DEPARTMENT OF HEALTH AND HUMAN SERVICES

BLOOD SAFETY AND AVAILABILITY

ADVISORY COMMITTEE

Twenty-Ninth Meeting

Wednesday, May 10, 2006

1:10 p.m.

Marriott Crystal Gateway
1700 Jefferson Davis Highway
Arlington, VA 22202

C O N T E N T S

P R O C E E D I N G S

DR. HOLMBERG: I think we may be losing people and people getting back from lunch, but we do need to get moving on our meeting today.

I am going to call the meeting to order, well, Dr. Bracey, you will call the meeting to order.

DR. BRACEY: We will call the meeting to order.

Our plan for today will be to review the discussion and the recommendations of the work groups that met yesterday afternoon and this morning, but before we do that, I would like to say a little bit about the work plan.

What I would intend to do would be to have after the work groups present their reports, we would form a subcommittee, and the subcommittee will work with staff to develop a final--well, not a final--but a draft, a richer draft of the strategic plan that will be brought back to the committee at our August meeting.

I would, at this time, ask for folks that

would be interested in serving on the subcommittee to please say so, which committee members.

Roll Call

We will proceed with the roll call.

DR. HOLMBERG: Dr. Bracey.

DR. BRACEY: Present.

DR. HOLMBERG: Dr. Angelbeck.

DR. ANGELBECK: Present.

DR. HOLMBERG: Ms. Birkofer.

MS. BIRKOFER: Present.

DR. HOLMBERG: Dr. Bloche.

DR. BLOCHE: Present.

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 is absent.

Ms. Pahuja.

MS. PAHUJA: Present.

DR. HOLMBERG: Dr. Pierce had to leave

already. He was here this morning.

Dr. Ramsey.

DR. RAMSEY: Here.

DR. HOLMBERG: Dr. Roseff.

DR. ROSEFF: Here.

DR. HOLMBERG: Dr. Sandler is absent. Dr. Sayers is absent.

Ms. Thomas.

MS. THOMAS: Here.

DR. HOLMBERG: Mr. Walsh.

MR. WALSH: Present.

DR. HOLMBERG: Dr. Wong.

DR. WONG: Present.

DR. HOLMBERG: Dr. Kuehnert.

DR. KUEHNERT. Here.

DR. HOLMBERG: Dr. Bowman is excused with activities up at CMS.

Commander Libby.

CDR LIBBY: Here.

DR. HOLMBERG: Dr. Epstein.

DR. EPSTEIN: Here.

DR. HOLMBERG: Dr. Klein.

DR. KLEIN: Here.

DR. HOLMBERG: Thank you.

DR. BRACEY: We have a number of reports and the targeted time for the reports will be 10 minutes, obviously, with some discussion to follow.

The first report is from the Policy Work Group, which was chaired or led by David Matyas. David.

Working Group Reports

Policy

MR. MATYAS: For the record, I will say the notion of creating a strategic plan to change policy and decision-making in three hours was somewhat of a undaunting task, but, well, see, it's so undaunting we don't have it here.

We came up with a few recommendations. As a preliminary cut, the first one is adopting a set of principles that define a federal strategic policy for blood and blood products that is relevant to the 21st century.

By way of example, it was brought to our attention that the World Health Organization has

suggested the following principles to be guiding us, which would be needs an outcome orientation to prioritize blood safety and availability within the health system and clearly identify desired outcomes and goals based on an assessment of the national need for blood and blood products.

The second principle would be transparency. Clear and open policy processes help ensure the legitimacy and effectiveness of blood policy.

Third, evidence-based health outcomes are maximized if decision-making is based on robust evidence.

Fourth is efficiency, ensure limited human and financial resources are being used prudently and to maximize the health impacts.

Fifth. Participation and partnership. Involve relevant stakeholders in the policy process to ensure legitimacy and effectiveness.

Communication is the last one that was presented to us that we throw on here, which is proactive communication ensures public awareness of

the needs, benefits, and risks.

While some of those may be seem like very high-level ideas and principles, I analogize it to there being a mission statement for an organization or a charter for a committee or the like, which is what is the set of principles that will guide us, and we figured that this was a good starting point for some discussion on developing it as one set.

The second issue that we raised was using the principles that are outlined above to evaluate and benchmark the system for purposes of conducting an initial gap analysis of the current system, and then performing ongoing reviews of progress and setbacks in the policy and decision-making processes.

In this process, it would propose that there be various scenarios developed that test the weaknesses and strengths of the current system, as well as any future changes in systems.

So, part of our discussion was the issue, as opposed to talking in the abstract, let's work through some of the emergent situations, things

that come up, and see how well or deficient we are in addressing and having those principles guide us.

The third recommendation is the Secretary of the Department of Health and Human Services demonstrating a commitment to the principles, so the notion of this being a top-down approach to adhering to these types of principles in our strategy.

The fourth, holding the Department and its multiple agencies accountable for following and achieving improvement in the principles by ensuring--and we had three subcategories under here--that the appropriate decision-makers are not only empowered, but that they are also involved.

The example that seemed to be coming up is that while there is sufficient structure within HHS with the various agencies, and that various agencies have purview over blood and blood products, when they are meeting with each other, the appropriate decision-makers don't seem to be involved, and therefore there seems to be a stalemate in actually effectuating any decisions.

So, the second one is coordinated activities among DHHS and the various agencies, and the last, sustainable support for outcomes research and development of evidence-based guidelines.

So, in our task, which again was recommendations for a structured process for policy and decision-making, those were what we started with.

What did I miss, group?

DR. BRACEY: We will open it up for questions now.

May I ask a question? That is, so obviously, there would be test scenarios that would be visited, but when this process is accepted or laid out, this would be then used as a--after we make our decisions, we would use this to evaluate what was done in future decisions?

MR. MATYAS: Yes.

DR. BRACEY: So, there would be sort of continuous improvement as a concept.

MR. MATYAS: Yes, as part of our concept, the notion in No. 2, which is there seemed to be

consensus that right now some type of gap analysis needed to be done of the current system to see where there are breakdowns and what we are doing right, but then also having as part of this decision-making process that it continue to evolve, because the need to continuously address these issues is ongoing and that we continue to test it.

DR. BRACEY: Thank you.

Dr. Epstein.

DR. EPSTEIN: David, if I could just embellish a little bit. Part of the idea here was that once you adopt and commit to a set of principles, we could also look at our current decisional mechanisms and ask sort of like a report card, how are we really doing, you know, do we rate well in evidence based, do we rate well in transparency.

That would then inform any future changes we might want to make in structure or practice or priority.

DR. BRACEY: Thank you.

Additional questions or comments? Ms.

Birkofer.

MS. BIRKOFER: Thank you. Is the intent of all of these principles or recommendations here only to impact the plan, the strategic plan, or is this guidance for how we make decisions and policies for all of the activities of the advisory committee, or is this only specific to the plan?

MR. MATYAS: No, this isn't specific to the plan, and it is not specific to the advisory committee. It would be to really HHS in guiding it through, making sure that its decisions are being made, FDA, CMS, NIH, and the like, that these are the principles guiding that process.

MS. BIRKOFER: I guess what I am missing is the input from the consumer and the patient organizations, where is the impact on patient access or assuring access in terms of availability, where is the viewpoint from the consumer in this? I guess that is what I am missing.

MS. PAHUJA: Can I say something? I think in terms of talking about actual outcome research and a commitment to looking at how a decision

affected whatever issue we are looking at, is sort of looking at whether the consumer has access, whether that decision changed somehow access to that product, and so on, and so forth.

I mean I think that is why we made sure that we talked about outcome, how important looking at outcome and evidence for outcome research and the commitment to that.

MR. MATYAS: But it is also, in terms of the process, it is in there in the fifth principle, participation and partnership, which is to involve the relevant stakeholders. That is not just the relevant stakeholders within HHS; that is the stakeholders relevant to blood and blood products.

The decision-making process, though, is made by DHHS, so these are the principles to guide it as an agency, but involving the relevant stakeholders as part of what we call America.

DR. BRACEY: Additional questions or comments?

[No response.]

DR. BRACEY: Thank you.

MR. MATYAS: Great.

DR. BRACEY: The next presentation will be by Dr. Matt Kuehnert. He is reporting from the Working Group on Bio-vigilance.

Bio-vigilance

DR. KUEHNERT: We had a little bit of a different format to the discussion, but I think you will see some recurring themes here.

First of all, just to go back to what we were charged with, there were two main focus elements for the strategic plan under the heading of Transform the Healthcare System: one, to look at ways to accomplish surveillance of adverse events related to blood donations and transfusions; secondly, error prevention in blood collection centers, transfusion services, and clinical transfusion settings.

So, faced with that, we first started to look at what we were talking about, so what is bio-vigilance, so broke down the word into "bio" and what was meant by that, and we took it to mean a comprehensive interpretation of biologic

products, so including blood, plasma derivatives, also immunoglobulins, albumen, and that entire line of what may be defined as not only biological products, but also perhaps drugs that have biologic components, and then organs and other tissues.

Also, we wanted to include potentially xenotransplants, genes, recombinant products, parts of devices, drugs, and vaccines, as is appropriate, and synthetics. So, it is a pretty wide category that we may want to be thinking about.

The second part of the word "vigilance," there were numerous facets for discussion, and included looking at donor surveillance concerning donor results that occur in the process of deferral in laboratory testing, concerning recipient surveillance focusing on adverse events.

Emerging infectious disease monitoring was another category which we looked at, which I will define in a second, but was a distinctly different category because of the challenges of detecting EIDs.

Also, included would be product quality

assurance, and then finally, that there needed to be a focus on availability and use assessment.

Concerning adverse event system parameters, we wanted to look at again a broad spectrum of adverse events, infectious versus non-infectious, severity, characterizing the event including what the root cause was and also what the threshold for intervention would be.

In discussing this, it seemed reasonable, at least for part of such a system, to focus on outcomes, because there, you are including the whole spectrum without having to worry about what it was caused by, but also, in looking at our two charges, to also include errors, which may not result in an adverse event or poor outcome, but is in a way an adverse event in and of itself.

Then, we also went through and just looked at the various stages of biologic product distribution and use starting with donation and collection, going to processing, going to banking and/or storage, going to the transfusion or transplant setting where use occurs, and then

finally, where it resides in the recipient for the length of the product life, and that there are multiple steps where bio-vigilance would have relevance.

So, we reviewed the current systems and the gaps, and basically concluded that blood, organs, and tissues all have systems for adverse event reporting, but most of these are passive and there are multiple pathways oftentimes to reach the same place.

Blood, for instance, has a regulatory pathway that extends into the hospital, into the blood bank, but it doesn't ensure participation of the clinician or recipient, so you may not have the reaction ever get reported, for instance, if it never gets to the blood bank, so there is a gap there as one example.

Also, in looking at outcome reporting, if that is really what we are interested in, the only system that came to mind for outcome reporting in a cohort fashion, as a denominator, was for organs, and tissue regulations in reporting can really only

be enforced from a regulatory standpoint to the hospital door, so there are some differences in both reporting and also regulatory oversight in regard to these different biologic products.

So, in looking at surveillance, we discussed what would really be needed, and there are two models that would need to be implemented to cover this. One is a comprehensive reporting model for common, well-defined events and outcomes, which would require an active surveillance approach.

Because a national approach to this would probably be extremely labor intensive and resource intensive, perhaps a selected site methodology would be reasonable to start with.

Second would be the Sentinel model for uncommon, unusual events and outcomes, which would utilize a passive surveillance approach, and this could utilize a uniform national methodology using existing reporting, which would then be enhanced in some way.

For either model, you would need to determine what would be the intervention threshold

and what the action should be, and perhaps there is also some synergy with preparedness and securing the homeland concerning reporting of uncommon events that were thought to be significant in terms of disasters or intentional introduction of, say, biologic agents.

So, the third model, I guess I would call the "third rail," because it was really difficult to quantitate, but with EIDs, it poses a unique problem. What we are talking about here are emerging infectious diseases whereupon you can't detect them in donors, there is no recipient adverse outcomes, so how do you even get a handle on these.

So, what we thought was that what was needed was a hypothesis algorithm based on potential risk, so if you have an agent that is transmissible between humans, you have an asymptomatic blood-borne state, then, that would trigger a concern that this might present a problem to the blood supply.

Whether then this hypothesis could be

tested using repositories would be an important question, but that the repository should reflect current donors, because if this is a new problem, obviously, older repositories might not be useful. We thought this would be a good synergy point with the research agenda group.

For any of this, particularly the surveillance portion, participation by healthcare and recipients are absolutely critical, and that is the point we thought was the largest gap.

One point we thought would be helpful would be to have central reporting of biologic product adverse events, errors and outcomes, depending on the setting, so, for instance, in the hospital, perhaps the blood bank might be the best place.

We talked about other settings, for instance, for plasma, where there are systems already set up for surveillance, for instance, universal data collection system for the hemophilia population, and also incentives to ensure compliance, what could those be, accreditation,

reimbursement, but that really, the most important incentive was to make it simple, make it simple for the end user to be able to report and then educate them on that simple process, and for institutions, perhaps tying reimbursement to quality performance parameters might be an incentive. So, this is something that perhaps could be synergy with the Reimbursement Group to discuss.

Concerning error prevention, the thought was it should be integrated into bio-vigilance, errors need to be defined. Talked about manufacturing versus bedside errors, these may result in an adverse recipient outcome, but may not, but still they should be tracked.

Error investigation should not be punitive, but it needs to result in an intervention, and it is essentially, this is the efferent or feedback arm of bio-vigilance, so how this is handled needs to be discussed with a number of groups, as well.

One example of an intervention we discussed would be comprehensive tracking for all

biologic products, which the tracking would need to involve available data on source, processing, release criteria, and the end user.

So, this is just one example of an intervention, which would then serve multiple purposes, would prevent errors, would improve product quality assurance, and would enhance bio-vigilance, so we have to think about interventions that would enhance this on multiple fronts.

We also talked about availability and use surveillance as being very important. If you don't have a denominator, surveillance is of limited usefulness, so need a system to track the products that are transfused and transplanted, but also products that are requested, but not received, and may result in secondary consequences, such as canceled surgeries.

An intervention portfolio, a group of interventions is needed to respond to inequities and to increase product availability, for instance, in response to unmet needs, to say increased

donation or even explore other sources.

Concerning just use, we found that the OPTN might be viewed as a model for organs, also, basis and rare blood registries are relevant to blood and could be also looked at as a starting point.

Finally, we discussed the numerous partners that would be essential to embark on such an initiative like this, and in addition to Federal Government partners, need to interact with State Government, with industry, trade organizations, patient advocacy and consumer organizations, accrediting organizations, healthcare organizations, clinical organizations, also IT companies, because we are talking about connecting a lot of these surveillance methods together, and even the media and the community.

So, in summary, we looked at and decided that the following bio-vigilance and elements were critical including error prevention in this, donor surveillance, recipient surveillance with an outcome focus, EID monitoring as defined, as apart

from these previous two modes of surveillance, product quality assurance integrated method, comprehensive tracking and adverse event error reporting from the source all the way to the recipient, and surveillance and assessment availability and use.

Finally, a collaborative partner involvement in education is essential, and what would be useful would be to look at all the systems and take best practices to develop a hybrid approach.

Just my own suggestions in reflecting on the discussions of the group. Looking at the strategic plan and the Secretary's principles, which are already on paper, would be to think about how this fits in with health information technology standards concerning adverse incident reporting, e-prescribing or e-use tracking, and data exchange.

Also, mentioned in the Secretary's principles are safety board for monitoring response. What is there now is for drugs, what is relevant for biologic product adverse events, and

also, you know, we really need to think about compatibility for biologic products, but also we need to think about drug and vaccine monitoring, because hospitals are going to be basically overwhelmed by all these requests for monitoring, so if they all can be in the same system, that would make it easier for hospitals to actually implement it.

Finally, my opinion is now is the time to do this. In other countries, hemo-vigilance is way down the road, but it may not be that far down the road for organs and tissues, so we are sort of starting fresh, and it is a way for us to work on this all at the same time, and be perhaps the only ones to have an integrated system.

I think that is maybe the only advantage we have, but certainly I think we need to take from what has already been done and look at the advantages and disadvantages.

So, that is basically the summary of our discussion.

DR. BRACEY: Thank you.

I have one question. That is, in terms of the plasma derivatives, you know, often they are treated as pharmaceuticals, and I may have missed this, but what was your strategy for surveillance of those agents?

DR. KUEHNERT: I think we wanted to be inclusive with it. I mean I think each product has its own unique characteristics. For instance, if you look at tissue, I mean it really is a spectrum. I mean there is some tissue that is essentially sterile, it has been irradiated to the point where no organisms could survive.

On the other hand, you have other tissues which are far from sterile, they can't be sterilized, so I think we need to be flexible. The system needs to be flexible, but I think we wanted to include it, and if some are classified as drugs, and others, that is why I think it is very important to integrate with drugs and vaccines, because it is going to end up being a spectrum really.

DR. BRACEY: Any other questions? Dr.

Klein.

DR. KLEIN: This gives me an opportunity to talk about this from a research standpoint. I think everybody agrees, at least most everybody, that the U.S. is disturbingly deficient in the area that most developed countries now call hemo-vigilance, and that you have you have referred to as bio-vigilance, Matt.

But we thought that there was probably a research approach to this and that the issues were two, the second issue being analysis of the data. We collect a lot of data today, but nobody knows what they mean. They are not even analyzed.

So, that would be a research issue, but the first issue might be not to either adopt one of the systems that the Europeans or others have, or even to try to hybridize them, but to recognize the fact that we are an enormous country, 3,000 miles across, 300 million people, and a system that works in the Netherlands may not work in the U.S.

So, we thought that a research proposal, giving the criteria that we would really like to

have, emerging infections, current adverse events, and allow experts in survey science, epidemiology, to propose models that might be unique based on perhaps new technology, web-based technology or others, so that we could really have an opportunity to let the best minds develop a system that might benefit the U.S.

DR. KUEHNERT: I think that is a great suggestion. We went a step further with bio-vigilance in saying not only should it encompass analysis, but also intervention.

So, you are right, if you just have data and no one looks as it, but also people look at it, but then nothing is done with it, you really don't have a system, so I think looking at it from that approach should be critical.

DR. KLEIN: We all agreed with you that the time is now.

DR. BRACEY: Ms. Lipton.

MS. LIPTON: Yes, Matt, I just had a couple questions and then one comment. Did you consider--you have errors up there, but not

accidents and near misses--did you deliberately exclude that from the discussion?

DR. KUEHNERT: No. Maybe someone else from the group could comment on how we fit that in. I think we were sort of including that under errors.

MS. LIPTON: So, the definition would just include that.

DR. KUEHNERT: Uh-huh.

MS. LIPTON: The second thing, I really would encourage. I had the opportunity to work on a consulting group. ARCO was looking at this issue in terms of reporting, and I think we really have to emphasize that there is so much that is required of hospitals now, that if there is any way to think about this as being a database that things can go into and then get reported out where they need to get reported out, I think that is a model to look at.

I know that they have a lot of information from this task force that was very inclusive in terms of the people who were at the table, and I

think there is a lot of data and information that would be useful to us as we move forward into this area, because it is very complex.

I think the biggest issue in terms of reporting is understanding at the hospital level who is responsible for entering in that and do they have the right staffing and do they have the access to, if you are going to talk about web-based, do they really have access to the Internet to do that, and it is really kind of where the rubber meets the road in the hospital where this system is either going to work or fail.

DR. KUEHNERT: Absolutely. I mean, you know, avoiding wheel invention would be really a major priority, but hospitals have been through this before with hospital infections, and this is where we were 30 years ago with hospital infections.

Some hospitals had infection control practitioners, but not everybody did, and they were convinced that they needed to have an infection control department that did exactly this sort of

thing in parallel, and that was all developed in a reporting system.

A voluntary reporting system was developed for healthcare infections, and the intervention was the feedback back to the hospitals on how they could improve healthcare. That is the kind of model I think would be well suited here also.

DR. BRACEY: Other questions?

[No response.]

Donor Recruitment

DR. BRACEY: Thank you.

I will give the next report from the Donor Recruitment and Retention Group.

I sat in for Dr. Sayers. The topic that we addressed were issues with donor recruitment and donor retention, and the process that we used again was a gap analysis, and then the surveillance of current environment.

What we came up with after a rather extended period of discussion were several points. One of the first points I think that has been addressed previously in forums was the notion of

exploring the possibility of establishing a National Donor Deferral Registry that would include deferrals for high-risk behavior.

The intent there would be to use that as a tool and then to measure ultimately, its efficacy in terms of enhancing the safety of blood transfusion.

We also felt that considering the changing demographic across this nation, that it was very important to develop a plan to expand the efforts to recruit minority blood donations and hopefully, that would improve our current status from that group, which often is underrepresented.

As a third item, we are aware that there are data from the Westat organization that is beginning to evaluate, or that will be available, that evaluates, in essence, the motivation or the core values based on data as to why people show up to donate blood and what the actual barriers are, and we would plan to use those date to hopefully improve the current yield in terms of donors.

Under No. 4, we discussed some of the

problems that we consider with regard to possibly invalid reasons for excluding certain donors, so we thought that it would be very important to have a process wherein there is a periodic review of donor exclusion criteria, and specific sub-bullets under that particular area included this reassessment of deferrals for hemoglobin and the very difficult problem of iron management, if you will, of blood donors.

We also thought it was important, again as a sub-bullet, to explore particular subgroups that may be particularly useful, i.e., some patients with hemoglobinopathies that, in fact, are sporadically debarred from donating. These would be relatives of patients with hemoglobinopathies, and perhaps some of these have unique RBC phenotypes that would be quite helpful.

Under No. 5, there really seems to be much sort of secretive approach towards donor recruitment. There is some sharing, but it appears that there really hasn't been a concerted effort to identify and disseminate the best practices for

donor recruitment and retention, and we would incorporate newly developed IT methods, such as web-based methods, as well as things such as text messaging.

No. 6 actually came up in the discussion of the Research Work Group, and that is the notion really that the donor center can potentially serve, not only as a place merely to gain for the community in terms of collecting blood, but we also would envision the donor center as a possible community health resource, and would suggest that we would investigate through that particular effort the linkage of blood donation and possibly an improved quality of life through health promotion, which served as one of the bullets in the Secretary's strategic plan.

We really thought it was also important to establish strategies to minimize adverse donor outcomes. We know that there are particular sets of donors that are prone to adverse outcomes, and there are steps that one can take to avoid these, and we thought it would be good to establish those

and promulgate those strategies.

The blood recruitment activity is often seen as an outsider going out to a group of willing individuals pressing the need for blood, and we thought it may be more effective to have a community-based health educator to serve as an educator educating constituents on the importance of blood donation and emphasizing what we think is probably an underappreciated importance of blood donation in maintaining the nation's healthcare system.

So, again, the move here would be away from sort of an external approach rather than a grass-roots approach towards education and trying to improve participation through a grass-roots organization.

Now, we talked a little bit about faith-based efforts and we did not include that within our discussion, but we did note that there is indeed potential, and this is something that we did note within the Secretary's plan and possibly could be something that would be considered as a

useful intervention.

In terms of IT, kind of along the lines of what has been discussed in other groups, now is the time to embrace the existing technology or at least look at technology that can be realized, and that is, to try to link our need, that is, the need to collect blood, to utilization data.

We thought again taking off the visors, not really dealing with what we have today, but what we would like to have in the future. That is the notion that there will be real-time utilization data that could be used to predict future needs or to rapidly assess the current status of our blood utilization requirements.

Now, obviously, our donor centers--and we talked about this a bit in the Research Group--our donor centers are really currently structured to have advanced planning, and this will require some restructuring of the approaches that are used within the world of blood collection, but again this is sort of a blinders off, sort of a "what if" vision using IT to its ultimate.

This Item No. 10 also came up in the Research Group. Again, part of the problem that we see is that we have a restriction in terms of the availability of blood components by specific groups, an imbalance, if you will.

So, we thought it would be important to promote research that would make blood components interchangeable for use by all, and methods that could be used to achieve these end goals would be things, such as antigen removal or antigen blockade.

One could look at ex vivo/in vitro culture methodologies, again with the principle being that rather than having a restrictive availability or a limited availability of blood for a given set of patients, we would try to have components that would be more widely useful.

Under No. 12, we felt that really the understanding of the need for donation begins early and that we are missing the boat by having really underpowered educational programs starting at an early level.

So, we thought it would be important to establish mandatory blood donation education at an early phase in one's education.

Then, we thought that under No. 13, that we clearly need to make sure that the automated systems that are currently in existence are optimal, covering the full extent from the interface of the donor all the way to the time of blood release to eliminate errors during product management.

This has also been covered in the Research Group, but again making sure that the systems that we have, in fact, are effective and as safe as possible, so that we can eliminate issues of concern related to product management errors, or at least make them extremely unlikely.

Under No. 14, we have not, I think, successfully used either willing repeat donors or in all cases select transfusion recipients as ambassadors for blood donation. Beyond that, we could see these people as really becoming advocates for health promotion fitting in with the plan of

the Secretary in terms of health promotion, and this would be something that we could accomplish, not necessarily by face-to-face interaction, but using electronic systems to maximize efficiency.

Under No. 15, we would propose that we would participate with the private sector and other agencies in design activation and analysis of disaster drills, but most importantly, to focus not only on shipment of existing blood population, but to make sure that the drill is effective in terms of seeking volunteer donors.

In fact, one point that we discussed is the notion of something like committed donor, i.e., a minuteman, if you will, who would volunteer to be available for a donation in the event of need during a time of disaster.

Lastly, we thought that we would convene the industry members to promote adoption and use of interoperable health information technology.

By that, what we mean is simply to make sure that our operating systems are as interoperable and interfaceable as possible,

because what we really need, as we see it, is this ability to exchange data in an electronic mode that would be ultimately most efficient, but what we need to do is to have groups convene that are involved in this process to make sure that we achieve that end goal.

That would be our last point and I will stop now to entertain any questions. Ms. Lipton.

MS. LIPTON: Just a couple of observations. First of all, there is a very good group called the ADRP, the American Donor Recruitment Professionals, and they do actually do a lot of sharing of best practices and donor recruitment.

Perhaps it is a resource that we could recommend to people to talk to. They have an annual meeting and they have a lot of materials that are put out. I think they actually have a very good program.

The other thing is that we did pursue this idea of working with the schools, and we went to work with the AABB, with the secondary school

principals, and one of the issues that we found was very difficult for the schools.

Number one, of course, the Feds don't control the curriculum in the schools, so getting anything that is a mandatory curriculum would mean going to every school district and trying to get that through.

The other thing we found, though, is that schools are so pressed these days by trying to get through their own curriculum, that they find it very difficult.

Even when we handed them a curriculum about blood donation, we had a lot of trouble getting it into the curriculum, and the most we could get is in some of the human development courses in the middle school and upper school, we were able to influence them in some way to mention it, but it is a very difficult thing to do just because schools are so pressed to get through the actual, you know, the real knowledge information that they have to pass.

The third thing is in the disaster drills,

we have talked a lot about recruitment, but I must say our model in disasters with the exception of pandemic flu really isn't built around trying to recruit for the immediate disaster, but rather one of shipping in from other places, and then doing recruitment to do what I call the "backfill," that is, that generally, in an emergency, it is the blood that is on the shelf that you have to use, and not really that which you go out and have to recruit from donors.

In pandemic flu, it's a little bit different because we expect that there are going to be multiple cities that are affected, and you could have the entire nation not able to donate, and that is why we are focusing there on trying to identify potentially platelet donors or maybe even repeat donors who can be immunized prior to the outbreak of flu, so that they are kind of what you might call dedicated donors or what you called minutemen donors.

But I think that most blood centers have found that it is much better in a disaster to have

the agreements ahead of time to ship in rather than to go out and try to immediately recruit donors to respond to that immediate disaster.

DR. BRACEY: Right. Actually, part of the thought was really more or less for backfill, sort of the catchup to make sure that there are folks that are committed.

The other notion really was that if you can get people to submit to donation for a sort of patriotic reason, it is more likely that that individual might also participate for other reasons. It gives you a point of contact, but that's well appreciated.

Ms. Birkofer.

MS. BIRKOFER: Thanks, Dr. Bracey.

Just a clarification. Was it the intent of the discussion group to focus only on blood donation?

DR. BRACEY: Well, again, this was a donation for all purposes, and this could be broadened. That is a good point. We were focusing primarily on blood donation, but really this could

be broadened to derivatives, as well.

MS. BIRKOFER: I would just like to clarify that source plasma donation at the collection facilities does include rigorous screening for healthy donors. They then are defined as qualified donors, and we feel it is very important to assure a continual supply of plasma that can be manufactured into the life-saving treatments in medicines.

In addition, there is for plasma donors a National Donor Deferral Registry, the NDDR, that is administered by Fifth Dimension, that has been in place--it's a model system--for years. So, I just wanted to point that out, that not only it is important in consideration of the homeland and safety to assure a steady supply of plasma for the manufacture of the life-saving treatments, but also the fact that the NDDR does exist for source plasma.

DR. BRACEY: Right. Again, there are within the world of whole blood the regional cooperatives, some more effective than others, but

we thought, you know, really, as you describe, the formation of the national registry is an important step.

There was a question from Dr. Epstein?

DR. EPSTEIN: More of a comment. You pointed out the issue to focus on donor motivation, and some of the experience in other countries is that peer relationships can be very highly reinforcing for donor motivation, and I have been struck by the fact that we don't have donor organizations in our country.

I am not sure what kind of role there is at the federal level, but I think that efforts that might foster peer organizations of donors could go a long way toward creating a sustainable donor base, and that that could be, and is in other countries, linked to the idea of promoting healthy lifestyles, because after all, what you want are safe donors, and safe donors are people who lead healthier lifestyles.

I just wonder if that thought should be captured.

DR. BRACEY: Actually, that was, in part, the intent when we talked about donors serving as ambassadors. It really is to begin to focus on the capability or the potential of donors to really serve as catalysts for the system.

In addition, we think that, as you mentioned, the promotion of a healthy lifestyle with the appropriate education and application of resources from the blood donor center, not only will make those donors more available for us, but we think could potentially serve as sort of an infectious activity.

You know, your husband explains to the wife, you know, these healthy lifestyles, so if 7 percent show up per year, and we know that as many as maybe half of people present for donation, this will be a way to potentially help improve the public health.

There was another question. Dr. Klein.

DR. KLEIN: Art, you mentioned several of the research opportunities. I thought if each speaker does that, I won't have to give my

presentation, but when talking about the donor center as a community health resource, one of the things that we certain approached in addition to the education and research in donor health activities, was the issue that if somewhere between 25 and 50 percent of healthy Americans come through a donor center in their lifetime, 5 percent per year, but a great deal overall, that this would be an outstanding resource for genomic testing for healthy lifestyle issues, a wonderful research resource, recognizing that there are legal issues involved in doing that, but in terms of research, this is something that shouldn't be overlooked.

DR. BRACEY: Thank you.

Dr. Holmberg.

DR. HOLMBERG: I just would like to follow up on Mr. Birkofer's comment. I think that the plasma industry has really moved and set a good example of healthy lifestyle and the dedicated donor or the pedigreed type donor, and I think that as we go down this path, I think that there is much that we can learn from both types of donor, whether

it be whole blood donor or plasma donor.

So, I would just encourage the committee to look at that as far as the National Donor Deferral Registry that the plasma community has, and then also the educational and the healthy lifestyle that they have done, the campaigns that they have done to really move beyond that stigma that they had years ago.

DR. BRACEY: Right. Again, this is something I think that is really central to the Secretary's plan, their examples of it in the plasma industry, and I think now is the time for the blood industry to catch on.

Additional questions? Otherwise, I will move to my next speaker, Dr. Roseff. She will talk on Transfusion Practice Standards.

Transfusion Practice

DR. ROSEFF: I am going to report on our discussion of the Work Group on Clinical Practice Standards for Transfusion, and we were lucky to be joined by the Donor Retention and Recruitment Group, so I want you to listen to them, too, as

participants.

When we started our discussion, we used the Secretary's 500-day plan, and I encourage you all to look at that plan again to see how we tried to incorporate our thoughts and our recommendations.

The first thing we discussed was the need for a national database, is there a need, and we commented no to that. Many different hospitals have computer systems that capture data constantly. Where this data goes sometimes no one knows. If it is captured, is it analyzed, is there someone to analyze it, and this is happening all over the country in many different spheres.

So, can we use this data and harness it in some way nationally? Can we centralize the data to be able to look at it across the country and make more comparisons and come to more conclusions? Can we then use this data in any way possible, how can we use this, what can we think of in terms of this data, bringing it together?

Then, finally, if we do decide we need to

do this, how can we make sure it's done? If it's voluntary, we probably won't be any better off than we are today where we will all be doing our things independently and still not coming to some central point.

Having said that, we did decide that there was a need for a national database, and the first thing would be to establish an incentive to foster the collection and monitoring of transfusion data.

We were very regulatorily of mind when we thought about this, so we thought if CMS required a database or some other accrediting agency said this is part of how we are going to accredit you and evaluate you, that would be a better way to have a hospital or any other agency that accredits require this in order to get accreditation.

The next step then would be to develop a plan. We wanted a prospective monitoring system of transfusion outcomes, again, as others have spoken about, so we can take this and then bring it back to the patient and the recipient of the product in order to be able to see if what we are doing really

does have measurable benefit, and we can use this plan, too, to answer critical clinical questions.

The important thing was again to decide what you want to get out of the database before you design the database, so we wanted to make sure that was a part of the process, and then finally, to then develop the national database to be able to answer our questions and come to these objectives.

Another interesting discussion that we had was when we think of a database, not to forget about special patients around the country who may have needs that aren't met when they go to different hospitals.

For instance, patients with sickle cell disease or certain antibodies, if they come into a different hospital in a different part of the country, we may miss the fact that they have had previously identified antibodies, and not give them the best product possible, and any patient who has special transfusion needs, we think would be ideal to be able to have that data available, so anywhere this patient goes, they can get the proper care.

Then, we tackled another question, which was sort of difficult, the development of national transfusion guidelines. We all decided that somehow this needs to be done.

The process, of course, is difficult and fraught with many problems, but one thought that we had was to develop these guidelines at a local level using literature, evidence-based where it exists, realizing that there is not a lot of evidence-based literature, and then again with expert consensus, and something that might be helpful in developing these guidelines nationally would be to have a good repository of data.

There are many physician and public access areas available where you can do a search, but to try to really find a specific piece of information from Pub Med or one of these other available databases is sometimes really hard even for the professional.

So, wouldn't it be great if we had some kind of location where the public can go, where physicians can go, and they can find this data,

especially important for doctors who are outside of transfusion medicine, who may not even realize some of this data exists, so again something easily accessible, a one-stop shopping kind of area for information.

Once we do develop these transfusion guidelines, they have to be promulgated. This includes the use of hemostatics. It includes plasma derivatives. Every product, there needs to be education again to the end user and to the patient, and we need to link this to local practice.

So, part of this aim would be to develop an educational program. Again, we got back to our regulatory focus, and that is, in order to really make sure this happens, is there a way to link accreditation to the establishment and conformance to guidelines that are locally generated.

We also discussed adverse events. As you have heard in one of the previous talks, we do also believe that it's important to develop a system to identify and track post-transfusion adverse events.

The current system, as we know, is voluntary and doesn't capture everything especially when we think of some of the non-infectious complications for transfusion, inflammatory reactions that occur, and immunomodulation.

The other thing that we thought was very important was the establishment of a blood safety officer, someone in a facility that transfuses to look at the effects of these products and make that their primary responsibility. This has been recommended by many agencies, but is not yet in practice in some facilities.

So, again, getting back to a way to enforce this, to require a blood safety officer in all CMS facilities, and that this blood safety officer needs to have defined roles and responsibilities, not just be a title that someone tacks onto someone in the hospitals filling the requirement, but someone whose job really is to monitor what happens with transfusion and the adverse events that may occur.

As a fifth point, and this was something

again we had the benefit of having a member of the FDA with us, the use of special technology that is in the Secretary's 500-day plan.

It can be a national collaboration to develop and certify information technology, to read all types of machine-readable information on blood components and drug labels, and we discussed this a little bit yesterday about some of the problems in trying to get everything to be able to read everything in a hospital between the pharmaceuticals and the blood products, and between different hospitals and different computer systems, but again the group thought that it was important to bring this to the table and maybe see if we can reconsider this as a way to get better data.

Something finally that we discussed during lunch, and it isn't on this presentation, but that I want to bring up, is the importance, too, of the reimbursement system. Currently, as we try to enhance the safety of blood products and we add new tests, we have new products, new technologies, reimbursement has not kept pace with the cost of

some of these innovations.

So, again, it would be important to try to find a way to link the cost with the payment methods.

I will take questions.

DR. BRACEY: Thank you.

Dr. Ramsey.

DR. RAMSEY: One of the things we mentioned today in our group, and we will come back to this, is that not all blood products are used in hospitals and not all are used under Medicare jurisdiction, so that is an issue for mechanisms which would use, you know, hospital-based or Medicare-based mechanisms, or accreditation, or regulations, et cetera, et cetera.

DR. ROSEFF: Right. I think that we used Medicaid and CMS, we were just talking about one group, but obviously, this needs to be disseminated to other kinds of agencies or accrediting facilities.

DR. BRACEY: One of the things that we did discuss in the group is the tremendous impact of

CMS initiatives on hospital practices in terms of the various points that they are looking at in the health checks, i.e., wound infection, DVTs, et cetera, et cetera.

The hospitals and their staff pay great attention to those, so we thought again it is not a complete, but it's a good inroad.

Ms. Lipton.

MS. LIPTON: I just wanted to mention one thing. At the AABB, we are going to start issuing transfusion guidelines, and this has been a subject that has been hotly debated, and for precisely the reason that you have articulated there, that just even trying to do a literature search of all of the studies that are out there has been very difficult, and, in fact, when we looked at the cost of this, the biggest part of the cost was going to be into the research.

So, I absolutely agree if there is any way to really try to bring all of the research together and the published studies, it would I think go a long way toward facilitating or just maybe

standardizing practice a little bit better.

The other issue is would you accept a friendly amendment, instead of a blood safety officer, a transfusion safety officer, because I think a lot of what we are going to be looking at doesn't just relate to the product, but hopefully, also, relates to administration issues also?

DR. ROSEFF: Absolutely. As far as defining transfusion guidelines, I think we all understood at the table yesterday that it is hard to get something nationally acceptable and nationally enforceable, but at least if we have the data to have local practice that we can follow, and then we can again assess how we are doing following that local practice, it will bring it into more standardization, not necessarily total standardization, but closer to what makes more sense, and that there is data to be able to rely upon.

DR. BRACEY: Additional questions or comments?

Thank you.

The next reporter will be Dr. Greg Bloche. He will report under a new topic Modernizing Medicare and Medicaid, and this is from the Reimbursement Work Group.

Modernizing Medicare and Medicaid

Reimbursement

DR. BLOCHE: We are a bit less polished. My lame excuse is we had our discussion this morning. Hold on just a moment because there is just a single short document.

Thanks a lot. The subject of the future of the Medicare and Medicaid program is, to put it mildly, bitterly controversial, and we don't know what directions this will go, and rather than to quote the great philosopher Yogi Berra, "Open all these boxes of Pandoras," what we tried to do is focus on some common themes that we hope will be a part of any future trajectory of Medicare and Medicaid.

We had spirited discussions and as a result, a short text. This is a rather incomplete list, I think, of possibilities, but these are some

themes, some suggestions that we felt should be part of any effort to keep the Medicare and Medicaid programs up to date.

I want to thank all the members of the working group for contributing. Julie was not at this meeting, but I gather she has some thoughts to add. It was recommended, and we did this, to try to fit this within the box of modernizing Medicare and Medicaid, hence, the preamble, and we recommend basically four rather short things.

First of all, the coverage decisions, where possible, should be national and should be based on empirical evidence.

Second, where empirical evidence supports coverage of a product or device or service, CMS should act quickly to issue a coverage law.

Third, the Secretary should have special authority to adjust reimbursement rates to prevent and to cope with breakdowns in the chain of distribution and administration of blood products and plasma derivatives when the breakdowns impair access.

I might add that there was lots of discussion as we developed No. 3, lots of discussion about how you create this special authority while, at the same time, preventing a long line of potential folks who love their reimbursement rates up, who might see an easier route towards getting the rates raised as a result.

Finally, to develop a comprehensive and effective program of post-approval, post-marketing surveillance and analysis of adverse events arising from the administration of blood products and derivatives.

Manufacturers should be required to comply with this program in order to continue to distribute their products.

Finally, based on the example of someone who went before, I decided to throw in my own hopefully uncontroversial recommendation. Finally, while the future of Medicare and Medicaid is a complex and controversial matter, and that future is going to be decided by the political process, but however these programs evolve, pay for

performance should be part of the picture.

They ought to be representative indicators of quality and clinical appropriateness. These should be developed and refined for provision of blood products and plasma derivatives, and payment ought to be linked to how well providers score on these measures.

A lot of this is controversial stuff, we know, and let's open things up to conversation. I know Julie had some concerns, and I certainly want to give you the opportunity.

DR. BRACEY: Ms. Birkofer.

MS. BIRKOFER: Thanks, Dr. Bracey. Thanks, Greg.

I guess my first concern is with No. 1, where you talk about the recommendation of a national coverage decision, and NCDs have an impact on patient access that I am not sure has been thoroughly evaluated and would be desirable and best serve the consumers that need to access life-saving treatments.

In particular, the local Medicare

carriers, and I believe there are approximately 23, 25 Medicare carriers, they all reimburse based on local practice patterns and local physician practices, and I think it's just troubling to me just without input and without further discussion or thought, I am just not comfortable recommending a national coverage approach. Again, I don't think that is in the best interests of patient access. That would be my first comment.

DR. BRACEY: Discussion on that comment? Dr. Holmberg.

DR. HOLMBERG: Ms. Birkofer, I just would like to ask your opinion on why do you not think it would be wise, because at the current situation, there are regional contractors and regional decisions, not based on the local level, but more on the regional level.

So, I guess I would like to understand why you would be opposed to a national coverage.

MS. BIRKOFER: I think currently, right now, Medicare pays for several--I know, for example, for plasma therapies, Medicare allows

patients to access and pays for and covers the usage of certain therapies to treat certain diseases. Putting in place a national coverage determination could have an unintended negative impact on patient access.

I just think that right now local carriers respect local practice patterns, and to divert from that on a national level, I personally don't think it's a good idea.

DR. BLOCHE: Ms. Birkofer, can I ask a question? When there is solid empirical evidence that indicates that a current use that might well be the local practice pattern in some geographical areas, is, in fact, not helpful to patients or even harmful, what would be the rationale for not having a national rule declining coverage in such cases?

MS. BIRKOFER: I think what you just laid out, I mean that is kind of an obvious, of course, I mean that makes perfect sense, but I think across the board, to encourage national coverage decisions or NCDs as opposed to respecting local practice patterns across the board, I have concerns with

that.

I mean obviously, if there is evidence that it's not effective or it's harmful, I mean, of course, that is obvious.

DR. BLOCHE: Let me offer just a little bit of context. This may be something that lots of folks are familiar with, so I apologize if I am repeating.

But there is a huge amount of empirical evidence that has built up over the last several decades, reported in literally thousands of studies going back to the early 1970s.

Some of you may be familiar with John Wennberg, who is a pioneer, a health services researcher and a physician at Dartmouth, who is a pioneer in this area. We know that practice among small geographical areas, common clinical decisions vary enormously in their incidence without an empirical basis for it.

We also know, for instance, that Medicare spending varies enormously per person by region. If you live in Miami, you are I think something

like per Medicare patient, twice as much money gets spent in Miami as in Minnesota, twice as much money gets spent in Boston as in New Haven, and there is no known empirical basis for this, and it's the public money.

Why shouldn't there be in that unfortunately still small subset of situations in which we have the empirical data to make a decision as to whether a practice is helpful, harmful, or just a waste, why shouldn't there be a national rule, and why should patients have access to care that is providing no benefit and wasting public money, and may even be harmful?

DR. BRACEY: Additional comments?

MS. BIRKOFER: I don't know if he is asking me, if that's a rhetorical question, or if you are directing it to me, my response would be patients should have access to all therapies as prescribed by their physician, period. It's up to the provider.

DR. BLOCHE: But when medical practice is not based on empirical data, then, I would suggest

that should be asking the question.

DR. BRACEY: I think one of the directives or at least the committee, I think is moving in the direction of having national standards. You know, when we speak of, for example, transfusion practices, we don't envision that those practices would differ by region.

In fact, some of what we propose will hopefully help expose within the world of transfusion, regional variances and then raise questions about such practice, and I, for one, think that really all practices for patients throughout this nation should be standard, and they should be based upon reasonable data.

DR. BRACEY: Dr. Epstein.

DR. EPSTEIN: I have a question for Greg in regard to your personal comment about pay for performance based on quality indicators. I guess I have mixed view, because on the one hand, the idea of the incentive, you know, you do better, we pay you better makes good sense, but you can get into the reverse paradigm, you know, the beatings will

continue until morale improves.

If you have a poorly performing center and that results in loss of funds, they become less able to perform, and you also promote a vicious cycle. So, I think the key idea here is that poor performance should trigger corrective actions, but I am not sure that the direct linkage should be that you lose reimbursement, because that actually compromises your ability to make correction, which is usually revenue requiring.

So, just your comment on that, because you have thought about it more than I have.

DR. BLOCHE: Well, I think you raise a really, really important issue, and there can be these kind of vicious cycle positive feedback loops that can pull an institution down.

Maybe when an institution is replaceable by the services of others, and it is not doing well, then, maybe there is a case for the answer being closure, but lots of institutions are really safety net institutions, and their deterioration and closure would be really bad news from an access

perspective.

It does seem to me, and I certainly can't claim clinical expertise in this area, but it does seem to me that a whole lot depends on the particular pay for the particular performance measures that are identified.

If they are both really well grounded in the sense that they are representative of high-quality practice, if they are outcome oriented, and if they are, at the same time, linked to particular tangible behaviors that centers can change, then, I think the risk of this kind of downward cycle of morale and resources can be reduced especially if they are linked tightly, if the measures are linked tightly to behaviors that can be changed.

DR. BRACEY: One of the experiences that I have from the world of the hospitals is that clearly, the message of these incentives to link performance with reimbursement are striking in terms of their impact on a hospital.

I have seen a number of physicians change

their practice under the direction of task forces within the hospital, so while there may be that downward spiral, it really does, at least in my experience, direct people toward a more positive mode.

Ms. Birkofer.

MS. BIRKOFER: No. 4, I wanted to I guess talk about that one a little further, as well, with regard to post-market surveillance. I think there might be some confusion there with regard to plasma derivatives versus blood for transfusion.

Plasma-derived therapies currently right now do report adverse events to the Federal Government. Companies do handle complaints. Unless there is a pattern of complaints that result in a recall, complaints are not reported, but PPTA member companies currently have active post-market surveillance programs already in place where I think what you may have been focusing on, that may need some clarity, is that blood for transfusion currently only requires reporting for fatalities, so I don't think it is appropriate, No. 4, for

plasma derivatives to be included.

DR. BRACEY: Thank you.

We have a question from Dr. Roseff and then one from the floor.

DR. ROSEFF: This is just getting back to incentives. We discussed incentives in our group, too, and I always want to put a precautionary word out, to be aware of how you incentivize people.

I have had two experiences, one in a blood center that I worked in, where our deferral rate was going up on certain drives, and the rumor was that it was because they were at 5 o'clock and everyone wanted to go home early, so there was a high deferral rate as the day went on.

So, we incentivized the staff that if your deferral rate was--we compared deferral rates, that was very dangerous. We stopped that very quickly, because people were incentivized and how were they going to change their deferral rate.

The other issue is someone in another hospital, whose Department of Pathology was going to give better bonuses based on whether or not you

were able to decrease your expenses. In that Lab Department, where you are the medical director of a blood bank, your big expense is buying blood, you are also someone who is trying to influence practice, if your use of blood goes down, is it going down because it's better for the patient or because you are incentivized financially.

So, I just wanted to add those precautionary words.

DR. BLOCHE: Those are crucial points. Incentives have a checkered history, when really high-risk, high-stake incentives were offered up to physicians by some Mass. Care companies in the mid-1990s to get them to practice more cheaply, that at times became dangerous.

But I think what I have in mind is a much more modest set of incentives that is linked to objective measures of performance. You can create market baskets, you can create formula that include measures of things ranging from patient satisfaction to different kinds of objectively determinable errors up to compliance with norms of

best practice.

I am certainly no hematologist and could come nowhere near to coming up with what those norms should be, but if the hematology community can come up with norms of best practice that are evidence based, and that are measurable using the kinds of information technology that is hopefully coming on line, then, that is the way to do this in a modest and measured way.

DR. BRACEY: Comment from the floor from Ms. Wiegmann.

MS. WIEGMANN: I am struck in just looking at this list that it does not reflect several of the recommendations that have been put forth by this committee in previous years regarding reimbursement, and those recommendations specifically deal with the need to ensure that CMS is using reliable data when making its payment decisions.

With blood components as opposed to some of the issues that the derivatives face, our issue is not so much coverage, but payment.

There are all the complexities with the DRG system and how we are bundled there, but at least in the outpatient setting, you have got specific payments for blood components that are grossly inadequate.

I think that the committee should continue to reiterate the need for CMS to base those payments on realistic cost data as opposed to the data that they are using, and potentially to say something about how one indication of those inadequacies is the new data that is coming out with the biennial--or no longer the biennial--but the nationwide blood collection and utilization survey.

We collected data that show that the cost of blood, the major blood components has increased dramatically in the last few years, as I think most everyone on this committee knows, and at the same time, the APC rates are going in the opposite direction.

So, I would urge the committee, if you are making a strategic plan, that you need to include

that issue of having CMS and Medicare base its reimbursement payments on reliable and realistic cost data.

DR. BLOCHE: That's very helpful. Thank you.

DR. BRACEY: Thank you.

Mr. Walsh.

MR. WALSH: I just have a comment in response to Julie's observation on No. 4. We spent a lot of time discussing this issue, and the concern from one plasma user community at least is that this passive surveillance system does not work, it is broken.

When you get distributors that the manufacturers don't have any responsibility for making comments that patients don't need to report adverse events or what could be considered an adverse event, it completely erodes the credibility of that system.

We need to create a mechanism that would basically a more active surveillance program, and I know that's expensive and everybody cringes when

you talk about it, but we are talking about patient safety here, and unless the manufacturers are going to make a commitment in a Phase 4 commitment or whatever to do more specific, broader, active surveillance, it currently does not work. I mean that needs to be done.

Julie, if you have an ideas on that, you know, we have a situation in our community that you are familiar with, I don't know how we can fix that.

DR. BRACEY: Thank you.

Dr. Epstein.

DR. EPSTEIN: I have two comments, the first about adverse event reporting related to transfusion products. Fatalities have to be reported, but biologic product deviations also have to be reported, and there is passive reporting of medical adverse events through the Med Watch system, which can come in independent of the mandatory requirements for reporting.

Also, FDA has under consideration revising regulations, so that serious adverse events of

transfusion may become also mandatorily reportable.

The second comment is a question to the committee, which is whether there was any discussion about the need to link CMS reimbursement policies to product approvals by FDA and/or process requirements of FDA, and/or CDC recommendations related to clinical practices, because one of the gaps that I see is that there tends to be a delay in reimbursement, which often is measured in years, well after products get approved with specific indications or there are other kinds of practice recommendations.

I think that that is, in itself, a structural issue that needs to be examined here. So, was that--

MR. MATYAS: That was the notion of No. 2.

DR. EPSTEIN: That's the specific question.

MR. MATYAS: That was the TC way of saying CMS, get off your duff. I mean that is where we were, which was what led to that language of if a product has been--as I see it, the issue of product

and device approval goes down one track with the FDA, and then the coverage process begins.

There needs to be a way of having dual processes at the same time, so that we decrease that coverage gap.

DR. BRACEY: Ms. Lipton.

MS. LIPTON: I think the problem is in the language that you have used, because it isn't coverage of a product, device, or service. Sometimes it's that you have to make a change to a product or a safety enhancement, and it doesn't mean you relicensing something, it just means you have to do that which can increase the cost.

So, I think it's the way you have described it that is a limiter, that I think we need to change the language to address Jay's issue.

DR. BLOCHE: Suppose it just said a product, supports coverage of a new or revised, or whatever the right word it, product, device, or service, would that do it?

DR. BRACEY: But it does sound like we do need to do some wordsmithing on that.

MS. LIPTON: I think what it is, it's a regulatory requirement, so if there is a new regulation that comes out, that we have to comply with, it increases the cost of something, it might not be a new or even a revised product.

DR. EPSTEIN: In the context of a Public Health Service recommendation, in other words, if you have a federal agency, be it FDA or CDC, are coming out and saying we recommend a certain practice, if there is no corresponding reimbursement strategy, then, it becomes a disincentive for anyone to implement a Public Health recommendation.

I think this may be an area where one needs to be blunt rather than subtle.

DR. BRACEY: Ms. Thomas, did you have something on this topic?

MS. THOMAS: I did, I just had a comment, but it was on Item 1. So, can I go ahead and say my comment on Item 1?

DR. BRACEY: Yes.

MS. THOMAS: Julie had brought up a very

good point when she had said locally, for her, it works well, and sitting on this committee, for us, locally, it doesn't work, and I think that was the whole basis of us wanting a change to make it national, because it does depend on what areas you go, where you go.

I really do feel it should be consistent for everyone.

DR. BRACEY: Thank you.

Ms. Wiegmann, did you want to make a comment?

MS. WIEGMANN: I am sorry, just back to that one point, again, on No. 2. That is where you would include not just coverage rules, but payment rates, so that you adjust, you make new coverage rules and you adjust payment rates based on new data and new requirements put forth by FDA, or new blood safety advances.

DR. BRACEY: So noted.

Mr. Matyas.

MR. MATYAS: One question, which is what I am surprised is that no one has commented on No. 3.

I am not trying to re-open up Pandora's Box, but I thought of all the ones on there, that that was going to get the most reaction.

DR. EPSTEIN: I think the committee, in previous recommendations, has already suggested that in a variety of ways, so I think what you are hearing is silence is assent, we agree.

DR. BRACEY: Mr. Walsh.

MR. WALSH: I would just like to acknowledge that we did have a representative from CMS in this working group session, and it was extremely effective to have a person there, and thank you to CMS, thanks for coordinating that.

DR. BRACEY: Thank you.

Executive Secretary.

DR. HOLMBERG: What was the CMS representative's, Ms. Newman, what was her impression of No. 3?

MR. WALSH: Her impression of No. 3 was that the only way the Secretary can take any specific action now is if it is a national health crisis, and that's a pretty high bar. She felt it

would be very helpful if the Secretary had that type of authority. She agreed with it.

DR. BRACEY: I guess one of the questions that was raised in our deliberations was whether or not there would be a requirement for Congress to get involved. Do you want to expand on that?

MS. PAHUJA: I think we drafted No. 3 with the understanding that right now, the Secretary can only intervene and change reimbursement rates when he declares a public health emergency, and that the Secretary is reluctant to do that. There is really no grading, the Secretary has no sort of graded power to sort of say, okay, let's try and avert a public health emergency by implementing certain steps before that occurs.

That is sort of I think why we drafted No. 3 the way we did in terms of averting the development of a serious emergency. So, giving the Secretary some sort of power to act when something less than an emergency has occurred, realizing that that would be a statutory change, not realizing that the Secretary himself couldn't decide that he

wanted to do it, you know, or she, that he or she would have to ask for that power.

DR. BRACEY: So, this would again, as you mentioned, would be a recommendation for a statutory change.

MS. PAHUJA: Correct.

MR. MATYAS: And some of that comes from Ms. Newman's, you know, enlightening us, as well, as well as knowledge of the Department's feeling that their hands are tied right now, because they don't have special authority without currently saying there is a full emergency situation, therefore, there is no way to deal with it without a big legislative change to correct some things that are going on today, which we all know can't be corrected by legislation for a year or two from now.

DR. BRACEY: Thank you.

Ms. Birkofer.

MS. BIRKOFER: Again, just another point on the post-market surveillance, John. I think there is a distinction between post-market

surveillance for safety versus ongoing surveillance for efficacy, and I think there is a fine line there that we probably need to further discuss and consider when we finalize any recommendations.

DR. BRACEY: So, the four point, actually, can you pan down, including--actually, there are five points. Is the committee comfortable with Point No. 5, as well, since this is a personal rather than a work group recommendation? Mr. Matyas?

MR. MATYAS: For purposes of a draft, because that is where we are, we are coming up with a draft, I don't have any issue, but I do think, as with all of them, it is going to require some further discussion be it heated or otherwise.

DR. BRACEY: Thank you.

Dr. Epstein.

DR. EPSTEIN: I want to ask another kind of fundamental question. We have talked a lot about the fact that there is no DRG for blood, so therefore, the costs of blood services in hospitals are embedded in other procedural elements that get

highlighted when the hospital get its budget, and the need to fund blood services loses that highlighting because there is no line item.

I just wondered whether the committee thought at all or would want to consider at all a recommendation that the potential value of a line item for blood products and services could help focus the need for reimbursement in that area.

DR. BRACEY: Thank you.

Comments from the working group? Ms. Pahuja.

MS. PAHUJA: We didn't actually discuss one of your suggestions in terms of specifically recommending a line item, but we definitely sort of danced around this idea or notion that blood isn't directly reimbursed for and how it is sort of bundled into a larger group of services, and thereby sort of hematological services or clinic or units have suffered as opposed to blood products infused with oncology services.

We definitely sort of discussed it. We just didn't come up with a formal recommendation.

DR. BRACEY: Dr. Epstein, did you have a response?

DR. EPSTEIN: Well, again, I am not an expert on CMS reimbursement. You know, FDA doesn't usually deal with a cost issue, but it just seems to me that you have got a visibility problem, that blood services in hospitals are seen as a cost center, not a revenue center, and that is because they are not directly reimbursed for their operation.

You could change that whole mind-set around if there were sort of line item visibility and that when hospitals got their budgets, it was clear that so much of the funding was intended for blood services.

Since I have got the floor for a moment, I am not sure that the same shouldn't apply to surveillance activities in the hospitals, that one way of ensuring that it would occur would be if it were directly reimbursable under a CMS scheme.

DR. BRACEY: Thank you.

Dr. Holmberg, comment?

DR. HOLMBERG: I think that this really goes to a deeper issue, which may come out. I don't think we discussed it in the Research Group, but I have been asking for a long time if there could be a study done on utilization and taking the DRGs that intensely use blood products, blood and plasma products and recombinant factors, and look at that, and see what portion it actually represents for the blood plasma recombinant products, and also to see the increase and to see whether it has increased over the years in the DRGs.

That is one thing to do, but I think what you are talking about, Dr. Epstein, is a little bit more dramatic in the fact that you are really parsing it out. One of the things that we have tried to do even with the new rulings, or the proposed ruling that--I should say final ruling that eventually will be coming out on hepatitis C lookback is actually trying to make it, so that there is some reimbursement aspects of that, too.

DR. BRACEY: Dr. Klein.

DR. KLEIN: I want to point out that it is not just a visibility issue. We are always told, those of us who use blood, that it is such a small portion of the healthcare budget that it's just a speck of dust and not worth a DRG.

On the other hand, when you actually do some analysis, you find that frequently, it is not billed by hospitals, because they don't see it as a profit center in any way, it is just a cost center, and it's not worth their while, but I can guarantee you, you wouldn't need a study if you had a DRG that was reimbursed, because suddenly everyone would be billing for it as appropriately and collecting the amount of money that is being used to transfuse blood across the country. That's the way the market operates.

DR. BRACEY: Dr. Duffell.

DR. DUFFELL: What Jay said is a hot topic here of sorts. I think you are right on that it needs that kind of visibility. I think if you lump it, as Jerry was mentioning, into the DRGs, it is going to turn out like you said, Harvey. It is

such a small piece that it would get lost. So, the only way to really ensure that visibility is probably crank it up to that notch. Unfortunately, it's almost probably an Act of Congress to get it done, so to speak.

DR. BRACEY: Dr. Kuehnert.

DR. KUEHNERT: On that topic, I mean this has been discussed in terms of reimbursement for a long time on this committee, and it hasn't gone anywhere, so maybe I would suggest really thinking creatively, because one topic that has a lot of legislative attention right now is tissues, so which vote do you really want to be associated with.

Right now, being embedded in DRGs, blood is sort of like a drug, but maybe it is sort of more like a procedure as organ and tissue transplants, you know, may be characterized, might be a better way to go.

It is just a matter how you want to package things, but you may want to think about that as far as how we want to frame the discussion.

DR. BRACEY: Dr. Bloche.

DR. BLOCHE: I just want to offer a thought about this, which is neutral with respect to the outcome, but hopefully, offers a bit of a perspective on it.

Going back to the origins of the DRG system, this is kind of the health policy wonk view from 50,000 feet here. The basic vision behind it was that it was a strategy to get control over Medicare costs by giving hospitals and the physicians who make clinical decisions within hospitals the task of managing resources for patients within set budgets.

You could win or lose on an individual patient basis, but overall, you had to come close to breaking even or you were in pretty deep trouble. The basic premise involved in bundling anything into a DRG as opposed to separating it out on a line item is that doctors and hospitals are in the best position to make these hard allocative decisions.

Insofar as the DRG system still has some

policy belief behind it, the case it seems to me that would need to be made--and again I am taking an agnostic position with respect to whether or not this case is persuasive--the case that would need to be made is that blood is different in the following sense - that there are unique features of blood or its use such that doctors who make clinical decisions in hospitals will not take fair account of its value in the process of not just making clinical decisions, but making purchasing decisions.

If that is the case, then, there is a powerful case for pulling blood out. If it is not the case, then, overall the rationale of setting limits and asking doctors in hospitals to do the allocation within the limits ends up being more persuasive at least from the perspective of the theory behind the DRG concept.

DR. BRACEY: Thank you, Dr. Bloche.

I think that we have had lots of discussion on four or five bullet points, and we will certainly hear more. Now is probably a good

time to take a 15-minute break and then we will reconvene at about quarter after.

[Break.]

DR. BRACEY: In that there may be some committee members that will need to leave a little early to catch their plane, there is one brief recommendation that I would like to propose, and that is as follows. Basically, the intent is to incorporate what we have discussed today into a draft strategic plan for review at the next HHS ACBSA meeting.

So, in brief, the recommendation would be as follows: The committee recommends that the Executive Secretary take the recommendations of the work groups as discussed before the whole committee for drafting into a strategic plan for review at the next HHS ACBSA committee meeting.

If that is agreeable with the committee--Dr. Epstein?

DR. EPSTEIN: I think you might have a practical problem saying it's for the next meeting. Perhaps the next suitable or next available or the

most timely, because, you know, we already have our issues for our next meeting.

DR. BRACEY: Right, okay. For the most suitable.

DR. EPSTEIN: Or for the easiest feasible.

DR. BRACEY: All right. I will put the earliest feasible HHS ACBSA. Additional comments? Motion?

DR. ROSEFF: Approved.

DR. BRACEY: It has been motioned. Do we need a second?

MS. THOMAS: I second.

DR. BRACEY: Okay. Any discussion?

Call the question. All in favor? Any opposed?

All right. It stands approved.

Next, we have Dr. Klein. Dr. Klein will be presenting the report from the topic of Advance Medical Research, the Strategic Research Agenda.

Dr. Klein.

Advance Medical Research

DR. KLEIN: Thank you. Our group met this

morning and so we are even less sophisticated. I don't have five points. I have five sheets. What I am going to try to do is give you an idea of where we thought the strategic research issues lay in this area of blood safety and availability.

There are several other members of the committee sitting around the table, so I know that I am going to miss some of these points. The discussion was lively, it lasted the full three hours, could have lasted probably another day. So, I will ask them to fill in should I miss points here.

In terms of how to organize this, we adopted Dr. Epstein's suggestion and looked at the blood transfusion process from the beginning of recruitment through post-marketing survey, if you will, and tried to look for the gaps in research funding or the needs.

If we start with recruitment and availability, I have already mentioned the genomic repository, so I won't go into that in any detail, but we did recognize that research into motivation

for donation, for new donors, and perhaps more importantly, retention of people who have already donated blood needs to be done especially in this era since most of that research has been done many, many years ago, and the kinds of people who are donating today are possibly different than the World War II veterans.

We also thought research into the donor room as a healthcare demonstration project looking at healthy lifestyle issues, and this might include such things as iron deficiency from donation and replenishment of iron.

In terms of what might be deliverables for the Secretary's 500-day plan, and I would like to emphasize that most research, of course, is not a 500-day deliverable, a 5,000-day horizon is clearly more appropriate, but I think there are some deliverables, and one might be to initiate a research into motivation.

A second might be the male sex with male issue, which is a hot topic for blood donation today, and there are several pieces of data that

are missing and certainly could be acquired by research.

A third deliverable might be to begin perhaps with a workshop trying to determine how new technology, another research area of interest might be applied to donor recruitment and retention, new technology particularly in the information technology sector, web-based methods used for donor recruitment.

In terms of long-term issues to expand the availability of blood, there are several issues that are clearly long-term research issues. One might be blood alternatives, transfusion alternatives.

A second might be what has been known as blood substitutes, not just red cell substitutes, but substitutes for other blood components including plasma proteins and platelets, and perhaps the ability to expand blood cells ex vivo to replace part of the blood supply recognizing that it would be very difficult to replace 13 million units by brewing them up, but perhaps one

could, in fact, make cells for individuals who are particularly difficult to transfuse, and move from there to perhaps O negative units and maybe to other units, as well.

But this kind of research is actually being carried out in small laboratories around the world, very little being done in the United States.

We also long term ought to study, not only those people who qualify to donate, but we probably should study the individuals who have been deferred as donors to determine if, in fact, they were risky donors by our current criteria, and using this information, to refine our donor screening criteria.

Most of us realize that the donor screening criteria that we use today have not been validated by scientific studies.

If we move from recruitment and availability to the collection and processing of blood, there are many gaps in this. Short term, one could conduct research to look at universal leukocyte reduction and its import, its necessity,

and positive and negative. No studies really have been done.

We ought to be doing research, as this committee has noted, on TRALI. Since right now our method of screening for infectious units of blood is really a testing paradigm, using modern technology to do multiplex testing, whether that is chip technology, or whether it's nanotechnology, or whether it is some other platform which will allow us to screen multiple agents effectively.

We also noted that we don't have a screening test for prions, and that is important, and perhaps there are some areas, such as developing a standard or being able to concentrate the protein in way that would allow us to develop an assay that federal funding could jump-start.

Longer term, we recognize the importance of the different paradigm for blood safety, that is, a pathogen inactivation or a pathogen reduction strategy, and certainly a lot of commercial research dollars have gone into that.

The question is where are the gaps where

the federal funding should support pathogen reduction, and we need to look at the potential cost/benefit of doing that.

Also, in the collection and processing area, we emphasized that the current typing and compatibility of testing of blood uses an early 20th century technology, by and large.

We ought to be using immunohematology at the genetic level, looking at genetic variations, probably expressing purer proteins and looking at different immunologic ways at the genetic level for identifying blood groups, individuals who potentially will make antibodies and typing by this technology.

Moving to the area of storage and release of components, we recognize that the storage lesion of virtually all of our blood cells, but particularly red cells and platelets, is recognized, but not terribly well defined, and if one could better define the red cell storage lesion, perhaps one could have a higher quality component, as well as a longer shelf life.

Certainly, the major issue perhaps is platelets, which has such a short shelf life, and if one could identify the storage lesion, primarily in the refrigerated platelet, then, this would be a good use of research funding.

This might also include looking at the irradiation lesion of the red cell in storage, so that one could pre-irradiate blood components and store them without having them outdate more rapidly, would also look at the storage lesion in reference to multiple organ failure syndrome, which has been associated with large volumes of red cell transfusion. This is a research topic, because that may or may not be a true association.

Also, short-term deliverables, one could validate the extended 7-day storage of whole blood derived pooled platelets. That could be done and would be of great value to the country. One could look at the issue of buffy coat versus platelet concentrates, buffy coat platelet, derived platelets seeming to be a higher quality component, but again that has really not been very well

determined.

Look at the toxicity issue of a DEHP, the plasticizer in many blood bags. That could be studied and delivered over the short term, possibly in a primate model.

Over the long term, looking at the effects of the storage lesion and the components that have been stored on outcomes. Perhaps that is more in the outcome monitoring area.

Another short-term deliverable might be to look at the release systems using RFID as a release system. There is the question that has been raised whether the radio frequency waves affect the blood component. Again, that could be done with federal dollars for a relatively small amount of money, and give us the answer as to whether that system would have a down side to it in terms of blood quality.

There were other long-term things that we just kind of put into a big bin, knowing that they would take a lot more thought than we had in the three hours today and probably more money than is immediately available, things like research into

the question of national blood reserves, cellular therapies based on blood components, such as the plasticity issues with hematopoietic progenitor cells, and point-of-care therapeutics, such as the fibrin gels and fibrin bandages.

So, that was the storage and release areas or gaps in research. There are a number of areas in transfusion outcome. One of the most important we felt was to use federal dollars perhaps, but certainly research dollars to develop a permanent research infrastructure for clinical studies, recognizing that today, if one needs to do a clinical study, it takes a year or two simply to set up the infrastructure to do so.

The Heart, Lung, and Blood Institute has set up a type of infrastructure for transfusion and hemostasis, their transfusion and hemostasis network, but we really need a permanent structure, so that we can look at outcomes in clinical trials.

We need to use better technology, new technology to improve the standards for the use of blood, and one example was given that we don't

really know why you should transfuse red cells or when you should stop transfusing red cells.

People use the so-called hemoglobin transfusion trigger, but in point of fact, we now have technologies, such as imaging, PET scanning, and there are a whole host of other oxygen sensor type technologies where we could, in fact, determine whether red cell transfusion really was doing what it is supposed to do at the tissue and organ level rather than simply taking a measure that seems to be totally irrelevant to the human being at the end, and then using the data derived from such studies to perhaps find more easily measurable objective tests, such as mixed venous oxygen saturation or perhaps lactate production, or there are a hundred others which might correlate with what is actually happening physiologically.

Those kinds of studies are not terribly expensive. They are certainly a lot less expensive than large multi-center, randomized trials comparing one kind of red cell with another kind of red cell.

One could say that if you set up a system to look at, for example, red cell transfusion, you could then use that same system to look at red cells that have been stored in different anticoagulant preservatives of those who apparently have the storage lesion to determine whether, in fact, a storage had an adverse effect on what happens to the human being.

We also thought in the area of outcomes that one should be using genomics to look at how patients respond to blood component transfusions, and respond in terms of making antibodies, in terms of tolerance, in terms of immunomodulation since we have that kind of new technology available today.

One area that has been highlighted was using genomics to try to predict who might produce antibodies, for example, to infusions of plasma proteins, factor 8 being the model disease in that area.

Finally, on the fifth page was new products, and certainly federal dollars might be used to stimulate research into development of new

products for rare diseases, since there is rarely any commercial interest in doing so.

It also might be used to look at the safety assessment in patients who receive new components, such as modified proteins, which might have an effect on the human being.

We talked earlier about a hemo-vigilance system and federal dollars might be used to design such a system and to evaluate the data although not to establish it or to continue it.

Finally, in terms not so much of new products, but in outcomes, research using modern technologies could be used to define evidence-based medicine rather than some of the studies that are currently in the literature, albumen fusion being one such example.

So, those were the areas and those were the gaps, and I am sure that perhaps members of the committee might remember things that I didn't put on my list, and I would welcome the comments and then the comments of other members of the assembled committee.

DR. BRACEY: That was great coverage of five pages as opposed to five points. There is certainly a lot for discussion. I will open the floor for questions and comments for Dr. Klein. Ms. Thomas.

MS. THOMAS: I apologize. I didn't hear your comment when you had mentioned about MSN, and I just wanted to know what you had said about that.

DR. KLEIN: I think there are a number of research questions that need to be answered. We don't know the impact, for example, on lifting that particular exclusion for blood availability as one point. There has been a question of transmission of HHV-8.

We don't know whether that would, in fact, be an issue. It is a readily testable phenomenon, and I think there are several other issues that really could be looked at to give us better data on which to make a decision about whether that would, in fact, increase the risk of blood or increase the availability, or both, or neither.

DR. BRACEY: Thank you.

Question or comment from the floor?

MS. STARKY: I am Jane Starky with America's Blood Centers. I am not sure if this is necessarily a research issue, but when you talked about research money to stimulate orphan products, something that we have been grappling with are orphan devices and more specifically, tests, HTLV confirmatory tests.

As we are working, trying to address malaria tests, we have the issue of non-universal tests and how manufacturers are very reluctant, not surprisingly, to make a test that is not going to be mandated for the entire population.

So, I don't know where that fits in the policy issue, but I am sure you can come up with several other kinds of tests that are needed, but not available.

DR. KLEIN: Thank you for bringing that up, because, in fact, that was something that was discussed in the group that we do need better confirmatory tests in order to again look at individuals whom we have deferred in the past, who

may or may not be risky to the blood supply, and right now we have no way of answering it one way or the other.

So, yes, developing both standards for which a test could be developed, and developing the test itself, is certainly a research interest and a research priority.

DR. BRACEY: Dr. Holmberg.

DR. HOLMBERG: Just as a point of reference, the committee did discuss orphan test procedures, I believe back in September of 2005, and so it was part of the discussion in the strategic plan, so thank you again, Ms. Starky, for bringing that to our attention.

DR. KLEIN: I am not sure that it's so much as an orphan, but again on the listing here, which I didn't mention, was the next generation of testing for bacterial contamination, because although we do have tests now for bacterial contamination, and some people are quite satisfied that they are effective, we do know that probably they are only about 50 percent effective at best,

and that is certainly not good enough.

DR. BRACEY: I have got a question for Dr. Klein, and that is, given your being at the NHLBI planning meeting yesterday as far as their emphasis on research dollars, do you sense that we are in a fairly parallel position, i.e., the same general topics, or what is your perspective on that?

DR. KLEIN: I think that the conclusion of that meeting was prioritization of research based primarily on science, and I think the group that worked today certainly was interested in good science.

I mean there is no advantage to using poor science, but I think we also looked at where federal dollars might best be used to advance public health, both short term and long term, and where the best bang for the buck might be. Those were not priorities for yesterday's discussion, which really did concentrate more on hard science and maybe a longer horizon, if I might say so.

DR. BRACEY: Thank you.

Ms. Lipton.

MS. LIPTON: One thing that was helpful today, though, although I think we looked at six yesterday, is that right, Harvey, at the end that we were trying to decide?

DR. KLEIN: That's correct.

MS. LIPTON: The four that did not get any kind of--really, probably are not going to go forward, we did pick up today, not because we suggested it, but because this group brought them up, so I think that they were captured.

DR. BRACEY: Thank you.

DR. KLEIN: One of the top issues that NHLBI did highlight was better research into red cell physiology, and I would point out that the first studies of successful human red cell transfusions by James Blondell in 1818 reported 10 cases of blood transfusion, five of whom, by the way, died, in great detail.

However, in reading those cases, one really couldn't determine whether the patients who survived did so because of the red cells, because of the volume, or because of neither one, and

whether the patients who died did so because of the red cells, the volume, or the toxicity of the blood.

We are not too much further along today, so I do think we need better physiologic studies to tell us what the red cell is doing and when we need to do it.

DR. BRACEY: Thank you for that perspective.

Dr. Epstein.

DR. EPSTEIN: Harvey, I might have taken a micro-nap, but you also have the summary of the long-term effects of donation, and did you want to comment on that?

DR. KLEIN: Yes, thank you for reminding me, because obviously, the donor is extraordinarily important to us. I missed that because of my own fault, and not because it isn't a high priority.

But we did wish to look at the long-term effects on the blood donor, and that has to do with a number of factors, cell depletion, for example, iron deficiency and what the impact long term on

the donor is of iron deficiency and iron repletion, because that is a very important issue. The issue of plasma protein depletion since in the United States, we collect more plasma from single individuals than is done anywhere else in the world, and yet long-term studies, to the best of my knowledge, are lacking, but they are necessary.

There are other areas where we recognize toxicity, for example, in giving large volumes of citrate over long periods of time. We know that we mobilize calcium from donors' bones, but we don't know what the long-term effect is, if any. It, in fact, could potentially be advantageous, but we simply have never studied that.

The potential for developing cataracts in people who are stimulated with steroids when they donate granulocytes repeatedly over many years. Again, there have been reports in the literature the long-term effects have never been studied, and probably going into the 21st century, stimulating donors with cytokines in order to collect more blood components and whether that's granulocyte

colony stimulating factor, or whether it's erythropoietin, or maybe thrombopoietin in the future, certainly we need to think about what the long-term effects are going to be on the donor, and if we decide to go ahead with such strategies, we need to be set up to study the effects.

DR. BRACEY: Thank you, Dr. Klein.

If there are not more questions, I would like to proceed to the next presenter. The next presenter will speak on the topic Secure the Homeland, and it's Commander Mike Libby.

Secure the Homeland

CDR LIBBY: Our topic was Secure the Homeland. That's kind of a tall order, to say the least. The three topics here was integration of the blood system and the public health structure, risk communications, as well as disaster planning, and we kind of followed the Secretary's vision, which stated the disaster response is seamless and rapid, we are needed anywhere in the United States.

I think quite obviously, in a lot of the past events we have had to deal with, and not it's

looking at the future. Believe me, this is a strategy, not a strategy plan on how we are going to do this, because this is indeed a very tall order, and that is really to define the functional leadership of the blood industry, and actually who is in charge when it is needed, when there is a disaster we have to deal with.

It has to be stratified for the circumstance in order to have flexibility. Each situation is going to be different whether it is dealing with a pandemic type situation with some kind of virus being introduced in our blood supply or affecting donors, or whether it be a terrorist act, whether it's a nuclear event or a radiological event that we may have to deal with.

So, each situation has to be different, it is going to be flexible, you have to be flexible. The situations will be such that you have to have one person in charge, will have to direct charge of blood product movement, managing, supporting supplies and services that's available, or lack of or re-applying those, and also coordinate risk

safety type communications.

The person has to coordinate blood program requirements amongst the executive departments meaning we have seen this during like Katrina hurricane type events, you know, you may have a logistics requirement. The blood products is a logistics. You either provide fuel to your donor centers or to provide transportation access to get the blood or supplies or services to where it is needed.

Also, requirements for planning elements that will integrate locally, in other words, what is the local requirements local, whether it is from a city or your county or state, how does that get integrated into the Federal Government type system for their responses, and actually, who is in charge to do that. We have 50 states. Who is going to look at each 50 states plans and how they would actually deal with disasters or situations.

Also, formalizing the role of several organizations. One is the AABB Interorganizational Task Force in Domestic Disasters and Acts of

Terrorism. We have known that this organization has come to play a very important role in some of our recent events, you know, the hurricanes that we dealt with last year, the AABB Task Force was an entity where there was a lot of information and coordination presented, not just between the government, DoD, or between the Red Cross, the ABC, and the other people that are members of that community.

It is a very powerful, I think a very well organized system, and I think we definitely have to formalize its role and its integration into whoever is going to take the leadership role into the organization.

Also, the American Association of Tissue Banks needs to be formalized, the Eye Bank Association of America, the National Marrow Donor Program, Contingency Planning Task Force needs to be formalized, and how does it actually play into the role of integration of the blood system into the health system.

Also, to be able to create redundancy of

critical infrastructures, as an example, the Internet, who is taking charge to make sure there are redundant systems, whether it is the Internet. You know, we rely on the Internet very heavily, how do we get test results back, how do we clear blood products, how do we look at deferral lists.

Redundancy in transportation is an example. There is also redundancy in our testing facilities, how do we get our testing done especially if our transportation assets is interrupted.

The national blood response plan, provide in it, blood and tissue, very specific itemized play in the national response plan, and also for threat identification, realistic risk determinations, what is the threats out there, and then what are the risks.

If you look at the threats, okay, then, what is the population at risk, and how do we play these out, how do we play out exercises. We need to be able to be in a position to exercise this, look at our weaknesses, look at what we need to do

to shore up certain gaps that we have in our system. You do that through exercises, and you exercise your weakness. You know what your weakness is, put it into the plan, put it in the exercise.

Also, plan for staged responses for disasters and events meaning you have a local plan, you know, starting at a local hospital, how does it deal with a situation, how does the city, how does the county, the state, pretty much a staged event. How does everybody coordinate to respond to an event.

Also, to have predefined plan and how do we adjust our regulatory standards in order to meet a risk, you know, what part of our regulatory base or standard can we lessen to deal with a risk. You take a risk, you know how do we adjust our system to respond.

Risk communications, clarify responsibility for information and dissemination including risk communication, what is the risk in the blood supplies that are biologic out there,

that we may not want blood donors to come donate, how do we get that information out there. Need for blood donations, how do we put public service announcements, information one way, to get the word out there that there is a need for blood, and also, what are the tissue resources that are available.

The other part of risk communications, centralized and dissemination of key information among public health stakeholders, who is the centralized point to gather all this information and get it out there to the population for surveillance. An example, the Secretary's operation center database, who manages that and who gets out information, how does the Secretary actually get that information, the data to put out to the country.

Situational awareness, communications of signal events and important events, how do we communicate that and tell the world what's going on, and also to get the word out or to manage shortage of reagents and supplies, as well as services.

Disaster planning. We have to be vigilant of what do we need for capability to respond to a disaster. Some of these disasters, we have got experience in the past, but there is new stuff over the horizon that we are preparing for, what technologies do we need to actually meet that requirement.

What industry infrastructure do we need to meet it, what logistics and bases do we need to be able to provide service to our folks here in the U.S., and also emergency communications, how do we communicate with each other. I don't think we do this very well. How do we talk to each other, how do we talk in the states, how do we communicate especially with somebody, if your infrastructure is down, you know, your cell phones aren't working, how do we actually get the word out and the coordinate important resources.

That is the end of the presentation.

DR. BRACEY: Thank you, Commander Libby.

I will open the floor for comments and/or questions. Ms. Birkofer.

MS. BIRKOFER: Thank you. I think in past meetings, when we talked about preparedness issues, we had also talked about the need for plasma collection facilities to be included in some way in the Secretary's national response plan, the importance of the collection of plasma donors being able to get there. I would just like to raise that.

DR. BRACEY: Thank you.

Dr. Epstein.

DR. EPSTEIN: I support that comment, and I think that we need to also recognize that there is a pipeline issue with plasma derivatives. The time required to replete the blood inventory on the shelf of transfusable products is potentially short, whereas, the time needed to make available plasma derivatives, if you have a period of time during which you lose donors, is potentially long, so we have a whole additional set of issues that we haven't ever talked about, I don't think.

You know, should there be stockpiling of frozen plasmas, for example. I am not sure there

is the capability to have excess derivative production per se, or how you would manage that, but the whole inventory question and the whole reserve question for plasma has really never been discussed.

We have talked about it for the blood component, but to my recollection, we have not ever talked about it for the plasma derivative.

DR. BRACEY: Thank you.

Dr. Holmberg.

DR. HOLMBERG: I agree, Jay, that is what really concerns me about the potential pandemic influenza is that entire pipeline and the impact that that pipeline would have on the plasma industry may be even much more of a problem than in the whole blood arena. So, I support that, too.

DR. BRACEY: Dr. Duffell.

DR. DUFFELL: Did your plan take into account the need for disposables and things of that sort at the blood center level? A lot of the blood centers I know are operating on a just-in-time type inventory basis, so in the event of some sort of a

disaster, there could be the issue that you have got the donors lined up, but you are lacking disposables.

CDR LIBBY: Yes, we did. We looked at that, but we didn't present it here, but a lot of discussions, we kind of rolled it into the supply and services infrastructure in order to keep our industry operating, so we didn't get into those specifics here, but yes, we did talk about that.

DR. BRACEY: I have a question. In your lead slide, there was the question of who is in charge, and I guess I sort of scratched my head, and I am certain that there has been some discussion of that at least in the AABB Task Force and perhaps governmental agencies.

I would be interested to hear if anyone might be able to shed some light on the current status of who would be in charge in such a situation.

Dr. Holmberg. He's in charge.

DR. HOLMBERG: No, I am not in charge. That is a very good question and I think that that

is something that really needs to be strengthened and reminded once again to the total U.S. blood industry and plasma industry as it pertains to safety and availability.

I have to say that coming out of the IOM report, the Assistant Secretary for Health is the blood czar for this country, and so I do work for the Assistant Secretary for Health, and in time of disaster, if there is problems either in availability or safety, it is the responsibility of the Assistant Secretary for Health.

So, I think that that is very clear there. Now, one of the things that we have struggled with over the years has been, of course, working with the private sector and we are very thankful that the AABB Task Force came into being after 9/11, so it is really coordinating between the government and the private sector to make sure that things are moving ahead, but just to emphasize, I think that in the past, I think the responsibility has been looked at primarily that the only responsibility that the Assistant Secretary has is just risk

communication and unifying a message.

I think it is much more than that, and we have to be mindful of that, but once again, in a disaster, you know, the government, first of all, will try to do as much as it can to help, but the direction comes down from the Assistant Secretary, and we will need the reliance upon the local blood banks.

The blood organization does what they do very well in moving blood products around the country, so, you know, we have to be mindful of that, and it's a synergy that really has to work, but the main man is the Assistant Secretary for Health.

DR. BRACEY: Thank you, Dr. Holmberg, for that clarification.

Dr. Ramsey.

DR. RAMSEY: Just two quick points. One is just think about how, in terms of preparation for disasters, two points. One is how do we mandate that the facilities do their preparations, and secondly, how do we reimburse them for it. I

will just leave it at that.

DR. BRACEY: Dr. Holmberg.

DR. HOLMBERG: That is a very good question. One of the things I am glad that in the audience, we do have some HRSA representatives, and really, HRSA has a responsibility. They do give money out to the hospitals for preparedness, and so that's very important. Even the hemophilia treatment centers are supported by contracts, grants from the HRSA.

I know that even with the Rita and Katrina situation, we had several hemophilia treatment centers that moved back and forth, and it was a real eye-opener even in the last hurricane season of how do we build up redundancy and what happens even in the hemophilia treatment centers, because there were issues that fell out after the hurricanes of even reimbursement, because you had Medicaid reimbursement of people being treated in one state, but were really citizens or belonged to another state.

So, the Medicaid issues got all messed up,

and there was a specific office that really had to deal with those kind of issues, but the bottom line is that HRSA does give money for hospitals to work their emergency preparedness out.

DR. BRACEY: Additional questions or comments on this topic? Dr. Bloche.

DR. BLOCHE: Just one. I was struck by the increasing reliance, and it seems to make really good sense to do this, on the military to provide immediate surge capacity including medical capability in case of a catastrophe, treating large numbers of civilians.

I am wondering, I am not sure who to direct this to, so I just raise it in general to anybody who knows. To what extent is there interface between the military system of distribution, collection and distribution of these products, and the civilian side, given that we might have military units going in and providing care to civilians on a mass scale including blood, are there the mechanisms in place to move blood from, say, civilian populations in other areas to

the military in the event of a catastrophe?

DR. BRACEY: Dr. Holmberg.

DR. HOLMBERG: Commander Libby, would you like to answer that?

CDR LIBBY: Actually, we kind of played it out a little bit during the Katrina event. What we do is, there is a network, well, the military has an option to--there are several ways. I have asked for direct guidance on how the military, through Homeland Defense and Homeland Security and FEMA, the whole structure actually works, and there is nothing that is set, you know, each situation can be covered by a certain plan or an outline, because each situation is different in response, and each situation would be different in how the Secretary of Defense responds in agreement with FEMA and the way certain requirements are asked for by the states.

So, what there is, is there is a mechanism. Take an example of Katrina. There was a huge DoD outlay of medical facilities out there in Louisiana, as well as Mississippi. We had an

option with our blood player, blood support to the military facilities out there to either use our DoD assets, and that would fall under--because of the Stafford Act--FEMA would have to request that from DoD in order for DoD to get reimbursed the dollars by the states, to DoD, to reimburse whatever the medical outlay was.

What would happen is the blood products would be supported and would fall under big mission assignment that FEMA puts out to the DoD to support that civilian event. There is a lot of discussions on civil assistance in DoD and how the mechanisms work.

We tried to do, because the national response plan and also the national blood reserve, during Katrina, we wanted to have a blood-specific mission assignment from FEMA to come directly to DoD to say we have got military facilities out there, and now we are still trying to determine what the patient at risk was and what would be the actual requirement.

But we wanted to have FEMA give us a line

item for just blood products, so that we could provide blood products to our military sites and be reimbursed by the states for that.

Now, that didn't work because there were several issues, one, because the State of Louisiana, they were concerned if they put the money into the pool for the DoD blood products, that perhaps the blood may go to Mississippi, and vice versa. That was the complication that we actually saw during the event.

But I think as we take this and we try to play these out, we were exercising these options, and we are trying to resolve those kinds of complications. Now, either we do it through real events like this or do it through exercises, that is something that we are going to continuously bring up, how does DoD respond to civil assistance with the blood products, whether it's logistics, moving stuff around, or by the actual product, or the other way around.

You know, if we have DoD facilities that are out there, how do we get blood support from the

states to support those DoD in CONUS facilities, because we have a big operation requirement going on overseas.

DR. BLOCHE: Was there any stoppage or delay in the actual flow of products as a result of this?

CDR LIBBY: No.

DR. BLOCHE: Did the products flow and the money get worked out later?

CDR LIBBY: Yes, that's what happens. Local commanders have that authority to look at the risk, and they have the authority to take action based upon risks to the population and go back after the event, and then ask for the money or ask for them to approve authority to do so.

DR. BRACEY: Dr. Holmberg, you had a comment?

DR. HOLMBERG: Yes. Just to ease your concerns, since Katrina has happened and even before that, we have had strong dialogue with the DoD and to the point where we have even been over to see the Under Secretary well before Katrina, but

just to ease your concerns, we are working very closely in working out some memos of understanding between the DoD and HHS on how do we work in the future and working out some of the kinks that were identified in some of these disasters.

DR. BRACEY: Thank you. That is certainly a kink that we will need to take care of.

If there are no additional questions for Commander Libby, I would like to take this moment to read into the record the recommendation that we did approve.

That is that the committee recommends that the Executive Secretary take the recommendations of the work groups as discussed before the whole committee for drafting into a strategic plan for review at the earliest feasible HHS ACBSA committee meeting. That is in essence just to have it read into the record.

That ends the business that we have at hand, unless there is a need for additional discussion from any of the committee members. If not, I would entertain a motion for adjournment.

DR. DUFFELL: Yes.

MS. THOMAS: Second.

DR. BRACEY: The motion is recognized and seconded. We are adjourned. Thank you.

[Whereupon, at 4:03 p.m., the meeting was adjourned.]

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