There are many other reasons that we might perhaps want to know. For example, if we were to find out a certain lot of a certain product was contaminated or something, it would be very useful for us to know exactly who the patients were that received that product. We collect it as part of our surveillance what they receive. But we don't know who they are.

It's the balancing act that you do to be able to get the information and be independent and not subject to subpoena or whatever.

By the same token, you need to have information for an active emergency situation.

DR. BRACEY: Ms. Thomas?

MS. THOMAS: I definitely think this is a very good initial system, but I would also like to see it extended to different groups, especially sickle cell disease.

Part of my question was answered a little earlier, but I would also like to ask what do we do as consumers to see that it is expanded into those other areas?

DR. SOUCIE: I think as consumers, the role of consumers, is let government know that this is something of interest to the consumers. That's about all I can say.

DR. BRACEY: Is it true that the authorization for the thalassemic portion or part of the study is about to expire? What is the status of the funding long term?

DR. SOUCIE: There are a number of steps. I don't claim to know all of them in the way that Congress works, but one of the first steps is to look

-- you come up with the President's budget, which is an overall look at all things.

It's true that the money that was allocated for the thalassemia program that I mentioned to you, in the President's budget was cut. The consumer organization rightfully took exception to that, and has made their wishes known. It's my understanding that in the House budget it was restored, but there is another step to it before it will be restored.

DR. BRACEY: Question from the public?

MR. SCHULKROS: I am Len Schulkros. Mike, has your surveillance of B19 enabled you to tell whether there has been a reduction?

DR. SOUCIE: That testing was just getting underway when we did this other study. The difficulty with doing the study is you have to do it with your very own children. By the age of 12 or 13, almost half the people are exposed to it. You have to get them very young before another group of people get old enough to be able to tell, and whether it has made a difference.

That's basically what we are doing. The other issue is, I am not sure that it is doing to be able to be done again. Many of the children that are coming up these days, are being given recombinant products. I don't know that we will have the opportunity to have a large enough group of plasma-derived patients to be able to do it.

DR. BRACEY: Thanks. I think we have time for one last question. We are going to have to take a lunch break, then reconvene shortly.

MS. HAMPTON: Jan Hampton, Hemophilia Association of America. One is, are you seeing any TJD? And the other is the identification situation that you mentioned. Does anybody know who the donors are on that? Because all the patients keep a log with all those blood numbers on it. And in response to the question asked over here, if somebody has a record of who the numbers are, and you know a certain lot was accepted, everybody keeps logs. Or, they are supposed to, of what lot numbers are used in their patients.

DR. SOUCIE: Well, those are two really

difficult questions. I guess I will address the second one first. It is extremely difficult to get information about the product that is being used by the patient.

The bottom line is that it is not a matter of routine that people collect that information, particularly those who use a lot of the factor concentrates. It's a very tedious task to keep up with all the lot numbers.

We are working on a pilot study right now because of another complication of hemophilia, and that's antibodies to certain of the products. In that case, we need to have all the exposures.

So, we are working to find out what ways we can encourage patients to keep track of the products that they are using. Why patients are encouraged to do that. In the United States they are not mandated to do it, and many of them don't.

MS. HAMPTON: The health care company knows about that. I assume you could do the same.

DR. SOUCIE: It's possible. You can get information about what's being distributed, but

because it's a genetic disease, there is often more than one person in a household and while it's assumed all the blood you send is actually used all the time, but there are a lot of issues involved.

I'm sorry. I've forgotten the first question. Oh, VCJD. That is obviously the subject of great interest, not only just in the United States, but in the world. To date there has not been a VCJD person with bleeding disorders, but they are certainly being heavily watched for that in our system.

All the physicians have been advised of what the symptoms are. The system has been set up with CDC that allows that anyone who has a patient who may be suspected of having VCJD, not necessarily in bleeding disorders. And any hospital anywhere can contact this group at the CDC and get pre-testing and biopsy results and so forth, for VCJD.

All the cases, it is my understanding -- and Dr. Epstein would know this better than me -- that have been discovered in the United States have been cases from outside of the United States. And

none so far in the bleeding disorder community.

DR. EPSTEIN: Those statements are correct.

DR. BRACEY: Thank you. In the interests of time, we will close the session for this morning. I would ask that we take an abbreviated lunch, if possible, then have the audience return at 1:00 -- as close to 1:00 as possible.

For the committee members, all who are interested in working on a draft recommendation for the Assistant Secretary on the topic of biovigilance, you can have lunch delivered here, and we will working lunch for all members working on the draft.

It's 12:25, and we are in recess until 1:00.

(A lunch recess was taken at 12:25 p.m.)

A F T E R N O O N S E S S I O N

1:15 p.m.

DR. BRACEY: Our next speaker is Theresa Horan. Theresa is the surveillance coordinator for the Infection Surveillance Program of the National Health Care Safety Network.

MS. HORAN: Dr. Bracey, Dr. Holmberg and the committee. Thank you very much for the opportunity to present today about the Health care Safety Network. I did change some of my slides based on yesterday's discussion.

The first few slides that I will talk about are not in your handout.

(Slide.)

MS. HORAN: The first slide came up yesterday and I wanted to address this. How did infection control programs start, why are there infection control professionals in hospitals.

(Slide.)

MS. HORAN: A brief history, as best as I can put it together from memory, and I wasn't here in the 1950's physically here. I was a baby, but I

wasn't one of the ones involved in an outbreak of infections in nurseries nationwide. But in the 1950's, there were a lot of outbreaks in nurseries, and we proceeded to investigate these outbreaks. These were well babies, and those investigations -- it was felt that there were no data to baseline, to compare against. So the idea of doing surveillance at the time in hospitals those were called nosocomial infections.

So the CDC actually started a very small pilot project or surveillance called CHIP. That was Comprehensive Hospital Program. I think that was what it was called. That was started in the 1960's. Also started in the 1960's the Joint Commission on Accreditation of Hospitals, as it was known then, added its first standard for infection control to the hospital set of standards, which was the beginning of what became over the years or decades, very strong language.

In the 1970's that standard was strengthened to include trained personnel designated to conduct infection surveillance, prevention and

control activities. During the 1970's as well, CDC established training curricula and conducted courses in infection surveillance, prevention, and control. We invited any hospitals that wanted to come down to train.

In the 1970's CDC replaced the CHIP Program with the National Nosocomial Infection Study, a voluntary system of hospitals selected initially, for the people who were invited to participate were those that had participated in the infection control training course.

They realized at that point that in order to do surveillance, it needed to be someone who was already trained in infection control in surveillance as it was at the time, to begin collecting these data.

It was voluntary, and at the time there was no confidentiality protection despite the fact that patients were identified with the data that were collected. But this was the 1970's.

(Slide.)

MS. HORAN: CDC realized that

confidentiality protection would be important because these data could be potentially used against the hospital in the case of a liability claim. When CDC was afforded the opportunity to grant confidentiality protection, in 1982, the NNIS system was the first system that applied for that assurance of confidentiality and has had that protection in place ever since.

It is not a blanket protection in the sense that when you apply for it you always have it. It has to be renewed. We constantly renew that and review the need for it. We currently do have confidentiality protection in place.

This protects the institution's data as well as the patient's data. In the 1980's also, CDC reported the findings of the SENIC study, which was mentioned here yesterday. SENIC was a study of the efficacy of nosocomial infection and control. That was a study conducted at CDC beginning in 1976 that really established the science.

The main finding of SENIC was that about 32 percent of hospital-associated infections could be

prevented if appropriate surveillance, prevention and control activities were performed.

These would be conducted by trained infection control professionals and hospital epidemiologists. In the 1980's, CDC also gave over the training activity to the Association of Professionals in Infection Control, or APIC, which is an organization established in 1972.

Also in the 1980's, APIC established certification for infection control professionals. That requires experience as well as passing a certification examination in five years.

(Slide.)

MS. HORAN: In the 1990's, the NNIS system expanded to include more than 300 hospitals. It had developed by that time protocols for targeted surveillance of high-risk patients that yielded the data useful for inter- and intra-hospital comparisons. These were risk-adjusted rates of infection that were found to be useful for comparative purposes and helped drive prevention practices at local institutions during that time and

to the present.

We publish an annual NNIS report which has all these data in it. The result of this is that hospitals that are not participating in the NNIS system -- at that time there were at least 300 and some -- were able to use the same methods, definitions and protocols to compare their data to the national aggregate, even though they were not actually contributing data to the system.

So, it had a large spread. The NNIS system really has been a model, I think, for nosocomial health care associated infections in hospitals for the entire world.

In this decade, patient safety has become one of the buzzwords. And one of the issues that has brought the spotlight onto infection control, and it has really helped to galvanize many other organizations that are interested in protecting the patients.

Because we have data, it's easy to say, well, gee, if there are two million infections annually in the hospitals, surely we should be able

to do something about this, especially since we know that at least a third of them should be preventable.

Many activities that are going on around the country right now through the Commission, through the federal government, for work on prevention initiatives, bundling together, if you will, prevention best practices and monitoring those processes and also continuing to collect the data on the outcomes. Those have proven to be quite powerful initiatives. And lots of infection reduction has been reported by groups, such as the Pittsburgh Regional Health Care Initiative in Southwestern Pennsylvania; the Keystone Project in the State of Michigan and others.

In addition, the other driver of movement and activity in the infection control world right now are state mandates for public reporting. This has largely been consumer-driven. These are consumers who have information about hospitals that can help them make decisions as informed consumers as to whether they want to have their care in that facility.

And infection rates are deemed to be one of the aspects that is important in making that decision. Currently, 14 states have passed legislation. Each state has a different set of laws that are struggling to figure out how they are going to make this work.

Most of them didn't get any money. Six of those states have chosen to use the National Health Care Safety Network as their reporting mechanism for meeting their state mandates. I'll talk a little bit more about that later.

(Slide.)

MS. HORAN: What are the key features for success? In a system like the NNIS system, or its predecessor, who have a 35-year history. The standard definitions for the events themselves, specified monitoring protocols, descriptions about a how the surveillance should be done, are key aspects. Equally key is feedback of actual data to the participants. That's not to say that we manipulate and feed it back. We do that in the form of the aggregate, but each individual facility is

responsible for their own data analysis. We give them the tools to do that in a variety of ways.

Part of the training we do with them is to help them understand how to do the analysis, how to report that, and how to motivate them to change their institution. It's very active surveillance on all levels. The key player here is our trained personnel for data collection and prevention and intervention.

These people are the local experts in their facility that are the go-to folks when the white powder incident hits. Anything that has to do with infectious diseases or even semi-close to infectious diseases, that happens in communities, the infection control person is the champion, to decide it. So, having a person in the institution taking responsibility and be empowered to have responsibility is the key issue. And I know it's one they are starting with biovigilance.

(Slide.)

MS. HORAN: As a system, we have been able to show a reduction in rates, as you see from the decade of the nineties and beyond. These are some

sample data of central line associated BSI rates, by ICU type, and the amount of reduction, 44 percent, I believe, in the medical ICU.

We also have reductions in surgical site infection rates as well. This was all before the national patient safety prevention initiative, as we carried it up to 2006.

(Slide.)

MS. HORAN: The purposes of the National Health Care Safety Network, or NHSN -- there are actually three systems that are integrated into NHSN. The NNIS system, which I mentioned. We also have an outpatient dialysis surveillance system. And that is integrated into NHSN now. And we are in the process of integrating our National Surveillance Health Care program into the system.

Exposure to blood and body fluid, vaccines for non-preventable diseases, and vaccinations of health care personnel. Our purposes are to describe the epidemiology of adverse events among patients in U.S. health care facilities to monitor compliance.

With proven infection prevention practices

in the facilities, to promote the use of epidemiologically sound surveillance methodology, and to establish comparative rates that can be used for local quality improvement efforts. And further, to have a ready pool of facilities that would engage in collaborative research on a variety of issues.

(Slide.)

MS. HORAN: There are three components currently to the National Health Care Safety Network. One is patient safety, which is an extension of the NNIS system, but it can grow to accommodate may more events than we do currently.

The health care personnel safety component, again, is focused on health care workers, and we have a research and development arm, who do one-time surveys or pilot studies, that sort of thing.

It is still a voluntary, confidential system.

(Slide.)

MS. HORAN: To focus on the patient safety component, because I think that's of interest to this

group, we have three modules. A device associated module, one is focused on procedures, one on medication. The devices that are of interest to us currently are those medical devices associated with infectious outcomes. Central line and blood-borne infections, urinary tract infection, and pneumonia. The facility chooses which event and which processes they want to monitor on a monthly basis, and which patient population they want to focus on. It's very dynamic and it is up to the local facility to know where their problems areas are, or what areas they need to focus on and choose those to do the monitoring.

It's always of value to them. We are not telling them what to do. It's up to them to apply it to the area of their institution where they need to.

For a procedure-associated module, the facility chooses the events or processes they want to monitor and the procedures. In this case right now, we have operative procedures. But those procedures, as I will show you, could expand. They can choose which procedures they want to focus on. These can be

in-patient or out-patient procedures.

And the medication-associated module really is currently focused on reporting anti-microbial resistance data and anti-microbial use data in relation to the infection.

In discussions with this committee before, and in discussions with NAT, what would a possible transfusion recipient surveillance look like, if we were to incorporate it into the NHSN? Everything I tell you about this, after this morning's presentation, can probably be done at the donor center as well.

There is nothing magical about a hospital here. You've got to continue most places where you might be able to gather data. There is no reason you shouldn't use this in a donor setting as well.

But the focus now, is sort of on the hospital or places where transfusion recipients events are. We envision that our procedure-associated module might be able to accommodate something called a transfusion-related event. Whatever you want to call it.

Numerator data could be collected that includes patient data, transfusion reaction data, whatever the appropriate data are. In the numerator, including risk factors. Also, denominator data, could be collected on whatever the relevant bits of information are for each type of blood product, transfusion procedure.

But of course we consider whether the process monitors might be useful as well.

(Slide.)

MS. HORAN: I took our demonstration application and I created an event type up there called transfusion related reaction. I made up a procedure called blood transfusion. These are other data fields that exist on the form, but after risk factors, whatever the appropriate risk factors were detailed about the event, could be built in here or down here, under specific event details. A blood transfusion if these -- or particular events associated with a blood transfusion, you might want to have them here, and have specific information selected about them.

(Slide.)

MS. HORAN: On the denominator side, the procedure model, a blood transfusion is also considered a procedure. We might want to put in additional procedure details here.

Another important to consider, if some of these data reside in other databases at the facility could they simply be pulled in. I think there are definitely ways that can be done, so that nobody has to manually enter them.

Of course, they have to exist in another system in order for that to happen.

(Slide.)

MS. HORAN: I want to talk about data sharing. The model that we use right now for NHSN is that a hospital or a facility -- it doesn't have to be a hospital, it can be any type of health care facility -- joins NHSN.

Their data then come directly to CDC and are stored in a centralized database.

The facility always has access to those data through the internet. Any time they want to,

they can download their data and put it in their package and store it anytime they want to.

But there was a need before mandatory reporting, and there is a need for facilities to share their data with others. Maybe their corporate headquarters they would like to get data from.

So, we wanted to find a way we could enhance the data sharing that wouldn't violate our confidentiality protection with the institution. Because CDC is not allowed to send data to state health departments, for example, or other entities. We wanted to have a way that the facility could make that happen.

One way it can happen is shown at the bottom here. Hospitals are facilities that use NHSN that can create data files of a variety of types and give those to anyone they want to, with the actual data in them.

They can take identifiers out if they wanted to, but that always exists. But another functionality is at the group level that we created. The way this works is that a group can enroll in

NHSN.

(Slide.)

MS. HORAN: That is a very simple process. Once they enroll, they have an ID number. They give that information to whatever NHSN facilities they would like to have join their group. The facility then is the one that makes the decision about whether they want to join the group. And then they grant access rights to some or all of the data.

One of the rights they obviously would want to give to the group is the ability to analyze as well.

(Slide.)

MS. HORAN: This is a shot of what that confer right looks like now. Although we are now in a process to make it actually more granular so that the facilities can really kind of limit what they share.

If you can imagine where they are in a situation where they are mandated to share data with the state health department, and there could be some negative action by the state, if they so chose to do

that. Then the facility is not going to give any more data than it has to.

We are trying to make this even more specific, but currently this is what we have. The way that it works, as the facility brings up the screen, they will be conferring rights. In this case, this is the one that I actually created for training the New York State Department of Health. We heard yesterday that they are one of the states that is using NHSN. The actual group in New York is the New York State Department of Health and the facility in New York would grant view rights to the patient in New York. They didn't want the identifier. They indicated they did not want a patient level identifier. At the event level they choose which events they want to share. In this case, New York wants blood stream infection, so they got a view right to that. And surgical site infection. You can imagine those would just be on this listing to be specified for sharing with other groups.

(Slide.)

MS. HORAN: In addition, the denominated

data need to be shared if one wants to calculate rates or levels or view rights to the appropriate denominators for those numerators. Then something we call our patient safety plan really the road map that CDC uses because there is so much flexibility built into the system, they input a lot more stuff in there that isn't part of one of our surveillance protocols.

We don't really want to analyze anything that is not part of our protocol. We want to know on a monthly basis which of these data they do need as protocols so we can appropriately analyze the data in the aggregate. That is what the plan is about.

Annual surveys are data once a year, supplied by the hospital. In the case of the hospital survey, it gives us information about their microbiology laboratory, their staffing for infection control, do they have people available to do surveillance and that sort of thing.

These would be useful indicators for us as we analyze the data.

Finally, and again, very importantly, is the analysis. Usually what a group wants to do is

pool the data together across facilities and figure out what is going on at various levels.

(Slide.)

MS. HORAN: I know these questions came up yesterday. I will pose them again because we are struggling to find the answers. But as you are thinking about what kind of system or systems are needed for hemovigilance or the broader biovigilance, one main question is, are the data readily available? Do you have sources of data for numerators and denominators if you want to collect? Also, do you have data collectors?

I think I have heard they really don't exist at the moment, at least not as a parallel position, like the infection control practitioner. If there isn't a data collector, what is the incentive for institutions to have one?

I give you the experience in our history -- infection control. But I would like to add to that, and say that there is a new position that has been established, in the last several years in many hospitals called a patient safety officer. The

hospital pays for that, and it is not the infection control practitioner in many cases. It a response to a push by the community and the consumers saying, hey, we need patient safety. Somebody needs to stop these errors from occurring.

So the patient safety officer has sort of sprung up in institutions. Perhaps that is a position that could be taken advantage of. What adverse events are you interested in collecting? This is a sentinel. Do you need all of the patients or a sample of the patients? Should you choose what you monitor based on what is most frequent or most lethal?

Those are all questions we can consider. And can it be phased in? Does it have to be the entire enchilada all at once? Or can you have sort of a pieces and parts approach? Where you gradually grow into something that is bigger and more comprehensive.

(Slide.)

MS. HORAN: Confidentiality and voluntary was mentioned already. Also, what about other

systems? There still seem to be more to come. Should there be a linkage between these systems? If so, what kind of data sharing agreements would be necessary? Are there database manager and even integration issues? Is that more realistic in the short term or is that more part of the vision for the longer term?

But of course the resource question is obviously critical. With that, I will leave you with our members web site. That web site will be going public. But for now you will have to type that in and take it to your bookmarks so you can find it again later.

Otherwise you won't be able to find it. But we are in the process of moving. With that, I will stop.

DR. BRACEY: Thank you very much. Ms. Lipton?

MS. LIPTON: Thank you. I am glad I had the opportunity to see some of this. Could you share with the committee the same question of how is this funded. What does it cost, and particularly, the

module that we were sort of looking at developing, a blood module, roughly, what would that cost?

MS. HORAN: We don't have any module for surveillance. CDC has a history of surveillance as part of its mandate. A lot of that is done with base funding that we get. To be quite honest, we have cobbled together lots of hobby horses to build what little I have shown you of our system.

I would not say that it is fully funded at this point. We don't have a source of funding, like an earmark. We would love to claim that. However, we do make it work.

How much does it cost us? Honestly, I can't tell you. In both salaries and development I can tell you to develop the patient safety side or the application, the web based application, has cost us probably, if you count our salary time of our staff, probably in the order of $3 million to $5 million thus far.

But it is the infrastructure. The hard part, if you will, is done. So much of the work of integration is done. The security aspect is done.

The analysis capability framework is there, so I think a lot of the major work has been completed.

That's one answer. What is the cost to the hospital, might be another answer. It is free to join NHSN. No annual cost. CDC incurs a fee of $100 for every additional certificate that is used. A person who uses the system has to have a digital certificate in order to ask us. That is part of our security.

The hospital pays for that, and right now we have over 600 users and about 250 hospitals, so we expect -- and those have to be renewed annually. That cost so far is being absorbed somewhere that I don't want to ask about.

(Laughter.)

MS. HORAN: We have cobbled together money for this fiscal year to do some enhancements for the system to the tune of about $840,000 for some enhancements. I wish I could say I know exactly how much it costs. Trying to do something with this group, it would only really be a guess.

So, I am kind of reluctant to do that kind

of guessing, but I would say you ought to think if terms of at least half a million dollars to get started, and that wouldn't be in a year. That would be over some period of time, again.

MS. LIPTON: And you don't have any idea what the training costs are? There are costs to having a professional in the hospital, whether that person is an infection control person or not, which they are, but clearly the organization has some cost involved.

MS. HORAN: Again, the Association for Professional Infection Control offers lots of training courses, which hospitals or individuals can pay for.

We provide for our system and our protocol and methodology training. In the past with NNIS, we actually had funding from an outside source, to bring them to Atlanta, to train them for three and a half days, and with the computer and with the experts, as well as other training opportunities. We don't have that set up right now. But that really worked well when we did. What we would like to see and what we

are working with the states on that are using this, is to have their chapters of the Association for professionals in infection control to train the trainers.

For us to train the trainers and for them to take over state responsibilities for training others. That seems to be resonating with them. They are actually doing that in New York right now. That would be five states. They seem to like that idea. We are going to try and feed on it.

Training is an incredibly important aspect, and as much as the organization can help do that, I think it would really help a lot.

DR. BRACEY: Dr. Whitaker?

DR. WHITAKER: Did you say $3 million to $5 million or $35 million?

MS. HORAN: Three to five.

DR. WHITAKER: My second question is, the infection control officers in the hospital, could you describe their training? And perhaps their other responsibilities?

MS. HORAN: Infection control

practitioners are by and large 50-something year old nurses. We need to train a whole lot of new ones. Most of them came out of a background of nursing, although I was an infection control specialist in a hospital. I came out of the biology lab. So there are some laboratories as well as environmental health specialists. By and large, it's largely nurses.

As I have heard discussed here, these are people who become the experts in a wide variety of the infection surveillance, prevention and control. They interact with all levels of the institution, from the housekeepers to the CEO, to the nursing staff concerning everyone that touches a patient. The infection control departments and professions don't prevent infections. Patient care still prevents infections by doing the right thing every time with the patient. So, it's no different from what you are struggling with. Each person that has a part to play, from drawing blood to giving transfusion to following patients is involved somehow.

I had to laugh. I was recently in

Northern Ireland to present NHSN to their Pan Celtic Society. They have adopted as their motto, infection control is everybody's business. And I laughed because when I took my job, my first infection control job in 1979, that's what my predecessor told me. It hasn't changed. We don't make the difference. It's getting the information to the people who can use it, to actually give better patient care.

The training they have is largely whatever they get in their professional discipline and then again, CDC used to provide a lot of that training. We are out there, talking and training people all the time in our methodology. They do have a certification exam that they have, with their own practice. You have to have at least two years of practice and then a comprehensive exam, which is renewable within five years.

There are states now that are mandating and certifying infection control professionals be hired.

DR. RAMSEY: Sometimes there has already

been some overlap in many of these institutions. Infection control professionals can be very helpful.

MS. HORAN: They can be a very useful partner in patient safety in general. Certainly they would be interested in the infectious aspect, as well in both the surveillance methodology and prevention and control activities.

DR. BRACEY: Thank you. Our next speaker is Dr. Harold Kaplan. Dr. Kaplan is Professor of Clinical Pathology, familiar to many in the audience, from Columbia University. He has been instrumental in putting together a system for error detection, and he will speak on that.

(Slide.)

DR. KAPLAN: I am getting off to my usual good start.

(Slide.)

DR. KAPLAN: This cartoon underscores, in an eloquent way, what we are about. It also underscores an important point. Adverse events and also safety are really emergent properties for very complex systems. I think the success of failure of

any central biovigilance program is very much needing another example of an emergent property.

(Slide.)

DR. KAPLAN: One of the things I am going to stress in this talk is that the local data complexion -- what goes on locally -- has a big effect going out, and what the central system has to say is has a big effect on what goes on at the local level.

(Slide.)

DR. KAPLAN: The MERS system was developed just parenthetically in two stages. One, with a Delphi, which we actually identified from their point of view, expertise in other reporting systems, and human factors. So, we started with the ideal method, rather than working from where we were what would be ideal. That was a three-round Delphi.

Then we had experts in transfusion and human factors and participation on the part of FDA, ARC and others. That second set of meetings was defined based on the ideal coming on down from there, rather than coming up, what was actually

implementable.

It started as a paper-based system. It's now web-based, at 22 hospitals in several countries. The events are deviations from certain current policies or current operating procedures. These events are classified by actual severity or potential severity, and the presence or absence of recovery.

(Slide.)

DR. KAPLAN: This is really a little personal humor here. Late last night, after a few drinks --

(Laughter.)

DR. KAPLAN: But it's not because of that. I just noticed that I went from a PC to a MacIntosh.

(Laughter.)

DR. KAPLAN: And the MacIntosh didn't transfer the print. So, late last night I put the print in, there's a flash disk. So I will go through this with you.

Actually, it's a teaching device.

(Laughter.)

DR. KAPLAN: The upper portion of the

slide is the local system. An occurrence is then detected and then a report is submitted into the local system. The system operator -- the SYSOP -- then looks at that, validates it, expands the information about it, and then it goes into the local system.

And on the management side, an action is taken, whether or not the report requires or is desired to be reported. I think with the PSO, the recent PSO legislation, the encouragement of reporting is general and there is somewhat fear associated with it, but it may be decreased.

The important kind of grid statement is the feed factor. That is the fundamental thing locally, and I think maybe in the central system. The feedback has to take place, and has to be locally useful. I'll get back to that. That feedback point is very valuable.

I didn't think of bringing the data with this, but I'll just mention -- because the issue of nursing came up, and at what level we approach the nursing, because they are so critically involved in

the process of transfusion.

The place to approach nursing is locally. When I say locally, that needs to be defined further. It was defined by one of the hospitals using MERS. We were reporting, for example, selected specimens to MERS, the general nursing department. Everybody was concerned. But there was a big difference when we started reporting the local nurse managers, the unit managers, because they could get their arms around their own units.

The feedback we gave to the individual unit managers was a critical value. We extended that relationship with nursing and approached them because we got some discarded units from the floor that hadn't been given the required time interval.

Looking at that, some of them had been actually set up to be administered. Supposedly the patient had been identified, and was at the point of final give, that they recognized that it was the wrong patient. We recognized there that people often were ordering blood to get them on the floor so that they are available and we can give them.

We carefully try to control issuance of blood, one at a time. What would happen was we would issue one at a time and they would sit there because they didn't have venous access or permission to transfuse, so we had to come back. Because within the 30 minutes allowed, they couldn't administer it.

It gave us some insights because now, we have this clever idea of controlling the number of units available. The units were building up on the floor, and that unit was available, but it may be the wrong unit. It became a problem for the director of nursing.

They redesigned the forms. Before they would call for pickup, we do have access and we do have consent forms. I think that is an example of engaging nurses at a very important level that reflects what you want in the feedback. Down there, you can see the system then reports into the MERS. The MERS database becomes available then to the local hospital who reported it.

The difference here is that we don't know who they are.

DR. KAPLAN: They know who they are. They can get their own data. We don't know who they are. They can also look at aggregate data. The numbers are numerator numbers. We have a number of people interested who are willing to send us the denominator. We have groups from the hospital, some not sure how to use the benchmark data.

Most of what we have is a pull system. People can pull data and play with it. It comes into an Access database, or Excel. They can get the data as they will.

As far as the push goes, this is something we hope to expand considerably. We had some preliminary discussions with AABB. Instead of making more readily available the on hand reports, I am not sure that pool systems have all the truth in them.

(Slide.)

DR. KAPLAN: I want to make a comment now. The good news about PSOs is what I think everybody understands. Hospitals, as they start getting more aggressive about having hospital based reporting systems, where does a domain system fit in?

New York State, as Dr. Linden said yesterday, has kind of early on, solved that problem by breaking out the transfusion domains, specific reporting. So people don't view that as redundant extra work.

The most important element in the reporting systems, particularly at the local level, is detection and reporting. Selection is critical both at the local and at the higher, aggregate level. Analysis, application, and monitoring are all important.

But I want to stress the detection and reporting for the moment.

(Slide.)

DR. KAPLAN: Believing is seeing. Our definitions define what we see. Organizations disregard events outside their classification scheme.

For this meeting, an important point is, that compliance often sets the limits of visibility. Somebody up high says, I want you to report, is what people are going to be paying attention to. It is important to keep in mind there may be valuable

information locally that will get short shrift if you don't keep in mind that people are going to pay attention primarily to what they've got to do.

(Slide.)

DR. KAPLAN: The classification scheme to be used in MERS, events with harm and misadventures, events without harm for one reason or another, they may not have the potential for harm, the near-miss events, whether planned or unplanned, recovery, that's an area we haven't studied enough, recovery.

Errors occur throughout medicine all the time. We don't really look at recovery the way we should.

Then, finally, the dangerous situation. I don't think that has gotten enough play. We have to wait for the event to trigger looking into something.

(Slide.)

DR. KAPLAN: One of the virtues of near-miss reporting, the criticism is it's very reactive. That's true. But as you look at events without harm, and near-misses, you become much more proactive. That changes the nature of what's being reported.

Event reporting. I don't believe there is ever going to be fundamentally a good quantitative system. But it does have other virtues. The other is it engages the staff in looking at the things that can be improved.

(Slide.)

DR. KAPLAN: It's what you do, not what you say. Now, the importance of near-miss reporting, and this idea of making things more proactive, has hit on many of the reporting systems.

In the U.K., they have defined fairly aggressively what a near-miss is. They are very concerned about the fact that less than half the hospitals are reporting. They are also concerned about what is the power-weight ratio. How do you handle that ratio if people do report it? There is going to be a workshop and some other discussion in November on how to handle reporting.

There are going to be aggregate problems on summary data in the central system anyhow. The question of near miss reporting can be very important at the local level if the numbers go up tenfold, as

they may.

France has a hemovigilance system. It has near-miss defined as grade zero. It reaches the patient, but there is no detected adverse event.

The U.S., the FDA has, I believe since 2001, the requirement for reporting. Components are issued from the transfusion service. Nothing to do with whether there is a bad reaction or not, other than a fatality.

Canada, we have heard about. And there are some Canadian hospitals.

And Ireland had a three-year pilot, MERS event reporting four near-misses. I hope they get funding to go forward with that.

(Slide.)

DR. KAPLAN: By the way, we understand they are using a paper-based system in Croatia, which they got off our web site. The changes in AABB standards clearly now require monitoring, and tracking and treating them as important occurrences.

(Slide.)

DR. KAPLAN: We got the definitions. We

got how we would detect. How do you get them to report it? The issue here is to get adoption rather than compliance. Compliance is where most of us are. For adoption, trust and motivation. I want to get into the issues, both in terms of trust locally and in terms of punitive action. But also at any level centrally. That will stop any system in its tracks.

Finally, for motivation, we were talking about timely and effective feedback, and demonstrable local usefulness. So, it's not something in a black hole. I am busy enough, I don't want to do anything else.

(Slide.)

DR. KAPLAN: Heimreich's ratio was found true in industrial systems. They studied many, many industrial systems and they found these holes. They found many situations in which it was suggested that the numbers are far greater. But, interestingly, the Heimreich ratio of one major injury for every 29 or 30 minor injuries and 300 no-injury accidents. It has been suggested as a way of seeing, are you getting reported to you in the system the things you

need to know. That was in the Department of Health, U.K. Organization.

In our current data, actually mid-'05, we had 43 events of harm, 2,698 reached the patient, no harm, almost 15,000 near-misses.

(Slide.)

DR. KAPLAN: If we divide by that 43, we get one harm event, 63 no harm events, and 339 near-misses. I think that is interestingly parallel to what would be expected from that triangle.

(Slide.)

DR. KAPLAN: We take a closer look at the near-misses. We find it's almost a 10:1 planned to unplanned. That is rather interesting, but not surprising. When you know what your weaknesses are, you put your barriers in, and that's how you get your plan barrier attack on the event and near-miss. But the 34 unplanned are very important.

How do you recover from there, because that's not a planned recovery.

(Slide.)

DR. KAPLAN: If we take a look at the

distribution of events, we see pre-and post-issue that final barrier, that issue barrier, is the important one. There's 100 percent of the events and 16 percent that actually reach the patient. Eighty-four percent are near-misses. And 87 percent of those are not issued.

For fully half of the near-misses of our collection are phlebotomy. Other than monitoring how we are doing, I don't think there is a whole lot of new knowledge to be gained in that group. We have some ideas on what we should do about that.

Now, what is being required to be reported is that 13 percent, at least of the near-misses, are ones that are issued that get past that final barrier. Obviously, those are probably the ones that would be stressed in central systems. And certainly the ones that harm. That very small total.

(Slide.)

DR. KAPLAN: When you look at systems, whether it is at the local level or the central level, it is very useful to say, have we seen this before, how often and how similar.

We have developed a really similar method -- we call it HAWK. Actually, I was told to reflect my ideas of hyper-augmented weight -- people who work with us are known as the Jayhawks.

This is a system. It's the first step. You call the Help Desk Op to say what your problem is. Then look up similar things in the database.

That's that similarity match. So we are using that. We look at all the attributes, and match the event with attributes. We rate the strength of the match from 1-100, and we weight different matches because different attributes have much more or less importance.

But something occurs. The exact day is very important, but not so important than the kinds of things we are looking for in similar cases.

But I think some form, to able to say, we have seen this before, how similar, is rather important. How much further investigation will do would be based on that. It also allows people to say, I put that into my database, but I am not going to fool with the system. I am going to monitor it

and see how often this is a problem.

I think that is a very important thing, putting something into the database and monitoring it is an action. It's good. And the regulatory component will accept that fact that I am not making a change in my system.

(Slide.)

DR. KAPLAN: This is from Bill Corcoran, our consultant in the nuclear safety field, and his Firebird Forum. He talks about doing cause analysis. The first time you do it, a root cause analysis, you get information. That probably provides the most learning.

The second time, you extend that learning, but if you do it again and again, it's diminishing returns.

(Slide.)

DR. KAPLAN: This was just a quick shot of how we do root cause analysis. It's a causal tree. It goes back in time, and cause -- we carry it down to the root causes. The important thing here is we do look at the recovery side of this near-miss. Not

only the failure side.

The other issue here is this isn't an iterative process. One of the problems with filling out a form is it doesn't encourage that kind of sense-making process. You are just trying to fill out a forms. Forms have a virtue of standardization, but they have some weaknesses.

(Slide.)

DR. KAPLAN: I would think we would all benefit from taking a look at events. Again, this is from Corcoran. And safety isn't so much what caused this, but really about the consequences to the patient. What were the factors that affected the consequences? What were the vulnerability factors? What are the latent errors or failures going into the system?

Like, for example, staffing. The triggering factor. What was the act? A guy didn't double-check something. Didn't follow a protocol. The protocol may not have been follow-able.

But that's the vulnerability factor, how latent factors and triggering factors combine. Then

you want to know, what made it worse than it had to be? What were the exacerbating factors? What were the mitigating factors?

If we begin to get these pieces into the mix, I think we have another level of understanding. We have at least moved toward lessons learned.

(Slide.)

DR. KAPLAN: When you say all this, how do you decide? Which procedures are you going to spend time on? At the local level and the central level, I think the two issues -- this is just a hazard matrix. The probability of it recurring again. And the consequences of it recurs.

That is the most extreme consequence. But what do you think the most critical consequence is? The probability, which is High-High, number 1, is the one you want to spend your time on.

Number 3 is a little more difficult. That the low probability, high impact. Those are the ones that take some thought as to what kind of resources do we expend. That's just another example of the matrix.

(Slide.)

DR. KAPLAN: That's one of the ratings. We calculate a number on the back of the envelope. Is the risk extremely high? Medium? Very low? And we convert it to a number. And we take the legal precedent -- 6.5 or more, it's more likely than not. That's our cut-off.

(Slide.)

DR. KAPLAN: The use of near-miss reports, you decide what you are going to look at. If we do this, it's a portal to view the potential system dangers. It's a safe way to learn lessons. And very importantly.

A lot of what we do, we do routinely. Often. People are on automatic pilot. This provides exemplar cases in support of being mindful.

(Slide.)

DR. KAPLAN: This is something that's interesting. It was a CAP phone survey in '99. They queried CEOs of hospitals and heads of nursing departments, and asked, what was their awareness level of medication errors and specimen collection

errors. You can see there is quite a drop-off from awareness of medication errors to specimen collection errors.

That's not only important in the individual hospital, that might be fed back into the system. But I think this is another place where central information ought to be put back into the hospital.

(Slide.)

DR. KAPLAN: Nothing recedes like success. I was worried about when we look at the peak of the pyramid, with the harness -- and we don't worry about the bottom.

The reality is, I think people carry this model in their heads. I just did some quick numbers. I wouldn't argue about their accuracy, but I think most hospitals, even with a pretty accurate transfusion service, don't see the worst problems.

I know we have a good system for sharing and reminding people about the danger that is being faced on a daily basis. I don't mean blood, I mean the rest of the system.

(Slide.)

DR. KAPLAN: Finally, we don't have a good system for feedback at all. When there is a mistyped heart transplant, it was the media that had everybody in the transplant program sitting down and going over the flaws they knew in their system.

We had a recent event in a blood center, a contaminated unit. Platelets. I hear about it, and as I am looking at it, on one of the web sites that captures this information, but I think we really need some of the analogies, that NTSB and aviation, which is investigating and sharing information, not the police, and NTSB. I talk to Jerry about this and he said maybe the National Transfusion Safety Board.

But I think the idea of our being much better than just NBC, and CNN and the times being a source of how we get information is critical.

So, it gets to the feedback loop.

(Slide.)

DR. KAPLAN: I couldn't pass this up. "Safety is not bankable." That's a quote from Weick and Sutcliffe. Safety and reliability have to be

accomplished over and over. Safety and reliability are dynamic, non-static events.

The issue is, any system we have has to be sustained. That's one of the reasons why I think the approach is sentinel rather than getting the whole world, and maybe more important. And my final one, weak signals do not require weak responses.

Thank you.

DR. BRACEY: Thank you, Dr. Kaplan, for a great presentation. Questions from the Committee?

(No response.)

DR. BRACEY: I think your message was clear.

DR. KAPLAN: It has marvelous staying power.

DR. BRACEY: There's one question from Dr. Epstein.

DR. EPSTEIN: A lot has been said about the issue of finances and sustainability. You have 22 hospitals doing this. Have they been able to show a payoff? Can the lower costs by doing this?

DR. KAPLAN: That's a good question. I think we show payoffs in changes that occur. For example, in one of the Canadian hospitals, they studied and found that they had a lot of blood collection errors, sample collection errors, that were due to PRN hiring of nurses, short fill-ins.

They realized they had no education program. They captured that later and they carried out an educational program and found that the nurse

became more aware, but they still had a high rate.

Rather than looking at that as a failure, what they were able to do, was take that data and show that the educational program was necessary, but not sufficient. It was sufficient data, however, for the administration to go ahead with a bar code system.

It gave support to making a financial decision by using one of the functions, which is monitoring change. We'd seen other kinds of uses of the system in our own hands.

We decreased wastage on the floor with this interaction with nurses. We haven't really calculated the cost.

Wastage of blood was driver here for us, but we didn't capture the costs. I think the mantra we need to adopt to figure out how we can try to tie these things to length of stay, any hospital administrator who can show the impact on length of stay with regard to his patient, what we've done, I think, has really been focused properly on this. Thank you.

DR. BRACEY: Thank you. In the interest of time, I think I'd like to ask the Committee, if the Committee feels okay with us beginning the discussion and postponing the presentations until the follow meeting; is that agreeable? All right.

The task at hand now, is to try to assimilate all this information that we've reviewed over the last two days, into a recommendation for the Assistant Secretary and Secretary with regard to this activity.

We briefly, informally discussed this, but, at any rate, we will have the head of that subgroup on biovigilance, Dr. Kuehnert, once we get the computer up, present the draft.

(Pause.)

DR. BRACEY: Do you want to go ahead, Matt?

DR. KUEHNERT: Over lunch, we talked a little bit about a recommendation. We have basically had a number of different suggestions.

This was one of the composite suggestions, so I can -- maybe the best thing to do is just to

read this first page, and then stop.

DR. BRACEY: Do that.

DR. KUEHNERT: Whereas, promoting the safety of the U.S. blood supply is a principal activity of the Advisory Committee on Blood Safety and Availability, and inclusion of efforts to improve organ and other tissue safety and availability, also needs to be considered, we recommend that the Assistant Secretary promote the participation or leadership by the Department in developing a national program of, quote, "biovigilance," unquote.

Biovigilance is defined as a comprehensive national program for detection, gathering, and analysis of data regarding untoward and unexpected events of donation and blood transfusion and transplantation of cells, tissues, and organs. That's taken from the AABB manual.

Formation of a PHS Biovigilance Task Force, including the Assistant Secretary and representatives of PHS agencies would be an initial important first step of identification of the vision, goals, and processes needed to advance these

objectives.

This Task Force is needed to participate with private-sector efforts, including the AABB Interorganizational Task Force on Biovigilance, to advance public health in this effort.

Then I think we should stop there.

DR. BRACEY: Then we had another version. Jerry, can you help?

(Pause.)

DR. BRACEY: The other version states: Whereas, the Committee recommends that the Secretary establish an interagency task group -- whereas, again, would follow from what we've read before -- the present Committee recommends that the Secretary establish and interagency task group to develop an analysis and operational proposal for enhancing safety monitoring and response for biological products, including blood products, cell and tissue products, and solid organs, in partnership with initiatives in the private sector.

The task group should address the following issues: A gap analysis regarding the

effectiveness of the current system, the need for mandatory versus non-mandatory and regulatory versus non-regulatory reporting, the scope of reporting with regard to product problems, medical errors, and clinical adverse events, including recognized and novel events, database centralization versus data sharing, database governance, ownership, and accessibility, format and standards for data reporting, including confidentiality, funding mechanisms for a sustainable system, and design and feasibility of suitable pilot programs to determine the characteristics of a value-added system.

DR. BRACEY: There are distinct elements from both proposals.

DR. KUEHNERT: Does this one follow the first one?

DR. BRACEY: I was thinking we would have the first one that goes the definition. We talked about the need to do it. Then this really addresses the issue of the important areas that need to be explored. But I'll leave that up to the Committee.

MS. LIPTON: I was going to say I think they can't actually be worked together. My concern is I would hate to see the task force get together and do this all by itself.

I want to reinforce that this should be in partnership with the initiative that's already going on. What I might change about the second one is where it says "Task group should address the following issues."

Those are all the right issues, but I think it should be not just the task group itself.

DR. BRACEY: Dr. Epstein?

DR. EPSTEIN: Actually, the previous

paragraph states this should be established in partnership with initiatives in the private sector.

DR. BRACEY: That's true.

DR. KUEHNERT: I think the language needs to be changed just a little bit. This is more what should be done in the big effort, with a capital "E," but not necessarily with PHS.

DR. BRACEY: Dr. Duffell?

DR. DUFFELL: I think the remark earlier about the buy-in -- I think the bullets add some specificity to it, and I think Jay's remark is true.

DR. BRACEY: Let's do this. Let's combine the two. Then we'll revisit after we've cut and copied. Meanwhile, Mr. Matyas.

MR. MATYAS: A technical question about the task force and the terminology. What kind of approval? What's needed in order to create the task force, and what's the charge of the task force? I just wasn't sure if there's hidden meaning behind "task force."

DR. BRACEY: I see it as a group of interested parties. The supporting organizations

indicating that they will allot the time commitment of those individuals to the effort. Anyone else?

DR. DUFFELL: Jerry might be the one. It is kind of a legal question. We had a discussion last time when we broke up into working groups on how that worked.

MR. MATYAS: What is the authority of the task force? Is it merely to come up with more recommendations, or does it have the ability to implement them?

DR. BRACEY: I would see the task force as being able to put up a set of recommendations, because there is at this point really no budgetary commitment.

Dr. Holmberg, what would you think? We were looking in terms of definition of the task force and the authority the task force would have. Would it have an authority that would go beyond recommendations, into let's say implementation?

DR. HOLMBERG: The task force, as we are defining it, would be the AABB task force.

VOICES: No.

DR. HOLMBERG: I think the word Jay used was a working task force group.

DR. EPSTEIN: I called it a "task group."

DR. HOLMBERG: A task group. It's just that, a task group. They have no authority, other than to put together a document for approval by the Secretary.

MR. MATYAS: AABB, because it isn't necessarily government, is able to go. It's able to do. The question is -- I guess I ask Karen -- does this help or hinder, because a task group that doesn't have any authority might stall what seems to be very good productive efforts.

MS. LIPTON: I think that's why my biggest fear is that an interagency group decides to go off and talk to itself and do things. What might be worse still, I'd really like to see the task group participate with the private sector initiative, so we'd all know what each other is saying.

DR. BRACEY: The way I see it, there really is no impediment for the private sector pursuing this activity. The critical question, I

think, is again, what is the role of the government and its resources and its existing networks, in participating in this activity? It could be a facilitator.

MR. MATYAS: My question is, isn't it then better to maybe have AABB have its task force with members of the government participating, as opposed to having this task force as part of the government, with AABB participating?

DR. BRACEY: I understand that point. But I think that it's important for the government to work with itself, to evaluate its current structure and systems, and perform an analysis to see, to really understand all the parts that we were discussing.

But Dr. Epstein, would you like to speak to that as well?

DR. EPSTEIN: First of all, as to what is a task group, it's a group that's given a task. What is the task? I think task, as I've tried to frame it anyway, comes out as a report, that the group generates an analysis and writes it up, and then

makes a proposal.

Now it's true that group doesn't have effective power. On the other hand, when task groups are created within the government, the point is that they've been empowered to advise the ultimate decisionmakers. The ultimate decisionmakers listen to these reports of the task groups.

As I understood our earlier conversation, this is an attempt to be responsive, to encourage the Secretary to take ownership of the issue, and organize engagement.

Now that engagement should be a partnership with the initiatives of the private sector, no question about that. But we have to have authority to come to the table and say "Here's what the government thinks the government should own. Here's what the government thinks the government should do."

That's sort of lacking right now. That's because we don't have -- that we have a problem right now. So what we're calling for in the proposal is to call for the Secretary to establish that activity.

MR. BIRKOFER: I support Mr. Matyas' comments. I don't have an insider's perspective on how the government works, but experts in the FDA and CDC and the other entities, they should be able to communicate quickly amongst themselves and join in and participate with the already-established well-structured AABB, an organizational task force.

I think the presentation was crystal clear. I would hate to see any bureaucratic machinations impede the work that's already done. Let's move on with this issue.

DR. BRACEY: Dr. Holmgren.

DR. HOLMGREN: I think we in the government have already worked on that direction already, in many, many events. It is easier for us to come to the table if we are invited to the table to discuss, instead of us bringing the private sector to the table.

In the past, we have done that with the AABB Task Force on Domestic Disasters. We've also done it on the pandemic. There are task forces that just keep popping up.

What I envision, and I don't know whether we have to be very prescriptive in our recommendation, but the way I would tend to interpret this and operate would be that it would be concurrent. We would be talking within the government and finding our position.

At the same time, we would be joining. So I guess I had pretty much the same thought, of PHS in the AABB task force, whereas at the same time, there could also be within the directives of the Department to really look at all of these elements and assess the gaps. I don't see those as mutually exclusive.

DR. KUEHNERT: That's what we've been talking about.

DR. BRACEY: Do you want to go back through it?

DR. KUEHNERT: Maybe we should just talk about this particular paragraph, and make sure that works for people. The PHS task group should address the following issues concurrently with the AABB Interorganizational Task Force on Biovigilance, and other private sector efforts.

MR. BIRKOFER: No. What my comment would be that PHS should appoint representatives to the AABB task force, and the PHS-appointed representatives. I think it's explicit that they meet beforehand and they make sure what the higher-ups in the government want.

The government's task group will drag its feet and not do it as quickly as the AABB. Non-governmental organizational task force.

DR. KUEHNERT: Let's say AABB talks in all their meetings and say "We don't want to do gap analysis, so we're not going to do it." So they got outvoted.

MR. BIRKOFER: But they have to be appointed by the Secretary. They need to talk amongst themselves before they show up at the meeting.

DR. KUEHNERT: No. I'm saying AABB basically is then driving the decisions on what's done.

MR. BIRKOFER: No. AABB is not. It's all the participants and their task forces. The AABB is

not the driver. It's all of the groups that are represented on their task force. The AABB is not driving the agenda. It's the groups that are participating.

DR. BRACEY: I guess the way that I saw it was that the PHS would appoint individuals to participate in the AABB task force, and at the same time or concurrently, the PHS task group would be meeting to assess its current structure.

So again, There's no delay, because you have people appointed, people participating. They're interacting. But they're also evaluating their own system, which could only be additive.

DR. KUEHNERT: I guess the issue of this committee is they can't really direct AABB to do things, can they? We can't say the AABB organizational task force needs to do the following. This Committee can't direct AABB. I'm not sure how you do that.

DR. BRACEY: But again, it's not this committee but the government would supply expertise to participate in the activity.

DR. KUEHNERT: So the government will have liaison representatives on the task force, but they can't direct the AABB task force to do anything. They can be safely recommended to do this or that. I mean I'm not suggesting that AABB is going to be reticent or stubborn.

It's just that there are some things that's going to put them in an awkward position as far as what they're supposed to do, and there are some things it isn't fully their mission to do. It's the government's mission to do it. That's where it gets awkward. I'm not sure what to do about that.

DR. BRACEY: Comments from the floor?

VOICE: Just a little bit of clarification on how the AABB task force works. Using the Disaster Task Force as an example, the member organizations from the private sector are formally called "members," such as AEBB, Red Cross, ABC, American Hospital Association, etcetera.

They're more our liaisons from the governmental agencies, who are not members in the same regard. So that for instance, if you wanted to

come out with a statement, we have determined that we didn't want to hindered.

If we needed to get out a statement quickly and couldn't get it adopted immediately by the department, by HHS, which I understand may take a little longer time, then we can issue the statement as a statement for the private sector organizations which are members. Then we just liaisons with the governmental agencies.

MS. LIPTON: That's with respect to the Disaster Task Force. But generally, in the organizational task force in our nomenclature, an interorganizational task force has a representative from other organizations, and they name those representatives.

So it's really a task force organization. What we do in the Disaster Task Force was very different. We did that specifically because we had to worry about the actions that were taken.

MR. BIRKOFER: How are decisions made on the interorganizational task force? Is it AABB or is it the vote of the members of the task force? Is it

a majority?

MS. LIPTON: I don't think we ever had to come to a vote like that. What generally happens is each organization goes back and they sign off. When we have an organizational task force, if the Red Cross were a member and the Red Cross, their leadership would be part of it. But if we can't agree, then that gets noted.

DR. BRACEY: Dr. Holmberg.

DR. HOLMBERG: Let me just give an example here. I think what I said earlier, what I was saying was that the government comes to the table on these Interorganizational task forces as a liaison.

Specifically, we had a situation during Katrina where the task force went in one direction and the government could not take that position.

So we had to back off, and it was very important that this was not the government's point of view on this. The government was extremely split on this issue.

I think we have to be extremely careful that when the government comes to the table on these

interorganizational task forces, they're coming as a liaison. It would clarify this if we just said the PHS task group should, and then end it right there, and list the things it should do.

Then one of the elements should be a liaison to the AABB task force.

DR. BRACEY: I guess one of the guiding principles that we're thinking about is issues such as ownership of the data, how broadly the data would be integrated. There are pieces that currently in essence are owned by the government, mandatory reporting.

So it's a very, you know. The government will say "Well, you run the system because currently" -- in other words, private industry would run the system because currently government has a system for reporting, etcetera.

I think we have to be really cautious about that. We have to go to the point of looking at it from the liaison perspective. We really are saying at this point we haven't really changed the ownership of the data or in essence the data still

resides within the government. Jay? Comment on that? Dr. Epstein?

DR. EPSTEIN: I think that's one of the unsolved issues, is where data should reside. Who manages the database, what database elements are and so forth. It's all still unresolved, so it's not clear where the government should hold this.

I've certainly heard some arguments that there are elements of it that some people think the government shouldn't own, that it should be voluntary, non-regulatory, non-punitive reporting.

I think my concept here is that the government needs to figure out what the government needs to do. What we're trying to do as a committee is encourage the Secretary to be proactive on the issue.

A couple of us have been playing with some language that may need the Secretary to coordinate federal actions and programs to support and facilitate biovigilance, in partnership with initiatives in the private sector.

This idea of the task group would generate

a report for the government. As a subsidiary action, you have another element which is provide adequate liaison to the AABB and to the organizational task group.

DR. BRACEY: Right. The thing I see is we need to have action on the topic taken by those at the top, and we need to figure out exactly how the operations should take place. Let's make that change.

MR. MATYAS: If I may, just reading it, it struck me that what we were recommending was really a task group as opposed to the Secretary taking action. That action may result, but I think our recommendation is merely that the Secretary create a task force.

DR. BRACEY: Holmberg. Jay, where are you saying this goes?

DR. EPSTEIN: It would be above the current recommendation, right after the biovigilance.

DR. HOLMBERG: Right down here.

MR. MATYAS: I think it's in the recommendation.

DR. BRACEY: You're thinking higher up.

MS. LIPTON: I think it belongs in the first paragraph with what you just developed. The idea is for the coordination of federal actions and programs. That's usually what we're tasking the Secretary to do.

DR. BRACEY: We would strike the portion after promote, and then insert "coordinate" in that place? Strike "promote." Whereas promoting the safety of the U.S. blood supply is a principle activity of the Advisory Committee on Blood Safety and Availability, and inclusion of efforts to improve organ and other tissue safety and availability also need to be considered, we recommend that the Assistant Secretary coordinate federal actions and programs to support and facilitate biovigilance in partnership with initiatives in the private sector. Comments?

DR. DUFFELL: I'll make the comment that I think it works.

(Laughter.)

DR. DUFFELL: Somebody say something,

right?

DR. BRACEY: Can we move on? Let's move on then. There's a second piece, a paragraph that attempts to define what we're speaking of. Dr. Epstein.

DR. EPSTEIN: I'm concerned that that definition leaves out -- it talks about detection gathering and analysis of data, but doesn't talk about communication, or that the aim of it is to reduce the errors, something like that.

MS. LIPTON: Barbara Whitaker, didn't you have four pieces. We should include information on communication?

DR. WHITAKER: Early warning, safety issues, exchange of valid information, application of methods, practice improvements, promotion, education.

DR. BRACEY: Okay. So we would start another sentence here, with the objective of providing an early warning system of safety issues, exchange of valid information, application of evidence for practice improvement, and promotion of educational activities.

DR. WHITAKER: Start the sentence with "The system should be outcome-oriented with the objective" or "outcome-driven."

(Pause.)

MS. LIPTON: I just wanted to comment. That really is part of the legislative mandate, and that's the ownership issue and the direction things are going.

One of the things you might think about is including that type of concept in the definition, if we're going in a different direction, like a legislative mandate.

The nice thing about PSO legislation, it really does have bipartisan support. So that it has a chance of long-term survival.

DR. KUEHNERT: So language on patient safety?

DR. BRACEY: Yes.

MS. LIPTON: Create a patient safety organization in keeping with the purpose behind the organizational legislation. The legislation creating patient safety organizations.

DR. EPSTEIN: Why don't you just add the word "patient safety," defined as a patient's safety. That needs to be headlined here. The big picture people have said that the big picture is to improve patient safety.

If somebody was writing a newspaper story, what should be the headline? What do we want the headline to be? The headline is to improve patient safety. I would favor having that way up somewhere at the top.

DR. BRACEY: Patient safety program, yes. Scratch national.

DR. EPSTEIN: I'd like to put "national" back in, maybe a national patient safety program.

DR. BRACEY: Because of the federal element?

DR. EPSTEIN: Whether it's federally run or not, you really do want a national program.

DR. BRACEY: So national patient safety?

DR. EPSTEIN: Comprehensive and integrated national patient safety program.

DR. BRACEY: Can we move national in front

of patient safety program?

DR. EPSTEIN: You'd have to say that is comprehensive.

DR. BRACEY: Any other additions?

DR. HOLMBERG: Is it just patient, or has the Red Cross pointed out the donor also? So it would be a national donor and patient.

DR. BRACEY: In other words, we want to emphasize patient safety legislation, but we don't want to de-emphasize the importance of the donors.

MR. KAPLAN: If you don't have donors, you have no patient safety. They belong together.

DR. BRACEY: What does the committee think in terms of national patient safety, without reference to donors? Maybe that's something we could get to in the details. Comments?

MR. BIRKOFER: It does say an event of donation.

DR. BRACEY: Let's go through it again. Biovigilance is defined as a national patient safety program that is comprehensive and integrated for detection gathering and analysis of data regarding

untoward and unexpected events of donation, and blood transfusion and transplantation of cells, tissues and organs. It seems a little choppy.

MR. MATYAS: Comprehensive really should go before national. That way you have a program for detection gathering.

MS. LIPTON: I agree.

DR. BRACEY: So we'll move it.

MS. LIPTON: To detect, gather and analyze data.

DR. BRACEY: So we want to use both untoward and unexpected events? Actually, there are two separate. One's the actual event.

MS. LIPTON: What it leads to is the one that actually causes harm.

DR. EPSTEIN: I don't see it that way. I think what we're talking about is for the known events versus the rare and emerging events. There are lots of untoward events that we know about. I mean after all, hepareactions are expected, right?

MS. LIPTON: Should you say "and analyze"?

DR. EPSTEIN: What bothers me here about

donation and blood transfusion and transplantation, if they're also organ and tissue donors, shouldn't it be donation processing and clinical use of blood and blood products? So add "and tissue products and solid organs." We sort of stuck donations in an odd place.

DR. BRACEY: A good point. It will be donation, processing and clinical use of --

DR. EPSTEIN: Blood and blood products. How far do you want to go? We left out "other biologics in that," and transplants. It's only human products. On the second line, there should be a comma there.

DR. BRACEY: Right.

MS. LIPTON: It should be to detect, gather, analyze and report data.

DR. HOLMBERG: Can I read something here please? We have established a comprehensive system to collect, analyze and report on the outcomes of collection and transfusion, and/or transplantation of blood components and derivative cell tissues and organs, to provide an early warning system for safety

events and continuously improve donor safety.

DR. BRACEY: While Dr. Holmberg is editing that, do you want to go down to the next paragraph? Oh, he won't be, actually, able to change it, so let's wait.

(Pause.)

MS. LIPTON: It should be collect, analyze, and report.

DR. HOLMBERG: Should we just stop at organs? Excuse me, should we stop at organs, or should we continue on there with a new sentence, or should we add all that existing sentence.

DR. EPSTEIN: Put a period after organs.

DR. BRACEY: So, the following sentence is something that is added. I guess we put it in discussion, although it still, again, derives from certain bullets from the presentation on the AABB item.

I think it adds value. What does the Committee think?

MR. MATYAS: Okay, so, what system? Do we mean the program? that what we're referring to?

DR. BRACEY: Yes, so it would be the

program.

MR. MATYAS: Also, Dr. Holmberg, in the first paragraph, is it not that we recommend that the Secretary coordinate?

DR. BRACEY: Right.

DR. EPSTEIN: I think that in the second paragraph, under Exchange of Valid Information. I'd like to strike the word, "valid."

DR. BRACEY: Good point.

(Laughter.)

DR. BRACEY: The second paragraph, does it float?

DR. EPSTEIN: Application of evidence bothers me. Examination of evidence? What do mean by "application of evidence"? Practitioners apply it. What does the program do? The program doesn't apply it.

DR. BRACEY: You really provide it.

DR. HOLMBERG: Promote.

MS. LIPTON: Promoting the application.

DR. BRACEY: So you have to -- the application of evidence for practice improvement,

couldn't we just strike that, strike after "practice improvement."

You don't have the education piece, but you assume that if you apply it, that there is an educational activity associated with the application of such.

DR. HOLMBERG: Practice improvement for educational activities?

DR. BRACEY: Just strike "after practice improvement." That gets the key point.

MR. MATYAS: For grammar purposes, the objectives of providing, exchanging and promoting --

DR. KUEHNERT: I couldn't constrain myself. Making the assumption about educational activities, is a big leap. It doesn't happen by itself, and it isn't necessarily going to happen here, and I don't think that saying so, will make it happen, either.

But I don't think educational activities necessarily follow the fact that we're going to give people information. That has to be integrated into either some teaching program, it has to be integrated

into practice change. I think people understand why.

If you make the assumption that that's another guy's job, then the program gets too narrow.

MS. LIPTON: I think you're right; we could just say promotion, education, and the application of evidence for practice improvement.

DR. BRACEY: Actually, the application will come after the education, yes. Okay, education and the application, okay.

You'd have to scratch "and."

MS. LIPTON: No, because we are promoting both.

DR. BRACEY: Okay, I'm sorry. All right. Biovigilance is defined as a comprehensive and integrated national patient safety program to collect, analyze, and report on the outcomes of collection and transfusion and/or transplantation of blood components and derivatives, cells, tissues, and organs.

The program should be outcome-drive, with the objectives of providing early warning systems of safety issues, exchanging of information, and

promoting education and the application of evidence for practice improvement.

Comments? Is there a yea?

MS. LIPTON: Definitely.

DR. BRACEY: There's a yea. Let's move to the third paragraph: Formation of a PHS Biovigilance Task Group, including the Assistant Secretary and representatives of PHS agencies, would be an important initial first step for identification of the vision, goals, and processes needed to advance these objectives. The Task Group is needed to participate with private-sector efforts, including the AABB Interorganizational Task Force on Biovigilance, to advance public health in this effort.

Does that seem to work?

(No response.)

DR. BRACEY: Okay, let's look at the next paragraph: The Committee recommends that the Secretary establish a PHS Task Force to develop an analysis and operational proposal for enhancing safety monitoring and response for biological

products, including blood products, cell and tissue products, and solid organs, in partnership with initiatives in the private sector.

That can be deleted. Let's scratch that.

DR. EPSTEIN: After we scratch it, we need to bring back the issue of developing analysis and providing a proposal. I see those as outputs of the Task Group.

MS. BIRKOFER: Can you add that to the first sentence of the preceding paragraph?

DR. BRACEY: We want to add the output in the first sentence, so, formation of a Biovigilance Task Group, how about adding a second sentence?

DR. HOLMBERG: Where? Right here?

DR. BRACEY: Yes.

DR. HOLMBERG: The Task Group should perform an analysis -- I lost you.

DR. BRACEY: Wait a minute. The Group needs to do an analysis.

DR. HOLMBERG: Analysis is in the next paragraph.

DR. EPSTEIN: We want them to produce an

analysis. I have in mind, a white paper. They should produce an analysis and an operational proposal, based on the consideration of the issues.

DR. BRACEY: Let's say that, then.

DR. EPSTEIN: It can be above, or could be further down. The bottom now just says -- it previously said they should produce an analysis and a proposal.

DR. HOLMBERG: Let's put it right here. Would that be okay? Say it again?

DR. BRACEY: The Task Group will produce an analysis -- and what is it? Operational proposal?

DR. EPSTEIN: Yes. I like the term, "operational proposal."

MS. LIPTON: I would just be careful about saying operational proposal. That sounds like they're putting together the system, and I think what we would like to do -- if we're going to try to design a system, we're going to try to do it together.

It sounds like you said, you do the analysis and the operations. So, if we can construct

our Task Force, you do it independently, but altogether --

DR. EPSTEIN: I'd be okay with that. We would say that the Task Group should produce an analysis an operational proposal, concurrently. The PHS Task Group --

DR. HOLMBERG: I'm sorry, I didn't hear you.

DR. BRACEY: Should produce an analysis and operational proposal.

DR. EPSTEIN: Concurrently with -- just strike that. It's all there. Just strike that down to "concurrently."

MS. LIPTON: Then you just need to address efforts to include, and then you have the definitions that follow.

DR. BRACEY: So, we have a gap analysis regarding the effectiveness of the current system, the need for mandatory versus non-mandatory and regulatory versus non-regulatory reporting, the scope of reporting with regard to product problems, medical errors and clinical adverse events, including

recognized and novel events, database centralization versus data sharing; database governance, ownership, and accessibility; format and standards for data reporting, including confidentiality; funding mechanisms for a sustainable system, and design and feasibility of suitable pilot programs to determine the characteristics of a value-added system.

That's got the elements. That's a lot of work.

MS. LIPTON: What I like about this, is that there are certain pieces that can be done together, and other pieces that can be done independently, but everybody coordinates.

DR. BRACEY: So we would strike, then, the remainder, all that follows, because it really doesn't add anything.

DR. BOWMAN: Can I ask a question of some of the long-term members of the Committee? Have they, in the past, ever recommended the specific task group that the Secretary appoint, or have they just recommended certain objectives, and let the Secretary determine the best way to achieve those?

DR. BRACEY: Good question. I do not know that answer.

MS. LIPTON: I don't remember, but I'm sure Dr. Holmberg could go back and see.

DR. BRACEY: Is that a problem?

MS. LIPTON: I think the important thing, is that it should have interagency -- all the agencies should be involved.

DR. BOWMAN: The only reason I bring this up, is, there's already an excellent task group or task force out there. They're interorganizational, and the Committee is really trying to achieve those objectives.

The Secretary may find a number of different ways to actually achieve those, maybe even a closer relationship with the existing AABB Task Force, and, also, internally, within the Department, and not necessarily to create a formal task force.

We just say that we recommend that the Secretary consider or something.

DR. BRACEY: Actually, the bullets came from government representatives, suggesting that they

really need to look at issue of ownership. I don't know.

DR. BOWMAN: I don't disagree with the bullets. It's the specific recommendation that the Secretary appoint a task group, per se.

DR. HOLMBERG: Excuse me. The thing is that this is a recommendation, and really, internally, we'll decide how it gets done. I think we just leave it at that.

DR. BRACEY: Dr. Epstein?

DR. EPSTEIN: First of all, I agree with Jerry; we'll determine, in the end, whether that's what will happen, but there is a value in integrating a task group, which is that it will ensure interagency coordination, which is not automatic.

DR. BRACEY: Okay, do you want to take it from the top?

DR. HOLMBERG: Sure.

DR. BRACEY: The pieces that were deleted, which you hadn't seen, was a draft of the same elements. They were the same; they were duplications.

DR. HOLMBERG: Do you want me to read it?

DR. BRACEY: How about the Executive Secretary reading it?

(Laughter.)

DR. HOLMBERG: Whereas, promoting the safety of the U.S. blood supply is a principal activity of the Advisory Committee on Blood Safety and Availability, and inclusion of efforts to improve organ and other tissue safety and availability also need to be considered, we recommend that the Secretary coordinate federal actions and programs to support and facilitate biovigilance in partnership with initiatives in the private sector.

Biovigilance is defined as a comprehensive and integrated national safety program to collect, analyze, and report on the outcomes of collection and transfusion and/or transplantation of blood components and derivatives, cells, tissues, and organs.

The program should be outcome-driven, with the objectives of providing early warning systems of safety issues, exchanging of information, and

promoting education and the application of evidence for practice improvement.

Formation of a PHS Biovigilance Task Group, including the Assistant Secretary and representatives of PHS agencies, would be an important initial first step for identification of the vision, goals, and processes needed to advance these objectives.

This Task Group is needed to participate with private-sector efforts, including the AABB Interorganizational Task Force on Biovigilance, to advance public health in this effort.

The PHS Task Group should produce an analysis and operational proposal, concurrently with the AABB Interorganizational Task Force on Biovigilance and other private-sector efforts, to include a gap analysis regarding the effectiveness of the current system, the need for mandatory versus non-mandatory and regulatory versus non-regulatory reporting, the scope of reporting with regard to product problems, medical errors, and clinical adverse events, including recognized and novel

events; database centralization versus data sharing, database governance, ownership, and accessibility, format and standards for data reporting, including confidentiality; funding mechanisms for a sustainable system, and design and feasibility of suitable pilot programs to determine the characteristics of a value-added system.

DR. BRACEY: Dr. Epstein?

DR. EPSTEIN: Could I make a couple small suggestions? Back up where we talk about exchange of information, that ought be exchange of safety information.

DR. BRACEY: Where is that?

DR. EPSTEIN: Higher up. The safety issues -- it's exchanging of safety information. Then, do we really want to say that the Assistant Secretary, personally, should be a member of the Task Group?

DR. BRACEY: I thought -- I mean, it's a noble concept.

DR. EPSTEIN: A noble idea, but a little bit awkward.

DR. BRACEY: That's a good point.

DR. KUEHNERT: To reflect some representative from his office, and because we say representatives of PHS agencies, does that automatically mean that the Secretary's Office is included?

DR. EPSTEIN: I say the formation of an HHS and PHS interagency Biovigilance Task Group. Who else is on there? HHS and PHS Task Group, then strike the Assistant Secretary.

The third thing: I would say this Task Group, instead of, is needed, say, this Task Group should participate.

DR. BRACEY: Wait a minute.

(Pause.)

MS. LIPTON: Do you really want to say an initial first step?

DR. HOLMBERG: No.

(Pause.)

DR. EPSTEIN: I'm not sure it's a first step, anyway. I think we've been engaged -- would be a useful step.

DR. HOLMBERG: How about just an important step?

DR. BRACEY: That's good.

MR. MATYAS: One of the items that I was thinking through, that was presented over the last two days, is international efforts in monitoring. There seems to be quite a bit done overseas, and while it needs to be incorporated, I think, in some way.

DR. BRACEY: That's a good point. Really, integration with international efforts in standardizing definitions.

MR. MATYAS: Right.

MS. LIPTON: What I think came out of our group, initially, is, be careful that our standards reflect our transfusion practices. I don't know that I would adopt all the definitions.

Maybe that comes out of the gap analysis. Part of the gap analysis is really looking at other systems to see what they have to be done.

DR. EPSTEIN: Go to the bulleted items, Coordination or Cooperation with International --

MR. MATYAS: As Karen was saying, in the gap analysis, it's two different issues: One, seeing how we compare, and then another is to be involved in.

DR. BRACEY: I think it's a separate bullet.

DR. HOLMBERG: I don't know whether we want to put that in here right now. I'm thinking, let that fall out in the gap analysis.

MS. LIPTON: The only reason for looking at this, is that we've seen everyone else do it. I would just be very reluctant to adopt or not adopt anybody else's. I think we have to figure out what works for us.

There's a lot of information out there that shows what works and doesn't work.

DR. EPSTEIN: How about potential for coordination with international systems?

DR. BRACEY: I think it would be important to go through that process. There's a large universe of information.

DR. EPSTEIN: It says format and standards

for data reporting, including confidentiality. I would make the next bullet, potential for coordination with international safety reporting.

You should add non-U.S. safety reporting systems, potential for coordination with non-U.S. safety reporting systems.

(Pause.)

DR. BOWMAN: A small technical thing on the first bullet: It says effectiveness of the current system regarding gap analysis. I'm not sure if we have a current system. We have more than one current system.

DR. BRACEY: There is a system and we're saying that it's fragmented, so that the notion is to analyze. There's a question as to whether or not it may be --

MS. LIPTON: Just accept that it really is a system.

(Laughter.)

DR. HOLMBERG: How about current activities?

DR. BRACEY: All right. Do you want to

say current safety reporting activities? Well, just activities is fine. Okay.

MR. MATYAS: I'm going back to the working group discussion with you and trying to ask those people, have we captured all of the major concepts or otherwise missed something? Have we done it purposefully or not?

MS. LIPTON: I actually thought the Biovigilance Working Group came up with some recommendations that captured the category, but not necessarily this.

DR. BRACEY: I see this as really achieving the task, which is to charge the Secretary with moving forward. We won't have a final product, but momentum.

Are we ready to consider the final version? One more read-through? You don't need it.

Don't need it? Okay, let's take a vote, then. Could I have a motion?

MR. MATYAS: So moved.

MS. LIPTON: Second.

DR. BRACEY: All in favor of sending the

current recommendation to the Secretary?

(Show of hands.)

DR. HOLMBERG: Mr. Chairman, it's nine for, and I don't see any opposed, however, our quorum is ten.

DR. BRACEY: So the Chairman will vote.

DR. HOLMBERG: You were the ninth.

MR. WALSH: Mr. Chairman, I don't know what the parliamentarian would say. I tracked Bill Duffell down. He was the tenth, he was on the way out on the Metro ramp. I asked if he'd come back for the vote, and he said,no, just vote yes.

If we can get that by e-mail from him to confirm that he said that, is that an acceptable vote?

DR. HOLMBERG: I will take that up with our FACA representative.

DR. BRACEY: I think we can get a proxy on that, and if we do have a proxy, then we'll have a quorum.

DR. HOLMBERG: If not, this still could be addressed in a letter from you, and it could read, to

the Secretary, and it could be reintroduced again very quickly at the next meeting.

Dr. Agwunobi can take action on it before the recommendation comes in on it officially. There's always the possibility of doing that, but I will check.

DR. BRACEY: You can check and see if you can do that.

Other business?

(No response.)

DR. BRACEY: Thank you. This is an important step forward, and we hope to seize, again, the moment.

(Whereupon, at 3:55 p.m., the meeting was adjourned.)