UNITED STATES DEPARTMENT OF DEFENSE

DEFENSE HEALTH BOARD MEETING

DAY 2

Tacoma, Washington

Thursday, April 24, 2008

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P R O C E E D I N G S

(8:42 a.m.)

DR. POLAND: I think we'll get started here. We're a few minutes early, but remarkably I think we have everybody here, so we will do that. A couple of announcements. One is that you'll notice outside against the wall three of their scientific posters, so take a look at them. One's quality improvement and the other two are vaccine related. They're all vaccine related, but different topics. It's part of this idea of bringing more academics into the meeting, and I would invite other agencies or other individuals who have posters that are related to the work of the Board to please feel free to bring them to the meetings. I think it would be grand if our walls were covered with those sorts of things and that some of our break time might be used for those discussions. It may have a number of fallout

beneficial effects such as building scientific collaboration between members of the Board and some of the agencies here, and who knows where

that could take us either as a group or as individuals. So please feel free to do that.

I'm cognizant of the fact that several of you have travel plans. In the nature of the West Coast like this, you either leave by noon or you leave by 1:00 a.m. or something, so I will try with your help to move things along and if necessary we may have to flip-flop one or two things.

So let's go ahead and get started. We've got a lot to do. Dr. Kelly, would you call the meeting to order, please?

SECRETARY KELLY: Thank, sure will. As the Alternate Designated Federal Official for the Defense Health Board Federal Advisory Committee and Continuing Independent Scientific Advisory Board to the Secretary of Defense via the Assistant Secretary of Defense for Health Affairs

and the Surgeons General of the Military Departments, I hereby call this meeting of the Defense Health Board to order.

DR. POLAND: Thank you, Dr. Kelly.

Continuing the tradition of our Board, I'm going to ask in just a second that we stand for a minute of silence. I think this is important. I don't want it to become rote or routine, but hope that people will take the time to reflect on why we're here. To me personally the privilege of serving on this Board is an opportunity to serve and in this war few of us are asked to sacrifice much of anything. So please if you would consider that. I neglected to bring it this time, but at the next Board meeting I'm going to bring a video that gets a little bit at the nature of the sacrifice that our countrymen and -women are being asked to make. So if we could, could we stand to honor those who have served?

(Moment of Silence.)

DR. POLAND: Thank you all very much.

Again it's an open session today so we'll go around and we'll go to the left today to introduce ourselves and then for guests and others who are in the room.

COL GIBSON: I'm the Executive Secretary

for the Defense Health Board.

DR. BLAZER: I'm Dan Blazer, Board member.

DR. LOCKEY: Jim Lockey, professor of pulmonary medicine and environmental health, University of Cincinnati.

RADM. GAUMER: Ben Gaumer, Assistant Deputy Surgeon General, Navy Medicine.

DR. SILVA: Joe Silva, professor of internal medicine, University of California, Davis, and Board member.

DR. HALPERIN: Bill Halperin, Department of Preventive Medicine, New Jersey Medical School.

DR. LEUPKER: Russell Leupker. I'm professor of epidemiology and medicine at the University of Minnesota.

DR. MILLER: Mark Miller, Director of Research, Fogerty International Center, NIH.

DR. GARDNER: Pierce Gardner, professor of medicine and public health at Stony Brook University.

DR. REDDICK: Robert Reddick, Chair of

Pathology at the University of Texas at San Antonio.

DR. ZAKI: Sharif Saki, Chief of Infectious Disease Pathology at the CDC.

DR. BROWN: I'm Mark Brown. I'm representing the Department of Veterans Affairs.

COL. STANEK: Scott Stanek, Preventive Medicine Staff Officer, Army OTSG.

LTC. SILVER: Aaron Silver, Deputy Chief, Health Services Support Division J-4 on the Joint Staff.

COL. ANDERSON: Randall Anderson, the Director of the Military Vaccine Agency.

COL. DEFRAITES: Bob DeFraites, Director, Armed Health Surveillance Center.

COL. NEVILLE: James Neville, Vice Commander of the School of Aerospace Medicine.

CDR. SCHWARTZ: Erica Schwartz, Preventive Medicine Officer for the Coast Guard.

CDR. SLAUNWHITE: Commander Cathy Slaunwhite, Canadian Forces Medical Officer at Canadian Defense Liaison Staff, Washington, D.C.

CAPT. JOHNSTON: Richard Johnston, British Liaison Officer.

LTC. HACHEY: Wayne Hachey, Director of Preventive Medicine, Health Affairs, Force Health Protection and Readiness.

CAPT. NAITO: Neil Naito, Director of Public Health, Navy Medicine.

COL. BADER: Christine Bader, Executive Secretary, Task Force on the Future of Military Health Care.

DR. MULLICK: Florabel Mullick, Director, Armed Forces Institute of Pathology.

DR. SHAMOO: Adil Shamoo, professor, University of Maryland School of Medicine and a

Board member.

DR. MCNEILL: Mills McNeill, Director, Mississippi Public Health Laboratory.

DR. OXMAN: Mike Oxman, Board member, professor of medicine and pathology, University of California, San Diego.

DR. PARKINSON: Mike Parkinson, President of the American College of Preventive

Medicine.

DR. KAPLAN: Ed Kaplan, professor of pediatrics, University of Minnesota, and a Board member.

DR. CLEMENTS: John Clements, Chair of Microbiology and Immunology at Tulane University School of Medicine in New Orleans.

COL. CERTAIN: Robert Certain, former prisoner of war, retired Air Force Chaplain and member of the Board.

DR. LEDNAR: Wayne Lednar, Chief Medical Officer, DuPont.

SECRETARY KELLY: Joe Kelly, Deputy

Assistant Secretary of Defense for Health Affairs, Clinical Programs and Policy, and alternate federal official today.

DR. POLAND: Greg Poland, professor of medicine and infectious disease, Mayo Clinic, Rochester.

MR. DREBOLD: Ray Drebold, Armed Forces Institute of Pathology.

MS. HIGH: Dedrina High, support staff

for the Defense Health Board.

MR. PASCHAK: Steve Paschak, Cangene Corporation.

MR. KANE: Joseph Kane, Advanced Bio Services.

COL. JAFFIN: Jonathan Jaffin, Deputy Commander, Army Medical Research and Materiel Command.

COL. BALLARD: Chris, occupational medicine resident, University of Cincinnati and soon to be Commander of Aerospace Medicine at Elmendorf Air Force Base.

COL. LUGO: Good morning. Colonel Angel Lugo, Chief of Staff, Defense Center of Excellence for Psychological Health and Traumatic Brain Injury.

MR. ENGLISH: Good morning. I'm Dave English and I'm from the Western Regional Medical Command from MILVAX.

MS. ELLIS: Bridget Ellis. I'm manager of regulatory policy at Plasma Protein Therapeutics Association.

DR. POLAND: Colonel Gibson will have some administrative remarks and then we'll get started.

COL GIBSON: I want to thank Magidan Army Medical Center, Fort Lewis, for being our host for this meeting. We will be doing the tour this afternoon and get an opportunity to go out there. I also want to thank the Board members for being available for this tour. What we do is we try to go to the various military installations in the United States to give the Board members two

things. To give the Board members an opportunity to understand what it's like to be a service member, what their daily routine is like, what their risks, what their concerns and health concerns are. Sometimes I know Board members have to leave and get back because they have conflicts, but if we're not going to do that, if we're going to leave early, all of us, then there's no reason to go out to these things. The other thing that you're doing is showing the flag and it's an important, important job. So I commend you all

for staying and not jumping on a plane as soon as the business part is done. Thank you very much for that.

Thank you to Tina Olivera and Karen for what they're doing here today, and thanks to Lisa and Jean back home. Sign the attendance roster if you have it. That's a requirement. That's about it. The CME stuff, if you need to fill that out, please see Karen and she'll take care of it.

Thank you.

DR. POLAND: Randy, before we start we do have one bit of unanticipated bit of business and that is that we've learned that this is Captain Johnson's last meeting with us. Is that correct? So we'd like if we could to prevent the DHB coin to you. Very few of you will understand this, but I trust Richard will, stone the crows -- his uncle, that he's been with us all this time. Those are common English sayings. I have no real understanding. My pastor who's British told me -- do they mean something? Maybe tell us what they mean.

SPEAKER: I think the meanings got lost a long time ago.

DR. POLAND: One of a series of gaffs that I make. Richard, it's been a delight to have you here and we'll be interested to hear a little bit of what your next duty station is and what you'll be doing -- information about the liaison who will be taking your place, but I can say it's a pleasure to have worked with you and very much

appreciate the input that you've had the Board.

SPEAKER: Thank you very much.

(Applause.)

SPEAKER: It's been a real pleasure working with you. A more interesting and entertaining group of people would be hard to imagine. But I have also been really impressed with the work that you do. I think you make a genuine and important contribution to the health of service members particularly here, but that affects those across the Atlantic as well and I hope I've been able to contribute a little bit to that process. My next job is a staff job in

London looking at quality management in health care, a joint job trying to get the three services to work together, so I'm sure it's going to be a challenge. My relief will be here hopefully for the next meeting in September. He joins in August. He's a medical services officer called Alan Cowan. He's a very active and dynamic guy, and although he's not a physician, I'm sure he'll

catch up and use his brain to good effect. That's all I want to say, really. Thank you very much for looking after me and being polite to the Englishman amongst you, but it's been a real pleasure. Thank you.

(Applause)

DR. POLAND: Our first presentation this morning will be by Colonel Randy Anderson who Director of the Military Vaccine Agency and he'll give us an update on MILVAX and the vaccine health care centers.

COL. ANDERSON: Thank you, ladies and gentlemen. I appreciate this opportunity to come and give your annual report of the military

vaccination programs. This is the agenda that I'm going to follow this morning, looking at these items. Just kind of as a recap for many people who haven't been familiar with our program, we now are a DOD Executive Agent for Immunization Programs. We started off back in 1998 as the Anthrax Vaccine Immunization Program. It expanded

with the Smallpox Program in 2002 and has slowly grown to cover all the different vaccinations since that time. We are now celebrating our tenth-year anniversary and putting together a little historical report to cover our lessons learned from that time.

The bottom bullet there is a new one that we've added since the last time I briefed this Board. The Force Health Protection Council made the decision that the Vaccine Health Care Centers would fall under the Military Vaccine Agency and for that reason we've expanded our mission and scope to include that clinical function they also provide. Many of the other features such as education and scientific

understanding of vaccines were things they also cover and so it blended in nicely, and I'll discuss that a little bit further on.

One of the ways that we provide our services is in addition to an Operations Division and a Communications Division back at the Office

of the Surgeon General in Falls Church, Virginia, we also have a network of analysts. Mr. Dave English who introduced himself this morning is one of our regional analysts here in Washington. I'd say the reason I put this slide up here is this provides one of the best outreaches in abilities to touch the operational forces to find out what's happening out there in the field. You can see we also have someone in Hawaii, over in Germany, Okinawa and Korea. We find out almost immediately whenever there's an adverse reaction case, when there's a shortage of vaccine, when there's maybe a policy misinterpretation, and it provides us the liaison almost immediately and then we can work with the service to resolve this. This has just been an invaluable tool for the execution of our

mission.

Let me jump into the Vaccine Health Care Centers. We still have the four different Vaccine Health Care Centers, the one up at Walter Reed, one down at Fort Bragg, Portsmouth, and down in

San Antonio. While they have a regional basis, they also are tailored toward the different services, with Portsmouth for the Navy, San Antonio for the Air Force, and the other two for the Army. The different services that they provide are listed around that diagram of them there. One thing that I do want to highlight is that they're advocacy. There was some concern when there was the decision to put the Vaccine Health Care Center under the Military Vaccine Agency because you do not want to lose that ability to be the advocate for the patient to have that external viewpoint when you're putting them with the people who are developing mandatory policies. I think we've done a very good job of preserving this. They will still have the advocacy point and there is not the intervention,

but that's something to be careful of when you try to mix these two types of organizations together.

They still provide different education and outreach. Those two features have been

combined with our organization which was doing the same thing using many of the same tools, but now it's combined and we're speaking with a single mission, a single vision. We do maintain a 24-hour DOD Clinical Call Center that is used sporadically, but it's a nice feature to have. We track the different number of calls, where they come in from, and then there's a clinical review policy through our organization, the Vaccine Health Care Center, that reviews how they answered the calls. It is an external and not a DOD services that provides that.

Some of the challenges that they continue to face, the large numbers of people and to have four small organizations that do that. I think many people believe that the understanding of immunizations and the complexity of the adverse event case management is well understood by most

physicians, but that is not the truth. So the quicker we can get those cases into this little clinical center of excellence, the faster and

better results we have found with that.

I was going to provide a little statistic on the number of caseloads. They have tracked 1,899 adverse cases since they began in 2001. That doesn't mean that there's that many adverse cases or that those numbers match exactly what's happening, but those are people who might have been concerned about a vaccine and had a reaction and wanted to try to find out if causality was through a vaccination they received.

The other thing that's still a challenge for us and for this organization is the complexity of military immunizations especially when you throw in mandatory, and then you have the multiple anthrax and smallpox and all these other vaccinations that are not commonly given in the civilian population. You're always dealing with the risk communication, the perceptions, plus are there any true adverse events that are associated

with multiple or -- vaccinations. That's something that we continue to research and look

into.

Jumping ahead to your anthrax policy, like I said, that began back in 1998. Many people in this room have been around for that. It has expanded, it's retracted with shortages of vaccine. Federal judges have put a halt to the program. We executed the first emergency use authorization in the United States. We went into a voluntary period for a year and a half. Then in October 2006 the Deputy Secretary of Defense announced the policy that we execute today, that is, that it's mandatory for those at highest risk, mainly those over in the CENTCOM and Korea areas of operation, and a few special mission units. That policy is I would say in line with recommendations of this Board who said target those at highest risk and not everybody. We also allow voluntary vaccinations of anybody who started the series and wants to continue the series of get their annual boosters. Then there's

a third population, those who are not going to a

high-risk area and haven't started it can't have it at all. With those three different groups, it's hard to implement that worldwide with 100-percent accuracy, but I feel our forces and the people in the field are doing a great job with that.

As of September 2007, we've expanded that predeployment window of when they can start their vaccinations from 60 days to 120 days. That's a real positive thing. That allows the commanders a longer time to get their people vaccinated for anthrax to get over three doses in, for smallpox to get them vaccinated when they can be away from their family members but not pushing those vaccinations into the theater of operations.

Since the beginning in 1998 we've given 7.4 million doses to 1.9 million individuals. You can also see that the production is steady. The manufacturer is making plenty of that. The one big change that's happened in this last year is that there's been the decision that instead of the

Department of Defense purchasing this vaccine right from the manufacturer such as we've done, we will purchase it from the strategic national stockpile. So as vaccine expires from Health and Human Services' national stockpile, we will purchase that at a reduced rate and prevent some of that loss that they've been experiencing, and that was a recommendation of the GAO.

We continue to have multiple studies looking into this. We continue to sponsor different endeavors by Dr. Pittman up at USAMRID looking at this with a firm belief that as long as we're using this vaccine we should continue to try to know everything about the vaccine.

The final bullet there is we're still waiting on the route change and dose reduction. As I understand currently, the manufacturer had submitted that to the FDA. The FDA has returned it to the manufacturer with some clarification. We really are looking forward to that. Yes, sir?

SPEAKER: I'm sorry to interrupt, but I'm a little confused. You seemed to say we were

purchasing HHS's expired vaccine.

COL. ANDERSON: Expiring. Right, we will not use expired vaccine. The goal was to get it with about a year of shelf life left on it, but 6 to 9 months, that will be coming out of the S&S to the field. The field really should not notice a difference other than it's coming from a different address.

Here's a little media interest of the vaccine and you can see the peaks and valleys. This has driven a lot of our workload over the years. In addition to each of those peaks with the media, there are also peaks with congressional and other products that we've had to develop. As you look at the bottom here, the final 3 or 4 years really have reduced in the number of high peaks that we experienced back in 2001 and 1998.

Moving on to the Smallpox Program, this program since it began in 2002, we have now screened 1.6 million people and vaccinated 1.5 million. I like to highlight to the field when I go out there and speak that that difference is

very important. There are over I think about 110,000 people who were screed and not vaccinated, and for this vaccine that is very important and we continue to emphasize the importance of the screening process. The policy for those being vaccinated with smallpox is very close to that with anthrax, those at highest risk, once again CENTOM, Korea, and special unit missions.

We have had three cases of eczema vaccinatum reported, 61 cases of contact transfer, once again, mainly the bandage falling off, rubbing up against your spouse or Marines playing basketball. There have been no other significant changes with the adverse event profile of this vaccine, and of course, over the last 2 months we've transitioned from Dryvax over to the new ACAM 2000 product, and I will speak to that a little bit at the very end of the presentation. Media interest about this has been very low. You can see there have been a few little spikes, the eczma vaccinatum case of the child in Chicago, but other than there, there has been very little to no

interest in it from the media and Congress.

Looking at the seasonal influenza program, we continue to protect the force. This was a very good year. We had over 90 percent of the personnel vaccinated. Putting that onto a commander's report card, that's what we have done with the readiness reporting, is a very positive thing. We turn that on and they watch that, and so it's not just the medical personnel who are pushing it, but also the line commanders. This year we had 3.5 million doses of the vaccine. We continue to use mass vaccination for the flu drive at certain locations to practice training if there ever were a pandemic.

One of the interesting side effects of changing the intranasal vaccine from frozen to refrigerated is that we pushed more of that into the CENTCOM area of operation, but they now are finding that the bulk of it was overwhelming for them. So this year there has been a request not to use the intranasal vaccine over in CENTCOM. The positive side of changing it from frozen to

refrigerated is that you no longer have to have freezers and it was much easier to get through customs.

Additionally, Dr. Cassells has signed a new civilian health care personnel policy. I know that's been a recommendation of this Board and something we're very happy about. Of course, the military is already covered under a mandatory program, civilian health care workers are covered, but this now goes into the non-DOD personnel contractors. It can be written into the contracts, worked out, and that can be a condition for employment. So we're very happy with that change. There will be about a year or 2-year transition and commanders of the different medical treatment facilities will start reporting that out.

Dr. Hashi covered the pandemic influenza vaccine yesterday. We have that -- we bottled it and we brought some ready for us. We came up with a nice policy. Our organization built some beautiful glossy tri-folds. We put implementation

instructions out there and we didn't get many takers. The people that it was targeted for, the people that this Board recommended, the lab workers, I would say there's probably a perception of risk and the feeling of the efficacy of the vaccine. There were plenty of other people who were knocking on the door trying to get the vaccine, but currently the way the vaccine is licensed and with the recommendations of DOD and this Board it was not really aligned for them.

This is the magic slide that covers everything else and I have highlighted a few things on there. Coming down on the left side we have the Japanese encephalitis vaccine. We're looking at a replacement vaccine and we're hoping for FDA approval either at the end of this year or the beginning of next year. My organization is in touch with and dealing closely with the manufacturer on working any phase four post-marketing surveillance requirements of that and we'll be a part of implementing that vaccine.

The next one that I've highlighted down

there is HPV. That is something that I think we continue to wrestle with in the services and the Department of Defense on should this be a mandatory vaccination for all female accessions or should we stick with what our policy is now that at your first well woman that's the time on one-on-one interact with these people and try to transition that way. There still is a lot of discussion within our ranks about what the DOD policy should be.

We continue to do the tetanus, diphtheria, and pertussis, with the pertussis added in there we're trying to get the next time they came in for their tetanus show to make sure they get pertussis and implementing that. Then on the right side, the edno virus type 47. Just this week a lot of results came out of the final phase three clinical study and was very, very positive. I don't know if the Board has been briefed on the great results of that, but now as we look ahead we're looking at a BLA submission in August of

this year, hopefully licensure at the mid to end

of 2009, and in that interim period we'll be working with the DOD policy and making sure that the dollars are aligned there. They have put a wedge of money in there to make sure that it carries us out at least through FY 13, but we still do not know the cost of the individual doses of vaccine.

The other thing that I would like to highlight and Dr. Poland mentioned is that we've put a couple of our posters out there. The Army's program, the accession screening program, I briefed you that last year we had started implementing that and now after a year and a half of screening our basic trainees for measles, rubella, HEP- A, HEP-B, and bercela, we have found that we have averted 197,000 doses of vaccine. Those are doses that did not have to be given because someone was tested sero- positive and so in a year and a half with $5 million saved. Of course, the Air Force has been doing this and

we're working closely with the Navy to implement that for them and the Marines, and also we've made

with the Coast Guard. But that is just a great I think implementation of a recommendation that came out of the AFEB.

One of the things that our organization continues to work on is education. That has just been a huge endless hole. When you start to try to figure out exactly how many clinics are out there and how many people are providing vaccinations, you have to realize that the way some of the services work is a medic could fall into an immunization clinic and then work in there for a few years and then go on and do something else. It is not like we have people who are trained specific for immunology and that's all they ever do. So coming up with all those different types of little locations, the National Guard and Reserves, different places that give vaccinations, we've come up with about 1,500 different locations worldwide that actually

provide and they scope from giving thousands a day at such as a deployment site to maybe one or two a month if it's a Reserves site. So getting in

there, working with those people and making sure they have a standard understanding of vaccinations, adverse reporting, case management if there's a problem, is something that is a driving force for us trying to reach out to them.

One of the tools that we've developed and have been using is the Clinic Quality Improvement Program tool. It's pretty much an Excel spreadsheet, a self-evaluation for the clinic saying here's what you should be doing, here's what tells you need to do, here's how you can find it, and then working through a plan to implement it. That is one of the posters that we have put outside there just to show you how that has worked so far.

One of our main pillars of our communication products is our website. We continue to get about 1,200 unique visitors every

day to this. Through this website you can find out all of our policies for each of the services, for the areas, for DOD news. We have been transitioning to an interactive product. We have

got celebrity endorsements up here through public service announcements, videos, iPod downloads. Adobe Connect is a product that we can do live training where someone sits in a studio and reaches out. We did that with the ACAM 2000 product. We advertised that and worldwide said if you have questions about this, sit down with our expert. We gave them a presentation and answered their questions and we a great response when we ran that five or six times, and I think that environment will be our platform; prerecorded training sessions where we can record who's completed the training. It keeps transcripts. We can get them continuing education credits. And then also that we can run live things to deal with their questions one on one in a -- learning scenario. Our website also continues to have

these 31 diseases, and behind each of those 31 diseases is a tab that's got information pages, the vaccine information statement, the package inserts, all of that information about each of those different diseases and the vaccine

associated. As you can see, each of the tabs has AFEB recommendations or the Defense Health Board recommendations and we post those directly associated with each disease so they're out there.

Finally, the top five initiatives that I think our organization needs to focus on. With the anthrax and the small programs, the interest and the amount of effort that we have to put into that is diminishing. We've been able to focus more on quality of improvement, trying to get out there and train people under a standard, and also the post-marketing surveillance is going to take up a lot of our time. I mentioned the transition of the ACAM 2000. The actual operational transition went very, very well. We were given a short window of shifting that vaccine from once

again the national stockpile. We went down to the CDC's S&S and worked with them directly to make sure that the bottles and the packaging and everything looked good; the requirements from FDA to have a medical guide shipped to the field. The requirement finally came up that all we had to

send to the field was a CD. We were concerned that that was not going to translate into an actual single product getting into the hands of every person vaccinated so we went ahead and printed those and shipped those out in equal quantities to the number of doses. Then we had 1 month to destroy all of the Dryvax vaccine before that manufacturer pulled its license and that was very successful and we got all that documented.

The part that's ahead of us now is the post- marketing surveillance and there are five different major areas to that, long-term, shorter-term, a registry, tracking how well we do the screening. While the requirements for that post-marketing surveillance is really on the

manufacturer, we are the people who have to help them implement it, make sure it's done correctly working with the Vaccine Health Care Center on a registry. There's a lot of benefits from that. Yes, sir.

SPEAKER: Randy, sorry to interrupt you.

COL. ANDERSON: No problem.

SPEAKER: I just want to be sure that that's an old picture and that there are no jet injections.

COL. ANDERSON: I was going to get to that later, but that's exactly right. That is an old picture. We continue to see pictures of anthrax vaccine being distributed to the wrong location, people using pictures of the TB tine test as a vaccination picture. That's what we're trying to get away from, that mentality of just line up and shoot them. The ACAM 2000 transition is going good but there are many years of hard work ahead and from time to time we'll be working with the new the Safety, Efficacy, and

Surveillance Working Group to bring those issues to them.

I mentioned the anthrax vaccine. We're looking at that new route change going from subcutaneous to IM. That's going to be a very positive thing when it gets here and we're just waiting and waiting with great anticipation because that pretty much reduces, 60 percent of

females and 30 percent of males, that experience a local reaction to almost near zero. So the perception take from the field will be better. The dose reduction, just taking out one dose, will be great. The implementation is a little bit hard if you think about our electronic tracking systems, if I had four already and I take out that one, where is my next dose and we're working through all those issues with all the different service tracking systems. Then distribution just to make sure that that executes properly coming out of the S&S in that there are always issues when you change an established procedure.

I mentioned immunization tracking systems. We are making ground on this. The Electronic Health Record Tool which you're pretty much all familiar with. The immunization module that was added to that was an old product of the Air Force's tracking system. It was hardwired on there. Many of the features did not work. In certain examples it has cross-populated immunization data where it shouldn't. So

everybody now agrees that that is broken. We've gotten congressional interest and an amount of dollars that was given to us this year to help fix that and so we are well on our way and that is a great stepping stone to coming up with a universal immunization tracking tool. I think there will still be services having their own systems in the field and there's a need for that since ALTA won't be everywhere right away.

I mentioned earlier that outreach to 100 percent of the people. That is a very hard thing to do but we're trying to establish at least how

many people in each type of clinic, what type of people, and how often they should have reeducation, education on the policies, and trying to at least establish a standard for them and make sure that every one of them knows about the services available. Finally, those DOD basic standards for immunization training. Each of our services train people who give vaccinations a little bit differently. There is some great interest among the services here to say let's

establish that core, what should people do, either through online training or through hands-on training in OJT and then what kind of an evaluation before they start giving vaccinations. We're well on our way with that and think that that will be a great step in providing a standard of care across the whole Department of Defense. That said, I would be happy to entertain any of your questions.

DR. POLAND: Thank you. Let me just ask a few quick questions, Randy.

COL. ANDERSON: Yes, sir.

DR. POLAND: First of all, I want to say for the record how pleased I am that the Department has issued the civilian health care workers that are contracted with DOD's influenza and immunization policy. I think that's a real leadership stance and the Department will be widely recognized I think for that. The second is that the myopericarditis issue that you referenced is something that the Infectious Disease Subcommittee has had interest in and we

will circle back to that. I just wanted to mention it. We won't deal with it today, but we had interest in the ongoing resolution of those that were identified with myopericarditis.

You had one slide on the Immunization University and I'm sorry I missed that one. Is that available to non- DOD personnel, the teaching module?

COL. ANDERSON: Yes, sir. All the different features we have done two different

ways. One where you come in and register and so that way we can maintain almost a transcript of what you've completed, what you're participating in, what we recommend to you. And also we do it as a guest so guests can just come anonymously and participate.

DR. POLAND: Then finally, harkening back to 1998 or 1999 when we did a DOD-wide review of immunization policy, we had identified a number of service discrepancies and what the recommendations were, how they were implemented, et cetera. Is that also a focus of MILVAX and are

there still outstanding issues in that regard?

COL. ANDERSON: I would say it's still a focus. I think it's gotten a lot better since that time. There are still very minor -- some of them are based on missions. I can't think of any single one that pops out.

DR. POLAND: No big issues?

COL. ANDERSON: The discussion of HPV has probably been the one that brings it to the

forefront and how different services feel at different times. But otherwise we pretty much have got a standardized recommendation.

DR. POLAND: Mark and then Pierce.

SPEAKER: My question was related to the comment that Greg just made. Vaccines are very much based on risk assessment of both endemic and epidemic disease and it's quite a change of geospatial distribution over time. You talked a bit about the programmatic surveillance of adverse events but I didn't hear very much about disease surveillance and how the two might go to together, whether or not there is a process and a coordination that you do with

overall DOD surveillance for some of these diseases. And is there also a process for change in the policy? You have quite a complicated list of vaccines including measles, mumps, rubella, and I assume you're talking about the family members as opposed to perhaps the service members. I'm not sure who that means.

COL. ANDERSON: That is for service members that I mentioned.

SPEAKER: So is there a centralized process that you go through periodic reviews of these recommendations as needs change over time?

COL. ANDERSON: I would say it's not set, every single year or every 2 years we look at every single policy and see if it's still established there. It takes on a natural progression and it's an ongoing process and there are so many different people at play all the way from the people in the field who are happy to reduce the number of vaccinations because that's cost for them, back up to policy people such as the people in the room here. We do take that to our different committees but there is not a set

process that looks at those, but it's always ongoing when we start looking at what is the benefit of taking a certain vaccine off of the recommendation we do so, but for most part we watch the ACIP recommendations. We don't deviate unless it's a bio threat and for those we do have a very set process and very formal and bringing

all the different people to the table.

DR. POLAND: Pierce?

DR. GARDNER: A quick question. The myopericarditis issues with 168 cases, about 1 per 10,000 or a little more. In the transition to the ACAM 2000, how many doses of the new vaccine have been used and has the rate for the new vaccine been similar to that for the dry vaccine?

COL. ANDERSON: We give about 16,000 doses per month of smallpox vaccine and we're only into our second month of giving that, so I think it's a little bit too early to tell, but we're also at a level of heightened surveillance I would say. We have seen no change. It was anticipated that there would be no difference.

DR. POLAND: And I can say that's what the non- DOD clinical trial showed was the suggestion there was no difference.

DR. GARDNER: How big were the clinical trials?

DR. POLAND: Not large enough to be able

to get at the tens of thousands you really need.

DR. GARDNER: The other question I had, you purchased 3.5 doses of influenza vaccine last year and Wayne educated me last night that the live or attenuated vaccine is used quite widely in the military. What's the breakout in those 3.5 doses between the killed and the live vaccine?

COL. ANDERSON: I'll answer your question. I've got it before me but I didn't bring it up there. While I look, I also wanted to mention that every year based on distribution there is excess, some that's not used and they do a good job of spreading it around. But this also as a good news story the people over in Hawaii PACOM you might have seen in the press did a collection. They brought it in from all the

services and other locations and was able to share it legally with some of the Micronesia countries and it was very positive based on how you can do the sharing. The shipment of it was done by civilian organizations as a donation as well.

DR. GARDNER: Wayne mentioned some logistical issues and that the shipments of the live vaccine were cumbersome and less popular for far-reaching sites.

COL. ANDERSON: We used this year 1.8 million doses of FluMist.

DR. GARDNER: So roughly fifty-fifty?

COL. ANDERSON: Right. It was a little bit over 50 percent which is pretty significant for us.

COL GIBSON: Just a very quick comment. The Board has established a Work Group for Vaccine Safety and Efficacy and they will be meeting on June 2nd. We will go into excruciating detail about a bunch of issues with respect to efficacy. The Department wanted that, the infectious disease members of the Board were much in favor of it, so

we went ahead and that was established for the record.

DR. POLAND: Wayne?

DR. LEDNAR: A question I have is, is

the global animal health experience informing the military vaccine agencies? As we're talking about assessing risk and developing policy in regard to changing risks globally, are we seeing any connection between animal health and in our thought process on human vaccine use?

COL. ANDERSON: I can't think of any examples where that pertains. I'd be happy to hear any recommendations of how we can incorporate that into the review process, but I don't know if any.

DR. POLAND: Ed?

DR. KAPLAN: I compliment you on the report. It's very comprehensive. I have a couple of questions. One relates to the issue that Wayne just brought up and that is we've recently received from GEIS I believe the information about what's going on in Korea with avian influenza and

I notice that your four centers are all in the United States. I'd like you to address the issue of how you get feedback from overseas since it

appears at least from the slide that you showed that there are no overseas bases. Maybe that's just a misunderstanding on my part.

As far as the other question is concerned, recently as you are aware there has been an outbreak of measles in this country and among the places that have been at least talked about are San Antonio and San Diego and I wonder how this gets into the system or does it get into the system.

The third question, I wonder if it's possible perhaps at this meeting that Roger referred to on June 2nd for us to see what this immunization toolkit looks like. It's probably not worth sending us each one of those kits, that might be a waste, but at least to let us look at it firsthand.

Finally, to follow-up on Russell Leupker's question before, I wonder if the issue

of purchasing nearly expired vaccine is not a disaster waiting to happen in terms of public

relations and I wonder if you'd like to comment about that.

COL. ANDERSON: Let me take them in line. I would say the overseas presence, and I think when you mentioned the four locations you're talking about the Vaccine Health Care Centers. We went through a thorough process within the Department of Defense a review taking up the Force Health Protection Council and it was clearly established that we would not expand at this time, that those four centers based upon their workload could handle it. I think with email and teleconsulting and all the other tools that were used, I think they can provide their services to internationally as long as you've got the people in the field who know that their services are available and that's where the bigger challenge is. I threw up the slide of our regional analysts. One of the things we hit upon is every time you go out and talk to a clinic, make sure

they that there's a Vaccine Health Care Center.

If they don't know, then it's that delay before all of a sudden those people are called and we've run into a couple cases of that because we are an extra layer. There are still infectious disease specialists, there are immunologists around the services, so this is just an added buffer layer and it's not the only service available to them, but making that they're tied back to the experts is what's so important especially with adverse reactions. And we do have an analyst who sits over in Korea and when all of a sudden he hears about a case, it's tied right back within hours to the VHC.

The second issue you brought up was measles. We have different committees that deal with that. When we hear of an outbreak we go back and we look at kind of protection, what is our current policy, how well is it being implemented and make adaptations from that. Even with influenza outbreaks, before we had distributed all of our vaccine we were having outbreaks down in

Fort Benning, Georgia, which wasn't probably one of our top priorities and we switched our distribution policies to meet the needs and that continues to different outbreaks such as that.

The immunization toolkit that you mentioned, we would be very happy to send that to every single member of the Board. It's periodically updated, it's online, but it's a great tool. People really like it and it covers each of the vaccines. So we'll make that happen. Was there a fourth one?

DR. GARDNER: Expired vaccine.

COL. ANDERSON: Expired vaccine, yes. The challenge there is of course first of all we're up against a GAO report that says DHSS, you are just wasting millions of dollars. So as long as it's still licensed and we're able to get it in the clinics and use it, I see the efficiency between interagency cooperation important there. From an operational standpoint, the point I've been arguing with the people coordinating this is we need as long a shelf life as possible. A lot

of times people will forget that we put vaccine on a ship and it goes to sea and we don't have resupply and when you have something like a six-dose regimen, you've got to have enough vaccine there and you don't want to stop because your vaccine expired and you don't want to put people in the field in the position where I forgot that that expired. So it's a very deep concern and something we're in the transition of educating on.

DR. POLAND: Let me ask Roger to just make one comment to clarify something.

COL GIBSON: You had mentioned about feedback and what's happening overseas. We're going to have from the Armed Forces Health Surveillance Center. Keep in mind that MILVAX is the execution arm of vaccine policy for the Department of Defense and as we get information it drives policy change which then he puts into play. We don't want to go around that, i.e., Bob, we'll talk about how we get data and how we're doing surveillance and how that's feeding policy change because the four sites are really more dealing

with problems with the vaccinations, adverse reactions and those types of things, and that's their focus, the clinical focus on the people who have had vaccinations or there is a question of whether or not this individual should get a vaccination because of their medical history. So that's what those four places are focused on. If you go to the slide before that, he had the slide that showed that there were places overseas that were doing the monitoring.

DR. CLEMENTS: My point is that it would be important, and I think you've answered the question, to know what's happening so that it gets feedback into their system.

MAJ. GEN. KELLEY: It was the earlier side and it's the bigger network that does the monitoring.

DR. OXMAN: Two questions. First of all, I noted that you talked about the issue of making HPV vaccine mandatory and that raised the question of what's the basis for deciding to make a vaccine mandatory which isn't related to force

readiness and protection, so I just wondered if that's within the domain of MILVAX or is that a policy decision outside of MILVAX.

COL. ANDERSON: It's also like to clarify something that Dr. Gibson said. As the operational arm to execute policy, we really don't write the policy for the services. We're hopefully the coordinator and the synchronizer per se. There are different ways a policy can come down, the Department of Defense one standard policy services executive or each of the services go ahead and execute. If there isn't a concern to make a vaccine mandatory because of operational concerns such as anthrax or smallpox, there can also be regions within the services that have done the analysis and if we vaccinate our sessions and our people against HPV, we will save future dollars in health care or treating cancer or those kinds of issues. So it can be service specific based on other reasons besides force health protection on the battlefield.

DR. OXMAN: Does MILVAX have a seat at

the table in the formulation of such policies or is that done completely separate from you?

COL. ANDERSON: Typically we do. Definitely for DOD, we're one of the final shops for coordination. For service policy they can execute on their own, but most of the time there is an inter-department discussion in working out those policies so they're not totally out there by themselves.

DR. OXMAN: My second question was the issue of future planning with respect to adenovirus vaccine. Is that something that's on the table now looking at the possibility that you might down the line want to have a vaccine for adeno-14 or adeno-21 or adeno unknown at this point?

COL. ANDERSON: Once again as the operational arm I execute what's FDA approved and can be used, but that is definitely something within the Department of interest and of concern that the vaccine we have coming doesn't cover 14 which has been highlighted over the last year, but

that typically is driven by other entities and different organizations.

COL GIBSON: One quick comment. I'm going to put him on the spot. You were asking about vaccine policy. Captain Naito, can you give us 3 minutes on the JPMPG?

CAPT. NAITO: For those of you who don't know, JPMPG is the Joint Preventive Medicine Policy Group where all the services' preventative medicine heads get together currently about once a month and go over any and all issues related to -- and what's hot and what's kind of constantly brewing. Certainly immunizations is one of those things that is constantly brewing and certainly adenovirus issues at our recruit camps is a concern. Currently with regard to things such as adenovirus at least the Navy perspective, again the nonvaccine approach is what we really stress with regard to the hand washing, for lack of a better term, social distancing and things like that.

I have a personal interest along with

Commander Luke looking at the adenovirus perspective from a different point of view with regard to the convalescent plasma serum therapy which we'll get into later. But with regard to the immunization since we're on that topic, the Navy is working with our recruit camps and we'll speak to this later I believe with regard to using the titers and aiming our vaccinations that way. I had a good talk with Colonel Anderson about getting some funding to get that pushed through further, so again that transition going from mandatory vaccinations to titers is a tough one for us, but I think with some funding we can bridge that gap hopefully this year.

Other things with regard to immunizations, we did do the flu vaccine, so again the whole Thiomersal issue, I think kudos to the Air Force in that regard. So it looks like we'll have enough Thiomersal-free vaccines available with regard to flu that I think we're going to pretty much make it available to everybody who

wants to order it. So again that issue is seven

states that have a mandate for Thiomersal-free vaccines being available, but we're going to make it available to anybody else who wants it as well so that was I think a good success for this year.

COL. STANEK: The point is, the JPMPG meets once a month. MILVAX is at the table. JPMPG is a policy recommendation group. They go back to their services, they go to Health Affairs. So that feedback loop that you were talking about and having MILVAX at the table, the answer is a very, very clear yes.

COL GIBSON: If I can add one clarification, JPMPG do not policy. It's a forum for essentially those of us on the end of the table, and Roger, to get together and see what's going on within our services and reach a consensus. But then it goes back to the individual services where it gets signed off. JPMPG itself doesn't write the policy.

DR. POLAND: Is there anybody else with

21 a comment?

22 DR. PARKINSON: I want to start with a

1 little different facet. It seems like over the
2 10-year history of MILVAX you have moved into more
3 generic immunization support for the entire 6
4 million beneficiary population of the MHS. Can
5 you articulate a little clearly how you evidence
6 that? For example, are you involved in tracking
7 along with the services HEDIS measures for
8 immunization rates in the pediatric population?
9 Are you involved in proactive communication
10 campaigns through the TRICARE website and/or
11 consumer facing materials around this threat to
12 pediatric immunizations right now in the wake of
13 the recent decision to compensate a pediatric
14 patient? There's a furor out there I'll tell you
15 in the professional medical societies going on
16 right now, the American Academy of Pediatrics, the
17 American College of Preventive Medicine, what can
18 we do to stem this misperception. And if you are
19 the hub of the immunization effort now in the MHS

and not just operational vaccines, how are you evidencing that in terms of the things that you're doing?

Finally, do you track for example on your website where those 1,600 hits are coming from? Do you have consumer hits as well as health care provider or technician hits? Do you see your website as a consumer facing site or predominantly a provider support site? These are all embedded in this emerging role and I just want to make sure that the Board has it right. Are you the hub for immunization 6 million person support and if so what does that mean for your business model?

COL. ANDERSON: Starting with the retirees and children, we are not. Starting with anthrax and that was what started us, in this first round that was signed a year and a half ago, the DOD directive and the joint regulation, was really focused more on the military population. I think there's a lot of people covering the other parts of it, the retirees and the pediatrics, not

that it's all coordinated, but there have been efforts there primarily coming through TRICARE or through the local clinics. One a year in the month of August we expand. We outreach and make

it military immunization month and that's the month that we focus on. We go out to retiree clinics, the PX's and really focus on trying to touch those two groups that we normally don't just to make sure of shot schedules and answering their questions about the different pneumococcal and those kinds of vaccines, but it is not part of our core mission. It very likely could be, it's just that I don't feel right at this time that we are ready to expand into that. My deeper concern right now because other people are doing what have been discussing is the quality of improvement of the education and the execution at every one of those clinics and every one of those people. I think that is in much dire need of my services and my staff to focus on that right now. Once that's properly in place and standardized, then we can

move onto the next hot button issue, but we are not ready to go there.

DR. PARKINSON: It may be for the Board members that as we take on the expanded scope of the DHB that we make sure that populations don't

fall through the cracks. So have we seen a decrease in pediatric immunizations post these events, for example, is very important.

MAJ. GEN. KELLEY: And I would say, Mike, we do follow that. Our recommendations are pretty much based on the national recommendations and so we are not doing a tremendous amount of research into developing new things for those populations that aren't our active-duty population. However, we do follow benchmarks, the HEDIS- like measures, and immunizations, and actually that was one that almost got dropped off but we insisted because it's a pediatric one that's widely accepted, you compare your norms to the civilian community which is readily available, and so that will stay on there.

Speaking of that, based on our data collection, we have not seen a drop-off in immunizations, and I say speaking on our data collection because we have only been several years of collecting the data particularly on our pediatric age group and they have a lot more shots

to get. So the data has been getting better and the numbers have been going up. I suppose there could have been a drop, but our numbers don't show that there's a drop as we get better data and so I think we're going forward with better data and we are following it and haven't really seen a drop-off. I think that we'll have more emphasis because one of the projects that we're going through right now is to actually give facilities more money if they are in the higher levels of HEDIS ranges so that would be a factor that if you had all of your pediatrics above 75 percent, have all of their immunizations, that facility would be rewarded.

COL. ANDERSON: Just to also answer your

last question about the website, we do track exactly where people come from. There is no way of determining if this person is an individual concern or a provider but we do track where they come from, dot.mil or Air Force or Navy locations. What's really important to me is where they go, how much time they spend there. If I'm putting up

stuff that nobody visits or it's not of interest, then I stay away from it. If I see something that draws a lot of interest, then maybe we need more information in that area and so that is tracked all the time.

DR. POLAND: A couple more questions that relate directly to MILVAX and then we'll move on. Russ first, then Mike, and then Mark.

DR. LEUPKER: Since you've assured us that the vaccine you're getting from HHS is not close to expiration, I would encourage you as suggested here to expunge the word expiration when you're describing this because it's like waving a red flag in front of folks. Just a public

relations idea.

COL. ANDERSON: The contract says 6 to 9 months that it will have, but I know exactly the risk communication point you're making.

DR. OXMAN: This may not be the ideal time to ask the question and it may reflect my personal ignorance, but in an area of the issue of policies and where does the recommendation begin.

One example would be adenovirus because that's not going to come from the FDA, it's not going to come from outside the military. It's a relatively unique problem for the military. So the question I have is where is the beginning of the recommendation for shall we and if so when and if so how with a live attenuated vaccine or with a killed vaccine with plasma, all of these should be part of one decision process? Where is that happening now and who's taking the lead in that? I have the sense that there are many different independent foci within the individual services and that kind of initiation of planning and

initiation of policy can happen in many different places, but I'm not aware of where it is.

DR. POLAND: Who can best answer that question?

COL. ANDERSON: I think I can. First of all, set every single vaccination goes through this process. Each one seems to take on a little bit different life of its own. But pretty much the people who carry it all the way from the

concepts, coordinating it with their different services, up to execution are sitting in the first half of this room. It's with the JPMPG, with Ms. Embrey's office, with our office. All of those organizations take on the issue, try to come to a consensus if it's going to be a DOD individual policy. Also if we are having confusion or if we can't come to a consensus, sometimes bring it to the Defense Health Board for your position on it. And other times when the Board brings us an issue, then work it at our level and work it up through the policy. Anybody else? That's my take on it.

COL GIBSON: You've basically covered it. It comes from a lot of places including this Board who would make a recommendation to start it. Keep in mind though that it needs to be a deliberative process. I would say that particularly with 14 what we need to do is understand the natural history and the prevalence of that problem over time before we invest $30 million to approach that issue.

DR. OXMAN: It would seem to me that if

this were analogous to a very large corporation with factories all around the world that there ought to be one committee, one spot in the whole organization where you bring the question, shouldn't we think about an adeno-21 vaccine or an adeno-14 vaccine? I don't have any sense that there's one spot within the DOD.

DR. POLAND: So what you're hearing is there isn't such a thing currently.

DR. OXMAN: Yes, and I think there should be.

DR. POLAND: I will point out in our review from 1999 that that was one of the eight or so recommendations that that be established. So we should maybe revisit that in the Infectious Diseases Subcommittee. Mark?

DR. BROWN: Thanks. A quick question I think. You showed a slide of media interest in the anthrax vaccine from I think 2000. It was very interesting and it showed a lot of spikes early on and then a kind of diminution over time. Is that reflecting an increased acceptance of this

vaccine among active-duty service members or is there less concern among the recipients, particularly the active-duty members who are receiving this vaccine and those who are affected by the mandated vaccination? Is there greater acceptance of this as a good idea?

COL. ANDERSON: I would say it's a mix of things. I would say there is still a perception that the risk isn't there for some people. There is still a larger population that

says I'm told to do it and no problems, go ahead and get it. And there are other people who say it's the more educated service member that we have these days who say I have to get this, let me go to the internet and find out what's there and there's still the misperception and a lot of bad science readily available.

I'd say the acceptance though is better. I think what that chart more accurately reflects is all the effectiveness of its advocacy groups for those who don't want to be vaccinated and who don't feel that it should be mandatory. As a

follow-up, there have been the two federal cases. We had the anthrax one which put the stop to program. Finally when the Food and Drug Administration came back with their final rule and final order, that resolved that case. The second case which was in the courts over the last 2 to 2-1/2 years, the main thing going against the Food and Drug Administration was saying they still had not properly licensed the vaccine and the one case

against DOD saying that we had not followed the dosing regimen by when we stop someone we start where we left off. That case was just dismissed by the judge within the last 4 months. So those two cases have not resolved, and when there's not a big case, when there's not a lot of hot things going on in the media, have kind of lost interest in it.

DR. POLAND: We need to move on. Thank you very much, Randy, for that briefing. I'm doing our best to keep on schedule here because I'm cognizant of the need for some of you to leave so what I'm going to do is make the break after

the Health Risk Assessment. Let's go on to the next presentation which is a question to the Board on a Joint Pathology Center. Dr. Gibson is going to lead off with the question and then Dr. Kelley will discuss the ongoing work of the DOD's Joint Pathology Work Group.

To introduce this question about the Joint Pathology Center we need to go back and

provide some background information. We go back to 2005 when the Defense Base Closure and Realignment Commission provided their recommendations relative to the Armed Forces Institute of Pathology. They recommended that the AFIP be disestablished except for the National Medical Museum and the Tissue Repository. The Armed Forces Medical Examiner's Office, the DNA Repository, and the Accident Investigation Group would move to Dover Air Force Base. You can read that. This is what BRAC recommended, disestablishing, taking AFIP apart under the assumption that the workload or the needs of the Department for pathology capabilities would be

absorbed into other DOD and other federal agencies. The President accepted that and because of the way the law was written, Congress then allowed it to be passed into law in November 2005, and the BRAC Commission has been moving to execute on that.

In 2008, the National Defense

Authorization Act directed that the President establish a Joint Pathology Center. This is not just armed forces, this is joint which would include all the other federal agencies to meet their needs for pathology education as you can read there. At the minimum, this Joint Pathology Center was to include those issues that are bulleted in front of you and the President was to determine which agency should take it although Congress indicated that it should go to DOD unless the President thinks it should go some place else.

This resulted in the establish of a work group that Dr. Kelley leads to make determinations and to come up with a plan for how to establish the Joint Pathology Center without interfering

with the established law relative to BRAC. They're working on that. The question that ASDHA is asking you is to review their strategic plan for the establishment of the center and provide your opinion on the appropriateness and feasibility of the plan, and keep in mind the BRAC

Commission as you do that. The short straw here is that the President needs to determine by 2008 where it's going to go. So with that I'll turn it over to Dr. Kelley to talk about the work group.

MAJ. GEN. KELLEY: Health Affairs chartered a work group which has senior representatives from all of the involved DOD agencies and inviting Health and Human Services and the Department of Veterans Affairs to participate in this as they go through.

The key, and this is getting the camel through the eye of the needle, of getting a program that establishes a Joint Pathology Center that does those four things which if you look at the BRAC law says you can't do them. So there is some wiggle room in there, but it's kind of a fine

line that as we go through this process I don't think everyone will be happy with whatever comes out. These are the four services that the Joint Pathology Center just have, consultation, education, research, and maintaining and

modernization of the Tissue Repository. The options that we looked at trying to find things within this within the law that we could do. Do we have to redo the business plan? Do we use another agency? Looking for other options. Can we keep what the current business plan is? Actually, we can't really keep the current business plan because it doesn't mention anything about a Joint Pathology Center so we have to do something other than the current plan.

At the last meeting we discussed these different options. We had option 7, the slides were sent in originally before the last meeting, so 7 actually became a couple of options with one reporting directly to TMA and another work an executive agency. Since these are the things that we discussed and are continuing discuss, since we

had a multi-voting and narrowed that list down, but that isn't released yet and there's a lot of sensitivity to that so I'd be happy to share that with you in closed session but not the open

session if anybody would like to discuss the options that were selected as potentially the best coming out of there.

Funding. That's a very good question. There is no funding in the law that says you will establish the center and the issue has to go with the BRAC law because those things are disestablished and the money of that disestablishment piece is already pulled out of the budget and the future plans. So part of this will be figuring out a cost-effective way to do this and then seeing if the funding will come or Congress can always say fund within the money we've given you even though it's a new requirement. So we are looking at a way that we can have a Joint Pathology Center that can meet the requirements of disestablishing AFIP and then establishing a Joint Pathology Center that

includes but doesn't violate because the law also says you will follow the BRAC law. The second law that says establish a Joint Pathology Center says

you will follow the BRAC law. So we're working on that and that's pretty much where we are right now, looking forward. We will come back with some options to the Board to review our deliberations relatively quickly, and so this is moving fast. We're trying to put some more finalization on some of the models that we have and some funding associated so we see what those costs are in the various options.

DR. POLAND: I don't want to get into the details of that yet so the plan is that this established working group will bring their product to the Board for comment so we will know the details and we'll comment on that, or to the Subcommittee. So let's not get operational or details yet.

DR. LEDNAR: I think I have a big-question question. While the future needs to comply with BRAC and the four missions that need

to be accounted for, the question I would have is for the current state of AFIP, a we had a

portfolio of what they do for the Department of Defense. Will at some point we get to see how those missions beyond the four are going to have a future?

MAJ. GEN. KELLEY: If you would like that, we could. I think there's probably a short briefing of course we were familiar with, but a 10-minute briefing that goes through what are the functions and putting those laws together. There are some options on the functions that weren't specifically disestablished and are specifically told to be present in the Joint Pathology Center and there has been a review group, not the same one, but a group before the first business plan was written on how to deal with those various issues. So actually that probably is a reasonable thing for you to review in terms of did DOD get it right in what they determined needed to be maintained and not.

DR. OXMAN: Not to pin you down on

details, but it's such a major difference if it's

yes or no, is this contemplated to include more than just tissue so that it would be for example a collection of materials from a research project or a serum bank, et cetera? Are those on the table as well?

MAJ. GEN. KELLEY: The tissue repository is maintained by law. The other repositories, the DNA repository and some of those other things are maintained because the Armed Forces Medical Examiner's Office is maintained; it's moved, but it's maintained. So some of those are covered in that, but the intention would be to maintain those things. That's one of those things that's in the area of retain these things.

DR. POLAND: Just one other question. Is the idea of the Joint Pathology Center that it will include animal pathology? The reason I ask is, in fact I just recently got a request from the Navy-Marine Mammal Program and they've got a real issue with their dolphins. Will this include those possibilities?

MAJ. GEN. KELLEY: The veterinary pathology residency is one of the items that DOD said we need to retain and so there's active planning going on on where's the best place to locate that. Some of that planning is put on hold because it may be best to leave it in a Joint Pathology Center but there is some other planning from before going on to move it to I think it was San Antonio. No, to keep it here in the D.C. area.

DR. MULLICK: Yes, it was going to go to RIAD but only for the residency program. No budget.

DR. POLAND: We're going to move on now to the next briefing. This will be Dr. Bill Halperin. The Board was asked to address an issue involving an environmental risk assessment conducted by DOD at Balad Air Base in Iraq. Dr. Halperin as you know leads the Occupational and Environmental Health Subcommittee in these efforts and he'll provide some background on the issue and discuss the Subcommittee's approach. You have a

copy of the question in your notebooks. Bill?

DR. HALPERIN: Thank you. Before I start the presentation, off the record I wanted to present a few slides that will set a background. First of all, how many of you have read the -- so summarize a pivotal work of the 21st century, errors are not the result of individuals. Errors are the result of failing systems. So let's keep that in mind. The next is in thinking about some precepts to think about this report, I had the choice of either going to The New Yorker or to the New England Journal of Medicine so I chose The New Yorker.

A problem that clinicians and others were confronted by all the time, you don't get what you need, you get a lot of what you don't need, you got to sort it through and in the process you got to not make an error. We're talking $1,500 to find the dots and another $1,500 to connect them. Sometimes the answers are in front of us and we can't put not just 2 and 2, but 1 and 1 and 1 together to figure it out. So the

information by itself is only part of the deal. The third, if you will, is we have lots of information technology, we just don't have any information. So a lot of thinking about how errors occur is a matter of thinking about the systems but also what's coming through the systems and are they really serving the purpose.

To start the official presentation, all of that of course is off the right because I don't have copyright for any of it, this is a Subcommittee to assess health risk assessments having to do with burn pit exposures at Balad Air Base in Iraq. It's a committee and I'll introduce them in a minute. The outline is to go over the charge to the DHB, to introduce the Subcommittee members, tell you a little bit about Balad, to give you a little bit of background about health risk assessment in general, and then about the health risk assessment that was done by the military for this air base, then provide an overview of the status of the review, and then we'll talk about the path forward.

This comes from a memorandum from Ms. Embrey to Dr. Poland on 2/29/08 and it's a very good summary, and this is what it says. That burn pits were used in Balad for stuff. It started off with a few tons of stuff and at the peak before they went to use of real industrial incinerators it was about 500,000 pounds a day of stuff and the stuff consisted of food-related byproducts from Taco Bell and McDonald's, et cetera, it consisted of military munitions, it consisted of just a whole bunch of stuff, and the way it was burned was by putting jet fuel on it. If you can imagine, this is a very big pit and it created a lot of smoke, it created a very smoke environment, and this went on for a couple of years. So that's what's really generating the issue, a smoky environment and what are the health effects.

The military I'll use broadly did extensive air sampling at the base and in spring 2007 based on that air sampling came up with some erroneously high levels of dioxin in the results clearly exceeding military exposure guidelines,

and we'll come back to that issue. These erroneous results led to some pre- and post-deployment survey of some highly exposed individuals at the base, about 25 individuals, to see whether in fact there was more serum dioxin post-exposure than pre-exposure and that's part of the health risk appraisal. The erroneously high levels of dioxin led in the risk assessment to erroneously high levels of estimate of excess cancers that would be expected, so you can see how this thing starts to roll along. When the error was determined, that led to a revised health risk assessment and that's essentially what we're reviewing now, the revised health risk assessment. In Ms. Embrey's comments I don't usually count up these words in other charges, but I did in this one, she mentioned quickly, she mentioned earliest convenience, all of those words are there and it will become clear why there's a real urgency to get this done and why it's really almost done by now.

This is the Subcommittee. You know all

of the people now. Gary Carlson you don't know. Gary Carlson is the Director of Toxicology at Purdue and he's going to be a consultant to the committee and he's already offered his comments. And the unknown person is a doctoral-level certified industrial hygienist who we're trying to get on board the train and the train may actually complete its job before we get him on, so that person may not be there, and everybody else you know.

This is Iraq. All of these numbers are air bases. This is Baghdad. Number 15 over here is Balad. Balad is now a city of 25,000 people that occupies probably 25 square miles with a big uninhabited area around it and that's where this incineration was going on, but Balad is only if you will a sentinel. This kind of incineration is probably going on at lots of other air bases and lots of other military bases and there's a lot of potential for environment pollution and personal exposure of people at the base. And I'm not even sure whether these are air bases before or after

the initiation of the war.

The risk assessment and the federal government, this is just background. I think a lot of us know this. It was codified by the National Academy of Science in 1983 in what is called The Red Book. Risk assessment consists of hazard identification, are the agents there potentially hazardous, and the answer in this situation is yes. Is there a dose response relationship between the agents and the effect? What's the magnitude, duration, route, description of exposure by person, place, and time? And this should be part of the health risk assessment and we're going to be asking the question of whether this is adequate in the health risk assessment. Risk characterization which ultimately is how you take all of those dots and put them together and say what's the effect going to be on either disease in general or cancer specifically, so this is the actual quantitative risk assessment.

To continue, the risk assessment is

22 separate from the risk management. That is, let's

1 put in an industrial level incinerator, or the
2 risk communication, what do we tell people about
3 the risks, so these are three separate components.
4 The health risk assessment can certainly
5 consist of uncertainties. You're only collecting
6 a moderate amount of information. There are
7 uncertainties. There is variability in that
8 information. It leads to point estimates with
9 confidence intervals, et cetera. So there's
10 variability, there's uncertainty in what kind of
11 estimate of risk one can make. That assumes that
12 there are no errors. This is variability. This
13 is through error in the data. That is, is there
14 data quality? Was data essentially miscoded,
15 mis-entered, et cetera? So risk assessments can
16 be wrong because of uncertainties, because of
17 errors, and also if one goes essentially beyond
18 the data that you can have. You can extrapolate
19 either too high or too low and come up with
20 something that's beyond what you really should be

predicting.

At Balad there were area samples for

products of combustion. There was an assessment of respiratory disease surveillance data comparing respiratory disease in Balad versus other military areas in Iraq. There was the pre- and post-deployment sero survey for TCDD. And there was a quantitative risk assessment.

What's the status? This goes back and gives you a little bit different history. In the fall of 2007 before there was a request from Ms. Embrey there was a request for SMEs which I now understand to be subject matter experts with the members of our Subcommittee to talk with the folks in the military who had done the risk assessment and that included myself, Wayne, Jim Lockey, and John Erbel. So the four of us read the preliminary report, not this revised report, but the preliminary report. We read it and we listened to the authors, and it's like the fundamental competency of a physical saying is

this patient sick? Regardless of everything else, is this patient sick? The subject matter experts said there's something wrong in your report. We

couldn't put our finger on it. We advise strongly that the authors try to dig to the bottom of it, but they were expressing the dioxin exposures at the air base were probably 1,000 times higher than what they should be leading to all sorts of estimates of risk, 1,000 times higher than you would like them to be, and the group of us said there's something wrong with this report. We don't know where it is. It may be in the data. We just don't know where it is. You got to find it.

After that review, there was an internal release of the report unrevised to field commanders and the Office of the Secretary of Defense, so the word not on the street but within the military was the risk assessment is this 1,000 times high level than probably it was in reality. The report did not reflect the ad hoc comments

from the SME. At some point, and we'll find out as time goes by how this happened, they did find the error and the error appears to be one of those simple dosage errors, you ask for things in

micrograms and they're given in picograms or vice versa and suddenly the patient's got too much or too little. The same thing can happen in risk assessment. You put the wrong units in and you've got a real problem, and that's the basic issue here.

That led to a revised risk assessment and that's what we're reviewing, and then Ms. Embrey's request for the DHB to review the revised risk assessment. We've already now received comments on the revised risk assessment from members of the committee where it's being consolidated now. We've had meetings while we're here. We have I think reached consensus. We have to pull it together, revise, get some review, and we hope that we'll have this report done literally hopefully in a matter of I wanted to say days but

weeks from now and get this done. I got my first email from "I'm a sergeant at Balad" telling me what all of this means to him and it's based on erroneous information that's got to be corrected before it becomes engrained and really alarming,

so we really need to get this done. Questions from the DHB or anybody else?

DR. POLAND: Bill, thank you, and particularly thank you for moving with alacrity on this because for the reasons that you mentioned, it's important that the error be corrected as quickly as possible in the psyche of everybody who's touched this. Questions at all for Bill?

COL GIBSON: One comment first. The report that we've writing is part one. The Subcommittee through the Board is answering the issues with respect to the review of this revised risk assessment. Phase two is to look at how DOD does risk assessments particularly in a combat environment, a contingency operation, hostile area, and to provide general comments on that

whole process to include how to do QC to make sure that the process has the right checks and balances in it so we don't have these types of problems again.

DR. HALPERIN: It comes back the issue of how the system has to be tweaked. It's not why

this error occurred, but how the system has to be tweaked to avoid this happening.

DR. POLAND: Bill, can I ask that you communicate with Roger the time in which you think that will be done so that Roger can communicate with Ms. Embrey saying you'll have this and you'll have this on your desk by such and such a date because I know she's concerned and that's a great service from the Board if we can quickly give advice?

DR. LEDNAR: As a Subcommittee member, personally I'd like to thank Bill for the leadership he's brought to this very complex issue. One of the points, the picture of Iraq and the numbers of all the air bases in Iraq bought

out to me that this question arose at one of those air bases. The practice or question of the burn pit goes on at more than just Balad. So I think as we understand this site and this question, we need to be sure that if there's something about the practice of disposing of refuse that should be different for some reason on the basis of the

understanding of the correct data using the model we have to be sure that those learnings get leveraged and that's more than just in the Middle East, it's more than just CENTCOM. So to the extent that this practice goes on in theater anywhere in the world, we need to make sure again that there's a system way to leverage these learnings and institutionalize them.

DR. POLAND: Mark?

DR. BROWN: That was a very interesting presentation. I would echo Wayne's comment that it seems like there may be something systematic going on here in terms of waste disposal techniques going on in theater. You couldn't get

away with this kind of waste disposal here in the United States. I know back in the 1960s the way the military would get rid of excess chemical weapons for instance was the same way, throw them in a pit and burn them. We don't do that any more, so that's one issue.

The other point I would make is I thought your presentation was really timely and I

would just add the comment that from VA's perspective we have heard about this from veterans and concerns about this so this incident or this issue and this kind of situation and the potential consequences I think can be a problem and I agree with your points that this is something that needs to be looked into I think.

DR. POLAND: Aaron, you have sort of a unique background in this regard. Would you like to make any comments?

LTC. SILVER: I would. Thank you, sir. This is really good, and it is needed. I think that one of the things for me is that there needs

to be more of a peer review on things before they get out. About the way that we're doing waste management in the field, we have to understand that this started out as a fire base and expanded greatly and waste management is done by engineers which are completely separate from medical. The bottom line is the Balad burn pit could be really any place over there. It's not right in the area, it's about 4 kilometers from the actual base

itself, and wind direction and so forth.

We have something called the Overseas Environmental Baseline Guidance Document at the OEBGD that we use as our guidelines outside of the Continental United States for doing things like waste management. While it didn't have anything in it that said if you're going to be at a location for 12 months you need to move to a different type of waste management, they're rewriting that and I think that that will be very helpful in the future knowing when we need to transition in planning for that in the entire

planning process.

Back to the environmental health piece, we need a better way I think to conduct environmental assessments, environmental versus industrial hygiene because I think it's much harder when you're talking about open-air contaminants outside of thins like the criteria pollutants. It's very hard.

DR. POLAND: Thank you.

DR. SHAMOO: I think Dr. Silver may have

answered some of my concerns, that your implied conclusion that the risks are minimal to the soldiers, but I wonder if you've taken into consideration the length of time. This has been going on for 5 years, we are in the sixth year, and if it continues up to 10 years what is the effect on our soldiers. But another concern would be your main concern for the population. What is the air pollution going to do to infants in the nearby areas? Have you done any thinking on that or you should or should not?

DR. HALPERIN: They do have a station set-up at Balad that does the criteria pollutants and really the only pollutant that is potentially above the limit is particulate matter and that's through the entire region. In some cases there's a little issue with ozone but no worse than most metropolitan cities in the United States. We do that in Iraq and Kuwait. We have stations in both locations.

DR. SHAMOO: But in the United States we don't want to live all of us in L.A. Right?

Population in L.A. Especially 15 to 20 years ago was horrendous and controls became stiffer and the pollution went down.

DR. OXMAN: Just a generic question, I think you touched on it inadvertently, and that is there a procedure for the vetting of any report like this before it's distributed?

DR. HALPERIN: Absolutely, sir. I know that the organization that wrote the report has one but this got by it.

COL GIBSON: I wouldn't say got by it. What I would say is that the issue was they followed what they thought was the correct path to inform through their surgeon general on up. The issue is the error wasn't caught until way upstream, way upstream. In addition, because of the grapevine we have a lot of concern of service members who are getting false information, rumor and innuendo, thus the need to get this done fast and have an external group that is well respected, objective, review the process, make their comments, thus it isn't just the Department of

Defense saying oops, it's oops, you guys did this, this was a mistake, you fixed it and it's okay now.

DR. MILLER: With reference to that, Roger, I think the first issue is a public relations issue about the premature release of information and confidence restoration in the process and that not only in this particular event but future and current events. My question also

relates also then to the specificity of the findings and this is just one base of many and there are probably changes of time and practices and stuff that are disposed of in the various difference bases so I would wonder in order to restore confidence whether or not that you having one sentinel site may well want to restore some confidence by looking at several other sites as well and put in an appropriate level of surveillance. I'm not sure what that would be, how many bases, because again there is probably quite a bit of heterogeneity in terms of the practices. I'm not sure if jet fuel is normally

used for burning things. In the State, waste management is a complicated process. We have Tony Soprano in New Jersey. We have all different forms of waste management and without necessarily looking at the long-term consequences because it's easy to overlook those. So again looking at not only environmental exposures but also the process to restore confidence I think is something that we

should be attentive to.

DR. HALPERIN: We try to balance Tony in New Jersey with the academic.

DR. POLAND: Thank you. One more comment.

DR. LOCKEY: The relationship to particulate matter, you're looking at PM 10 I think.

LTC. SILVER: We're looking at PM and PM 2.5.

DR. LOCKEY: We spent some time on that because you're dealing with paralysis perhaps, your PM 10, even your PM 2.5 is going to mask any of the ultra-fines in relationship to particulate

number and surface area. So since you're dealing with a complex environment, complex paralysis, you're going to get ultra-fines given off and there might be a carbon core with a heavy metal with pH's on the surface. So I think one of the recommendations is that you got to stratify the particulates down to PM 0.1 ultra-fines or less to

see what is your real distribution of the particulates in relationship to size.

DR. HALPERIN: Just very, very briefly, this report is clear that it's not dealing with the particulates or the metals so one of the issues that I think Mark raises is absolutely right, that the risk communications are going to have to be coordinated with that because just to talk about dioxin and some other chemicals and ignore the fact that you've got the particulates out there is not going to fly all that well and it's got to be coordinated. Thank you.

DR. POLAND: Bill, thank you very much.

LTC. SILVER: May I make one more clarifying point? The vast majority of the

particulate matter in that region is from blowing sand. I just want to make sure that everybody knows that. It's so bad some days that you can't see 10 feet in front of you.

DR. POLAND: We really do need to cut off here because we're starting to get late

despite starting a half- hour early. So let's just take a 5-minute break if we can and then reconvene.

(Recess)

DR. POLAND: A couple of things before we go on that I want to be sure and clarify in regards to the Joint Pathology Center. That will be going to our Pathology Subcommittee, but I will be asking for some volunteers and appointing some individuals to that for the purpose of reviewing the product of Dr. Kelley's committee. The second thing is in regard to the posters that I mentioned, I should probably clarify that we can't have them on the inside where our meeting is occurring and we'll have them on the outside as they are and I just wanted to clarify that. I

would also ask that for those of you who want to do that, and I do encourage it, that you just pass them by Roger and his office first. The main sensitivity I have is what I don't want from some the visitors and others is commercials and

commercial kinds of posters out there. I wanted to reflect the science of the military agencies and of the individuals on the Board.

Our next speaker will be Colonel Robert DeFraites who is Director of the newly formed Armed Forces Health Surveillance Center. Colonel DeFraites will discuss the center's mission and structure. I want to add that the creation of the center is the culmination of a long and difficult struggle to centralize medical surveillance within DOD and it's something that the Board has had interest in over the years. There are a number of issues that will probably come up at the end of it and discussion will occur among some of the Infectious Disease Subcommittee members at lunch. So for the ID folks, I'd ask that we, no pun intended, quarantine ourselves so that we can talk

about some of those issues. Colonel DeFraites?

COL. DEFRAITES: Thank you, Dr. Poland. It's a great honor to be asked to speak and address the Board. Some of the slides that you

have in your binders, I'll try to get through them quickly and then leave a lot of time for questions. This is what I'll cover today, the background of the center and what was intended, the concept, and then the current status such as it is since it's been just recently officially chartered.

The history here starts in July 2005, though really the idea for a consolidated Department of Defense Strategic Health Surveillance Center clearly dates 2005. A lot of the lessons from the first Gulf War and the need to have some type of fairly comprehensive surveillance system from an operational perspective clearly predates 2005, but Ms. Embrey formed a task force to develop a concept of operations for an Armed Forces Health Surveillance Center again to realign those strategic health

surveillance capabilities that were scattered within various agencies within the military services and the Department of Defense. In the 6

months after the charter of the task force, the CONOPS was developed and one of the key ideas was that the center should be operated as an Army led executive agency in a staged or phased approach of formation and to start with using some of the legacy or existing components of those surveillance capabilities that existed within the TRICARE Management Agency, the Deployment Health Support Directorate, and some of the Army Medical Department executive agency surveillance activities.

In June 2006 the Force Health Protection Council which Ms. Embrey chairs, a two-star-level counsel, approved the concept of operations. In the ensuing year some additional staff and tweaking took place, but in May of last year the CONOPS was signed off for OSD review by Dr. Chew, the Under Secretary of Defense for Personnel and Readiness. In the concept of operations, this is

the division and the mission, and under that vision statement you can see those descriptives of

information of relevance, timeliness, actionable information, and comprehensive information, those types of qualifies of information of what we do with information that are common to all public health surveillance activities. Again the idea was to have this support available for all of the armed forces, for the military and what were termed military-associated populations, and I'll talk a little bit more about what those might be.

Again, in the mission statement you can see these other action words of acquiring, analyzing, interpreting, recommending, and disseminating information. Also a surveillance methodology standardization, some approach to at least have shared definitions of when we talk about for example a traumatic brain injury, what type of data when we're talking about rates of traumatic brain injury or any other disease or injury, to get some type of standardized approach so that different parts of the organization can

speak and can communicate accurately. So the

center was clearly given the mission to look at methodologies for surveillance. The center would be the focal point for sharing the products, the expertise and information. Finally, what I've started to embark on early on in the life cycle of this organization is delineating those roles, responsibilities, and relationships with the other health surveillance organizations in the services and other organizations that do things that the center may not do, and I'll talk a little bit more about one of those as we get closer.

This is germane I think to the question that came up about policy for immunizations, for example, but clearly in the idea of what the center was envisioned to do, one way to look at it is to look at what were those key outcomes or actions that it was supposed to do and who are the customers for that particular work. So for informing operations in terms of existing or ongoing health threats in operations, certainly the Joint Chiefs of Staff and the combatant

commands would be a key client. For readiness issues in terms of individual medical readiness of the force, that's a Title X responsibility that the military services and the military departments have for manning, equipping, and training the force and clearly the individual medical readiness is a service responsibility and having some type of standardized approach for defining the individual medical readiness is something that Health Affairs and the services have been interested in and certainly the health surveillance information can help inform that.

For policy of all different types, and again it's not just Health Affairs but also other OSD policy offices, the information that's generated by our Health Surveillance Center does at least to plant the seed or begin the process by which a requirement for a new immunization for example might be made. For researchers, and again researchers are always looking for updated current threat estimates of disease and injury trends within the military, clearly the Health

Surveillance Center would be involved in that. And from a national and interservice federal agency perspective or even international perspective, we have relationships with the Department of Homeland Security, DHHS, the Centers for Disease Control, the VA, and World Health Organization. I'll get specifically into WHO because the liaison with WHO is with the Global Emerging Infections Program which is part of the Armed Forces Health Surveillance Center as it's been rolled up under AFHSC. As far as looking at the products, again you can look at this is just the way the health surveillance and the epidemiologists would look at life in terms of stratifying or analyzing data by these aspects. This is one of my favorite slides. It shows a number of things. You can look at this and see a number of things happening. For one thing, it shows the multiple mutually supporting relationship between the VA, research and academia, the other national federal agencies, and even states and metropolitan areas, because the

data we have come from posts, camps, and stations around the world and within the United States that are parts of the communities. So we have a relationship through those installations and again the roll-up or the comprehensive nature of the date we have allow us to support the work even in the metropolitan areas. As I mentioned, the unified commands, the combatant commands, the deploy sites, the TRICARE management agency, and through the service surveillance of U.S. Air Force's School of Aerospace Medicine now their epidemiology and their consultant service and risk assessment programs are still extant, and again we have a relationship with the Air Force and with the Army at the Center for Health Promotion and Preventive Medicine, the Navy-Marine Corps Public Health Center, again working out the relationships of what the AFHSC does and what these service agencies still do is a work in progress.

The other thing I wanted to say about this particular slide though is that you can see it has mutually supported relationships. The

other thing you can see is that it looks you could be pulled in many different directions on this slide so you have to balance the needs of all of these. Or it could be viewed as being trapped in a web and you're waiting to be eaten up, so there are a number of ways. It depends on what kind of what I'm having depends on how I interpret that slide.

Again from a public health perspective, this is our functional organization. Right now I'm working on how this functional organization is actually going to play out in terms of a diagram for command and control of the center, but again as a data function for collecting, integrating, and managing data, so we have certainly databases, the Defense Medical Surveillance System is part of our Armed Forces Health Surveillance Center, and that's probably the largest single database that we have along with the serum repository to manage. But there are other data systems such as ESSENCE (?) that's going to come into the fold. The analysis function is very important in terms of

making some sense of the data and again getting to where we're actually supporting operations through dissemination of the information through reports and a response piece in terms of how the Armed Forces Health Surveillance Center helps to coordinate public health response. That's going to be a partnership with the Surveillance Centers of the services and then on a national in coordination with Homeland Security, DHHS, states, and local entities, depending on what's appropriate for our involvement.

I mentioned the phased approach from a provisional center, to an initial operating capability, to a future operating capability. The provisional operating capability was viewed as those pieces from existing agencies, the Center for Health Promotion and Preventive Medicine, the Navy, the Air Force, the Global Emerging Infections Program, and Force Health Protection and Readiness. This is part of Ms. Embrey's staff. Right now as of February 28, the Center for Health Promotion and Preventive Medicine has

contributed the Program 30 which was their Army Medical Surveillance Activity. The Global Emerging Infections Program which you're quite familiar with includes the DOD Influenza Surveillance Program and the existing GEIS programs. It's a total $52 million per year program. Then the Force Health Protection and Readiness piece, we're still negotiating to see how we're going to migrate that and that's a work in progress.

It was envisioned that this provision operation would be a split-based operation but we're very quickly working to consolidate it generally into a single location, but at least for our analysts and our headquarters operations, it's in a single operation. The initial operating capability, this means within the next 8 months, by the end of the fiscal year, we're really supposed to have unity of command collocated operations with 24/7 coverage. I'm still trying to actually articulate what the 24/7 really means in terms of what level of capability is really

expected or needed at that level. Then we get into the wider set of populations, and again, a lot of our work is defined by the population for whom we have the most relevant and useful data. So starting with the Defense Medical Surveillance System which is a very good set of data on that active-duty population, those personnel who have separated from active duty, again, some of whom are in the VA system, some of whom are not, that's a challenge. Then retirees and family members, and again I'm negotiating with other organizations who have a better handle on these databases. We do get some medical outcome data on these other populations but those populations are not nearly as well defined as the active-duty population so from an epidemiologic and a surveillance perspective, it's not as handy a population to deal with but we're working toward that. The future, I'm not going to really spend much time on that because the future goes beyond the horizon and it could be anything and it's growing and

22 expanding your capabilities.

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1 Just a little bit more detail of what we
2 thought was potentially coming from these various
3 existing organizations, the Center for Health
4 Promotion and Preventive Medicine, the School of
5 Aerospace Medicine formerly known as the Air Force
6 Institute of Operational Health, some of their
7 expertise, Force Health Protection and Readiness,
8 and a big piece of this with the Joint Medical
9 Work Station, the Joint Patient Tracking
10 Application, MSAT (?), especially the JMEWS data,
11 they have access on the secure side to the data
12 that's generated within theater which is
13 classified as secret and one of our limitations of
14 our center now is that our particular building has
15 no access to secure data so right now all of the
16 data that's being accessed on the secure side is
17 in the Skyline Building with Force Health
18 Protection and Readiness so at least for the time
19 being we're going to be operating in two different
20 locations at least to get access to the -- data.

The Navy and Marine Corps Public Health Center has some particular expertise developed with HL7 data

(?) messaging with laboratory data that we're interested in funded through the GEIS program. Then the GEIS program in particular, their global coordination and monitoring and emergency response functions, the training functions, they fund the surveillance programs by an entire worldwide network of partners, the overseas laboratories -- respiratory illnesses at basic training sites and -- mortality through the Armed Forces Medical Examiner's Office. So the GEIS program being part of the AFHSC brings a lot of capability.

This is interesting in the sense that this is what we thought in the concept of organizations is what the center will not focus on and the idea of doing health care systems analysis in terms of cost of care, bed occupancy, customer satisfaction, medical management, utilization management, disease management, quality of care, and clinical research in terms of the -- comparing

particular treatment protocols was not considered to be within the scope of the operations. So one of the duties that I have as a professional

director is to say if you don't do it, who does and to make sure that we get that interface very well defined. So number one, for better customer satisfaction, if somebody calls me for that particular -- at least I have one person or one agency, the appropriate agency, to refer them to with one phone call and not just say I don't know how does that. So one of the things I did this week was at Brooks Air Force Base, the Air Force has developed a fairly robust population health program, I forget what their name is now, but the population health, and really a lot of this work is their business. And again, there are other organizations that do this too so I'm basically going to improve my Rolodex capabilities to know exactly who to refer. Then I think the next piece will be how does this get better organized if it needs to be beyond the scope of my particular

center.

Our current status of the center, as I already mentioned, back in October to get a jumpstart on things, there were a number of

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issues, very specific, very operational tactical issues, dealing with an expiring lease on our space for the serum repository in 2010 and also our servers and part of our organization for the Army Medical Surveillance Activity is on Walter Reed's which is under the BRAC. So there are a number of things that happen and General Pollack as the Acting Surgeon General formed a provisional AFHSC that merged the three Army Medical Department executive agencies, the GEIS program, the Defense Medical Surveillance System, and the serum repository, and to start moving out executing the task force draft CONOPS within the limits of the Army at the time. This has now been overcome by events, and on February 26 the Deputy Secretary of Defense signed a memo that established the AFHSC and now we're negotiating

with our other partners to get to our initial operating capability by the end of the fiscal year. This is where we are located now at 2900 Lindon Lane. This is right outside the Walter Reed Forest Glen Annex complex on Lindon Lane. My

office is here. We have two out of the three floors of this belong that belongs to the AFHSC. We have the analysts for the Defense Medical Surveillance System, we have one Force Health Protection and Readiness program analyst that sort of migrates back and forth between the two sites between Skyline and our office, and the GEIS program is mostly located on the first floor. Our serum repository is located at the Tech Road campus which is about 5 miles away. And as I mentioned, we still have our technical staff for the Defense Medical Surveillance System and our servers in Building 220 at RAMSEE at Walter Reed. So part of the job of the director is to consolidate these disparate scattered organizations into one place. Just to refresh

your memory on the Defense Medical Surveillance System as I mentioned, it's fairly comprehensive for the active-duty population in terms of the longitudinal data system to report medical events and other sort of personnel relevant events linked with the serologic data on the specimens that the

Board is well familiar with, the serum repository, and so it's a very nice way to start a very, very solid foundation, to start an Armed Forces Health Surveillance Center in terms of data capability which does need to be enhanced in the future. One of the key products is the Medical Surveillance Monthly Report which on purpose is modeled after the Centers for Disease Control MMWR. It's published on a monthly basis and there have been 100 issues of this published so far. The staff does publish other articles. One of the things Ms. Embrey really wants to see from the GEIS program and from the Health Surveillance Center is that we get more visibility in the peer-reviewed literature.

One of our other key partners that I didn't mention but came up before was the Military Vaccine Organization, MILVAX. We have been coordinating with them even before the ACAM 2000 vaccine was launched in February to assure that we had the ongoing surveillance looks at the health events associated that would be occurring among

the cohort of service members who were receiving the new vaccine so that as we transition from the Dryvax vaccine to the ACAM 2000 we could follow the trends across time. As Colonel Anderson mentioned, we're only in the second full month. They started with ACAM 2000 exclusively on March 1, so we're only in the second full month, but thanks to their foresight and preexisting relationships, we had already started cranking this back up before the transition. This is where the serum repository is located. There is a chance that we could get additional space within this huge building and consolidate everything here, so that's a possibility. We have about 43

million specimens on 8 million different individuals collected since the late 1980s and 1990s and that's clearly a basis for a growth for the Health Surveillance Center to do some more ongoing surveillance using the serum repository.

Just a couple of words about the GEIS program. For the Global Emerging Infections Program, these are the infectious disease focus

areas for the GEIS program, acute respiratory disease, gastrointestinal disease -- infections such as malaria, drug-resistant organisms and sexually transmitted infections. The capabilities that the GEIS program has focused have been in the surveillance and detection arenas, response and readiness, integration and innovation, cooperation, and capacity-building. The modus operandi of the GEIS program has been for the most part building some innate capability within the program itself but most of the funding goes to external partners through an extensive network, both what it's called, I think it's a great name,

they have two programs, the Influenza Program, and they have something called EBI which is everything but influenza which are the other things. But both programs are operated very similarly in the sense of coordination with Health Affairs and with the combatant commanders around the world, requests for proposals and funding of priority issues within these areas.

Just a brief review of the GEIS program.

It started in 1996 and the DOD's mission was expanded. At the time it was a two-way street. For the most part though the biggest emphasis was that DOD would link arm in arm with other federal agencies to combat emerging infections around the world as part of a national effort. Again these are the areas of surveillance training, research, and response. Also though I think as part of that and clearly fleshed out since 1996 was not only what is DOD doing for emerging infections diseases around the world, but also what can the DOD GEIS program do to assist the military health system in

terms of a force health protection mission for emerging infections surveillance and control within the Department of Defense, so those two missions of assisting the U.S. Effort for worldwide partners as well as a force health protection mission. This hasn't changed and this is going to continue, but I want to point out one thing in particular, that the DOD will strengthen its global disease reduction efforts, again global, and again particularly the President at

that time pointed out the overseas laboratories. I know the AFEB before the Defense Health Board was very intimately involved with the support and evaluation of the work of the Overseas Research Laboratories and I'll say since 1996 the research mission of those overseas laboratories has been enhanced with the surveillance mission and now some of these labs have about a fifty-fifty split between the emerging infectious disease surveillance mission and research.

This includes those countries in which

GEIS funded activities operate. Again, these are not all operating out of Silver Spring, Maryland, but through the worldwide partnership in 77 countries. This in particular since the flu program started in 2006, we have a $40 million pre year DOD Influenza Surveillance Program that the GEIS program operates and again through the extensive network, it's an interesting combination of military assets here. You see the overseas laboratories of USAMUK in Kenya, NAMRU3 in Cairo, NAMRU2 in Indonesia, AFRIMS in Bangkok, and Naval

Medical Research Command Detachment in Lima, Peru. Those research entities are contributing their part to influenza surveillance. A key piece, this is the U.S. Air Force School of Aerospace Medicine, but AFIOH is responsible for their worldwide network of again collecting culture specimens around the world and you heard yesterday about the influenza strains that are contributing to next year's vaccine and I believe, correct me if I'm wrong -- but I believe the South Dakota

strain did come from one of the specimens that AFIOH collected in a DOD beneficiary so that's been a fairly routine occurrence. So this surveillance network really is unmatched by any in the world. The Centers for Disease Control has nothing around the world like this. Where we're expanding efforts, the area for expansion now is going to be in Africa through AFRICOM. Colonel Loren Erickson who is the Director of GEIS has been very proactive and energetic in engaging the combatant command surgeons and in particular with the newly established AFRICOM.

The other part of this slide I wanted to point out is that not only do we have the research laboratories, but also Landstuhl Regional Medical Center in Europe, that's a medical treatment facility, AFIOH 18th MEDCOM again is an Army operational agency, and Naval Health Research Center out in San Diego which operates the -- Respiratory Illness Surveillance programs on basic training posts. One of the things in particular

that I viewed as very key is what were the implications for the GEIS program now that it's part of the Armed Forces Health Surveillance Center and a couple of things I thought were true is that certainly the vision and mission of the GEIS program remains relevant and supportive. GEIS headquarters certainly has a key piece to our emergency response communication and coordination functions. I mentioned the OCONUS laboratories, and within the military health system, the Emerging Infections Disease Surveillance, the -- Respiratory Illness Program, mortality work that's done by the Armed Forces Medical Examiner's

office, et cetera, that support will continue. For the time being, the business process of proposal submission and review and funding through the network of partners will continue. The GEIS website is still available and linked to the AFHSC. We have www.afhsc.army.mil that is now the AFHSC's website still operating and as funding continues for the DOD's AIPI Pandemic Influenza

Surveillance Program, as long as that funding is coming, we are going to continue to administer it the way we have.

Again, one of the issues for me and for the Force Health Protection Council who's my board of governors is how to better integrate GEIS with the other DOD surveillance programs and is one of the key concerns of Ms. Embrey. Here are the initial tasks, some are very bureaucratic in a way, but we've got some paperwork to do in updating some DOD directives and writing a DOD instruction that helps us cement the Armed Forces Health Surveillance Center as a DOD entity. We're establishing the provisional operating capability,

that's where I spend most of my time, because these existing organizations have to continue to do the work they've been doing. We're not giving any time off so we continue to rum. I've been named the provisional director until next summer and at that point there's going to be a tri-service nomination process like we had for the

GEIS director where the future directors of the AFHSC will be selected from tri-service nominees and I'm supposed to provide a plan to achieve the initial operating capability bask to the Force Health Protection Council by July 26. One of my things as I mentioned earlier this week, I was with the Air Force and I needed to work with the Navy on how to transfer or at least make sure we have the appropriate seams defined between what the AFHSC does and what the services' surveillance agencies will continue to do, namely, AFHSC is not going to displace the function for example of a Navy epidemiology team going aboard ship. There's no way that I'm going to have people unless we're invited, of course, and then we will come, but

clearly the service direct support functions are going to remain with those surveillance agencies. I think that's where I'll end and entertain questions.

(Applause)

DR. POLAND: Nicely done. Thank you.

Questions?

DR. HALPERIN: As I recall the organizational chart from yesterday that Colonel Gibson and the staffing of the various committees, I think that it's an odd match, but it's occupational, environmental, and surveillance.

COL. DEFRAITES: Yes.

DR. HALPERIN: If that surveillance means this surveillance, then we've got to figure out a way to relate to what we've just heard and figure out what our role is, whether it should be ad hoc responsive or a visiting committee or what.

COL GIBSON: Let me address that if you don't mind. Yes, it was an odd match we decided as a Board to make that match. Historically we had a requirement to do a review of GEIS.

Obviously the Armed Forces Health Surveillance Center didn't exist at that point. But if you notice the dates that Bob put up there, that was just during the transition from the AFEB to here so the decision was that we would not do a formal

obliged review recommendations to GEIS but to wait until we were at a point where we had an Armed Forces Health Surveillance Center and then talk to ASDHA to codify a process, a formal relationship. In addition to that, responding to the Armed Forces Health Surveillance Center on an ad hoc basis, that's part of our mission and we would continue to do that if and when they asked questions and want our opinion on either an organizational issue or a technical issue relative to surveillance. Does that answer the question?

DR. HAPERIN: Yes.

DR. POLAND: Joe?

DR. SILVA: Just a couple of quick questions. Your monthly surveillance issue, medical surveillance monthly report, can we get access to that?

COL. DEFRAITES: Yes. It's published on the website.

DR. SILVA: It's on the website?

COL. DEFRAITES: But, yes, I'd love to

include all of the members. We do publish a written paper copy.

COL GIBSON: Who on the Board doesn't get it, because we've been sending it out. I've asked Mark to send it to everybody.

COL. DEFRAITES: I think I've got everybody's address. Isn't in the binder?

COL GIBSON: I asked Dr. Robitone to include you on the distribution.

COL. DEFRAITES: You keep moving or something.

DR. SILVA: Secondly, this serum repository or other tissues, this is an incredibly valuable resource. We have all kinds of people exploring the genetics of man and other animals and they're being posted in other countries where they have excellent records like Iceland and it's sort of protected. Can the civilian sector get

entry to these samples for research?

COL. DEFRAITES: Some.

DR. SILVA: How do they do that?

COL. DEFRAITES: There is a process. Generally, access to the serum repository is limited to those proposals that meet several criteria. One is an approved protocol with an IRB, a military co-investigator to be named so that there's some active-duty military co-investigator who's actively involved in the protocol. That's been our criteria up to now. I think a lot of the operating characteristics of the repository need to be reviewed, but that's currently our approach right now.

DR. POLAND: It's only serum.

COL. DEFRAITES: It's just serum, yes.

DR. POLAND: So the genetics aspects are difficult.

COL. DEFRAITES: There are some proposals underway from USHUS (?) to look at what genetic material might be available in the serum.

COL GIBSON: To quite Dr. Ennis, there's

enough cellular filtrate at the bottom of those tubes to do just about anything you want

genetically. I would comment that we talked about this dioxin test -- serum repository. We ran serum dioxins on a random group of 25 folks from blood pre and post.

DR. LEDNAR: Bob, a really nice description of this global network that you'll be managing. My question is, as you're thinking about the plan to operate this center, will that include evaluating whether or not the dissemination is reaching all of those places throughout DOD that you'd like this information to reach, that the action messages are clear and get some feedback whether or not actions are considered are implemented or not, and that the products of the center from the eyes of the customer are meeting the needs?

COL. DEFRAITES: Yes, I would be open though to suggestions of how better to do that. Right now I have no doubts of some of the readers of the MESMA (?), for example, just to give you an

example. I get phone calls and public affairs

officers get involved just about every month on a regular basis and it's usually "USA Today," "Army Times," and "Stars and Stripes" have questions about articles or data they've seen in the MESMA. So I know somebody's reading it and at least it's getting somewhere. They're very good. And there are a few others I get too. I am concerned about who else might be reading it or not reading and why and I'd be open to suggestions on how to do that.

In terms of the other outcomes, I mentioned all of these other clients or customers of our products, for example, to generate policy recommendations or to inform operations, the feedback loop is indirect. I'm hoping that the board of governors of the Force Health Protection Council in their busy times, they have a lot of things they have to do, but I'm hoping that that venue, it's a two-star venue, the Deputy Surgeon General, the Joint Staff Surgeon, and a few others, at least a way to get entrée. But again,

that's very close to the flagpole, very close to the Beltway, and it doesn't answer your question about the hinterlands. I think the partnerships with these service surveillance agencies and their reach and then the reach of the installations helps to a great degree because the data we have are generated locally.

DR. POLAND: Chris Ballard, and then we'll move to Kevin.

COL. BALLARD: Just a couple comments from a customer who's personally using the system right now as I'm doing a thesis for my residency on a population study, I want to piggyback that the DMSS is an incredible database. Imagine doing an historic population cohort or case control studies on any medical diagnosis that's occurred in the military over the past 15 to 20 years. You streamline everything by having this database. As for the Air Force division, it's called PHSD, the Population Health Surveillance Division. Sadly, on a review when I was working at the DMSS, there are only about 20 studies out on all of Medline

that comment on anything on DMSS yet this database has all of this historic data. One last comment is unfortunately probably a little bit of a hole in the database is if you want to drill down to specific service specific populations, there's difficulty getting data and the reason is that once DMSS gets all the data, they convert all of the ASFC's (?) or MOS's or duty codes to a DOD general code. For instance, I'm doing my study on fighter pilots and I can't pull the data from DMSS because they do not have an Air Force specific code for Air Force fighter pilots. It gets combined with a few other pilots such as bombers.

DR. POLAND: Kevin?

DR. MCNEILL: I enjoyed your presentation, Bob. I had the privilege to serve on the recently published IOM report on the DOD GEIS Global AIPI surveillance efforts. Actually I was very surprised during the course of the discussions how dependent the overseas laboratory system has become on funding provided through the DOD GEIS system to the extent that a very

respected member of the group said that pretty much the DOD funding was now the lifeblood of these laboratories as a partial result of lower levels of funding through their parent services, primarily Army and Navy in terms of the overseas labs. Frankly, looking at this on the surface, this looks like a step away from the DOD level organization that DOD GEIS is clearly now recognized to be. It's becoming more of an Army appearing organization under the CHIPM (?) and I would like to know if there is any reassurance that we on the Defense Health Board could get that the current global medical surveillance mission that is now being performed by DOD GEIS primarily through the overseas laboratories will be protected, will be appropriately emphasized, and that this so-called ATM effect of collocating GEIS with other programs, this was openly discussed at the meeting in Bethesda in January, will not in fact become a reality. I for one am very concerned that we're about to lose a global public health resource here in these overseas

laboratories. I think it's a sad day that these laboratories have to depend on GEIS for funding. I think that's the responsibility of the Army and Navy medical R&D commands. Where are you guys? But having said that, what's going to happen to these labs?

COL. DEFRAITES: I see that Colonel --

DR. POLAND: I see that Colonel Jaffin is here from MRMC. Just to reassure Dr. McNeill, the oversight of the AFHSC is not from CHIPM. The executive agency responsibility -- Army for the care and feeding of the organization. The chain of command goes back to Ms. Embrey and the Force Health Protection Council's joint council is the oversight body. I think that board of governors is there to assure that there's a DOD mission that's being preserved and it's not Army only. I would say to its credit the Army has put up most of the assets so far. That's one of the reasons I went to see the Air Force this week too. There are some checks in the mail from the Air Force.

MAJ. GEN. KELLEY: I think that it's an

overall plan to get there and I don't think that there's any intention to decrease the surveillance capability. As a matter of fact, the idea is to centralize the surveillance capability so that things like MILVAX when you're talking about what's happening in the world has a single source to go to to get the information. That works in many different ways. The other services as Dr. DeFraites said were concerned that it was going to be Army centric and they did not initially kick in as much people and resources. But I think that it's going and the idea would be to show its value as a DOD resource and then the other services could decrease their service specific requirements for doing their own surveillance because you've had a system in place that could tell you service specific data but not have to have a separate system for that service.

DR. POLAND: Mark and then the two Mikes.

DR. MILLER: This is a related question to Kevin's. You mentioned that GEIS is funded

with influenza funds and that makes sense given the rapidly transmissible nature of influenza and other like viruses. I'm curious though about the long-term funding and whether or not that's just due to the flavor of the month type of funding or whether or not there is long-term secure funding for diseases such as influenza.

COL. DEFRAITES: The funding for GEIS for the base program, that's the EB (?) program, is stable through what we call the pom (?) years, that's fiscal 10 through 15, at about $12 million dollars. The flu program right now was a supplemental started in FY 06. That level of funding for flu surveillance specifically is locked in for FY 09. They're still discussing now and still making decisions as to what the appropriate amount is going to be through the pom years, the fiscal years 10 through 15, and I have not heard the final answer on what that number is. These things get built up and then the decision has to be made from a big perspective of which of these enhanced programs do you need to maintain

and at which level. I think the base program is safe, is secure it looks like through the foreseeable future, the flu program is still being worked on in terms of what level of funding.

DR. POLAND: We're running about a half-hour behind now and I'm cognizant of how many of you have come up to me saying we got to move along because of airplanes. So please very brief comments and answers that can't be handled at the subcommittee level which we're planning at lunch. So if it's crucial, please go ahead, if not, hold it.

DR. PARKINSON: Just a formal request following Dr. Silva's comment. I think it's time given the increasing federalization of our effort, Dr. Cassells's attempt to get AHRQ and other players involved, that we take a systematic review of both the tissue repository and the serum repository, their history, capability, current operations procedures, and potential to advance both the DOD and federal missions. I'll just put

that on the agenda. I think it would be a great

time in the history of the DHB to do that.

DR. OXMAN: I'd like to point out something and also question something. First of all, because of the strength of the overseas laboratories, the President tasked DOD with the main responsibility for the whole country's surveillance for emerging diseases, so not just influenza, for emerging diseases although the funding because of the timing came from influenza. You mentioned when you presented to us a few minutes ago that the future of surveillance in GEIS would depend on what happens to that $40 million. I for one had hoped that that would be transited into a basic equivalent funding level from DOD as a whole to underwrite that those gems of the overseas laboratories which are really most of the assets that we have outside the United States in terms of surveillance for emerging infectious diseases. So rather than have a statement it depends on what happens with those

resources, that lifeblood of $40 million, not just $12 million, depends on what Congress decides to

do. I think there's a more important issue and that is that DOD really needs to consider what it will do to assure that there is a steady and level funding that's independent of the flavor of the month.

COL. JAFFIN: One of the things MRMC very much acknowledges and appreciates is the support for the overseas laboratories. We view them also as real gems and unique assets that the military brings to the table. Ms. Embrey has been very involved at the Health Affairs level at looking at how we can increase support to the overseas laboratories. We have tried to increase the pom slice for the overseas laboratories from the MRMC perspective and working with the Assistant Secretary of the Army for acquisitions, logistics and technology, as well as AT&L within the DOD to get more funding as well for them, and also looking at other federal partners to try and

leverage that money as well. So we're very actively looking for ways to fund them. In tight money times unfortunately things get tough.

DR. POLAND: I think we'll have to stop there. Thanks, Bob, very much. The next briefing is going to be Colonel Jim Neville who will bring the Board up to date with changes in the Air Force public health structure and I'm sure the Board will see in this effort how this effort and the AFHSC are aligned.

COL. NEVILLE: Thank you. Like Colonel DeFraites, it's an honor for me to be here and I appreciate your allowing me a few minutes to go through this reorganization. It's focused on the School of Aerospace Medicine and what used to be AFI which I'll describe a little bit more, an organization one level higher.

Here is the outline. I'll first talk just briefly about why this was done. It's largely BRAC driven in a way. The Performance Wing organization components, a little bit about

the wing itself and then a quick summary. I'll emphasize that the School of Aerospace Medicine which is the organization I belong to now as opposed to these others, and just a quick notes

about USAFSAM.

The 2005 BRAC directed the creation of a joint Aerospace Medicine Center of Excellence at Wright-Patterson Air Force Base. It did not describe how that Center of Excellence should be organized so subsequent deliberations ended up with the creation of a new wing in the Air Force called the 711th Human Performance Wing. The idea for this Center of Excellence was to use what's been called the university model which I'll describe in the next slide in a little bit more detail. The university model combines education and training, research, and what we're calling operational consultation. Those three legs of the triangle I suppose is the university model.

The organizations that were put together to create this Human Performance Wing include the

Human Effectiveness Directorate of the Air Force Research Lab, AFRL, formerly known as AFRLHE and now it's AFRLRH, and now it's HPWRH and that's the form science and technology organization. The Air Force Institute for Operational Health which we've

had has been disestablished or inactivated and all the missions and resources rolled into the Air Force School of Aerospace Medicine. So that doesn't exist anymore and it's all USAFSAM now. This is largely, but not exclusively DHP program funded. Then a smaller Performance Enhancement Directorate otherwise known as the Human Performance Integration Directorate, maybe 20 folks or so, from Brooks is also part of this new Human Performance Wing. The Navy Medical Research Lab or parts of it from Pensacola are moving up to Dayton, but a separate reporting chain, so that's one reason it's going to be a Joint Center of Excellence in Aerospace Medicine.

Just a little bit about the university model again. These three main domains of work or

mission, research and development which again is largely program six S&T but not exclusively S&T, education and training which is historically the mission of the School of Aerospace Medicine, and operational consultation which has historically been the focus of AFIOH. So generally AFIOH,

generally the School of Aerospace Medicine, generally -- bring those all together and that constitutes the wing. That doesn't mean that the school doesn't do any consultation or research, it doesn't mean that AFIOH didn't do any training, but largely AFIOH, USAFSAM -- are all under the same organization and each one of those missions can be done more effectively and efficiently when they're all in the same organization and all feeding off each other, research feeding the instructors, feeding the consultation consultants and so forth. That's the theory, and we're pretty excited about making that happen.

Of course, in the Dayton area is not out in the middle of nowhere, there are a lot of other

Air Force certainly and other community assets there that will be brought to bear to make these things all work better, the Air Force Institute of Technology which is an advanced degree scientific educational institution there on Wright-Patterson, the Air Force's major weapons systems acquisition community is on Wright-Patterson, and

of course the local community there plays a role as well.

Just a quick couple of slides on the other two major pieces of the Human Performance Wing, and then I'll talk more about the School of Aerospace Medicine. This is the Human Effectiveness Directorate, the AFRLRH it used to be called, and their focus is on human effectiveness, nonclinical, nonmedical kind of research, but focusing on things like the psychology of human decision making. They have a pretty big investment in directed energy, bioeffects, and counterproliferation technologies. They're spread out between Brooks, Mesa, Arizona,

and Dayton. All of those mission are consolidating at Wright-Patterson with the BRAC. The other one, this is a smaller one, 10 to 20 folks headed by a pilot physician and that's the Human Performance Integration Directorate. They focus on assuring that the human factor is integrated in acquisition programs, man-machine interfaces and so forth, and the training and

policy doctrine related to all that.

The School of Aerospace Medicine, combining AFIOH and all USAFSAM into a new USAFSAM or the really new USAFSAM. This is the vision. The mission includes education and training of all the Team Aerospace. The way we use that in the Air Force is not just pilots and the flight crew and medical issues related to them, but also the nonclinical aspects of occupational medicine, industrial hygiene, and public health, physiology, those are all wrapped up in the aerospace in how we use that term in that Air Force. So the School of Aerospace Medicine instructs all those

specialties, enlisted and officer, and conducts ongoing training for those specialties as well. Our goal of course is to create a world-class Center of Excellence that does all these things and to make the transitions that we're undergoing right now with the organizational changes as well as the BRAC planning to physically move the location from San Antonio, to Dayton, Ohio, to make sure that the services that are provided to

their customers and clients throughout that time are transparent and maintained and take advantage of this new organization of the university model including research and operational consulting and education and training to make all three of those work better.

The next five slides just real quick are the main departments of the Air Force School of Aerospace Medicine. The Aerospace Medicine Department focuses on the clinical aspects of fliers. So the Air Medical Consult Service is one of the main aspects of this department. When a

pilot or flight crew has any medical issue that might be odd, not odd, maybe threatening to their careers as aviators, they come to the school and get that figured out. The history is that 80 percent of those people get returned to the cockpit. They also field questions from flight surgeons and others around the world with questions related to the flying community and health aspects of that. They do some education and training in physiology and aeromedical

operations that go on at the base level. And also advanced training programs on aerospace medicine are handled out of here.

The next department, International and Expeditionary Education and Training at the School of Aerospace Medicine conducts most of the expeditionary medical skills training for the Air Force including the critical care air transport teams. There is CSTARS (?) which is geographically separated locations in Cincinnati, Baltimore, and St. Louis, where trauma skills are

polished before people deploy, so expeditionary medical training is managed out of the School of Aerospace Medicine. This department also exports courses to different countries and brings in foreign nationals to go through training at USAFSAM. In the previous slide, too, a lot of aerospace medicine experts in a variety of countries have been trained at USAFSAM. I can't remember, but the number is something like 80 of the other countries' surgeons general have been trained at USAFSAM over the course of its history.

The Department of Occupational and Environmental Health focuses its efforts on health hazard assessment, education, and training first of all, and also consultation both receiving phone calls if you will for questions as well as going out to bases and sites to do work that's needed for the Air Force. We also have the chemistry lab and the Air Force Radiation Assessment Team that are housed in this department. And of course, 24/7 phone calls for answering consults from

around the Air Force.

The Department of Public Health and Preventive Medicine is where all the epidemiology support goes and what we used to think of as the Air Force's operational public health surveillance hub is now in this department. We're calling it USAFSAM because that's the organizational home, but the Epidemiology Services folks, the clinical reference lab is here, and the surveillance program is placed here and a deployable epidemiology team.

Then of course you have the Office of

the Dean that takes care of all the school stuff that needs to be done which is a fair amount of work when you have 5,000 students rolling through the school in any one year with a whole variety of courses. I should probably know the numbers, but there are several hundred courses that go on in each year, and maintaining accreditation and so forth.

Just a quick snapshot of the scope of

the Human Performance Wing. This is FY 06, I don't have FY 07, unfortunately, it's roughly the same in FY 07, maybe a little less, the bulk of it of course is the Science and Technology Program Six funding and this is mostly but not all DPH funding. Almost 1,300 people that doesn't include the extras, if you will, and quite a variety separate operating locations including a couple overseas. In mind there's a unique mix of manpower skills that the school has. And MILCON, military construction, which has been awarded last week, sometime hopefully in May or June they'll start turning dirt there at Wright-Patterson that

brings all those organizations into the same complex. There are still going to be some operating locations separately, but the main bulk of organizations will be in the same suit of buildings which will be nice. It's a pretty large effort there. And hopefully if all goes well that building will be available May or June 2011, about the same time that we have to depart Brooks. So

planning for that transition and the phasing of all that is the challenge we're faced with right now. It will be a nice new facility with labs and the whole thing.

The vision of course, and I have mentioned this before, is to be the world leader in human performance defined broadly, the Center of Excellence in Aerospace Medicine, collocating all these functions will make it all work better, state-of-the-art facilities, we're pretty excited about that with altitude chambers, a new centrifuge which may take a few more years to put in place, but a brand new facility will be exciting for us. Then we're trying to make all

these transitions transparent to the customer and I keep telling myself good luck because it's going to be a challenge to do that. So this is all on track. There are lots of details of course with BRAC and that's not news if I say that, but it's all working slowly toward fruition sometime in the summer of 2011.

In summary, we feel this is a great opportunity to enhance all three of those mission areas I described. We're in the middle of trying to work through some of the details of the organizational structure which is no big deal, but it will take some time to do that, and we're looking forward to it. I think that's the last of it, and if there are any questions, I'd be happy to answer.

DR. POLAND: Just a little historical note, I think the first human centrifuge was built at Mayo Clinic in association with the predecessor of the Air Force and the flight suit first developed there.

DR. PARKINSON: Jim, a great

presentation. In many ways it's kind of back to the future, bringing back in the public health function of the School of Aerospace Medicine. Not necessarily for immediate response, but just a thought, the model of associating the Wright-Patterson functions with a civilian

university seems to be if not a new model an extension of a model that doesn't really exist much of anywhere else in DOD. As we look for best practice models when all federal agencies are short of money and there's a lot of duplication, when you got the VA that for years has had close partnership with academic medical centers for good or for ill, there may be some intellectual work in here to say what does a best practice model look like for a military-civilian-academic collaboration based on either your experience or experience going forward because clearly with earmarks coming from Congress with directed DOD money one way or another going to civilian-academic institutions, we're kind of going there de facto anyway through the will of Congress. So

just a reaction and a thought going forward, maybe there is some work around the DHB to think about what looks like a real model that you're building as we speak or a desirable model that's out there that hasn't been articulated yet because this is

different I think. Your reaction to any of that would be welcome, but I think it's qualitatively different.

COL. NEVILLE: I think it is different than others and maybe that's one reason it was designed that way. How to actually implement some of the vision remains to be seen in my mind. I'm not in charge of it all of course, but, for example, how do we hire an officer into this organization? Is that officer's time supposed to be spent 20 percent teaching, 20 percent research, 60 percent consulting? Or is that person an instructor and another person a researcher? I think that's one detail of an example of how to implement this thing when it gets to the individuals and the expertise and whole career field and so forth remains to be seen.

MAJ. GEN. KELLEY: Mike, I'd just make a comment. That's not a common concept, but it's the model that's in place already at Wright-Patterson. The medical center commander is

on the executive committee of the medical school to ensure the integration of the programs. So the programs are combined and I think that that move will go easier because there's a model in place that does that for the more typical clinical specialties.

LTC. SILVER: Thank you for the presentation. I think this is a move in the right direction particularly if the Department of Defense eventually wants to nourish good research programs whatever its missions are. On the slide on Office of the Dean, I would encourage you, one critical thing that occurs in most universities where there's active research is that the faculty have to define who's qualified and also the evaluation of faculty in terms of research. You shouldn't join for 20 years support if you're only doing one publication a year. So there has to be

some conceptualization of targeting the faculty at steps, maybe an academic entitlement, and the concept is tenure, that you got to work in a

productive way, and others around the table have survived the tenure system.

DR. POLAND: Thank you very much. We're going to keep moving here. The last speaker of the day is John Clements. He's going to provide us with a brief regarding recommendations for development of guidelines for the use of convalescent plasma for pandemic influenza. You may recall at the last meeting of the Board we recommended that DOD pursue development of these sorts of guidelines in the event of a pandemic and since then our Pandemic and Influenza Preparedness Work Group served as a forum for bringing together experts to discuss how such guidelines might be developed and John will update us on that and the recommendations that are coming out of that.

DR. CLEMENTS: The operational phrase here is brief. This is in fact a continuation of a dialogue that we've been having a pandemic

preparedness and this is one more option in the arsenal of weaponry that we can bring to bear in

the event of a pandemic event. I'll just point out, and I think we all know this but it bears repeating in that when we think about pandemic influenza we're not just talking about H5 although we have discussed H5 extensively and it certainly was on our minds as we were having this conversation. So I always start with the bottom line. It saves us a lot of time. The Subcommittee urges DOD to consider development of convalescent plasma therapy as part of the national pandemic influenza plan and as an important adjunct with other treatments. The Subcommittee further emphasizes the development of convalescent plasma therapy as a national effort and the Department should co-partner in this issue with our other leading national health organizations.

By way of background, the cause of the limited H5/N1 vaccine production because of resistance to tamivir and other antivirals and the

possibility that a different influenza strain may

emerge as a pandemic strain, the use of convalescent plasma therapy and its application for pandemic influenza were considered by members of the DHB Subcommittee. This meeting took place on February 5 and 6, 2008.

The rationale for us to consider convalescent plasma therapy is that active-duty personnel are at risk for exposure to natural or bioterror infectious disease epidemics, and in particularly with respect bioterror epidmics, it is entirely possible to engineer potential bioterror strains around existing vaccines, and there are other issues for which novaxins currently exist. DOD has the capacity to collect, produce, and transfuse large volumes of convalescent plasma for military personnel and convalescent plasma can be used with the DOD and civilian populations. I would also point out that this is not a new concept. Convalescent plasma therapy has been used extensively in this country and elsewhere for quite some period of time. It's

been used successfully with scarlet fever, rocky mountain spotted fever, pertussis, measles, mumps, polio, influenza, and a variety of other diseases. The NIH has ventured into this area as well and has established programs in convalescent plasma therapy for anthrax and also for H5, and we also have the issue with immune globulin. So this is something with which we have a great deal of experience. It is a safe technology and we think it has application as an additional component.

There were eight presentations to the Subcommittee on February 5. Dr. Autoro Duval gave us an historic perspective on the use of convalescent plasma, serum, and blood products. Dr. Luke then followed up with his blood products for Spanish influenza and pneumonia. You will recall that Dr. Luke did a very extensive and highly regarded meta analysis of the use of convalescent plasma for Spanish influenza. Dr. Enriat presented the national program to treat Argentine hemorrhagic fever virus with convalescent plasma. Dr. Trainer talked about

human antibody responses after recovery from H1, H3, and H5 influenza or from vaccination. And the other possibility is that we can use plasma from individuals who have been successfully vaccinated and not just convalescent.

Dr. Lightman talked about observations from the Transfusion Medicine Medicine Service at the National Institutes of Health. Dr. Katz talked about convalescent plasma production from an industry perspective. We heard from Dr. Williams about ravotory issues associated with production and use of convalescent plasma. And finally, Dr. Hoffman on clinical guidelines, data collection and reporting, and IND applications from the FDA.

That led to a series then of national and DOD specific recommendations, and I'd just like to talk about those very briefly. The first national recommendation that there be someone, and it wasn't the Defense Health Board, we kind of tossed this back to Autoro Duval and to Commander Luke to work on, publish a peer-reviewed article

discussing alternative therapies for pandemic influenza focusing on convalescent plasma therapy with collaboration from members within DOD. The article should provide established knowledge, current gaps in knowledge, guidance and awareness on convalescent plasma therapy to health care communities at a national level.

The second national level recommendation was the establishment of regional blood banks as control points for plasma collection to ensure the availability of plasma to individuals requiring plasma therapy. The committee considered that the existing regional blood banks would be the right point for national level collection because they have the facilities already in place.

The next recommendation was that DOD act as a vested partner with other leading national public health institutions to contribute to the development of national standardized guidelines for using convalescent plasma therapy as an alternative in pandemic influenza, and would further investigate applications of convalescent

plasma therapy for use with other infectious diseases where no known alternatives existed. And the final national level recommendation was the identification of gaps in capabilities for plasma collection, distribution, and tracking. In this case we felt that DOD could work as a partner in an interagency group to identify gaps and capabilities for efficiently distributing and implementing.

The DOD-specific recommendations, and this goes back to something that we've talked about as well, we have an issue with adenovirus for instance for which there are no existing appropriate vaccines. There are some in the pipeline, but adeno is a moving target that the DOD should propose and carry out research initiatives for the purpose of providing data and information about convalescent plasma therapy's effectiveness against adenovirus, also determine the logistical processes and appropriate equipment involving treatment with convalescent plasma therapy and much as we use the existing seasonal

influenza immunization as a model for pandemic immunization, implementing this with adenovirus would also give the DOD a way of establishing processes and procedures that could be put into place for other infectious diseases. The DOD should identify gaps and capabilities within DOD to effectively implement convalescent plasma therapy within the services. Finally, that the DOD should consider utilizing these guidelines beyond pandemic influenza and implement convalescent plasma therapy as an alternate treatment for novel, natural, or man-made bioagents or novel emerging biological threats in future research and practices.

The conclusions of the committee, the Subcommittee concluded that a national effort is essential to explore convalescent plasma therapy as an adjunct treatment. The DOD in its national security role has a stake in ensuring that guidelines and infrastructure are in place within the department if use of convalescent plasma is needed. And finally, the Subcommittee concluded

that within the national context of an approach to convalescent plasma therapy that DOD is not and should not serve as the lead effort, that the DOD has a vital stake and interest in acting as a copartner with other national health organizations such as CDC, DHS, and NIH. Then just the disclaimer that in preparing these recommendations, the Subcommittee engaged in regular discussions and received a series of briefings by experts from NIH, CDC, the National Vaccine Program, Office of the FDA, DOD, among others. So those were the findings of the Subcommittee that met in February and our report back to the Infectious Disease Subcommittee and recommendations to the Board.

DR. POLAND: Thank you, John, and let me publicly acknowledge, John, I couldn't physically be at the meeting, I participated by teleconference, and John masterfully ran what turned out to be a very large meeting with a lot of national interest in it. Again apropos of how the Board will work, there are recommendations now

coming back from the Subcommittee to the Board for discussion and approval. They have been previously circulated too. Comments?

DR. OXMAN: I think it's a superb report and actually many of us have discussed it already so if we don't spend a lot of time discussing it, I'm ready for it to be adopted.

DR. POLAND: No other comments? All those in favor? I think we did it. I had some minor grammatical and other comments on there, but that was all. We did it. Thank you again, John. Are there any other questions or comments? Russ had a comment that I was going to ask him to make, but are there any others so we can plan our time here? Russ?

DR. LEUPKER: Just a quick suggestion and thought. I think I like many of you here picked up the paper this morning, the Tacoma paper, and saw some of the very issues that have taken this committee's time. We had a number of presentations last year on suggestions and

22 recommendations for mental health services. I

1 would like to hear some follow-up on what's
2 progressed since then because it hasn't gone away
3 as an issue obviously.
4 COL GIBSON: The Psychological Health
5 Subcommittee is standing up and literally Dr.
6 Cassells will make the nominations for those
7 members Monday. You heard from the Center of
8 Excellence on Psychological Health and TBI. What
9 you will hear the next time we meet is what they
10 got done, where they're going specific to
11 psychological health issues and the outcomes, not
12 only the due-outs, but the progress that the
13 department has made in the area of psychological
14 health which is what the department is using to
15 encompass the whole breadth of mental health
16 issues.
17 DR. LEUPKER: If you could add to that
18 list the issue of public health surveillance.
19 Essentially it seems like the controversy is about
20 a failure of public health surveillance to provide

accurate --

DR. POLAND: I don't know the details of

this, but I would urge us, and it's not to diminish the point made at all because it's vitally important, but let's not rush to judgment based on the media reports yet and get the full details. As one said, we seem to have moved from evidence-based medicine to medial-based medicine in many aspects of our culture. But Bill and Russ bring up an important point that deserves additional work by this Board. Are there other comments? If not, then for lunch we'll have the ID Subcommittee eat together and have a discussion. I want to thank everybody for their participation and forbearance as I tried to move the meeting along and keep us on track, so I apologize if there's anybody that I didn't get to. And I'll ask Dr. Kelly to adjourn the meeting.

SECRETARY KELLY: The meeting of the Defense Health Board is adjourned. Thank you all for attending. I appreciate all the presentations

and especially thank you for your support to the Defense Health Board and everything that it means to us in the Department of Defense. Thank you

very much.

(Whereupon, at 1:30 p.m., the PROCEEDINGS were adjourned.)

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