THE DEPARTMENT OF DEFENSE

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P R O C E E D I N G S

(9:07 a.m.)

DR. POLAND: Good morning, everybody. Welcome to this meeting of the Defense Health Board here in San Antonio, Texas. We have a large number of topics to discuss today and tomorrow, particularly those related to treatment of wounded warriors; both while they're under the department's care and then when they transition to the VA when they're no longer fit for duty.

I first want to thank Brooke Army Medical Center (BAMC) for hosting this meeting and in particular Brigadier General James Gilmore, to my left, the Brooke Arm Medical Center Commander for being here to welcome us. I know you're very busy taking time out of your day to come and see us and inform us about the mission is a treat for us.

Dr. Kilpatrick, would you call the meeting to order, please.

DR. KILPATRICK: Thank you, Dr. Poland. As the duly appointed alternate designated federal official for the Defense Health Board, which is a

federal advisory committee to the Secretary of Defense, and serving as a continuing independent scientific advisory body 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. Following the tradition that we started at the beginning of my tenure, could I ask all in the room to stand for a minute of silence to honor the men and women who are serving our country?

(MINUTE OF SILENCE OBSERVED)

DR. POLAND: Thank you. I want to go around and have members of the Board introduce themselves. We'll start first with some of the distinguished guests that we have visiting us today.

The first is the Honorable Bill Carr, undersecretary of defense for military personnel policy.

Mr. Tom Pamperin, the Department of

Veterans Affairs.

Mr. Arnold Fisher, I don't see him yet. You'll get to meet him, of Fisher House Foundation and also a member of IRG on rehab care and administrative processes of Walter Reed Army Medical Center.

Dr. Chip Roadman, retired Air Force surgeon general and also a member of the IRG.

Dr. Charles Rice, Dean of the Uniformed Services University. I don't see him here either.

Major General Michael Tucker. Actually, he'll be with us tomorrow.

Colonel Jim Neville, Commander of the Air Force Institute for Occupational Health.

Colonel Michael Bunning, Chief of Public Health Air Force Surgeon General's office.

So if we could, I'll ask Dr. Kilpatrick to start and we'll go around the Board and then in the back and along the sides to introduce ourselves.

(INTRODUCTIONS MADE)

DR. POLAND: I think we have everybody.

Colonel Gibson has some administrative remarks before we begin the morning.

COL GIBSON: Very quickly. Make sure you sign the attendance roster. It's one of the Federal Advisory Committee requirements. We need to keep track of everybody who attends. Because this is an open session it is being transcribed, so if you come to the mics, please speak clearly, speak into the microphones and state your name before you speak. Turn your cell phones and Blackberry's to off, vibrate or stun whichever you want. Try to keep the Blackberry's below the table, if you will, sometimes they'll interfere with the microphones. Refreshments will be available for both morning and afternoon sessions. We'll have a catered working lunch for the Board members, preventive medicine officers, speakers and distinguished guests. For others attending there is a wealth of very fine restaurants nearby. We're getting two Continuing Medical Education CME credits. We would have more, but folks need to get the paperwork into us so we can provide more -- early enough so we can

provide CME credits for this meeting. For the Board members your paperwork is inside your notebooks. For others we have additional paperwork, see Karen that you'll have to fill out to get credit for that. Finally, the next meeting of the Board is the 11th and 12th of December in Washington, D.C. We haven't quite nailed down the hotel, so please check our website and we'll be sending out invitations as well to that meeting. This meeting we will receive and deliberate the report from the Task Force on the Future of Military Healthcare. That report is due to the Secretary of Defense by the 20th of December, so we will deliberate it before that and we'll address a number of other issues that come before the Board. Finally, I want to thank Karen and Britt Triplett, who are here, and Ms. Jarrett and Ms. Ward, who are back home, for their assistance in putting this meeting together. Again, thank you to Brigadier General Gilman, who used to be my boss when I was at OTSG, for being here with us today.

DR. POLAND: Very good. It is my pleasure now to introduce Brigadier General Jim Gilman. General Gilman is a 1974 graduate of the Rose-Hulman Institute of Technology, with a degree in biological engineering. He received his M.D. Degree from Indiana University School of Medicine in 1978. He's board certified in both internal medicine and cardiovascular diseases. As a career Army doc, he served in a number of locations including Darnell Army Community Hospital, Fort Hood, Texas, Madigan Army Medical Center, Fort Lewis, Washington, Bassett Army Community Hospital, Fort Wainwright, Alaska; and the Office of the Surgeon General. He is currently Commander Brooke Army Medical Center in Great Plains Regional Medical Command. Brigadier General Gilman has served as the commander of the Walter Reed Healthcare System. His full bio is in your briefing books. General Gilman, welcome.

BG GILMAN: Thanks. It is a pleasure and an honor to number one, welcome you to San Antonio. What Dr. Poland didn't tell you is that

I have spent an awful lot of my Army career here and this is sort of our second home next to Indiana. It's an honor -- first of all, Roger said that I was his boss for a brief period of time, and when I arrived at the surgeon general office and I looked around at all the things that I was supposed to know something about, there was this cat called the Armed Forces Epidemiology Board and the then executive director, I made him come talk to me three or four or five times just so I could begin to understand what the AFEB was about. That was really still early in this global war on terrorism, so this -- my impression from what I see in the topics that are being addressed here is that it's gone from being a deliberative laid-back body to a body that really presumes to tackle some of the most difficult issues that we face on a day-to-day basis at the macro level. And the approach that's taken is the one that's taken many, many times, and that is: You take a bunch of busy people and you give them one more thing to do because they can't just keep adding to

their plate, they really do have to get some things done. So I commend you for your service to the country through this forum and now I'll just sort of tell you a little bit about this place where we work and that we care a great deal about called Brooke Army Medical Center. Next slide.

This video doesn't launch, you'll have to trust me, this was going to be a great video clip that lasts two or three minutes that really shows you the young men and women we take care of. About half the patients were from Walter Reed and about half the patients are from Brooke Army Medical Center. It was actually put together by the recruiters for us. They never show it, because they don't like to show people that get hurt. I still think that for recruiting healthcare professionals it's a great video because everybody wants to take care of patients like we get to take care of. Next slide.

My mission statements are all short. They almost always say "We". They say warrior instead of soldier. And because my mom is an

English teacher, they have a verb. The key here -- and I was the one who saddled Walter Reed with "We provide warrior care", by the way. I got Walter Reed from 51 words to four. Brooke Army Medical Center down to six. The goal here is not to have a mission statement that only the colonels in the organization can understand. This is meant for every E-3, PFC (Private First Class) in the organization to learn and understand. But we mean this in very global and holistic way. We spent a lot of time -- when I introduced this to new employees regularly, it is talking about if you're taking care of kids in the pediatric clinic, that's part of warrior service. If you're taking care of the spouses of soldier's down-range, then that's warrior service. If you're taking care of people who are too old to be active warriors anymore, but you're taking care of them within the culture that they understand and you understand the nature of their service, that's part of warrior service. If you're taking care of their medical records as an administrator. If you're billing so that we can provide a few

more services to those that have other health insurance, that's warrior service. The challenges to every member, every new employee, is if you can't figure how what you do relates to warrior service, you get on my calendar and you come see me. So far nobody has showed up, but that's not too surprising either. Next slide.

This is a typical day at Brooke Army Medical Center. In parentheses below the first numbers are the number of those that involve warriors in transition. I will tell you that the admissions of warriors in transition to Brooke Army Medical Center has gone up and you'll see -- so that this average, this slide average over a while doesn't probably reflect this. But if you look at what we do, it's not too much different that you would see in any medium-sized civilian hospital. It doesn't qualify as a large hospital based on some of the institutions that many of you represent. A couple of things I would note is at Brooke Army Medical Center and Wilford Hall Air Force Medical Center are both part of the San

Antonio City's emergency medical system. We do take civilian trauma. Two ambulances to University Hospital, one to Wilford Hall and one to BAMC is sort of the way the emergency operation center of the City and the County work that out. Again, this -- taking care of civilian trauma is especially important between wars because that's really our combat casualty care battle lab. And to stay involved in that mission, we think, is very important. So important that as we start talking about base realignment and closure, we intend to take care of our share of the trauma and Wilford Hall's share of the trauma, both at Brooke Army Medical Center when that becomes the only inpatient facility. We have a very busy emergency room. We have a great dining facility. It's too bad you won't get a chance to eat over there. A couple of things are notable by their absence. First of all, we don't do labor and delivery at Brooke Army Medical Center. That's been done at Wilford Hall for over 10 years. All of the OB care is -- and we do clinic at Brooke Army Medical

Center, but all the deliveries, at least all those that we can plan, take place at Wilford Hall Air Force Medical Center. There have been a grand total of two deliveries at BAMC, since I took command over two years ago. One was a lady who came to our emergency room, severely pre-eclamptic, who required delivery in order to get ahead of her medical problems. And the second one was a delivery in our OR as a mother's life was ending a baby -- an emergency C-section was done and the baby's name is Andrea Isabella Escamilla and the baby is doing just fine. She was delivered there and taken to one of the city hospitals for care of her prematurity. So two deliveries in a little over two years. That makes us different from just about every place else, except Walter Reed, which sort of is in kind of the same boat. Next slide.

Brooke Army Medical Center is sort of at the center of the Great Plains Regional Medical Command. The Army is organized into geographic regions for the delivery of medical care. The Great Plains Regional Medical Command, as you can

see, is the -- as you could probably guess from this slide, is the largest regional medical command besides Brooke Army Medical Center, there are nine other health centers or hospitals that fall as part of the regional medical command. The three largest are in Texas. And then we also have a number of occupational health missions that take around to places that we wouldn't otherwise get to like out here in Utah. We do still provide the National Guard support and the summer camp support. The Minneapolis VA is part of -- liaison with them is part of our responsibility within the Great Plains. We just recently annexed Minnesota from the North Atlantic Regional Medical Command, and we've got our eyes on Wisconsin. We're going to get them next. Next slide.

This illustrates the way patients come back to us from Iraq or Afghanistan. Injury on the battlefield and initial care is provided by a combat medic or this 18-Delta would then be a special-forces medic. They are trained, they are well equipped. They have a tourniquet that works

that you guys know everything about. And probably the biggest change in the Army medical department between the first Gulf War and the current conflict is the fact that General Peek almost single- handedly transformed this MOS (Military Occupational Specialty)from a kind of a nursing assistant point of view to being a real emergency medicine technician who can take care of trauma, transforming the second largest MOS in the Army was a Herculean task completed just in time. We are in the final stages of this transformation. From there they're taken by ground or by air to a forged surgical team where life-sustaining surgery, but not definitive surgery is done. They go from there to some sort of in-theater combat support hospital or the Air Force's hospital in Balad where additional stabilization and preparation for transport; more definitive, but still not definitive. Taken from there then out of theater to Landstuhl Regional Medical Center. Jointly Army, Air Force staff hospital where additional stabilization is done and then they are

loaded for the transport across the Atlantic ocean, either to the east coast to Walter Reed or Bethesda or on to us. I would say that the Air Force in particular has done a remarkable job in terms of providing care and safe transport and all the en route care necessary to get -- almost without a single loss in the air to the continental United States. This, of course, is us. There are some things that we don't know very much about yet. We don't know very much about taking care of the severe TBI patient. We don't know -- we basically have no expertise in spinal-cord injury patients. So we do send patients to the VA for those kinds of things. Some are taken care of here in San Antonio. There's one Marine and one soldier at Audi Murphy VA today. We have several that are getting treated for TBI (Traumatic Brain Injury) up at the VA M Polytrauma Center in inneapolis. Five years ago this h arrow would only ave had one head and it would have been from us to the VA. Now it's very common for us to send patients to the VA. We get them stabilized; take

care of their acute problems. We send them to the VA, they do the traumatic brain injury rehab and then they come back to us for maybe another surgery, maybe some cosmetic or reconstructive surgery or for it's for more work on their prosthetics and more rehabilitation. Next slide.

These are the numbers to date that we've taken care of. Not as large as Bethesda or Walter Reed, but probably third only to those two organizations in terms of the numbers that we've had. I'd say a little bit about burns. All the en route care is provided by critical care and the air transport teams and other Air Force assets except for the burn patients. We usually have a burn surgeon who is stationed in Landstuhl who starts the care and then when we find out that there are burn patients ready to come our way, we launch, by commercial air, a burn subject-matter expert team from the burn center at the part of the Institute of Surgical Research. They go to Landstuhl; they pick up the patients and with the Air Force bring them directly to San Antonio.

That's' different for burns then for any other category of casualty patients I know of. Next slide.

You're going to hear from Mike Tucker tomorrow and you're going to hear -- you've been hearing a lot about the Army Medical Action Plan; we are almost completely through the phased implementation of this. And with a lot of support from the Army and resources, I think we're well on the way to accomplishing this mission. It has been a difficult delivery for this new program, but we are well into it. We briefed the acting Surgeon General yesterday and we brief the vice chief of staff of the Army again on the 1st of October on our progress. We have the people that we need to manage the warriors in transition and everybody has come online across the Army to support this program. Next slide. Go ahead, Next slide.

This is our warrior transition unit. I just got my new battalion commander this week, who will command the warrior transition unit. This is

their job and this is what their mission essential task list consists of. Next slide.

You're going to visit the Center for the Intrepid later on today. One of the blessings of being the commander of Brooke Army Medical Center is having the oldest building that houses patients or families at Brooke Army Medical Center was built in 1992. The facilities have been very, very well maintained. It doesn't mean that there's not a little scum on the bathtub once in a while, but it does mean that the facilities have been very, very well maintained. The two Fisher houses are actually the oldest building, built in 1992. And Mr. Fisher isn't here, but he will tell you that he goes over there to check to make sure that we take care of them pretty well. The hospital itself, I was here in 1996 when we moved into the hospital, into BAMC. Since then we've added the guest house, which also houses the warrior family support center. We dedicated the new Center for the Intrepid on the 29th of January this year. Our barracks opened in about 2000 and

our troop command barracks -- not our barracks, but our office spaces are also of about that same vintage. In execution of the Army Medical Action Plan, one of the things that we've done is: The soldiers who are assigned to Brooke Army Medical Center actually moved out of these barracks up onto Fort Sam Houston. It's astonishing me, but we did it with nary a complaint. The soldiers knew that it was more important for the patients to be co-located with the hospital than it was for them to be located close to the hospital. In adding the new people the stand up the warrior transition unit, our command and control, what we call troop command, actually moved into a temporary building that's not nearly as nice as these, up on the main part of Fort Sam Houston, also without a complaint, because they recognized that it was more important for the warrior transition unit cadre who are taking care of these guys to be close to them than it was for the troop command folks to be close to the people who work over here in the hospital. That is, these people

can go up to Fort Sam Houston, take care of their administrative issues. These people can come down to BAMC when they need to, but having these people as close together to make sure that we're taking as good of care of the warriors in transition and their families as possible. It was the right thing to do. We broke ground on Saturday for a new warrior family support center which will be located right over here. That's also going to be built with private money, $4 million. Mr. Fisher started something that some folks in San Antonio are going to continue, it's a 12,500 square-foot building. Next slide.

From my perspective, and you guys are all aware of this and I noticed General Franks is not here, but General Franks probably introduced many of us to this topic. The biggest -- the requirement fight a long war with an all-volunteer force pushed us, immersed us really in the business of rehabilitation, because you cannot want people to volunteer for the Army, you can't have moms and dads want to let their sons and

daughters join the Army if when they get hurt there is the impression that they're not being given the chance to rehabilitate and stay in the military if they want to, or if they're sent out of our system to any other system before they're ready to go. So we are heavy duty into rehabilitation medicine. I didn't know what a physiatrist was five years ago. I'm getting pretty smart on physiatry now and boy do we have some good ones. Next slide.

Center for the Intrepid you're going to visit. I'm not going to steal the tour guides thunder, but they'll probably tell you my sound bite. The essence of the Center for the Intrepid is that it uses the current younger generation's fascination with technology and extreme sports and it leverages those in order to accelerate rehabilitation. That's what it's all about and you'll see some of the ways that that's done when you're over there. Next slide.

65,000 square feet, 4.5-acre site. We gave Mr. Fisher four or five sites when he came

down. He didn't like any of those. He picked the one he wanted. We have two adjacent Fisher houses east with 21 handicapped-accessible rooms. The usual Fisher house configuration was set up for families, but wasn't necessarily handicap-accessible rooms. We went from start to finish in 15 months and two weeks after we cut the ribbon -- again, because Mr. Fisher is watching me every day, two weeks after that happened we're doing patient care in there, because I promised him that if he built it that we would operate it. He was over on Monday -- there's actually been a conference at BAMC all week on care of the military amputee and Mr. Fisher was there to give a few remarks to open it up. Next slide.

These are the guys we get to take care of. All I can tell you is that every doctor and nurse I know, and every therapist would love to have patients like we have. Next slide.

When you're not too far from Fort Hood in the footprint of the 1st Cavalry Division having a horse around is okay, too. Next slide.

We do have some challenges here. You know, whoever -- when you think about handicapped parking spots you're not usually thinking monster truck, you know? Now, we don't necessarily encourage this, but we did -- by the way this parking spot is actually the one next to mine at the hospital and I pulled in and I just -- this was too cool. This young man is missing both legs and he had given up an awful lot of other things he enjoyed in life, but he didn't want to give up his truck. We don't really encourage this, because this really a fall from a two-story building for him, but it's his choice, it's not ours. We tried to talked to him, we counsel them and we try to get them to do safe stuff, but every once in a while they're going to do this. So I had to go talk to people about widening our handicapped parking spots. Those are some of the new challenges. And they're good challenges. These guys are not happy to ride down the hallway in a wheelchair. They want to walk and soon as they can walk they want to run, and once they can

do that, they want to climb stairs, and once they can do that they want to climb mountains. Next slide.

Just a little bit about the ISR. Again, comprehensive trauma burn and surgical critical care service run -- it's a separate command that does not technically belong to me, but you can't separate us from them in the eye of the public so we wind up having a fairly complex relationship that we somehow or another are able to make work. Next slide.

Burn injuries are harder. Those of you that have been Walter Reed or those of you who have dealt with amputees the rehab is not as media savvy, because it's small muscles. A lot of it is stretching, a lot of it is contractures, a lot of it is range of motion. Much of it is painful. Technology does not have as much to offer in the rehabilitation of the burn patient. It has had a big role in the survival of the burn patient, but it doesn't have a lot to offer in terms of the rehab of the burn patient. It is just plain hard

work. And from our perspective -- for all those reasons there's a little bit more in the way of existential anger that we deal with in the burn patients. And we tell people before they -- and you will see burn patients this afternoon at the CFI. Anybody who says that that was just for amputees is wrong, that's never what it was meant to be. Mr. Fisher made that very clear early on and we moved burn patients into CFI (Center for the Intrepid) very, very early on and they're doing there.great out They're with us longer. They are with us even longer than the amputees. Next slide.

Just a slide or two about BRAC.

Inpatient care at Wilford Hall closes, Wilford Hall doesn't close, the 59th Medical wing does not go away. We have to tell people that all the time. Wilford Hall is going away, no that's really wrong. There's going to be a lot of great medical care provided at Wilford Hall, just people aren't going to be spending the night down there. And all that moves us to the, what we call SMMAC North, which is what I've been calling Brooke Army

Medical Center all day. We are managing to work our way through this pretty well. General Travis now, before him Brigadier General Dave Young and I have been working on this for two years. We have already integrated a number of services. We have a plan. We didn't need a lot of help to make our own plan. We went up and briefed the senior military medical advisory council a couple weeks ago on the plan. They're comfortable with it. We didn't ask for any additional senior oversight. We have lots of help in getting this done and so far we have the resources to keep it on track. Next slide.

This is what the north campus sort of is going to look like. We have to build a couple parking garages here and there. We have to add on because all the battlefield health research and trauma research from all three services moves to San Antonio so we have to build onto the Institute of Surgical Research and change its name to Battlefield Health and Trauma. I'm sorry, that's that part. This hospital is built for 450 beds to

begin with so we can take those areas that we converted into admin and clinic areas and convert them back into wards and move the admin and clinic stuff over into the new building. We have to have a bigger ER, we have to have more ICU space, and we have to have more OR's and that's over here. These are the buildings that are already there, The Center for the Intrepid and the two Fisher houses. Next slide.

Down at Lackland, this is all renovation. Next slide.

This is what we look like at end state 425-inpatient beds, this many ICU's, that many on the wards, 31 OR's for inpatient ambulatory surgery, doing the combined amount of trauma of BAMC and Wilford Hall already and then SAMMC South is largely primary care, but there is the Center of Excellence for eye care down there and an awful lot of sub-specialty clinics. Next slide.

That concludes my brief. Thanks for letting me tell you a fair amount about Brooke Army Medical Center and a bit about what the San

Antonio Military Medical Center is going to look like. I have a little time, I'd be glad to take a question or two if that's desired. Thank you.

DR. POLAND: Questions from the Board? General Gilman, we want to thank you for coming and present you with the brand new coin. You're actually the first recipient of the new Defense Health Board coin. Thank you very much.

(PRESENTATION MADE)

DR. POLAND: Our next speaker this morning is Colonel John Kugler, Deputy Medical Director of TRICARE management activity. He will give us a briefing regarding TRICARE's healthy lifestyles and disease management campaign. These are areas that the Board's legacy committee on health promotion and maintenance under the AFEB addressed through a number of recommendations in the past, so it's good to see progress being made by the department in these areas. Welcome Colonel. The briefing slides are under tab 4 for the Board members.

COL KUGLER: Good morning everybody it's

my pleasure this morning to give the Board and overview of two very important programs for the MHS. It's a little bit different than what I think you'll hear the rest of your couple of days here, but it's -- I think there are some connections. Hopefully, I'll try and make that clear to our warrior care. These are major programs which I think are very close to the overall mission of the MHS (Military Health System).

We'll talk about the case management and the healthy lifestyle initiatives that are going on. The overall MHS mission, of course, is fourfold, is to preserve patient care, training and sustain skills and direct support of the deployed forces as well as the peacetime forces and their dependents and to promote and deploy a ready- medical force. In direct support of this mission is a continuum of care, which I know you're all familiar with, anywhere from health until impairment in this care. In this continuum of care is the case management model and the disease management model as well as a focus of

wellness and health promotion all that contribute to addressing the patient at their level of need to facilitate optimal outcomes.

The first area we'll talk about is the disease management program. The direct goals of the disease management program are to optimize patient outcomes through a patient centered model of care utilizing evidence-based medicine and patient partnerships, use the best practices to promote optimal outcomes. Increase provider and patient satisfaction in the process and at the same time appropriately utilize scarce medical resources.

A bit of background on this: In September of '05, two years ago, ASD/HA, Dr. Winkenwerder at the time, charged MHS with going over the current status of disease management programs and to develop an action plan for system-wide coordinated approach to disease management. As a direct result of that summit two years ago, the department devised the unified approach that is meant to tie the efforts of the three

contractors opposed to the purchase care section as well as the services into a cohesive, comprehensive approach to disease management.

Details first initiate the concentration on three major diagnostic conditions and implemented a year ago was concentration on congestive heart failure and asthma and then the condition of diabetes which was implemented this past June. It's directed at both the purchase and the direct care system and includes primarily prime beneficiaries, but also there is a demonstration project which will include standards in extra patients as well. The government's role in this is the identification of high-risk patients as well as the uses of a methodology to access the outcome of the program. It's left up to the contractors to design a program and to initiate their protocols. For example: How often to call the patients, or what type of technology to use. They are to provide us with the details of that and that's all part of the evaluation process.

Again, as I mentioned the major role of the government is the identification of at-risk patients that would be identified as being -- to benefit from disease management. Primarily use administrative data to basically target patients that are high utilizers or high-cost patients particularly CHF (Congestive Health Failure and asthma. We get data runs on a monthly basis from Kennell & Associates. The patients are stratified in one of four levels by these criteria of utilization and cost and levels three and four are targeted specifically for disease management intervention.

As I mentioned the purpose is to assess what works best for these populations. Who should be targeted for disease management? What sort of services should be provided? How can the program be improved? And how do we compare with other nation-wide disease management efforts? The purpose of the evaluation is to quantify the impact on patient health status and clinical outcomes including quality of life. And also secondarily to look at healthcare utilization and

expenditures.

The first report is due this December and again the three major focuses will be on clinical outcomes as measured as the changes in the clinical processes; such as percent of diabetics with A1C's done in the past year, a common HEDIS measure. A measure of utilization or the appropriate consumption of resources; for example, emergency department visits for CHF or asthma patients. And then finally, connected to utilization are financial outcome measures, changes in costs. And with this an assessment on the return on investment of the disease management program.

Some baseline data that was gathered for fiscal year 2006 for CHF patients, this is to kind of give you an example of the patients that are being targeted. These are level 3 and level 4 patients. Again, these were patients that were specifically chosen as high-cost, high-utilizer groups. You can see that over $69 million in annual total costs were connected with these

patients. Primarily 80 percent of these had to do with emergency and inpatient care. This is a little different than the other two conditions that we'll talk about. This is why CHF for a long time has been recognized as very -- as a condition it could respond very well to disease management approaches. Again, it's estimated that almost 14,000 PMPY (per member per year) related costs out of the 36,000 total TRICARE costs are direct on these patients.

For asthma, again, looking at the higher- cost patients at level 3 and 4, most of the costs here is in pharmaceuticals and that's likely not going to go down, in fact, that will probably go up, but the area that's being targeted for reduction is emergency care and hospital inpatient care. While a small cut of the pie, certainly is not an insignificant one.

This is an example of the outcomes card or the draft score card for DM (Disease Management). Again, you can see it's looking at the three main areas we talked about, the utilization and those are the metrics that are currently being utilized. So it's

financial and clinical measures. You can see each of these are weighted, an evaluation score will be done by the contractor that's doing the evaluation.

In 2007, the NDAA (National Defense Authorization Act) had some very specific requirements that they want DoD to attend to with regard to disease management. And our office the Office of Chief Medical Office, the office that we work in and we are working with the service subject matter experts and the TROs (Tricare Regional Offices) to meet these requirements. And there are five basic ones, we're well on our way, I think, to doing this, but it's important that we specify what they are. One is that Congress wants to specifically address very specific disease conditions, not only diabetes, heart disease management, but also cancer in general as well as COPD (chronic obstructive pulmonary disease and depression and anxiety disorders. They would like us to make sure we meet nationally recognized accreditation standards as defined by the DMMA, Disease Management Association of America. That basically has to do with population identification processes

and evidence- based guidelines as a guide.

They want to make sure that we specify outcome measures and objectives which we've been doing. Specifically to capture and report the data across the services and the purchased care arenas and to give Congress a report of how we are evaluating this in an integrated fashion. Also to include strategies which also include Medicare beneficiaries or dual-eligible. And in the process to make sure we are conforming with current HIPPA laws and regulations. The report on a design and the development and the implementation on these conditions is due to Congress March 2008.

I think the main challenge with meeting this is making sure that we are providing consistent DM services and a uniformed program evaluations, not only within the services, but within the three managed care support contractors. That we avoid duplication of services and increase in costs in our complex systems. At the same time that we allow flexibility and creativity among the

-- not only the services but among the contractors to address the needs of the patients under their areas of responsibility to make sure that we're not losing any of that in the process of having the uniform -- the ability in producing the duplications. So it's a balancing act, but an important one. And that we manage the complexity, which has probably the greatest challenge of identifying the at-risk patients, especially when you use administrative data, it's a difficult chore and it's a fair amount of validation of that data to make sure we are truly targeting the patients that will benefit. The other problem with administrative data is that it lacks some clinical information particularly when we're dealing with managed care support contract would allow you to evaluate it, so we could identify those who have had A1C tests done but we can't capture what the A1C levels are. So there are some built in barriers, basically to be able to do that with the inherent nature of the data.

However, as I mentioned, significant

parts of the 2007 NDAA requirements have been met by what we're doing basically now. We're trying to put the uniform processes in place and refine these processes as best we can and as I mentioned we were identifying the patients and risk stratifying them and having a uniform method of evaluation. We're well on our way to defining a cohort of beneficiaries. Certainly with three of those conditions we're working on identifying those with the other conditions as well. We're tapped into the expert clinicians and the subject-matter experts in both the services and in managed case support contractors to get them involved in developing interventions and state-of-the-art educational materials. Taping on the resources in the MHS particularly with regard to the VA/DoD clinical practice guidelines, the population health portal which is a data system that captures both network and direct care system data to some extent on these conditions and in the well-refined dashboard and evaluation method for quality measures that's being used fairly

extensively within the direct-care system and to some extent in the purchased-care system.

Now there's a system-wide approach requiring collaboration and coordination that's kind of been the main focus and main work that's going on in our office with managed care support contractors as well as the services and I think our big challenge is to continue that and to refine it, and to make sure that the programs that are developed as the end result of this are complimentary for the existing programs within the services and that they meld well with the efforts from the managed care support contractors. Any questions before I go on to healthy lifestyles about these -- Yes, sir.

DR. KAPLAN: This is perhaps peripheral, but it just dawned on me, are there differences between how HIPPA laws are applied in the military and how they're applied in civilian (off mike)?

COL KUGLER: Not that I'm aware of. There all the same regulations.

DR. KAPLAN: The same?

COL KUGLER: Yes, sir.

DR. KAPLAN: Thank you.

DR. POLAND: Mike. State your names first, please when you speak.

DR. PARKINSON: Thank you Colonel Kugler, I'm delighted that the DoD has been more involved in disease management, but I will tell you as someone who has been deeply involved with this for the last seven years and kind of turned, what I think is the entire paradigm on its end, which is rather than being provider centric to being truly consumer centric and to actually look for competent incentives for immediate and early self referrals. Our DM programs traditionally tend to be, I got you through claims identification, which this is. It is the state of the art unfortunately, but what are the provisions -- or are you thinking about, if I've got those five conditions, how do I self- identify as soon as I'm enrolled in TRICARE, how do I self-identify by being taken care of at BAMC that I would love an educational program to understand the seven

things for my diabetes. That's one question.

The second thing is: What are your plans of going forward to maybe perhaps spend less money on ROI evaluation, because as you know the GAO and others find no costs savings for these program, at least as their currently practiced as opposed to redesigning the program so they do demonstrate cost savings. Every single one of us believes in this room that patient behavior modification saves money, but the program, as currently put together, there is no standard methodology to evaluate them, as you know, AMA has not come out with that, so how are you going beyond the current industry? Because the current industry, I will tell you, needs your leadership with new self-referral models and new engagement model for the much deeper than post cards and phone calls because they really, by and large, don't work that well. Just your reaction to some of those to go on, but I appreciate that and I wanted to get it on the table. This Board, by the way, gets very much -- this is probably the first

briefing, I'll note for the Board, obviously, that deals with these issues in our new hat as working with the department in the healthcare operations as opposed to our historical charge. So thank you for being here and that's just some early reflection.

COL KUGLER: Well, I think those are great reflections and I hope we're going to be doing those things. I didn't mean to be overly rigid in the presentation of the methodology; other than we are required to have methodology and to get the job done, but you are absolutely correct, it should be much more patient directed. We should be much more open to self-care models and it's really a partnership with the patients. I apologize for maybe not emphasizing that component of it. And also don't want to lose the flexibility and creativity of the individual services as well as managed care support contractors in tapping into their patient population. We purposely don't want to lose that. It's kind of a balancing act between trying to

make sure we meet the mail on what the standards are for evaluating these programs, but in this process we want to basically tune into best practices and I think you're right on target identifying those best practices. They are the ones that are most directed to the patient. Most of these is the relationship between the provider and the patient, particularly the patient with the initiative to recognize when they are getting into trouble and getting the help that they need to get control of their life. And I think any program that does that is going to be successful. I hope we don't lose that process. The folks are very much aware of that and very much share your philosophy about that. I can't show you a metric other than ensure you that is definitely considered and will be promoted as we go. Yes, sir.

DR. LEDNAR: I'd like to also, like Dr. Parkinson, applaud you for bringing this topic. I think this is a good example of where we are moving to and that's population health management

as opposed to individual patient treatment quality assessments, both of which are important, but this is really where we will get ahead of the macro-forces on cost control in terms of healthcare.

I'd share an observation that we have had looking again at populations across the strata. You used the strata of one to four, in terms of what to do about it. It's a different intervention for a different strata. For those who are at the more severe end of the disease spectrum, clearly each patient's care, like the CHF admissions, will each be costly. But when you look across that set, clinical variability is a very, very big and costly dynamic. Now, one of the criticisms of course to evidence-based medicine is that my patient is different, and therefore, I should tailor the care nonstandard work. So I think in terms of understanding this population health experience in that more severe end, clinical variability will be the issue. In the earlier end, the earlier risk factor identification and early disease, it's much more

utilization issue. If you look at the actual costs that will be a group, the early asthmatics, for example, who will be your big spend as a group. So our natural inclination is to go to the individual high-cost event area, the ICU, and missing the fact that unless we deal in the outpatient setting in earlier stage and do that very effectively, we're missing a tremendous opportunity, not only for costs but it to just sort of slow down that disease progression.

So I think you have the ability for all of us in the nation to develop a very sound population-based methodology and we cannot get to a standardized way to evaluate disease management fast enough. So if you come onto any insights I'd really encourage -- and I hope that the Board would have an opportunity to hear some of these methodologic thoughts that we all could help to drive for adoption.

COL KUGLER: Yes, sir.

COL GIBSON: I've got a couple of hopefully simple questions. I noticed in your

disease management goals, you talked about provider satisfaction.

COL KUGLER: Yes.

COL GIBSON: And certainly in this time of stress, a lot of stress on our providers, that is a certainly important goal. We're hearing stories about because folks are deployed the in garrison people are under a certain amount of stress. TRICARE, because of its nature of having network providers, they have a little less hands-on control with those folks.

I also noticed that in your outcome measures, I didn't see any way to assess the impact that these disease management interventions on provider satisfaction. So how are you planning on doing that? Is there some sort of survey approach to this? What's the way of collecting the data on them?

COL KUGLER: There is actually going to be a provider satisfaction query or survey on select providers. I don't know the details on the managed care's side of that, other than that they

are going to be doing it. I don't think that's necessarily worked out yet, but it is part of the data collection. It's very important -- we've certainly got a lot of feedback from places in the direct care system of doing just in disease management. They're concerned that we're going to be messing with their program or driving a wedge between patients and providers and that's why we're tending to that. It's not the intent to do that. It's actually the intent to enhance that and the focus of the provider satisfaction and patient satisfaction evaluation is to make sure that's happening and that we're not making matters worse, we're in fact, enhancing that relationship and that's primarily the focus.

DR. POLAND: Yesterday the Board established a new subcommittee on healthcare delivery so I think both the disease management evaluation report and the comprehensive report on pain management, chronic pain management, that you mentioned, will be of interest to that subcommittee. We need to finish up this part in

about 15 minutes. You've got a lot of slides left. If it's okay, we'll move ahead and grab your question at the end.

COL KUGLER: I'm going to talk next about the current healthy lifestyles initiatives that have been going on for a couple years through our office; basically focusing on the conditions of tobacco use and alcohol abuse or alcohol inappropriate use as well as obesity and overweight issues.

The vision is that we make efforts as a system to reverse the negative health trends that have been identified throughout the country as well as among our active duty population and their dependents, the military family populations, to look at a proactive process that will coordinate with commands and communities to support healthy lifestyle choices by our beneficiaries.

I'm sure you're all familiar with this slide. There are variations of it. It basically illustrates the cost connection between healthy lifestyles that not smoking, having a healthy

diet, exercising, using alcohol in moderation and avoiding risky behaviors, you live longer and you don't cost the system as much. And the consequences are very well documented that the more these lifestyle risk factors come into play the less you live and the more you cost. I mean, that's the cold fact of life that's been particularly dramatic for tobacco use.

If awarded, contracts in a program known as TOBESAHOL, coined by our department, to specifically look at initiatives, MHS-wide initiatives, to deal with tobacco, alcohol and obesity concerns. There have been some studies in a health behavior survey that, for the past couple of surveys, showing that there is a trend upward in lifestyle issues and that we've been tagged with basically making sure we are trying to do something that will help reverse this trend.

First talk about the tobacco cessation efforts. There's very good studies, many of them done by military providers, documenting the negative impact of tobacco and readiness. Overall

it's estimated that in 2004 the cost to DoD was $1.6 billion per year in additional medical care. But beyond that our -- very documented that impacts on military training, increased injury, decreased night vision ability, exacerbation of noise-induced trauma, increased surgical risks, poor wound healing and so on and so forth. There's a very much direct link, and we make this case to the line commanders, a direct link between tobacco problems and mission accomplishment.

The demonstration program running right now is the tobacco-free me demonstration program that has been subcontracted to Lockheed Martin and it's basically a demo project that tests the participation in the tobacco quitline program which targeted in four states that have a large population that are not followed by MHS programs. This is basically to test the benefits of making availability to a quitline and to pharmacotherapy basically and nicotine replacement therapy and bubproprion. So as a web component, behavioral counseling via telephone quitline and well as

personalized "quit kits" as well as pharmacotherapy. As of August about almost 400 beneficiaries were enrolled. The demonstration is set to end next September. The primary metric is looking how much this is utilized, how successful the program is and the purpose is whether what the costs and the impact would be if we could change the benefit that would allow coverage for this service.

Another portion of the tobacco program and probably more, I think, germane to the issue for the active duty is the tobacco counter-marketing campaign called "Make everyone proud".

Basically it was a result of very intensive focus-group efforts of the younger enlisted. This is precisely the group of beneficiaries where smoking has actually increased over the -- and has stayed at an unacceptably high level over the past several years. This is a group we asked, Well, what is it about tobacco and the military; and got some interesting feedback. First off these groups thought it was prevalent

than it actually was, but they perceived it as normative, that it was consistent with the military image, that they saw some barriers even though the smoking cessation classes and the pharmacotherapy that was available that there were some scheduling issues and some barriers that they perceived. They thought that indirectly, even though there was a message to not smoke, that there was indirect support of it by the having smoke breaks or the fact that tobacco sales are less expensive than a civilian marketplace.

These findings were basically evaluated by the marketing contractor and crafted into a campaign including both print materials, radio messages and a website that's been rolled out just basically this past year at some target market areas. As of July 2007, we had over 100,000 hits on their website and average time about 10 minutes per site, which isn't bad for a smoking cessation website. Most of it comes from Pendleton and I would say that was, of course, a Marine Corps base. There was a lot of command emphasis to --

on the program there and that's probably the reason why there was a fair amount of traffic. The other aspect that's not on here is a program that our office is promoting in terms of seeing if we can get a change in the pricing of tobacco products in commissaries and PXs. Also promoting advertising -- a ban on advertising from post media as well as engaging some more of the line and other senior leaders in the anti-tobacco message.

Alcohol abuse prevention. Notice in the past healthy survey overall alcohol use has decreased. Binge drinking has increased particular to the Army and Marine Corps. It's identified as a concern. Impact of inappropriate use or heavy alcohol use is not insignificant. Estimated medical cost for active duty about $360 million per year. It contributes to about one-fourth of private motor vehicle accidents. Over 700 admin separations per year and a loss of productivity almost 1,700 FTEs per year.

The program that's being has been rolled

out has been an off the shelf type of program for educational online product targeted at young people, similar to what's been used at college campuses been modified for the active duty. It's called PATROL, Program for Alcohol Training Research and Online Learning.

It's targeted at these facilities of the Air Force, Marine, Navy and Army. The pilot project is winding up about now and can report that actually has surprised us, but actually has had an impact of sustained self-report behavior in binge drinking.

The red line basically reflects self-report in amount of alcohol consumption and it reflects intervention group for the intervention. Not only do we see a change at one month in those we were able to obtain follow-up on, about 859 of the participants, the change was sustained at six months. So right now we're going to assessing the next steps and see if we want to roll this out on a wider basis or target specific groups or whatever, but there's definitely a sustained

impact from an educational intervention for young people, which is news in and of itself, I think. We're very hopeful about it.

Another major program that many of you may have heard about is the "That Guy" campaign. Again, we looked at target groups to come up with this theme.

It basically looks at the negative effects, from a young person's perspective of alcohol overuse; and basically identified the caricature of an individual who, while in control and may be a regular guy and together when they have alcohol on board really become a laughing stock and folks being laughing at them not with them. Everybody could relate to that. This really struck a chord among young folks and the program was kind of developed around that with the "That Guy" image. I ask you Google "That Guy" sometime, it will take you to the website and I think you'll see why this has been successful.

Again, a targeted audience young enlisted primarily males. Secondary group is the

commanders and the chain of command. I would say that this program has been highly successful in both target groups. The young folks a very popular website. It's also been popular with -- because I think this interest in the young people it's popular with post commanders and line commanders. They're responsible for the lives of these young folks, particular the safety issues, anything that can get their attention and behavior they're interested in and they so far have been quite enthusiastic in support of this program.

This is just a little bit about the targeting process for the "That Guy" program.

It was launched last December and this is just an advertisement of how widely it's been used already.

The last one I'll briefly talk about, about 30 seconds is the overweight program. The military is not immune to this. This is a health survey showing an increasing in self-report of BMI over the past several years reflecting the American population.

The link between overweight and the readiness issues particularly with injuries and medical conditions.

The costs associated with -- this is in active duty, you're not supposed to get by (off mike) and be on active duty but it does happen on occasion, but for our beneficiaries the escalation and costs in bypass surgery is pretty significant, not only in a direct-care system, but particularly in the purchased-care area.

The demo is a program called HEALTH, Healthy Eating and Active Living in TRICARE Households. It's basically an interactive program that utilizes both an online and telephonic nutritional counseling as well as some access to pharmacotherapy. It's targeted at states and residence, beneficiaries in Illinois, Indiana, Michigan and Ohio. So far it's been highly successful enrolling folks as opposed to the tobacco program; it's got almost 2,500 enrollees that are participating.

Other areas of focus: The folks with

the commissary agency is a program where they scan labels on shelves indicating nutritional values of products. With the Navy exchanges. There's a DoD/VA CPG (clinical practice guideline) that was rolled out recently on obesity. And then there's the overweight and obesity metric is monitored on the MHS score card at the senior level.

In summary, we're funding basically evidenced-based demo projects that address the major causes of preventable death and morbidity. We're looking at ways that we can go forward. What kind of feasibility and effectiveness of these interventions. Maybe change a benefit if that makes sense; anything that will encourage healthier lifestyles and will move us along. We think that we see a strong link to readiness and definitely strong links to preventing chronic disease and reducing healthcare costs in the long term. Sorry for running through that. Any questions?

DR. POLAND: Thank you. Bill, you had a question, first.

DR. HALPERIN: Very briefly. I think you demonstrate in the presentation that you're using prevention all the way from primary prevention to tertiary prevention in clinical care, detection medical errors, collection of data, et cetera, et cetera, the whole spectrum.

But you know it's interesting in your early model population health and medical management model it's actually -- prevention is limited to a little corner called primary prevention. It's kind of an old model. So it might be, to make your model consistent with the very impressive work you're doing, you might want to change the model.

COL KUGLER: I'll bring that back to the -- I think that's a valid point.

DR. PARKINSON: Again, wonderful that the DoD is looking systematically at four of the factors that drive 90 percent of the healthcare costs. But a couple of points.

Personally, and I know that this is not the charge of the DHB, anytime you mention the

benefit word, that is a retention and accession issue brought within DoD. I can assure you that cutting-edge employers are no longer doing demo projects as to whether or not they should pay tobacco cessation. No co pay, no deductible, 100 percent payment with additional incentives for program completion. So please don't interpret, again, from my perspective, we have to demonstrate whether or not tobacco cessation without economic barriers saves costs to the employers in the first 18 months. Kaiser has published an excellent study on that. It saves the health plan itself, medical care dollars in 18 months. So please press on, look at the data, but talk to real employers, 100 of which I can give you the names of who are paying for it.

Additionally then getting differentials based on smoking stats, which again is a benefit decision, but until and unless you get that we're not going to get going the other things.

Weight management, as you know, the evidence is getting better. Finally coping skills

and stress management, which gets back to something that General Roadman worked on years ago called resiliency training. Don't underestimate peer-to- peer relationships that don't exist on the phone. This is an emerging area and we're delighted that you're doing it and look forward on these committees through the DHB to work you ongoing.

COL KUGLER: If I can just respond. Again, I agree completely with your points and certainly would not argue with them at all. They're certainly valid. The demo is not any proof. The demo is because we have to convince Congress to change it. We have to do a demo. We can't just change it without, because it involves CFR change and so forth, because the way the benefit has been written from statutes through CFR for tobacco specifically and to some extent for obesity. We don't have coverage right now. Yes, sir.

DR. BROWN: First of all, I want to echo Mike's comments about tobacco cessation programs.

The VA has a variety of programs that we feel are core programs that you might want to take a look at.

COL KUGLER: We have actually.

DR. BROWN: The second thing, I have two quick questions that I should probably know the answer to, but in terms of our deployed troops, deployed to Iraq today, for example, my impression is that their access to alcohol is very limited.

My second question has to do with tobacco cessation and why -- I've heard this before, I've never understood it completely, why is tobacco cheaper on military bases? Is it just because of the difference in federal taxes is there some other reasons?

COL KUGLER: That's a complex one. It has to do with the commissaries, PX system and the pricing regard to that. Again, tied to the laws that set up that system and so forth.

DR. BROWN: But if it's just an obvious -- why not just raise the prices?

COL KUGLER: We're trying to do that.

DR. POLAND: Let's keep moving on. Dr. Silva and then Dr. Lednar.

DR. SILVA: A lot of campaigns for smoking have also incorporated the family particularly if you look at upper respiratory infection rates otitis media in children of smokers in the house. Have you used that in your campaign?

COL KUGLER: Yes, sir. Absolutely. That's a big focus. You'll see a lot of the pictures in the campaign are of folks with kids and the impact upon children and the family, particularly with regard to trying to have a model of a warrior that is healthy, making their family proud of licking tobacco and keeping them healthy as well.

The question about the deployed troops there has been an increase in smokeless tobacco use. There's not as much access, but tobacco is a concern. We've gotten NRTs (nicotine replacement therapy) in theater and so forth and are looking at other ways to try to address that issue. It's tough

though. The war is tough with regard to those kind of behaviors. There's some effort, particularly is doing it and many other places we're looking at targeting folks when they come back to make sure that issue is addressed and focus on that group and like to see more of that happen. That's a very important area, extremely important.

DR. LEDNAR: As we're trying to manage this clinical activity from one that's been focused on acute and episodic care to the needs of chronic management of patient conditions. One of the interesting thoughts that TRICARE proposed is taking advantage of the very high impact doctor/patient relationship, the credibility that the doctor has with their patient even in a brief encounter and perhaps expanding our thoughts on vital signs. It's traditionally been temperature, blood pressure, heart rate and added to that what are vital signs critical for today's health needs. And perhaps that, do you smoke or do you use tobacco? What is your BMI? A short depression screen. Really in the process starting that

conversation we obviously have to equip our clinicians with what you do with the answers you get, because I don't think they're ready for that and the programs that would support them. But in the end to sort of bake that into what we use to judge is clinical care of appropriate quality to meet today's needs. So I just thought for that as a thought as you're thinking about how to take advantage of the one-on-one patient encounters to compliment what you're trying to do at a programmatic level.

COL KUGLER: That's an excellent suggestion; actually get the entire team in the process as well, the medics and the nurses. That has been in many areas -- and with the new AHLTA electronic record facilitates that and I think they're working to try to help that even more, but it's an extremely important point.

DR. POLAND: We have time for one more comment. General Roadman.

GEN ROADMAN: Dr. Kugler, thank you. I'm Chip Roadman, I really appreciate all your

comments. I would tell you I feel a little bit like Rip Van Winkle. The question I've really got is that with the number of people that are enrolled, 5,004 as the numerator and you put the denominator, you have about 5/10,000ths of the population enrolled in a disease management program, which I think would tell us that although making progress there is a force field here that I would really like to see what are the disincentives that we have, whether it's policy, whether it's centralization, whether it's behavior on medical doctrine. Because I think if we continue just beating the drum on once they have the disease we enroll them, if we don't go after the pre-disposing lifestyle issues, we will really never make a dent in the monetary or quality of life issues. I will, in full disclosure, I sit with some of the TRICARE contractors and listen to the inability to enroll because there's a centralized requirement for TMA to allow somebody to come into the program which puts an unnecessary do-loop into the program. Have you done that

force field analysis and do you have a systematic way to approach the policies and the practices to get a fundamental change in how we do this?

COL KUGLER: I think hopefully this will -- what we're trying to do is to get at that. The methodology we hope is open enough to tease that out and I agree, I think that the more we can do at the front end on this before it gets too far down the road -- it makes sense, certainly the long term makes sense, but we had to start somewhere. To get the easiest group to identify quickly and to get return on investment easily and to identify and have a program for was the higher end group. But I fully agree that I think it can't stop there and that's not our intent. To look to the experience with this and to move onto what's the next logical step I'm thinking probably more in line with what you're saying, sir.

DR. POLAND: Thank you, very much. I'll be the next speaker this morning. The Pandemic Flu Preparedness subcommittee has been very active over the last several months addressing a number

of questions that were presented to the Board by Ms. Embry, the deputy assistant secretary for force health protection and readiness and also our usual DFO. The subcommittee has developed a series of recommendations in response to these questions. As the members know the recommendations of the subcommittees are brought to the full Board for deliberation and vetting and then become products of the Board forward to the Department for their consideration and action. Do you have copies of these recommendations? I'll take you through them.

There were three primary questions addressed to it. One was to comment on the disposition of the current stockpile of Clade 1 avian influenza vaccine and the option of offering the vaccine to service members prior to the vaccine's scheduled expiration date in December of 2007.

We were also asked to provide recommendations on the Department's overall pandemic influenza vaccine procurement strategy,

particularly as it related to ensuring affective vaccine stockpiles to protect the armed forces.

Thirdly to comment on the possible procurement and expanded use of additional supplies of antiviral medications in the event of an influenza pandemic. So if we go to the next page, what would be recommendation 4.1. So it would be the second page, top of the second page.

To go through our recommendations and then we'll take questions or discussion at the end. The first was that we supported efforts to extend the shelf life of the currently stockpiled Clade 1 vaccine.

4.1.1 we reaffirmed that the Clade 1 vaccine, now that it's FDA approved, should be offered to persons within DoD who are at the highest risk of occupational exposure to H5N1, which we generously estimated at about 1,500 individuals and that the DoD should collect follow- up safety and immunogenicity data on the recipients. We also said in the next paragraph, given the limited data about Clade 1 vaccine's

effectiveness as a potential primer, we advised against offering Clade 1 vaccine's to service members outside of those at the highest risk of exposure at the current time. If additional safety and immunogenicity information became available or if the threat of pandemic increase, we would reconsider that position.

4.1.2 we recommended that DoD pursue the extension of the vaccine shelf life even if that needed to retrospective and that DoD and DHHS immediately engage in discussion with FDA regarding what data is currently available and what data would be required in order to meet the criteria necessary to extend the expiration date. Again, with the clock ticking and December 2007 being the expiration date there was urgency in this.

4.2. Given the subcommittee's recommendation to pursue an extension, we recommended that DoD not dispose of vaccine even were it to become expired, because of the possibility of retroactive extension of the

expiration date by FDA.

4.3. We supported increasing the pre-pandemic antiviral stockpile to allow DoD to expand prophylactic strategies which included purchasing 2 million additional treatment courses of Oseltamivir, so that would be 20 million tablets effectively doubling the stockpile. It would then contain over four million treatment courses of Oseltamivir.

4.4 we recommended further discussion and modeling efforts in order to achieve consensus regarding the optimum balance of treatment, which we've defined there. Post-exposure prophylaxis also defined and pre-exposure prophylaxis also defined. And the most appropriate target populations given a supply of anitvirals.

4.5 we recommended a strategy or at least developing a strategy for the long-term plan for acquisition of protective pandemic vaccines. We specifically reiterated a number of key recommendations that we had made in 2006, which has already been approved and forwarded to the

Board, but I'll briefly, very briefly review them. One was that, for a number of reasons, we felt strongly that DoD had to be a full working partner at the table with the other federal agencies because there was a number of studies and other issues that were more DoD specific and less likely to come up in discussion of civilian agencies.

4.5.1.1 was that data regarding the antigenic and genetic analysis of influenza isolates to be submitted to DoD for analysis; and that data regarding clinical trials involving investigational vaccines for H5N1 and other potential pandemic viruses be made available. I won't go through all the sub details on that.

Recommendation 5 on the following page. This is where we got into a little more detail about a procurement business model. The fact of the matter is that multiple industry partners are rapidly coming up with candidate vaccines. We didn't think the DoD should be leveraged on well, okay, this is the next one available; let's spend all of our money on that one, but rather a rolling

procurement model that took into consideration advances of vaccine technology.

No. 6, we recommended that this strategy ensure the broadest possible influenza subtype coverage and yet remain economically feasible.

No. 7 that DoD in particular actively develop, fund and sustain a PI/AI research and development focus in order to have content experts who would be so acknowledged and could most effectively participate in interagency efforts and planning efforts. The Board noted that this was traditionally and historically true of DoD up until the last decade or two.

No. 8, we remained concerned that DHHS and hence all of the agencies leveraged against them had relied on inactivated split or subunit vaccines as the primary vaccines being developed. The past history had suggested the superiority of inactivated whole virus vaccines other than a live attenuated vaccine. There are no manufacturers of whole virus vaccine anymore and new data suggesting that adjuvanted split virus vaccines

might be equally or more immunogenic. Nonetheless there's some controversy and we were quite concerned that rather than serial development, that is make a vaccine, okay, that one didn't work, make another one; that parallel development of multiple candidates be considered and tested and that's basically what 8.1, 8.2 involve. So I won't spend more time on those.

No. 9 was an issue that the committee had heard about earlier and that is the idea of further considering development of guidelines for the use of convalescent and immune plasma for PI and other military-relevant disease threats. We felt the most practical way to do that would be to convene a working group of subject-matter experts in the immune plasma and blood banking fields.

So that's an overview of the draft recommendations that we would like to forward on to the Department. I open it up for questions, after which Dr. Hachey will brief us on responses and updates to these recommendations. Comments? Questions?

DR. LUEPKER: Greg, as you talked about the vaccine facing expiration, you talked about extending that. Two questions.

One, what are the rules in technology that set these dates and allow that?

Second, are there perception and public relations issues associated with that?

DR. POLAND: Yeah, that would have to be managed and obviously we would not want to give vaccine that had expired. But the current vaccine that we're talking about is an FDA-approved vaccine. Manufacturers typically have a one-year expiration date. In part that derives from the idea that they don't want old vaccine still sitting on the shelves when the next season's vaccine becomes available and then mix-ups as a result of that. But the vaccines are immunogenic and safe past the year, but that's just been a traditional expiration date for practical reasons. Does that answer your question?

DR. LUEPKER: You hope that you get some relief from the FDA eventually?

DR. POLAND: Correct. I mean, we've got a lot of vaccine sitting there.

COL ANDERSON: I just wanted to also clarify that Department of Defense went back to the manufacturer, they're continuing the stability data and they will do the request for that extension so that will be a normal process and we want it approved before it expires.

The other thing is that we have taken possession of some of those vials for the use that has been recommended by this subcommittee and those are being kept separate from any seasonal vaccines for those reasons, too.

DR. LEDNAR: Greg, you mentioned that the vaccine remains immunogenic even past the one-year date. Is there some additional testing that the manufacturer should do and make available to the decision makers like DoD just to allay some of the concerns that -- while they say there is immunogenicity and efficacy that persists past the end date that there really is testing at some of those lots to confirm it is true.

DR. POLAND: In fact what happens is there is -- and I can't speak to the sub-details of that, but there is a protocolized and standardized set of criteria that FDA requires and they have to test sterility, purity, stability, immunogenicity and maybe its safety, I think. So there's a set of data that has to be collected and recorded in a standardized way in order for FDA to grant that extension. Is that what you're getting at Wayne?

DR. LEDNAR: I guess one other question. In times past there was some concern about sort of a U.S. national security concern that there be sufficient capacity perhaps within United States the manufacturer of vaccines as well as antivirals. Are we getting to a different place in terms of U.S. capacity?

DR. POLAND: That's a good question. I think the answer is -- will be yes with antivirals and will be no for vaccines at least with current approved technology. With the egg-based platforms, it is simply not possible to make

enough vaccine for the U.S. or the world. Now, with (off mike) reverse genetics and other technologies and perhaps the live attenuated vaccines that will be a different story.

DR. WALKER: What's the nature of the occupational exposure for whom the individuals would be recommended to?

DR. POLAND: These were individuals that were in the field. A number of them were veterinarians or laboratorians that would have exposure to the -- would have a high risk of exposure to the virus.

DR. SILVA: Greg, I think that's a really good summary of our many phone calls, so congratulations. For those of you that don't know about vaccine production, the egg platform, many of these companies are using 100,000 eggs a day. There is an industry out there of chickens that you can't believe.

DR. POLAND: Sometimes which came first. I think the egg might. And I invite other members of the subcommittee who have any comments or

elaborations that they might want to make on my summary.

DR. OXMAN: With respect to a homegrown capacity to produce influenza vaccine in the amounts we would need, there are, I think, contracts already for tissue culture grown vaccine. If the tissue culture platform is classical, normal, nothing fancy. Tissue culture platforms themselves will permit us to have that capacity of homegrown, but as Greg pointed out, not eggs.

COL GIBSON: We were privileged; Dr. Silva, Dr. Oxman and I were privileged to go to a meeting with HHS where they brought the vendors in that are working under these contracts to establish new vaccines; seasonal vaccines as well as PI. What we found interesting, there's a lot of money being thrown against them. They're talking about building infrastructure in the United States to do the -- as part of the funding mechanism to test these vaccines. Consequently the long-term end is more robust productions

facilities to meet epidemic/pandemic needs in the United States. So we're getting there. There's a down select process involved in that, but there's a lot of work being done in that area.

DR. POLAND: Just to give the committee an order of magnitude; well over a billion dollars has been released by the government to get us to the cell culture technology. Bill.

DR. HALPERIN: If I recall in WWI, it was President Wilson who went full steam ahead on keeping the military operations going while other people were arguing other social (off mike). And I wonder whether it's in the curfew here -- it's another chapter basically this is vaccine related as far as preparedness of DoD as far as social distance in the presence of the start of a pandemic whether they're plans -- we've heard from time to time reports of various corporations who have looked at school children and primary care and --

DR. POLAND: Very good question. And the Board previously in the July 2006

recommendations included things about distancing, quarantine, use of (off mike) there may have been one other non- pharmacologic intervention, but, yes.

DR. HALPERIN: School closings?

DR. POLAND: Yeah, school closings.

COL ROADMAN: Greg, as the conversation went about shelf-life extension programs (SLEP), for those of us who have been stockpiling, whether it's pharmaceuticals or anything else for surge requirements the SLEP program is not an unusual issue but it does have the public relations requirement of when that becomes obvious. Clearly the manufacturers are not interested in that. Us as the users are, but that's a common program that is employed.

DR. POLAND: Colonel Hachey, let's let you get on to your briefing. Is there a comment while he goes up?

COL NEVILLE: With all those resources going towards improving vaccine production capacity, is there any similar effort going

towards improving the vaccine component recommendations, predictions and so forth? Anybody know?

DR. POLAND: Actually I would say that is the area where the government has made the most rapid advances and that's in the -- let me just call it the surveillance activities in terms of understanding what's out there, what the resistance patterns are, et cetera. There's been a big political problem though and occasionally it erupts into public view and that is the willingness of those foreign governments to share that information or to let isolates out, so there's more work to do there. Go ahead, Wayne.

LTC HACHEY: I can't see what I'm talking about from here.

DR. POLAND: Just do it from memory.

LTC HACHEY: I'm happy to say that most of the subcommittee's recommendations as far as pandemic influenza we've already done and we'll see some evidence of that in the subsequent slides.

But to start out with H5N1 continues to mutate. It's persistence in wild and domestic bird populations, at least since 1987 is actually both worrisome and reassuring. Worrisome in that it just doesn't seem to want to go away, but reassuring in that it's had ample time to make that leap to be able to facilitate human-to-human transmission and that's why it has not taken that opportunity. There's now four distinct strains causing human disease, two clades and three subclades. The Indonesian subclade, 2.1, at least over the past year has had the highest mortality, around 80 percent; the largest number of cases and the smallest geographic distribution. Whereas the strain affecting Europe, Africa and the Middle East has the lowest mortality, about 30 percent, it's a little disconcerting to say the lowest mortality and 30 percent in the same sentence, but it has the next to the highest number of cases, at least over the past year. The largest geographic location and coincides with the majority or our deployed forces.

Staying with birds, the geographic spread is consistent with domestic and wild bird distribution. There's been no significant change in human-to-human transmission. Sporadic cases do continue to occur. The birds remain the primary hosts. Cats, dogs and other mammals have developed a disease without effective transmission and there's no evidence of transmission to humans other than via an avian or human root, so we still can't catch avian flu from Fluffy.

The next three slides are WHO maps that will cone done what's been happening with AI at least in the bird population since 2003 to the current time. This one chart depicts what's been happening since 2003 to date. The red colored is the areas reporting incidents in poultry and the tan -- those areas with just disease in wild birds. Coning it down a little bit since January of this year, we can see some hot spots in Indonesia, China, Vietnam and then in Africa. Coning it down even further just since July of this year, again, Indonesia remains a hot spot a

little bit of activity in Vietnam and China and some activity in Egypt.

Shifting gears to human disease Clade 1 had its hay day a few years ago, but over the past months we've seen less than a handful of cases. Clade 2.1, again, primarily in Indonesia. 2.2, most of the cases there are coming from Egypt. 2.3 seen primarily in China, Laos and Vietnam. There is some concern that the 2.3 may be underreported just due to the rather large geography they're trying to represent and some problems in reporting in more austere environments there.

Looking at, again, a WHO map now with human disease, we can see Clade 2.1 again in Indonesia with 30 cases since January of this year. 2.2 the lion's share of those cases occurring in Egypt and 2.3 in the China/Vietnam area. Recently Vietnam has reported an additional five cases there.

When we met last the concern of sample sharing came up and it's still an active problem.

Indonesia is demanding guaranteed access to benefits stemming from samples and this potentially will threaten the global influence of surveillance network. The good news is that there are ongoing negotiations and Indonesia has resumed sample sharing on at least a limited basis; however, some recent events do question the government in Indonesia's level of transparency particularly in light of their Minister of Health's denial of previously confirmed limited human-to-human transmission within the Indonesian border.

The next two slides are just more about what's new potpourri. First of all the WHO has recently changed its criteria for diagnosis of cases by in-country labs. This will improve more real time reporting of positive cases. Right after this change went into affect that's when we had the additional five cases reported from Vietnam. Also the good news is that the disease we see is probably the disease that's there. That they're more than likely or not a whole lot of

cases of either mildly symptomatic or asymptomatic diseases. Out of seven seroprevalence studies, our studies in Vietnam, Thailand, Cambodia and Russia all with negative findings. The only one with positive results is in Korea, four folks tested positive out of 2,000 poultry workers and all of these were without clinical disease. Some other news is that the mutations required for shipping from an avian bindings site to a human binding site have been identified and we're just two mutations away from that, which is a little scary until you find out that after that change the virus is still incapable of decent human-to-human transmission. So there seems to be much more to the story that has to happen than rather just these two mutations and binding sites.

Some bad news as far as Neuraminidase resistance. Previously there were only two mutations that were identified that were associated with resistance. Now there are a total of four and Oseltamivir is no longer alone. With at least Clade 2.1 and one of these mutations,

which is quite rare, fortunately, we have potential Oseltamivir, Zanamivir and Peramivir resistance. Also in vitro it turns out that Zanamivir resistance hemagglutinin mutants are much easier to generate than Oseltamivir is. So as we start using Zanamivir more for at least H5N1 its resistance pattern may blossom.

So this is some of the DoD activities at least in regards to antiviral. We recently released our new antiviral guidance, guidance for use that's based on a variable supply and disease severity. We use the National Pandemic Severity categories for disease severity. It reinforces the need for early and consistent implementation of the non-pharmacologic mitigation measures that the Board was just talking about a few moments ago. It also introduces the post-exposure prophylaxis strategy as an additional treatment modality or strategy for mitigation.

Shifting gears to vaccine. If we look at the National Strategy for Pandemic Influenza implementation plan, HHS and DoD have a kind of

common task. First of all, HHS is required to be able to immunize 20 million people against influenza strains that present a pandemic threat. DoD is required to establish stockpiles of H5N1 vaccine and other influenza subtypes determined to represent a pandemic threat adequate to immunize 1.3 million people. So translating that to doses, you need to double those amounts.

How much do we have as far as meeting that goal? Nationally we're just shy of 15 million doses of a variety of H5N1 vaccines. The DoD portion is about 1.2 million. The vaccine started being produced in 2004 and continued through 2007 and represent products from three manufacturers. The products use different reference strains reflecting the evolution of H5N1 virus as both in birds and humans. And only one of these products is licensed, which happens to be the product that DoD has in place. Most of the HHS stockpile is stored in bulk by the manufacturers and most of the DoD stockpile at the present time is in vials with the December '07

expiration date. We're actively pursuing shelf-life extension of that which appears to be going well. Additional vaccine contracts are being completed for 2007 and 2008, which will include vaccines to new H5N1 viral strains from Clades 2.1, 2.2 and 2.3 for the next vaccine run.

What are the current strategies for civilian for the pre-pandemic vaccine? Well, they're planning on vaccinating laboratory personnel who work with H5N1 and pandemic response teams. Then, vaccination of defined target groups, which are yet to be fully developed when the pandemic is imminent, each person getting two doses of pre-pandemic vaccine and the level of protection of course depending on how close of a match it is.

The DoD policy which was recently released mimics the national law strategy while offering the FDA-approved vaccine to lab personnel and teams with direct contact with high path H5N1. Within the policy we've also established a tracking, effectiveness and adverse event

monitoring as well as immunologic serosurveillance. Then with the imminent onset of a pandemic then the joint staff in cooperation with NORTHCOM as the synchronizer will determine the priorities based on risk, ability to receive two doses and critical role of DoD personnel, with, again the goal of preserving operational effectiveness.

Well the DoD and national strategies may actually change over time especially if we get a better vaccine, whether it be a universal vaccine or improved cross protection, across clades and subtypes or if production could be substantially increased and long term-wise that means either bigger or more facilities, non-egg based production as an intermediate goal. And the short-term fix is the use of adjuvanted vaccine.

So the current H5N1 vaccine studies that are underway include split virion and whole cell vaccines, adjuvants, different roots, intradermal versus IM, a mix and match adjuvant study and data on cross immunogenicity between clades and

subclades. I'll be presenting, at least, some preliminary data that touches on most of these aspects.

The first one is immunogenicity of whole cell Clade 1 H5N1 vaccine across clades. This is a Baxter seroderived whole cell Clade 1 vaccine dose of 7.5 ug unadjavented in people 18 to 44 who received doses on day zero and day 21. You can see that the response isn't bad. At 21 days 40.5 percent, at 42 days 76.2 percent, and then, looking at cross protection, again, better than what we currently have now with our unadjavanted split vaccine at 42 days 45.2 percent. Now this is a number by percent with microneutralization titers greater than 1 to 20. The problem is that the microneutralization test is not standardized and we don't know whether a titer greater than 1 to 20 will actually correlate with protection.

This next study is some older data that ties in with the next study, which is newer data. This is immune priming and cross-immunogenicity after a booster dose. Subjects received two doses

at a 21-day interval of a plain or adjuvanted H5N3 vaccine. Sixteen months later, 26 subjects received a third dose of the same vaccine.

You can see that the adjuvanted vaccine had a much more pronounced yield whereas the unadjuvanted the results are rather dismal. Then cross protection from the H5N3 reference strain to an H5N1 strain really were dependent on the specific strain with some being rather robust and others somewhat lackluster. Again, all of the unadjuvanted had rather dismal results.

The next study was looking at booster immune response following priming with an antigenic variant. Thirty-seven individuals vaccinated in 1998 with two doses of a 90 ug unadjuvanted Clade 3 vaccine, then they were vaccinated eight years later with one dose of a 90 ug unadjuvanted Clade 1 vaccine. Antibody responses were compared with H5 naïve subjects who received a single 90 ug dose of the latter vaccine. You can see that the primed response is substantially better than those who are unprimed.

The good news is that if this holds true for our current Clade 1 vaccine, even though it's not a good match to the current threat, may actually be a very good primer for a pandemic- specific vaccine.

The next study looks at adjuvanted Clade vaccine safety and efficacy data in a human trial. This is essentially the GSK adjuvanted vaccine. As an observer blind randomized trial, two doses inactivated split Clade 1 vaccine. Doses were administered 21 days apart, 400 subjects, eight groups of 50, with an age range from 18 to 60 with four antigen doses ranging from 3.8 to 30 ug. The vaccine was compared with and without adjuvant.

This is just a chart looking at the demographics. Mean age was mid-30s, pretty much an even gender split with a couple outliers in two of the groups and ethnicity was primarily a white population. The results were fairly impressive. After just one dose there was a substantial bump. This axis is the percent with HA titers greater than 1 to 40, so at just 7.5 ug and one dose,

we're looking at 50 percent coverage. After two doses we're in the 80 to 90 percent range.

This next slide just looks at some of the same data. The HI antibody response to homologous vaccine strains using the non-adjuvanted vaccine. Using the non-adjuvanted vaccine you see that the response is much less robust although it's reassuring even with the non-adjuvanted. 43 percent that's what we were looking at with the response from our 90 ug currently held and FDA- approved vaccine.

If we move on to the adjuvanted vaccine, I can see that the response is much more impressive with after the second booster dose seroprotection titers in the 80 to 90 percent range. More importantly if supplies are rather tight, even with one dose using 7.5 ug we're protecting 50 percent of the vaccines.

So the results that all eight vaccine formulations in this particular study had a good safety profile with no serious adverse events. And the adjuvanted vaccine induced, as expected,

more injection sites and general symptoms. They were mostly mild to moderate, and all were transient. All of the adjuvanted formulations had significantly more immunogenicity at all doses.

Now I couldn't leave without talking about ferrets at least once. Again, ferret data; this is looking at immunization with a low-dose adjuvanted split H5N1 vaccine demonstrating protection in ferrets against both homologous and heterologous challenges. Again this is using the current GSK adjuvanted vaccine. So ferrets were immunized with a Clade 1 adjuvanted vaccine and then challenged with a Clade 1 challenge and a Clade 2.1 challenge the Indonesian 5/05 strain.

Looking at the results from the homologous challenge, you know, if you get just the adjuvant, well, you die. If you get the unadjuvanted vaccine you're still likely to die if you're a ferret. But even with fairly low doses of antigen, have substantial protection with as little as 5 ug with 100 percent survival.

Shifting to a heterologous challenge,

again, the Clade 2.1 Indonesian 5/05 strain with doses as low as 3.8 ug universal survival. So pretty good cross protection across clades.

In summary, the H5N1 pre-pandemic vaccine studies, the adjuvants, short-term-wise appear to be the way to go in increasing immunogenicity and cross immunogenicity of H5N1 vaccine, and, in fact, a single dose of the GSK adjuvanted vaccine could protect now half of the vaccine recipients. Priming with one or two vaccine doses leads to a booster response to a subsequent dose of the same or even a different H5N1 vaccine. Some pending studies currently are mix-and-match studies using the GSK adjuvant with other companies' influenza antigens. That is currently under way. Also further trials on cross-immunogenicity and priming which I hope to present in greater detail the next time we meet.

That was a bunch of posters about our pandemic exercise, which you won't have the pleasure of seeing.

But we did have an exercise involving

the OSD P&R. It was to ensure preparedness and continue the mission essential operations with a diminished force and could safeguard its staff during a pandemic influenza. The exercise was designed to assess the overall preparedness, to identify vulnerabilities, identify strengths, capture lessons learned and identify a way forward for improvement.

The exercise goals, first was the ability to work at home, so trying to stress the IT connectivity and server capacity. Also to examine the capability of the communications systems designed for pandemic to include our 800 number for people to call in to report their status as well as telephone trees. The ability to employ social distancing at work and the ability to execute a sample of mission essential functions with a diminished workforce. Also to look at the flow of order of succession and delegation of authority and the ability to muster using a web-based tool.

The exercise accomplishments at

in-state, the overall readiness rating for P&R was 96 percent. Total number of participants, for this kind of pilot exercise was just 1500. Total on- site employees, about 1200. Total number of teleworkers representing about 17 percent of our population number 251. And the total number of incapacitations 54. We did find that teleworking does take some practice on the first day of the exercise the help desk got 32 calls and by the second day that dropped down to 14 calls. That was similar that we found from our satellite organization.

Some decisions that have to be made based on the results of this exercise is that we have to continue with readiness preparations to resolve some identified vulnerabilities. And PI weight four should be incorporated in the P & R coop plan. Geotrex exercises should more fully stress the IT capacity until we know exactly what the breaking point it. Also the exercise included folks in uniform and DoD employees, but had a fairly low representation as far as our

contractors and Geotrex decides who want to bring those in. Also need to assess the impact of pandemic influenza on Pentagon parking and food service for some of the ancillary services and to test the office of Secretary of Defense and interagency integration during a pandemic. There's also consideration of appointment of a full-time P & R emergency preparedness program manager who is going to oversee all of these activities.

So just in closing with the next update I hope to share the results of expanded PI exercise results. Also some policy adjustments after we increase our antiviral stockpile. The recommendations of the Board were taken and we're currently purchasing that additional 2 million doses of Oseltamivir and developing revisions in our policy to reflect a more expanded prophylactic role particular with post-exposure prophylaxis being an option consistent with the HHS community mitigation guidelines. Also some more data on pre- pandemic vaccines as those preliminary

studies get a little meatier and we have more to report, I'll have to share that information with you, as well as our acquisition plans. And, then, finally the results of vaccine modeling.

This, too, was a nifty picture of a women sucking on a pigeon head, which is in your handouts.

DR. POLAND: Thank you. We have just a couple minutes for questions. Wayne.

DR. LEDNAR: Wayne, very nice presentation. I've got really two questions or reactions coming out of the preparation, the exercise work you did. One was the teleworking information technology and the other with personnel issues.

The private sector assessment of the ability of telecommuting being a viable way to continue operations, in the most assessments I've seen, is that we are vastly overstating our capacity in working remotely during a pandemic, especially for operations that are very broad band dependent. I don't know whether the Department of

Defense has the ability of sort of getting a certain defined amount of capacity in a pandemic situation to support critical military operations. But what's entirely possible is all the rest of the country sucking off the capacity limiting what he has available to it. So I would be just a little careful about how much dependence on an IT solution.

The other is a challenge that we've seen several times and that's in the personnel area, dealing with the fact that if there is a morbidity, let's say an absence rate of -- pick a number, 30 percent, how, in fact, critical functions will be sustained because it may require the reallocation of people from one MOS to work in a different MOS in a different location. So it's just not finding a solution to work with one-third of your people in your office. It's how do you reallocate flexibly people who are cross-trained in multiple military specialties and apply them flexibly where you need them. If you had a personnel policy and implementation that's that

quick and adept. We don't see it in the private sector. We're not there yet.

LTC HACHEY: Well, I don't know how quick and adept we'll be, but the civilian personnel office did recognize that that what they need to do is have a good idea of where the talents are within the organization and to essentially move people around. So as holes become vacated that are critical that you can take someone who doesn't normally do that, but does have that skill set and plug him in. So in their personnel accountability they want to know where their people are, whether the people are sick or not or whether they're staying home for other -- pandemic is just scaring the bejeezes out of them or whether they're actually quarantined, but also what skill set they have so they have an inventory of what resources are available on a day-to-day basis. Now whether moving from that data to actual operations will be as facile as we hope, we'll have to wait and see. But the organization has considered those issues and is, at least,

collecting the data to potentially be able to do those kinds of switches.

DR. POLAND: Dr. Clements.

DR. CLEMENTS: In the Department of Defense Implementation Plans for Pandemic Influenza that was published in August of '06. There are 20- some odd preparedness and response matrixes of which vaccine acquisition and PI exercises there are only two. So who's monitoring the progress? These all have timelines of three to 18 months after publication of August '06, so we should be nearing the end of these. So who is monitoring the progress of these? And is there -- who's got the big picture here?

LTC HACHEY: Each -- for the -- at least the National Implementation Plan, which is reflected in the DoD plan, DoD has, I believe, a little over 300 tasks representing about a third of all of the tasks. Of those -- actually all of the tasks are being monitored by the Department of -- not the Department of Homeland Security, the -- yes, the Department of Homeland Security. So

they're the kind of the larger watchdog as far as all of the interagencies completing the task on time. You also have quarterly updates that each agency is required to submit outlining their progress in meeting those tasks so there is a fair amount of oversight. Now as far as meeting our two tasks, as far as antivirals and vaccines, we've met the antiviral requirement, gosh, before the task was actually written. So we've been in compliance with that one for quite some time. Meeting the 1.35 million capability of immunizing DoD personnel, we're somewhat limited; one, fiscally, just having the money to buy that much vaccine. And the other real rate-limiting step is there isn't enough vaccine to buy to meet that goal. So our acquisition plan is spread over the next couple years that we'll be able to be a position of omitting that individual task.

DR. CLEMENTS: But would the Board ever be able to see from a DoD perspective how the DoD is meeting these different tasks?

LTC HACHEY: Yes. In fact, let's see,

about two Board meetings ago, one of the PI updates included exactly which tasks we were assigned. Which ones fell under the medical arena and what our status was for each of those tasks? But we can easily include that in future updates.

DR. LUEPKER: Just to mention about the ferret experiment. It seems apparent from your data that protection is not only adjuvant dependent, but dose dependent. But it looks like the ferrets, which are much smaller than humans, are getting dosages similar to humans. Is that -- my perception true?

DR. POLAND: In their experiment they got ug and that's what you're commenting on is that in some of the human studies they go down as low as 3.8.

LTC HACHEY: Yes, I believe that is true that the ferrets are receiving essentially the equivalent of the human data switch would be, I guess, per unit of weight much more substantial.

DR. LUEPKER: Yeah, the question is: Are the dosages body-size adjusted somehow or are

they actually getting --

LTC HACHEY: No, they're getting 3.8 or the.5 ug.

DR. LUEPKER: And that's actually not uncommon to find that in small animal models you frequently have to use the same dosage that you use in humans because that observation is not out of the ordinary for these types of studies.

DR. POLAND: Okay. What I'd like to do now is ask for any last comments or concerns anybody has on the pandemic recommendations; otherwise, if I don't hear any I'll assume consensus and then we'll forward them on as an approved Board product. Good. Okay. We are going to take a ten-minute break here and reconvene at precisely ten minutes. Just one think that Colonel Anderson just passed on to me: The FDA just announced that they have approved the new formulation of flu mist for an expanded population, so basically down to age 2. So that's very good news.

COL GIBSON: Quick administrative point.

Those of you going on the tour this afternoon need a picture ID and we have 57 seats on the bus to take us over there. So if that's going to be a problem, we need to work on it. Thank you.

DR. POLAND: Okay. Ten-minute break.

(Recess)

DR. POLAND: We've got a pretty tight schedule to try to adhere to. We're going to look at the Southern Hemisphere recommendations from the subcommittee on pandemic preparedness. Then we have a bit of a change in schedule. We'll then go to the disability evaluation system plan. We need to do that done before lunch. And we'll do the adenovirus stuff right afterwards. Can we bring up the Southern Hemisphere or how are we doing that? Is that in the packet? Just go to tab 6. You have the material there.

We had been asked by the joint staff about the issue of southern hemisphere vaccine and whether our troops were at risk, and if so, should we do anything about it. We came up -- we had a number of teleconferences, had a number of

presentations during that, a number of pieces of data reviewed. Mark, in fact, presented an analysis that he had done looking at the different seasons and what the results of that were. And the basic summary of it, what I can tell you is that in general there appears to relatively little impact on U.S. troops by southern hemisphere strains that are so different from northern hemisphere vaccine that they cause widespread illness. There's a proviso to that, and the proviso is that we don't always have the best of surveillance, particularly in areas where we have a growing commitment but not yet robust surveillance activity. So for example there's more and more sustainment in Africa and there will be -- a command that will stand out, but we don't necessarily have great surveillance in Africa.

The other thing is traditionally the way people have thought about this it's fairly simplistic. The virus doesn't respect a border or an equator and yet we sort of think of well, there's a northern hemisphere season strain

circulating and there's a southern hemisphere and there's not much mixing. In fact, this is sort of a rolling time-dependent, sliding scale of these quasi-species of viruses. So it's an ever changing, complex issue contaminated now by the immense amount of global mobility that occurs every day of the week all through the year. So it really requires a real time, highly dynamic, comprehensive surveillance system; components of which are in place, but not all.

So if you skip down to No. 6, and maybe I'll make a comment about 5. The issue is whether troops should get southern hemisphere vaccine and those are not licensed to the United States. But there are a couple -- were there to be a unique strain that we thought was of issue, there are some fallback provisions for the military, for the country and that is IND or emergency use authorization, approval that would allow the use of the vaccine. So with those fallbacks, then, our recommendations come under No. 6.

We did not recommend the use of a

southern hemisphere influenza vaccine for U.S. Forces at the present time. If FDA licensure of the vaccine became available, obviously we would reconsider that issue. Apart from rare outbreaks, there didn't seem to be an overall impact that we could discern with the data available on mission from southern hemisphere influenza and an unclear association between what's in a southern hemisphere vaccine and what's circulating in areas where our troops actually are stationed.

We recommended that the Department have discussions with manufacturers and urged them to seek U.S. licensure. We believe one company is doing so. It was the fallback mechanism for DoD of the IND or EUA mechanism.

Then we recommended enhanced surveillance strategies, including collaboration with other agencies and other personnel in the southern hemisphere. Primarily because of our belief that even within the southern hemisphere what surveillance we had reflected assets in more highly developed areas of the southern hemisphere.

That may or may not be where our troops are actually committed.

There's a brief overview of it. Any comments, thoughts, et cetera?

DR. WALKER: If I recall, do we not need detection of appearance of a new HN type in the southern hemisphere, because they really appeared in the northern hemisphere, the change of it appeared first in the northern hemisphere from what we detected.

DR. POLAND: I think that's right. Mark, do you want to comment? Kevin.

DR. McNEILL: I was privileged to serve on an IOM committee that actually will be releasing a report next week on the DoD GIS, the global influenza surveillance program, and I think the recommendations in that report and some of the status update in that report that address your last issue on surveillance. They'd be a partner for this committee to review once it's released next week.

DR. POLAND: Okay. Good. We'll get a

copy of that and look at that.

COL GIBSON: There's a couple other dynamics that this subcommittee dealt with. One is that there's an issue of tropical or subtropical, year-round influenza (off mike) low incidence, but completely different from this seasonal thing that happens further down in the southern hemisphere.

The other is that other agencies, and if you remember when we discussed this, we had CDC there and HHS and others, State Department, Health and Human Services, Peace Corps, there's a boatload of folks that are interested in our comments on this and whether they feel as though it's important to vaccinate their folks. Now they're usually down there longer because a permanent tour where a lot of what we do are deployments. But they're interested in us finishing this up.

DR. POLAND: Okay. I'll take as consensus an approval, then. There are no other comments? Okay. Thank you.

We're honored to have the Honorable Mr. Bill Carr, deputy undersecretary of defense for military personnel policy with us today as the next speaker. Mr. Carr oversees the recruiting, retention, compensation and related human resource management for the 1.4 million active duty military members of the armed services. He's a graduate of the United States Military Academy and holds a Master of Science in systems management from the University of Southern California and has completed post-graduate work at the Kennedy school of government Harvard University. Mr. Carr's 20-year military career was performed in the field of military personnel management including service as chief of enlisted management for Army forces in Korea. He also served with the U.S. Army Military Personnel Center as the enlisted strength and readiness manager for the Pacific, Korea, Panama, Hawaii, and an officer accession manager for the Department of the Army. He's worked with the armed forces recruiting as the commander of the defense activity management recruit eligibility

screening for the Pacific regions. His bio is in your briefing book. One other thing. With Mr. Carr today are Lieutenant Colonel Nancy Fagan, program director of military public health. Mr. Tom Pamperin from the Department of Veteran's Affair. Mr. Paul Williamson with Creative Computing Solutions and I think that's it, right?

MR. CARR: Hi. I'm Bill Carr, I am (off mike) military personnel policy -- Mr. Tom Pamperin is my co-chair for the interagency group that's looking at this. Nancy Fagan, of course, from Health Affairs, and Paul Williamson who is over there on the wall who ran the Navy physical evaluation board for a number of years and is very familiar with it. As a baseline, let me describe a disability disposition, so that I can have baseline against which to talk about improvements. Let's assume that I've had a bad parachute landing and my right knew mobility and range of motion is severely limited and there's a definition for that. I go to the hospital and upon realizing just how serious it is, I probably will find my

way within that military treatment facility to the medical evaluation Board. They're looking at that injury in the context of my capacity to continue this career. If they concluded that I could not, even after considering job retraining, then that medical evaluation board will prepare a narrative summary and it will go forward to a centralized physical evaluation board. Army's in Washington area, Navy is Washington area. Army has some other active areas as well. And Air Force is at Randolph Air Force Base. It goes to that activity. They look at the facts and they notice that Carr has a bad knee. They will probably rate me 30-percent disabled because there is a book, a reference book that both DoD and VA use that say when the range of motion is this, then the percentage disability is that. It is 30 percent. A separate judgment; am I fit to continue in the Army? And if the answer is no, that I am unfit, and because I reached the 30-percent threshold, I will be medically retired. Had it been 20 percent or less, then you receive severance pay. That

very simply is the process. There is due process appeal. If you've reviewed my records and told me that I'm 30-percent medically retired, but I have some reason to say I think it should be 40 percent, then I would have a formal opportunity to talk to that Board.

So what does Carr do that has to do with VA? I've just settled it up -- squared it up with DoD on my knee, but I had certain other things that were not unfitted, hypertension and sleep apnea. So those, after I've left active duty, I would report to the Veteran's Administration as a service aggravated condition. If the VA felt that they were, then I would be awarded percentage disability for that. So often we hear, Well, VA gives higher percentages. Well, of course they do, because they are looking at a wider range of things. The military's interest is only in your fitness and whether an unfitting condition is upon on; that was my knee, not the sleep apnea and not hypertension that's controlled with medication. So, therefore, I'm 30 percent. When I came out of

VA I could have been at a much higher percent because they consider those other things. Why? Because they're making a judgment about your quality of life and your capacity to work and earn that you would have been at, absent that medical condition.

So when one says they're different, that's often overplayed. The issue is: Are they different on the same thing? Do they look at that knee, remember I mentioned we're looking at the same book, so if we look at that same knee against that same book, are we different? We went through a very disciplined one-week exercise a couple of weeks ago with a very strong performers and supervisors from VA and from DoD. And I'd report to you that when we look at the same knee against the same standard, we come out with about the same rating. There was a variance of up to 10 percentage points and that's not much. And these were in complexes cases and they were usually because of a mental disorder, which is the trickiest of all to capture and categorize its

impact upon your job and duty performance and job performance.

So at the end of the day, well-trained people looking at the same condition against a common standard, come up with about the same answer for a specific problem like a leg, but if they are going out of that scope and looking at things that don't limit their capacity to serve in the military, naturally they'll come up with other factors they properly may consider under law, do consider, and, therefore, arrived at a higher rating. It's no more complicated than that. So that's the baseline program and if I could put up the first slide, I'd like to describe from the baseline the changes that we'll have coming our way and I'll describe the schedule for that in just a moment.

Remember I mentioned the MEB, or the Medical Evaluation Board? That's the local hospital, Madigan at Fort Lewis. Ultimately if I have this serious problem with my leg, a narrative summary, that's the little folder to the right in

Step 1, is sent forward to the Physical Evaluation Board in Washington. And they'll look at it and decide what my disability is and so forth. I mention that for the baseline system. Now how are we going to change it?

Remember that under the old system, I had a physical from DoD; I had a rating from DoD against the Cook book. Then after I retired, I went over to VA, I had another physical, probably, and another rating. So that's two physicals, two ratings each different and arguably redundant. So the first change we make to accelerate and simplify the process is to say this is going to be a joint endeavor of DoD and VA and we can do this under present law. Congress doesn't do a darn thing, we could do this and we'll probably start doing it within the next few months. We would take Carr with the bad knee and say, Carr; tell me all the things that are wrong with you. Remember out here the VA is interested in a lot more besides my unfitting knee. They're interested in my hypertension or whatever could affect my

quality of life and my work. So I will fill out a form that will describe whatever maladies I believe I present with and capture those for the doctor. In just a minute I'll come to Tom, because he's going to talk about template and step 4. That DoD -- this says question mark, that's pretty much getting settled in DoD. That physician, probably at the same hospital, is going to say, Carr came in with a bad knee, he told me about hypertension. I scheduled him for a physical and before that physical occurred, there were things we wanted to discover systematically about Carr so that the disability could be rated and those are in the form of a template. I'll turn over to Tom and he'll talk about the template and the rating panel and then I'll come back when we get to this stage.

MR. PAMPERIN: All right. We don't have the template slide, do we?

MR. CARR: No, we don't.

MR. PAMPERIN: Good morning everyone. I'm the deputy director of the compensation and

pension service, and as Bill said, the co-lead on the line of action for this. And our approach has been that to have it as an integrated but plug and play, VA comes in, does its thing and gets out and DoD does what they need to do. When a person is identified for an MEB we have developed a new one-page application for compensation that will be completed both by the member and by the MEB doc who is deciding this. The MEB doc will identify what disabilities or disabilities are disqualifying. Then we'll -- the veteran will -- or the service person will identify what other issues they have concerns with. An important concept here is that at this stage, we are living in two completely different cultures. In DoD it is the Department of Defense that decides what is to be examined. In VA it is the veteran who decides what is to be examined, based upon his claim. In our environment, typically the DoD will examine one- and-a-half disabilities per separating service person who goes through the MEB process. We will process about 220,000 original

claims this year. About 50,000 of those claims will be from veterans who are claiming eight or more disabilities. So the level of complexity of the new exam will be significantly higher.

We have a series of about 90 templates or exam worksheets. The exam worksheets are paper documents that are parallel to the ratings schedule attempting to elicit from the physician the information needed so that rating specialist can apply them to the rating schedule.

VA is deploying in a pilot format a template, kind of, almost TurboTax if then sort of thing that will ensure that all pertinent information is provided. This is particularly important, particularly when you get into specialty and subspecialties outside of psychiatry, ophthalmology and audiology, because frequently the individuals who examine there aren't familiar with our requirements and have a tendency to generate exams that are more like a progress note and might not fully address every issue. So we have deployed templates inside VA.

They are not mandatory yet, but when they do become mandatory they have been demonstrated to significantly improve overall quality of exams although they do take longer. But we will do the examinations for most veterans who, if they have uncomplicated exams, a simple general, medical examination is sufficient to evaluate their disability. However, we do require specialist-type examinations in ophthalmology, audiology and psychiatry. Beyond that it really depends on -- an examiner may be, if I claim several things, might be presented with two or three worksheets that they would have to answer the specific questions relating to that disability. The exam is produced and will be provided both to the PEB Board and to, for purposes of our pilot, a centralized rating activity in St. Petersburg, Florida. Once this thing is fully implemented it appears that we will have two centralized rating panels, one in St. Petersburg and one in Seattle. VA would then rate, in our standard protocol, all of the

conditions that the veteran has claimed. Our rating decision is typically about seven or eight pages long, because it takes each contention and discusses, I am claiming service connection for post-traumatic stress disorder. What is the evidence to support that? What is the evidence that is missing? Okay. It is service connected. The rating criteria we assign 30 percent for the PTSD. The rating criteria for 30 percent are this. The evidence that supports this are that. The rating criteria for 50 percent is this and we fail to see the following evidence. So for each condition -- because we go through a detailed explanation like that a typical rating decision is six or seven pages long.

MR. CARR: So what we've established to this point is under the change, DoD will keep doing like it's done at the hospital, but this will change because a new form is going to have to filled out and this will change because the DoD physician is going to have to do a ballet with the A forms that they're unaccustomed to doing in the

past, which are fairly straightforward, simple, and doable so the physician shouldn't have difficulty with them at all. That will go to a rating panel. Let's say, coming back to Carr, this says 30 percent bad right knee, 10 percent hypertension. Now it's back in the hands of the services. And in that context the services look at that document that's come in and they have to decide right here which of the items are authentic. And so they might say, Well the knee is unfitting, but nothing else is. They would put an asterisk next to the knee, the asterisk is notional. So now we know that Carr has a bad knee and hypertension. Only the knee is unfitting. They'll write to Carr and say -- remember, I'm talking about under current law capacity. I'll come to Dole-Shalala in a minute. They'll say, There's the deal. And I'd say, Okay. Fair enough. I agree that I'm unfit. DoD would be done with it at that point. The member might say, and this is a little different, I don't like that rating. I think I'm 40 percent. I've read the

Cook book and I think I'm a 40 percent not a 30 percent. That would be handled by VA who indeed did it. And VA would have a decision-review official, which a normal part of VA disability, it's the first step in the appellate, and that person would hear and respond. At that point, if the member wasn't satisfied because we are appealing a VA action, then there's other things provided for in the VA system; the Board of Veteran's Appeals and so forth. The person would be told all about that when he got this letter in terms of what the options are and if they did chose to pursue that and this person looked at it and said I've looked at it, it's 30 not 40 and the member still thought it was 40, they'll take that up out here with VA in their processes. Should it become the case, for the military crowd, this may be interesting, that 30 becomes 40 a year later. Then it goes to the Board for correction of appeals. The service boards will say, Make it 40 effective the date it would have been and we can (off mike) from that point. So if later on the VA

makes the decision the member will be held harmless.

MR. PAMPERIN: Just a couple of things about the review process. Again, in the current DoD environment, a service member has the ability to rebut, or attempt to rebut a decision by an informal board and request and informal board. Everything to the left of that line, the separation line, is internal DoD. VA has not yet made a formal decision for VA purposes. We will have complied with our legal requirements up front, when we take that claim, we have to send the letter from hell to veterans, called the Veteran's Claims Assistance Act, which explains everybody's legal obligations. But -- and we do that up there because our decision is invalid if we don't provide that VCA notice prior to our decision. As long as the member is still to the left of that line, they are an active duty person, they are not a veteran. For purposes of compensation they have no standing, but we will do -- our decision review officer process where that

individual has the authority to change a decision based not only on new evidence, but on difference of opinion. If two people look at the same evidence and I think it could be rated higher, they can change it. That would feed back to the PEB Board as our final best offer in terms of what the disability evaluation is. When the member becomes separated, they will receive a formal award letter from us together with a copy of the rating that fully explains -- I fully believe they will have one prior to that as well, but they will fully explain how we arrived at our decision. At that point they have one year from the date of that letter to file a notice of disagreement with us about our decision, either as to effective date, evaluation or whether or not a particular condition is service connected. From there we enter our appeals process.

DR. POLAND: Before we leave that, from the left of the slide up to the red line, what's the mean amount of time and the range of time to traverse those processes?

MR. CARR: About 180 to 380. It's going to settle in at 140 to 240 and it may sound like a lot.

DR. POLAND: Is the mean?

MR. CARR: That's the range. I don't know the mean. I'm sorry. I knew it and I don't recall it.

DR. POLAND: It doesn't take longer than about a year?

MR. CARR: It does not take longer than about a year, but remember we talked only about this side of the line. Remember in the old days, in the current day, I have to after I've finished with DoD trudge over to VA and start all over again. Because we bought that, let's call that 180, so we have shoved that back here and achieved it within the 140 to 240 I mentioned. So we made it faster while burdening it more, but it can be done and we're not over promising.

So we have taken what is really a 500-and-some-day system, if you consider DoD doing it, trudging to VA going through their physical and

their rating and so forth. And we turned a 540-day thing into a little under a year with the possibility of hitting it in 140 days. But the mean is going to be somewhat closer to that.

DR. POLAND: One other question I have in that regard and I mean these terms in sort of the legal -- the way the legal system uses them. Is the culture or this process facilitative or adversarial?

MR. CARR: Well, I'd love to say it facilitative. There's an inescapable adversarial component to it because there is a debate about this condition and it meriting more. I wish I could say that debates like that are not adversarial, but I would say to defense leadership, I know you asked us -- and we'll have this discussion with them very soon -- to make this less adversarial. We can make it informative, well understood, transparent, compassionate, but when it comes to the decision, and if I am dissatisfied with that decision, I don't know how we label it other than adversarial.

It doesn't mean it's mean spirited, but it is adversarial. Again, adversarial processes can be conducted with great collegiality and they would be certainly under this. I hope that answers it.

MR. PAMPERIN: I'd like to supplement that a little bit. I tend to think and this is not a criticism, and please don't take it that way, but the stuff to the left of the line is basically workmen's' comp, whereas -- and we have characteristics of adversarial or there's a perception of adversarial to the right of the line as well. What is different about what is to the right of the line are really a couple of very, very, significant things.

First, we will be applying the approach that's mandated by title 38. Title 38 is fairly unique in the federal government in that in addition to being deciders, we are also advocates. And as a result, we have a duty to assist the veteran in proving their claim. Additionally, our standard of proof is the lowest standard of proof possible in a legal system in that it is

equipoise. If the evidence is balanced, you must provide the higher evaluation.

Finally once you get to the right of the system, until there is a final Board of Veteran's appeals decision, as long as a veteran keeps their claim active, there is no such claim as a closed record. The veteran can continue to supplement the record with additional medical evidence that must be viewed in context so that if an appeal takes two years and you see this steady stream of additional evidence, even though when we made the decision originally, it may have appeared to be correct. We will consider all that subsequent evidence and may very well go back and change it from the beginning.

DR. POLAND: I don't want to get too deep into discussion, but this is sufficiently complex that if there are questions or clarifications for this specific part. I think General Roadman you had your hand up and then Dr. Luepker.

LT GEN ROADMAN: Secretary, it's good to

see you again. I'm Chip Roadman. I come from it from having served on the IRG.

MR. CARR: Indeed.

LT GEN ROADMAN: It looks to me like you have the service still deciding fit for duty, yes/no; the VA determining the disability rating, and then coming back to a PEB that makes a determination to finally about fitness. What we found was that there was variation from service to venue and that was manifest most in the barracks in rehab with people from Guard reserve, different services, same injuries, different results. Where you have "Joint" question mark, that seems to be a pivotal decision on actually fixing predictability and accuracy. Where are you coming down on that?

MR. CARR: It's a decision that will go to -- in order to deal with this disability stuff and get it done with great participation, ultimately it came under what's called the Senior oversight Council. The co-chairs are Deputy Secretary of Defense England and Deputy Secretary of VA Mansfield, down the sides are the

secretaries of the military departments, Army, Navy and Air Force and usually the vice-chiefs, sometimes the chiefs. So that's the crowd. That's about as Pentagonish as you get when you're trying to review a matter. So they make the meetings, it's real -- stuff.

Now the question that will be facing them next Tuesday is what shall we do with that question mark? We tried various options in the tabletop. One was to say, let's make this a purple activity that is production. In other words, it's making decisions, as well as migrating off to different services, if you couldn't make it work out in the Army perhaps you could go to the Air Force. And that's really a false hypothesis as it proved out there, because Air Force doesn't have a lot of room for, as much as we might think, for circumstances, because they have so many non-deployables now and their chief is concerned about that.

So one is production. Second is appellate. That really proved to be a problem.

It was time consuming. It always had the service looking like the Grinch and purple daddy looking like the hero. The third is to say quality assurance and that's probably where it ends up because the General's right, there are differences, systematic differences between the way one service systematically rates a condition and another does as well as DoD and VA. As I mentioned earlier, they're small, but when they come up they can be reduced. So I think that this thing is going to end up being -- my preference, I don't know where it's going to end up. It's fair to say I think it will end up that the services will do the PEB as they have in the past. The results will be audited as will the results from the DVA rating panel and when we see systematic behavior away from the central tendency or the expected pattern, then we have to hold a Pow-wow, do training, or whatever is necessary to achieve convergence, because that does remain as a problem and it does have to be addressed, this matter of services waiting in identical condition in a

wholly different way. None of us likes it, but none of us knows how to get at it unless there's a purple activity. And when those happen everybody figures out a way to converge to --

DR. POLAND: Dr. Luepker. And unless it's very focused on this, let's get through the rest of the presentation.

DR. LUEPKER: Two quick questions. One, you said 220,000 cases this year. Are those all people asking for disability ratings?

MR. PAMPERIN: Those are original disability claims. We projected for this year 806,000 disability claims that's from the 2.9 million people who think that their conditions have gotten worse, plus 220,000 originals. We're going to finish this year at 835,000 --

MR. CARR: Well, let me help put that in context because I think I -- we're talking about the people who matriculate each year through the DoD system as a wounded in war, a motorcycle accident at Fort Campbell; that number is 22,000. So the number that's going to be running through

this, all services combined, in any given year, is 22,000 of whom some, many, are going to be returned to duty. They'll never be disabled and separated. Now Tom is talking about -- there are many who progress through their career, they retire normally for longevity; it doesn't have anything to do with disability. And then, as they are fully entitled to do, report the conditions that they believe qualify on the long policy and this nation's wishes, to recognize financially and medically, the hypertension, the diabetes, or other things that occurred over their life that are presumed to be service connected. All of those things. So that's a big number, but it doesn't mean they were disabled for a day while they were on active duty. It simply is they left, there are some things -- it didn't have to with fitness, but it does have to do with future quality of life and employability.

DR. LUEPKER: That's helpful. We are of course most worried, at the moment, about the 22,000.

The second question is the timing question. You said, well, we're hoping to get it down to 140, 240 days. Why does it take that long?

MR. CARR: Yeah, you're right. And we're going to have that broken out. It is -- generally the answer is the following: First the generality. That Army's longer than the Marine Corps; going to different services, I'll use those two poles to illustrate the case. The Marine Corps is a young force. It retains carefully in its career force because it has a mission, an organization, a grade structure where the pyramid is wider at the base. The Army, on the other hand, would be more inclined to remediate and to spend considerable time and effort remediating. Now the Marines could do that, but if the Marine were interested in departing, could be cared for on departure, and make room for another more fully utilizable, capable Marine then I think the commandant would say, That's what we should have the Marine Corps do.

The Army on the other hand will go through a lot more remediation. As a consequence the time spent in medical remediation is what eats at those 240, it's not administrative. More remediation, more work, trying to optimize so that they might be found fit and retained.

DR. LUEPKER: So part of this is -- you say "remediation" and I think rehabilitation. Is that what we're talking about here?

MR. CARR: Well, I don't know -- you're all better at this than I, not being a physician. But I meant by that that it could be a corrective procedure just as easily as it could be -- I don't know, maybe that is what rehabilitation means. Anyway it is: To make what is present and making it awkward to do your job, more conducive to doing your job by whatever medical procedures would be apt. I'm going as far as I can with the English language in the presence of so many physicians.

This really -- to this point -- and in a moment I'll call upon Paul, but to review what we've summarized so far, we have taken a sequential

process and made it concurrent. We've taken two physicals and made it one, albeit a little heavier burden, because it's got the VA stuff to it. We have taken two ratings and turned it into one and DoD will subscribe to this and they're not very different. Therefore, we will have saved time, generated something more simple and that is the system that we'll migrate toward.

I think we'll start -- we can start it around Thanksgiving, to start moving -- we're going to switch D.C. hospitals, Walter Reed, Malcolm Grow, Bethesda onto this system and Army leadership was a little bit reluctant like, I know you got it on paper, I know you've run it through a tabletop, I know you've rehearsed it, I want to see a proof of concept with about half a dozen or a dozen people going through it. So fine. We'll probably go to perfect concept from Thanksgiving into January and then January take the D.C. medical evaluation Boards, Malcolm Grow, Bethesda and Walter Reed and have them matriculate through this process.

DR. POLAND: There's -- I'm going to ask for very limited, succinct and focused questions as they pertain to this slide in process, otherwise let's hold --

MR. CARR: This, by the way, is the only slide.

DR. POLAND: Oh, it is? Okay.

MR. CARR: For that purpose.

DR. POLAND: Then I'm still right.

DR. KAPLAN: Your instructions were longer than my question is going to be.

MR. CARR: But precautionary, a prophylactic measure.

DR. POLAND: Touché.

DR. KAPLAN: Important to this is could you tell us about the qualifications of the people in these Boards that make this decision. You, for example, mentioned that you needed ophthalmology and psychiatry and I can't remember what the third one was, at some points along the way. What are the qualifications for the people in these Boards?

MR. CARR: Tell me turn to Paul for

that, because Paul has a very direct experience.

MR. WILLIAMSON: Thank you, Mr. Carr. Are you, sir, speaking directly to the qualifications of those who are on the physical evaluation board who are making the fitness/unfitness determination rating, was that your question?

DR. KAPLAN: I think all of the above. The MEB and PEB outfit, yeah.

MR. WILLIAMSON: Well, the MEB process, as Mr. Carr pointed out and we'll look at these slides here that I brought along. You know you have your patient source who come from the combat field or just the general population who end up going into medical. Now this is back to the question of how long does this process take? It depends upon where do you drop the chalk to start counting? Is it from the time that he first walks through medical and makes a presentation for medical condition until he walks out the service back door? Then Mr. Carr is correct in how long does it take if you're isolating it down to the

point of when the individual is referred to the PEB from the medical evaluation board process. That time frame is considerably reduced. It's done in a matter of 30 days in most cases.

DR. POLAND: But the qualifications of the individual --

MR. WILLIAMSON: Yes, I'm going to get to that. The qualification of the individuals who sit on the physical evaluation board -- let's go back to the medical evaluation board. You have specialists who are the orthopedist, ophthalmologist, specific to the condition that's being presented and they're the ones who develop the narrative summary that is presented to the medical evaluation board that makes the initial determination as to whether or not this case should be referred to the physical evaluation board because there's a question about the individuals being able to meet medical retention standards for that service or their fitness for continued medical service is in question. That's then referred to the physical evaluation board.

The qualifications of the physical evaluation board physicians, we're talking about 05s and 06' who have years of clinical experience as well as specialty experience. When I was president of the department of Navy physical evaluation board, I had six different positions; psychiatrist, family practice, aeronautics, internal medicine, a wide spectrum of specialties that considered those cases.

DR. POLAND: I think the issue may be -- I mean many of us are practicing physicians on the board, but we're not trained in disability evaluation, which has really almost become a science or a specialty unto itself. So do they have specific disability rating training?

MR. WILLIAMSON: Each of the services has a training program to bring those specialists into the occupational medicine rating process.

DR. KAPLAN: Are they members of the board, is my question?

MR. WILLIAMSON: No, sir, they're not.

MR. CARR: By the way on the board is --

it's not all on the physician. On the board are also line officers so the usual dialogue you'll see at a MEB and by design at the PEB, is here's the limit on range of motion. That's the physician's responsibility, and then the line officer says, Boy with that range of motion, it's not quite (off mike.) I believe that the capacity to do the work is limited. Really a disability determination is emerging in both, but in our case, in neither of these is it all on the physician. There is someone there saying give me the range of motion, the diastolic/systolic, whatever, you give me that and I will share with you information and between us we'll decide if this medical condition is a fit against a promising career. So it is a collaborative decision with neither party fully responsible, but both swapping information to try and get close to the right --

DR. POLAND: Half the parties at the table, then, have no training in disability evaluation?

MR. CARR: Well, if you were at the hospital, not much. If you are at the physical evaluation board, I think they're full-time professional. So if you are at the place over on the left, the local hospital saying do I have to refer it for a decision, they're not as hip in disability processing, which really means they're not familiar with the retention medical standards as would be the person of the centralized board, but they're the ones firing the real bullets. So when you get to a board that's making real determinations as opposed referral, they're full-time professionals. And you would not have it systematically the specialty representative unless it's psychiatrist. So if it's a psychological or mental, a psychiatrist has to sit on that -- has to present for the physical evaluation board, but for the other ones the specialties are fungible.

MR. McKNIGHT: I have a concern about your model. I think it's a great idea to combine the physical exams into one opportunity; however, my concern -- because Monday morning I'll be

seeing active duty troops and once a month I get my MEB list and I'm supposed to go through it. I'm concerned that the person who is now a warrior/vet is not going to get the comprehensive evaluation that they deserve, because in reality what I'll face Monday morning is is this Sergeant no go or go? I mean the line says we've got a guy who's got a bum knee, are they going to go under deployment two months or not? So we're going to be evaluating that issue for is this a warrior who can go off to deployment. If he says, Oh, I've got this arm thing and I've got this back thing, I've got this blood pressure, my concern is that we're going to say, Okay, we've got all this comprehensive stuff to go after; however, the orthopedics gone deployed or the cardiologist is now gone, things that really are not germane to the mission to get the troop going or not going on the deployment are going through the MEB process. So you said, Oh, by the way, we're going to dump a little bit more into primary care comprehensive evaluation, when in fact the ops tempo is so great

and the resources are so fluid that you really -- I'm afraid are not going to give that person the total evaluation that they deserve.

MR. CARR: And yet we cannot change the environment. So that's a environmental constraint.

MR. McKNIGHT: Well, I would say the VA's side of the coin would have a more stable environment to give that comprehensive evaluation.

MR. CARR: I'll tell you to that point how government decisions sometimes are made. Would Tom and I have viewed it the way you're suggesting? I always viewed it would be a VA physician doing the exam. Their templates, they do it already. They're doing the rating panel and that's the way it would be. Along comes Dole-Shalala. Fine commission, great leadership and they determine that it should be done by DoD. So I talk to the staff, how did you arrive at that, because it makes, to me, all the sense in the world that it would be VA. Workload-wise for reasons you mention and also that their rating

panel is making it or breaking it on the basis of that product. Why should they rely on DoD for that? Another agency an extra learning curve among a busy agency? Well, I tell you why that was, Mr. Carr, because the PEBs really want to hear from their own doctors. It was about as thin as that. I said, no, no, no, change that thing and at least leave it optional. No, no, no, no. Now part of that is that there are 58 cooks in the kitchen, so whenever there's a crisis they all go in there and start bumping into each other and so we have lots of self-appointed experts giving out lots of binding decisions and writing them into law. So that's how that one happens.

Will we visit it? Fine we're going to get stuck with it for a while, we'll revisit it, we'll come back to it, because you're exactly right and I'm where you are. That's how it happened, my apologies.

MR. PAMPERIN: But Bill, aren't we also saying that to the extent to which -- because I happen to agree with you. I think at the end of

the day this is going to be a VA exam, but right now it's DoD administered, which could be a DoD professional or a TRICARE provider and to the extent to which VA is a TRICARE provider in the area, they would have right of first refusal. And even where we're not a TRICARE provider. At McConnell Air Force Base where the VA medical center is a mile and a half away and the Air Force goes there every day anyway, it's going to probably end up being VA.

MR. CARR: I think that's exactly right.

CDR FEEKS: First of all, if I can oversimplify for the sake of clarification. The MEB is a medical process done by medical people in the medical treatment facility? The PEB is a personnel process done centrally and each case is reviewed by a board consisting of one physician and several line officers?

MR. CARR: You are correct in the context of the Marine Corps. If you go to an Army MEB they have an engagement with reclassification and they -- but, fair enough, for simplicity let's

go with that. MEB physical, PEB administrative, fair enough.

CDR FEEKS: My question to you, sir about this diagram, I promised you a question about the diagram. You don't go from step one to step two, and with step one it's going to recommend a finding of unfitness; is that correct?

MR. CARR: Correct.

LT COL DOMINGUEZ: If I could make one question. You have the step six there where the service determines whether they're fit or unfit after they've gone through the VA rating scheme. If the service member is determined fit and we can return him to duty, wouldn't we want to do that before we go through the lengthy VA rating process?

MR. CARR: We could do it. The thing I'd suggest is, our knowledge is most complete -- anything we did, anything we know here is going to be expanded here, so you could do it based on this, but why should we? Because we're going to have better information there and we should make

one binding decision because we're going to make it stick. It should stick and if -- we don't want to have a lot of this going on, but the member has to believe that every fact was known. There might be new evidence introduced up here, there could be a late breaking thing flying in here from the MEB to the PEB. So that's the reason we did that. Your point is a good one. The fitness could be adjudicated early. I'm not sure that we would write in a way that would prevent it, because if there's compelling, logical, you've got to be kidding me we're waiting, then I think we would leave room for that decision to go forward to the benefit of everybody involved. But as a general rule, we'd like to have the information expanded where possible. Does that satisfy?

DR. POLAND: Dr. Parkinson and then Dr. Shamoo.

DR. PARKINSON: Can I ask, Britt, go back to other slide? Because this will inform. The macro goal that I keep coming back to is the elimination of undesirable variation, that's every

step of the process. It's that undesirable variation that is literally causing a lot of problems.

MR. CARR: Credibility and everything else.

DR. PARKINSON: So every time I hear a stepping away of the opportunity to eliminate undesirable variation, we are compromising our opportunity to fix the whole thing. You'll hear a little later this afternoon that the Board has been asked the issue of evidence-based accession, retention and deployment standards. That lives on this diagram in that box right up above, dot, dot, dot, based on medical evidence, DoD instruction and military department regulation. So this subcommittee that will speak to that, on our approach this afternoon, that's where we live, but we can't have that be at all effective. My point at this juncture is to say if that then goes into a distributed, Well, maybe we'll implement it or not architecture, it's a huge undesirable variation that will undermine any effort, even in

defining principles to fill in that box up there. So listen up this afternoon when we talk a little more about what we're going to do today. This has been extremely helpful, but I would hypothesis it's not answering the mail for the opportunity to eliminate undesirable variation. It is answering the mail to reduce some of the redundancy, shifting of resources, as we've heard, if not solving the resource problem and I think it's yet to be determined about the capabilities of people at both the MEB and the PEB level. This is -- in the private sector and I look at Dr. Wagner at Dow and the companies I deal with, this is a very, very -- you have to have good quality people doing this. So that's just the context of where that box is and I wanted everybody on the full board to hear where that box is and what we'll talk about this afternoon.

MR. CARR: We will be -- we're in the business of smart, correct, compassionate, so I'll be listening up and if there's something in there for us we'll use it.

I did want to mention, by the way, so I'd be sure I get them in. Thus far, I haven't talked about Dole-Shalala, that was that commission. The president may make an announcement today where he's going to perhaps commit the administration to Dole- Shalala really says one important thing. There's many; but it says, You know, let's have DoD make a fitness and if they're unfit they get an annuity. It matters not if their 80 percent disabled or 10, they will simply receive an annuity and that's the end of it. All of the medical and so forth would go to VA. It could go on for a long time, but that is essentially the principal of it. DoD is fine with that. If we can -- it would mean that the PEB would look at the case, say this is unfit and from that point, either a straightforward administrative action to say what's your pay and years of service, multiply it by 2.5 and you're there on the percentage you get. So that would simplify and it would divide agency role, moving toward the core competency of DoD, I know if

you're fit or unfit ratings, I don't know if we're supposed to be experts in that. So that's Dole-Shalala.

The second part is the military audience. I got an earful at Randolph yesterday about something we've got to work out in house and that is the matter of what happens if I'm fit, but I'm non-deployable. So we are probably -- at about the time Dole-Shalala comes in, if it comes in, going to take a look and we may have to adjust our stance to say if you're non-deployable maybe we should look at the retention medical standards and say you're also unfit. Absent an exception, which could certainly be granted, as in the case of prosthesis, as in the case of super Marine, as in the case of whatever we wanted to make an exception of the case of, but we're going to have to take a look at this dichotomy because it's killing us at the top. It's unexplainable to the public that you're fit for duty, but you're not deployable. And now feeling pressure from your service to be administratively separated for being

non-deployable for what sounds like a medical condition. It's just too confusing.

DR. POLAND: We've got about five minutes left and there's a couple more comments. Adil, I think you were first.

DR. SHAMOO: This is a just a parenthetical. Do you mean they all get the same annuity depending on their salary or is it percent of their annuity?

MR. CARR: It's based on their seniority. So the more senior would get --

DR. SHAMOO: That's it. Regardless of the disability?

MR. CARR: Regardless of.

DR. SHAMOO: I'll go back now to my original question and that is: If I'm the lonely soldier come and face the system here, the power differential and (off mike) is so huge it would be petrified. The reason is the soldier really needs money, basically, and medical care from the government, whether it's VA or DoD. And that -- there's a conflict there. If the board, all the

time is going to give all the money to whoever requested, I would say the government will go bankrupt. So there is that huge conflict. Moreover the power differential makes the soldier really at a total disadvantage. All the people he is facing are MDs, PhDs, MV PhDs, officers, line officers they are all big shots. And I presume the overwhelming majority of these numbers you gave us, over 800,000 are soldiers, they are not line officers. So that power differential, it's there and --

MR. CARR: That's quite right.

DR. SHAMOO: No matter what system you do. If you don't -- please give that soldier some backbone to be able to face up to these Boards and line officers and MDs. Those problems will remain.

MR. CARR: We'll do more than that. Not just backbone, we'll give an advocate for exactly the reasons -- in other words what is the fullest information we can present. Now let me talk ethically, they are -- or in an ethical context,

which is exactly the context which you're correctly talking about. We would say that the people on the government end are out there to save money. I would report -- I couldn't prove, I rarely see that. Most don't think about that. Even if it were true, it's also true that they have to be mindful of the public resource that's part of their public responsibility and the member is not entirely pure here either or the patient because they have an interest in maximizing in one direction, even if that was true, you'd have a natural tug and the right to counsel and so forth. So in that context, the thing that gives me heart is that I don't see that kind of behavior in those who participate in the system there's certainly no reward for stingy. I'm not sure you could do it even if you wanted to, but to the extent it exists, it is the nature of a government benefit in which government officials, presumably with good public purpose carry out their responsibilities. But I don't think VA is necessarily viewed as being a conservative -- this

can be done.

What I see, as far as injured, is this incredible participation, compassion. You go to meetings, here's the four stars. It says something. For that crowd to show up, spend hours be intimately familiar about the processing details, the definition of traumatic brain injury, all says to me that on the government side is there interest is understanding, donating, making better and so forth. I think we went that way with motorcycle accidents and everything else. The war changed some parts of DoD, for example, the fact that we would retain one with a prosthesis, we've never done that before, so we're doing it now because they are far more sympathetic. So you could see our ethos, you could feel it as it was shifting. It's very much pro war. I guess as time goes on it might soften and become more jaded, because warriors are more sympathetic than automobile accidents or more loveable or more ethos. So we've got to watch ourselves. But for right now it's at a zenith in

terms of --

DR. POLAND: I'm sorry, but we're going to have to stop because our next speaker has a time limited place in which they have to leave.

I'll just summarize by saying that this is an issue the Board will continue to follow and will request updates from the department.

Our next speaker is Lieutenant Colonel Lorie Brosch. She's the chief of the trainee health and preventive medicine. She'll brief the Board on adenovirus at Lackland Air Force Base. For background information adenovirus infection and recruit training centers has been a legacy concern, really, of the Board. It has historically cost considerable morbidity and occasional mortality among recruits while adenovirus infection is not seen only in the military, its high incidence appears to be relatively unique to the basic training environment. So, Lieutenant Colonel Brosch, welcome. I'm sure the members are going to have some questions for you after the briefing.

LCOL BROSCH: Thank you for the opportunity to come and -- what I think is a very interesting adenovirus story at Lackland. I want to say that on the panel there are some people that work very closely with me. Colonel Bunning, my prior commander, Colonel Neville from AFIOH and Colonel Snedecor. They're very intimately involved with a lot of my presentation. Next slide.

I realize we're getting close to lunch and I'm a realist so I'm going to try to keep this as dynamic as I can and keep you interested. I will probably slip over some slides I was going to spend more time on. My slides are pretty detailed, and one of the reasons I did that is if I don't touch on everything you've got the information there. I'm going to review a little bit about the background on adenovirus, the surveillance we're currently doing at Lackland, talk about the outbreak itself, the response and where we are currently. Next slide.

You kind of talked a little bit about

already the background on adenovirus and it's really been a significant player in the training population. Normally causes mild to moderate respiratory disease. A severe disease is very rare expect in immunocompromised people. There are about 49, some people say 51 strains, distinct strains of adenovirus and it's always been usually 4 and 7 that have caused most of the outbreaks in military recruits. In 1971 an oral adenovirus vaccine was developed against serotypes 4 and 7. For financial reasons the production was stopped in '96 and the stores were depleted by '99. Not surprisingly, after that Lackland Air Force Base had its most significant outbreak of adenovirus which occurred -- I think it was actually stopped being administered in July of '99. Sure enough by November we see an outbreak of adenovirus. You can see the numbers here, it was very significant, we had a lot of hospitalization during that time at a very high cost. Actually the adenovirus persisted from '99 to 2004 and it's still causing quite a bit of illness. I want you to focus a

little bit on this rate because I'm going to talk a little bit more about where we are in terms of that rate right now, 1.3 per hundred trainees. And most of the illness is caused by Type 4 and another significant point is that we did not really have any life- threatening pneumonia, so the severity was less. Next slide.

I stopped at 2004 on the last slide, so what happened in 2005 and '06? Well, we're not really sure why, there are some theories, where -- the yellow line represents adenovirus activity. This is from NHRC, which I'll get into a little more detail, they do our respiratory illness surveillance, they help us with that. So they get samples from the trainees and as you can see we had almost no adenovirus in 2005 and 2006. You can see the population varies a little bit. We did have one dip in 2005, but we came back up in 2006. Next slide.

I want to switch a little bit and just talk about surveillance because that is how we kind of realized that we had a problem at Lackland

in terms of the adenovirus. In terms of active surveillance, as I mentioned we used the febrile respiratory illness, you'll hear me refer to it as FRI, F-R-I, and that's a study -- I'll talk more about that through NHRC. We have EOS, the Epidemic Outbreak Surveillance organization that works with us. In terms of passive surveillance we look from population health, we get the DNBI (Disease Non-Battle Injury)data which we look at. And also I didn't add it on this slide, but we are currently starting as a new medical surveillance a system THOR, Training Health Online Reporting, which is in its infancy, which will hopefully be an online easy way to monitor our training population. Next slide.

This is a little bit about the FRI study. Kevin Russell, he was here a little while ago, he was in the back there, from NHRC, I believe you were even PI (Principal Investigator) for a while on this study along with your staff. It's a tri-service study. It's on the high risk for the trainee population only. It does surveillance only for viral respiratory passages. I think there is one day

where do they do on (off mike) other than that it's viral. You can see all the bases that are involved in it and there we are. For those of you who may not be familiar with Lackland, we are the only training base for basic trainees for the Air Force. We process in about 6 to 800 trainees a week and we have a six-and-a-half week training program at this time. Next slide.

The FRI study, it's purpose is to determine the attack rate, which I alluded to previously of FRI in this high-risk population, to serve as an early warning system for respiratory disease, which in fact it did, and I'll talk about that; to see what pathogens are out there causing disease in this population and since flu and adenovirus have been the typically key players, viral-wise, in this population they focus on that and they're also working on some TCR testing that they do on the samples. Next slide.

The FRI case definition, this is very important because this is kind of the case definition that we use clinically when we look at

the outbreak. It has to be on a trainee, fairly a basic trainee; we expanded a little bit into the tech trainee population. A FRI case is someone who has to have a fever of 100.5 or greater and an additional respiratory symptom. For the actual study itself they use cough or sore throat. We expanded that a little bit in the outbreak and we included rhinorrhea and a few more respiratory-type symptoms. Any trainee who has pneumonia, clinical or radiological evidence is automatically considered a FRI case. And basically what happens is these trainees come into our clinic, Reed Clinic on Lackland. They're seen and the FRI study has people onsite ready to do surveillance and culture these patients that meet the criteria. The docs will call them and they're right there and they'll do the testing. For the FRI study they do a throat swab for viral culture and also beside the sample being sent to NHRC and that should be -- I guess it's been going on about seven years. I didn't realize that. We've been sending a sample to AFIOH simultaneously, so two

samples go out. This is a throat swab for viral pathogens on the trainees. Next slide.

EOS is another organization that's there with us. We're the real world test bed for EOS and as you can see their mission there. And they want to provide real time sample analysis and they have nurses there that are also collecting clinical samples now. The FRI nurses and the EOS staff kind of work together and a lot of times they are enrolled. Trainees have to be enrolled in these studies and they'll be enrolled in both of them simultaneously. EOS has an advanced diagnostic lab right on Lackland. The reason this is important is I'll talk about the PCR capability that they brought to the outbreak instantly for us. And they used a PRC and they're working on other advanced molecular diagnostic technology. Next slide.

The DNBI data comes from population health support division at Brooke, and what's interesting about it is that it has a unique identifier for trainees. The trainees are not

really considered active duty yet until they graduate, so they've kind of this unique identifier that you have to look for to pick out diseases and injuries and that's what we do. We look at that as part of our surveillance. Next slide.

So I thought I would review what the definition of an outbreak is just to show you that we really did have one. The definition the course of any disease at a frequency that is unusual compared with baseline or unexpected. So our FRI rates 2005-2006 point to the.4 cases per hundred. Actually when we look back at the data we had maybe four, three or four adenovirus positive in 2006 total. Next slide.

This slide is from 2007, it starts in February. I basically broke this up. I wanted to take you a little bit into what I call the acute portion of the outbreak, which was until the end of June. As you can see, green represents culture- positive adenovirus from NHRC. The red represent pneumonia which I'll allude to a little

bit later, but you can see, this is a number one here, counts for a day. You've already hit three or four in a few weeks or a month. Actually at the heart of the outbreak we had about 100 positives. Next slide.

This is what we started seeing. NHRC puts out a weekly graph for us on the FRI study and they do this for all the sites that I alluded to before. As you can see, one might wonder what was this. It was actually enterovirus, we saw some coxsackievirus last year. It was not adenovirus that caused this little blip here. But as you can see starting about the end of March we started climbing. Now, as I said, we had been at such low levels that this was really a big change for us. The red represents substantially elevated above the expected rate. Next slide.

I want to kind of walk you through a little bit of the thinking on what we did. We realized that we had a problem. I am the local co- investigator or the PI for the FRI study which does go through our local IRB at Lackland Wilford

Hall and I get the culture results of any patient that is enrolled in FRI. It has to be ordered under a physician's name and they all come back to me. So as you know, as we went along, I wasn't seeing very much of any respiratory disease, very low rates. Starting in March, end of March, I started seeing our FRI rates go up and it looked like, from the samples I was getting -- now these samples that I was getting were actually from AFIOH. Remember I mentioned that NHRC has a sample and AFIOH has a sample. That's the one I get in CHCS and that I could see readily and that was from the AFIOH. So I started seeing we were having adenovirus. I talked to the providers and said we've got adenovirus. We didn't know what serotype it was at the point. We hadn't seen it before. Let's use our normal respiratory precaution hygiene. We kind of dealt with it more at a clinical level at that point. We have a very good relationship with the Wilford Hall ID doc and this is actually Dr. Mark Raznick who has been separated from the Air Force. We started talking

to each other and he said, You know, we've been seeing some odd pneumonias. And I say "odd" because we can't figure out what the virology is. And he said, We better talk about this, because we hadn't really thought about adenovirus as a cause. So we progressed, as a team, and I'll get into a little more specifics and then we started our interventions. Next slide.

Just want to review a little bit of the lab testing capabilities. In May of 2007, which is kind of at the heart of when we were seeing our outbreak, all we could get was a viral culture from AFIOH, a viral culture, serotype from NHRC and a rapid adeno test from EOS. We had really -- like I said, NHRC had capabilities but it wasn't real time. In June EOS obtained CCR capabilities for adeno 14. I'll talk a little bit more about why we wanted adeno 14 and AFIOH started to do seroimmunization, in July AFIOH obtained for adeno 14. Just want to point out a little bit about the results. What happened was we communicated with NHRC and we said we're seeing

this adeno, what strain is it? They said, It's 14. When you look back at the history of last year, and we didn't know this until 2007, we did not know this in 2006, we had one 14 as a combination with 21. That's all we had at Lackland. Some of the other bases had started seeing 14 in low numbers. Mostly that's cold infections. When we ask them to type or adeno-positive cultures, 90 percent were adeno 14. Next slide.

I won't spend a lot of time on this. It's best to say that along with our clinical case definition someone having to meet the FRI criteria, they had to meet one of these laboratory case definitions to be able to be called a case. There are various ways we could have done that and I'll let you read that a little bit on your own. Next slide.

I'm going to spend just a minute on the clinical. Mild, moderate, severe is how we divided the case definitions because unfortunately we started seeing moderate and severe cases where

it involved hospitalization. Just to give you an idea, April to June, the same time period last year, we had 14 pneumonias total and that's looking at the DNBI. Only three were admitted at that time. From the same time period this year, 51 pneumonias, 27 admitted. You might argue there was some bias because we knew we had the disease and maybe we admitted, but still that's quite -- we're talking over 50 percent admission rates and that really was due to severity. A lot of these kids were very sick. Next slide.

This represents our pneumonias. And you can see in April is when we started seeing them and we got a cluster here in May and we realized that we really had some serious illness and it has actually persisted on and I'll show some recent slides as well. Next slide.

A little bit of epi about the pneumonias. For time's sake I won't go into details. I will say that the only patient who did die had another disease going on at the same time. She actually had mono first and then got the adeno

and she did succumb on August 7th. She's the only death we had. But I might point out that these are young healthy trainees, five ended up in the ICU with pneumonia during this time period and three needed to be intubated, so these were very sick kids. They had a very classic clinical picture; I'm actually going to be producing an article about this, because there was a fairly classic pneumonia presentation of these kids. And you can see at the beginning our capability was somewhat limited, but when we tested the ones that were adeno positive, this is on the pneumonias 100 percent were 14. Next slide.

Local response. Well, I can't really emphasize enough the team response that was necessary for this. There I am the only preventive medicine physician at Lackland. Public health, I can't say enough about public health. They did a fantastic job. You know it's an outbreak and public health is a really big player. Kudos to them. Like I said, the relationship with ID, the clinic missions in the clinic and of

course one of which is colonel Bunning. I would also say that we had a receptive line. They were willing to listen to their medical people in terms of our interventions, so that was very important. The biggest recommendation we made initially was that we segregated our isolated the sick trainees. What we did is we created, depending on determinology, a fever or a bed rest flights, the line liked bed rest a little better than fever flights, but basically these are the kids that met the FRI criteria. What we did is instead of sending them -- seeing them and knowing they needed quarters for a couple of days, sending them back to their flights, we segregated them, we isolated them. We put them in a dorm and we let them recover there. It helped in many ways because they got rest that they might not have gotten and basically it got them out of the general population. The other thing of all these public health measures, I won't go over these, they're fairly standard. Local measures on the trainees, cleaning, cleaning, cleaning, I can't

emphasize enough, everything, because this virus can be everywhere. Next slide.

Just to give you -- the other thing we did is just to show you some of the epi, some of the stuff we looked at, like I said, we could spend a whole day on this because there's so much epidemiology you can do with it. You can look at the individual squad unit to see if you had more disease in one squadron, that's what we did. Actually what we found out is that this would change, these were the pneumonia patients, but it depends on the month it seems to switch around. If we did see somebody that looked like an outlier we would go and investigate the squadron and see if there was anything unusual. Next slide.

The other thing we found more in the beginning, this goes up to September 3rd. In the beginning of the outbreak almost all the trainees were minimum of week four, so there was no question that they were transmitting it while they were there. Obviously somebody may have introduced the virus but it was being transmitted

later in their training. Now as we get into the effort we are seeing more cases a little bit earlier. Next slide.

Also want to emphasize the interaction we had with other agencies. AFIOH, AETC, the Army was involved at CHPPM and WRAIR, Dr. Cushman was doing the vaccine trials came down. We invited the CDC and we were working very closely with the Texas State Health Department all during this time. Next slide.

Here's the initial result of our response. This takes you to July and we're going to take credit for this even though it may have happened anyway, but our rates dropped. And what we did is on May; right about here is when we implemented all the measures that I showed you, isolating the trainees, started doing some aggressive measures. So our rates came down, which is good. Next slide.

Current status, where are we now? Well, I wish we could say this thing was over, but it isn't. Our FRI rates are lower; we vary from.6

to.9. Considering our baselines were.2 to.4 we're still elevated, but at that peak, we had hit two per hundred. So we're definitely down. We're still getting positive cultures for adenovirus; we're still getting positive PCR adeno 14. The majority are still adeno 14. We're still seeing more, if you combine all the pneumonias, we're still seeing a higher rate of about three times. What we are seeing a little different is that we -- our pneumonias where we had maybe 75 percent confirmed with adeno, we're getting less of a percentage of adeno-confirmed pneumonias so we're starting to look for other etiologies, mitochondria, Chlamydia, et cetera. We are continuing segregation of the trainees. Our threshold was when we hit less than ten in that flight we would close it. We can't seem to get there. We vary from 10 to 30 depending on the week. Next slide.

Here's the fever slide, just to show you or the bed rest slide. Trainees in and out and we've had a lot. I believe we're up to about 600

this actually starts here in March and goes all the way down. So trainees in, trainees out, still disease.

We're still seeing pneumonia. Actually, August, what was a little scary was we had kind of come down in our rates and August it went up again and so we again got public health out there. Some of the squadrons had run out of their cleaning product and we just have to stay on top of it at all times. Next slide.

I think this is pretty much my last slide. This is where we are right now. This is NHRC slide. Now NHRC is adding the serotype of the adenovirus in there for you to see. They never used to do that, which is nice. You can see this color represents 14, so basically still the majority of our adenovirus is 14; we have a few 4s in there and our new -- we've kind of new steady state that we're hovering at, and it's here. Now this is based on expected rates. NHRC calculates the expected rate by looking retroactively a few months. Now our expected rates are higher than

they were. So instead of looking at the color, you almost need to look at more the raw number because this would have previously probably have been at least a yellow, maybe even a red for where we were before. So we've reached a new steady state. Next slide.

These are just my acknowledgements. There were just a whole bunch of people who were involved in this. I just wanted to make sure I put their name on the list here to give them credit. We're still doing some more studies on the adenovirus. This is not over yet.

DR. POLAND: Thank you. I do want to -- just for members of the Board that aren't on the ID panel, recall that this is serotype 14 vaccine that's being devised as serotype 4 7. I don't want to put him on the spot, but Commander Russell is here and maybe he can give us a short summary of the phase II and III study that's being done to bring this to licensure.

CDR RUSSELL: Thank you very much. Fort Jackson, Colonel Kuchner is the PI there and Great

Lakes. I'm the PI for the phase II, III studies for the serotype 4 and 7 adenovirus vaccines. We've been enrolling since October of 2006 and we're currently about just under 300 shy of our total and 4,000 for the two sides. At our current enrollment rates we anticipate just two more Saturdays of enrollment, we enrolled every Saturday. We're very close to that. Then there's the active follow up of those enrolled individuals through the recruit training and then a six-month follow up after that. I think we're just about getting the trial over. Now, I'll mention, just quickly, that the data monitoring board is meeting now and the end of next week we will hear the outcome of their preliminary unblinding of the first 2,000 and to determine whether or not, based on that unblinding, there will be a recommendation for more enrolled or not.

DR. POLAND: Is Lackland one of the areas where the vaccine trial is being carried out?

CDR RUSSELL: Lackland is not. It's

being done at Fort Jackson and Great Lakes. Lackland had such low levels that you saw of adenovirus it wasn't a consideration for the trials.

COL GIBSON: So, Kevin, you would say that at least from the phase II, phase II study things are going about as expected.

CDR RUSSELL: Agreed. Things have gone well since we've started enrollment. We're on timeline pretty much. There are a plethora of other issues in the acquirement of the vaccine, but currently it's scheduled for late 2009.

DR. POLAND: Comments or questions from the Board? Ed and then Joe.

DR. KAPLAN: I was interested in two things. Have you looked at any evidence of seropositivity of new recruits coming to the base?

LCOL BROSCH: We actually -- we have not done that. We haven't gone through that step, but that's a good idea. What we have done though is we looked at slides that were fairly new, I think at one point, maybe you can comment Colonel

Bunning, I think we did look, not recently, but in the early part of the outbreak, I think we did look at one slide that was fairly new.

DR. KAPLAN: The other question is in this last handout that you just handed. It suggests that there has been an increase in type 14 at the advanced training bases also.

LCOL BROSCH: Right.

DR. KAPLAN: Public health implementation as you so nicely did at Lackland?

LCOL BROSCH: I didn't want to put that on the slides for time's sake, but that's why I just handed that out. That's the latest report from AFIOH. And you can see, yes, the tech training bases are also having problems. They're in communication with us, their doing --

DR. KAPLAN: But all of those people come from Lackland?

LCOL BROSCH: Correct.

DR. KAPLAN: I think this is an important point that shouldn't be lost in this is that oftentimes when we see recruit training bases

get it, people forget to look at the advanced training bases and that's a very nice example of that.

DR. POLAND: Let me ask, before you go, because I think pertinent to the discussion, if Commander Russell would just make a comment I just asked him about.

CDR RUSSELL: Briefly, I just want to point out that the adenovirus in this hemisphere is adenovirus serotype 14 is a pretty new occurrence or we haven't recognized that previously. There are some older reports of some adenovirus 14s in Eurasia. But in this hemisphere it hasn't been associated with the respiratory illnesses until some cases that we first identified in early 2006 and some outbreaks in the Pacific Northwest. So the question there comes, Well what about the vaccines that we're currently testing the adenovirus 4 and 7? Within the adenovirus and the different serotypes that Lorie discussed there are there are serogroups, A, B, C, D. And in general there's reason to believe that

there's some antigenic protection among a group and adenovirus serotype 14 is a serogroup B, as is serotype 7, so the vaccine, including serotype 7. The question is: Is that going to provide some cross-protection for the adenovirus 14s that we're seeing right now. Historically there is a report that shows that the strain of adenovirus 14, I believe, noted in the '70s, there was some cross-protection of adenobodies produced toward 7 to that 14. So there's reason to believe there might be, but I might point out quickly that this 14 is a little bit distinct from what we saw in those years. We've done some pretty extensive studies, both with genotyping and sequencing with RARE and the Lovelace Institute, Dr. Cayonne that shows it's unique 14. So those studies are largely being headed up right now by Walter Reed looking at this heterologous cross-protection and whether or not it exists.

DR. POLAND: Sorry, Dr. Silva.

DR. SILVA: I was a young major when type and 7 cycled at Wilford Hall. I have a lot

of memories with three of us rounding every six hours through the Quonset huts and we felt isolation was a key role. I was always impressed; they carried the spivot pitchers of the ugliest red exudative throats I've ever seen in dozens of men. Did these lead to a lot of exudate, I mean thick exudate, some I worried about --

LCOL BROSCH: Some, but, no, not really. I mean very sore throats but not necessarily exudative.

DR. SILVA: And you answered my question about 14.

DR. POLAND: Colonel Bunning.

COL BUNNING: I wanted to point out that you noticed a lot of different people on that slide. We have a whole series of studies that are in the analysis phase following through -- we are working with CDC. We have a cross-sectional study. We had a nosocomial-hospital based study as well. We have a whole series in working with our other service partners in the state. There's a lot more to come out of this.

DR. POLAND: Dr. Oxman.

DR. OXMAN: A question and a comment. Comment: I believe that the cross protection between 7 and 14 is really based on tissue-culture serology and not clinical if I'm not mistaken.

CDR RUSSELL: That is correct.

DR. OXMAN: The other characteristic of adenovirus infections is they have a very prolonged period of shedding after the acute illness and after sub-acute illness or asymptomatic infection and that would certainly affect the epidemiology when people move around from one base to another.

LCOL BROSCH: Right. What we're doing is because of that and because we've also in just some preliminary studies we did, we saw that there are a lot of asymptomatic patients out there carrying. So we know there's more out there than we've been seeing. But what we do is we screen our trainees the night before they leave, we get a temperature and we interview them and we screen them now before we let them go to the test agency;

for that reason, that they may be incubating and they may still be having problems.

In terms of the shedding, we actually have a study going on to try to delineate that, but you're exactly right, it can shed for a week.

COL BUNNING: We've identified over 30 days so far.

DR. POLAND: Dr. Lednar.

DR. LEDNAR: A follow-up to Dr. Oxman's point about the prolonged shedding. It was really an eye opener to see just how sick some of these young airmen were including ICU admissions. Is there any evidence that there was transmission of adenovirus from the patient to the hospital staff?

LCOL BROSCH: Yes. We did have --

DR. LEDNAR: Is there any evidence that that is beginning to get seeded?

LCOL BROSCH: We did a healthcare worker study which we haven't reported the results of, but we did. We had a definite -- in fact, we had one very sick resident, a resident that did get sick during this time. Yeah, you're right. In

fact, most of us, I'll tell you personally that I probably had it during this whole time. Not the pneumonia level, but I was sick for a couple weeks, a lot of us were ill from it, but not to the degree of some of these men.

DR. POLAND: Any other comments? Okay. Thank you very much.

COL GIBSON: Two very quick comments. Those of you, who haven't registered, raise your hand. Karen will bring around the sign-in. We do have to keep track of registration.

Also, we need a show of hands who wish to go on the Intrepid tour this afternoon. I think we're going to be okay on the bus, but we have two additional cars lined up to get us over there. The critical -- the critical part is not the Intrepid. They can take care of as many of us that can get there, the issue is the bus. Karen, which one do want raised first? Intrepid? Raise your hand if you want to go on the Intrepid tour. Now anybody who hasn't signed up, raise your hand so Karen can bring that around.

DR. POLAND: We're going to break for lunch and reconvene at 1:45. The Board members, liaisons, preventive medicine officers, distinguished guests and speakers can remain here for a working lunch. For everybody else there are several restaurants in the area. Do you need to know about dinner tonight?

COL GIBSON: Oh, yeah. Let's mention dinner tonight.

MS. TRIPLETT: I need a show of hands.

COL GIBSON: Dinner tonight is at County Line. We'll be leaving from the hotel at 6:15. This is a Texas barbeque. And we have enough reservations for everybody. You want a show?

MS. TRIPLETT: Thank you.

DR. POLAND: We'll reconvene at 1:45.

(Whereupon, a luncheon recess was taken.)

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

DR. POLAND: I want to thank again, Mr. Carr and his team for coming and briefing us and we would like to stay -- the Board would like to stay engaged on this issue. It's obviously a hot topic issue. So we'll be seeing more of each other. Thank you very much. I also want to introduce Colonel Chuck Scoville, who is actually at the Military Advanced Training Center, which is sort of a sister facility to CFI, which you'll see today. And I hadn't realized it, but Chuck was actually involved in the planning process of what we're going to see. So welcome, Chuck.

COL GIBSON: He's also the executive secretary for the panel on amputees and care for patients with amputees and functional limb loss, one of our subcommittees.

DR. POLAND: We've always tried to be cognizant of the need to be knowledgeable and recognize each other and I want to take a few minutes now to recognize a departing member of the DHB team. Commander Dave Carpenter, the Canadian

Liaison to the Board has been reassigned to Ottawa. He is going on to presumably bigger and better things. His replacement Commander Catherine Sloan- White will be with us in December at our Washington, D.C. meeting. So, Dave, can you come forward and we have a plaque for you in recognition of your service with DHB?

CDR CARPENTER: Which way is forward?

DR. POLAND: Thank you, Dave, and Godspeed. We'll go, then to our first presentation, Dr. Mike Parkinson, who is President of the American College of Preventive Medicine. He'll provide his subcommittee update, much like we did with the pandemic questions on a question that's before the board on evidence-based accession, retention and deployment standards. So, Mike, we'll turn it over to you. We have about 15 minutes or so scheduled for this.

DR. PARKINSON: Okay. We may not need that entire time, Mr. Chair, but I did want to give the full committee an update, both the question and the activities that the subcommittee

has engaged in since it was brought to our attention.

The question to the DHB is to ask the DHB to examine issues associated with the establishment and modification of DoD medical standards that span the career life cycle of service members from accession through separation. Here we're talking about accession, retention and deployment standards. What tools or methods should DoD use to establish and modify those standards that will ensure a medically-ready force to meet our nation's requirements while minimizing the potential to cause or aggravate medical conditions that could preclude continued military service? We conducted a conference call thanks to Colonel Gibson, Colonel Grieg and also I want to thank Lieutenant Colonel Niebuhr, who, as you recall in an earlier meeting, gave us an update on evidence-based accession standards and DoD considerable progress in that realm. We convened a conference call, the subcommittee, with those subject-matter experts and the first thing we

wanted to ascertain was essentially presented to us before lunch, and that is in the midst of three federal, extremely impactful reports, largely critical of the disability evaluation system and the interface between the DoD and VA, how big of a problem and how big an impact could this committee have answering these questions, because they're integrally tied, as I pointed out in our conversation before lunch, to that box that was right up there. So we are the -- we are the cerebrum, not the cerebellum, but the cerebrum the drives what happens in those arrows. So while the arrows look clean, what happens in those boxes is what's in the intelligence of evidence-based standards. We wanted to understand the current status of that. I think the Board also probably wants to monitor the progress of that and in that context then we were able to better define the scope of what this subcommittee can do to answer this question. And I think that our group will be very comfortable with doing the following, and we already have a draft that Bill has begun to think

about.

What we clearly can't do is go over 180 conditions and determine the level of evidence that the DoD currently uses times three different services with different ways of determining whether that retention standard, deployment standard, fitness for duty standard is equivalent or if it should be equivalent or should it be standardized. What we can do, however, is articulate through the answer to this question a series of guiding principles that we would ask DoD to pursue as it begins to standardize where standardization is necessary with the fall back being if it's not standardized across the services, you better have a darn good reason to say why it's not, rather than a default that says we're all different and therefore we can't.

We would articulate a series of guiding principles that would allow DoD to achieve its goal in the context of the re-engineering of the entire disability evaluation process. So we can't do it outside of that, it has to be done inside of

it. Things that would be in those goals would include such things as the use of a hierarchies of evidence approach, similar to something like the U.S. Preventive Services Task Force that could be built upon but tailored to unique DoD needs. We could then articulate the types of databases, case studies or even Fentanyl events which DoD should be looking for by type of standard as a way to continually validate their existing standards and (off mike) them accordingly. We certainly would rely heavily on the experience of the accession standardization project, which is evidence based to inform that and ask how far we can apply Colonel Niebuhr's group and their work to the area of retention and deployment standards. It may or may not be applicable. So in this way we would begin to purvey guiding principles that should then be translated by the relevant DoD and service members into applications so that over time, year over year, we get closer to a consistency of evidence and a unanimity of approach where that makes a lot of sense.

Areas that we would also consider in the recommendation would be the use of these to inform or perhaps, maybe, even create contractor and accession and deployment standards. We have as many contractors in theater today as we have uniformed service members. Contractors create a tremendous resource drain on our MTFs so that's another consideration that perhaps we want to look at in our principles.

NATO standards. We don't just fight alongside our contractors, but we're right alongside our NATO and NATO is looking at standardization of NATO standards as it relates to that. So certainly want to have some language in there. Recently there was a study, Dr. McNeill has served on with the Institute of Medicine around the National Research Council on the whole area of if you have that (off mike) Neil's you probably don't, but a good work out of the NRC on this area about accessions too, so we've already got some good work in the area. So we us not coming back with the "how-to" but the principles

that guide the "how-to" that could be very much consistent with and I think useful to the Department. So I'll open up for any comments from the other subcommittee members, but that's what we would bring you in relatively short order, Mr. Chair, so I think we're there. But it took a while for us to get a good problem definition, to get some environmental assessment as to where this TBE thing is because it's got to go in there right away and then the hard decision has to be made why don't we standardize.

DR. POLAND: Thank you, Mike. It's a complex topic and we're fortunate to have somebody who knows as much about the system as you do with your skill sets. So thank you. Questions or comments? Dr. Lednar.

DR. LEDNAR: I think one of the challenges in this rework of the disability system and its simplification; it seems like that there are two separate questions that this consolidated approach may be trying to address. One is a more service specific one about is the

soldier/sailor/airman fit for service duty? Yes? No? Or should they be separated.

Question two is: Is there some health condition in this service member which may have a connection to the service and is producing some disability?

And I think trying to keep some clarity in these two questions as they're both answered is important. One of the unfortunate aspects of the language that you used, and everyone using the term "disability" "disability plan" "disability programs" is the fact that there's a difference between impairment and disability. Impairment is more what it sounds like some of the rule sets sort of get at in terms of range of motion and these kind of -- what a doctor can observe, describe and document versus what is the servicemen's reaction to the change in their body part. We've all seen people, who, with a similar level of injury, some go right back to work and others are out of work for the next six months. So disability is really the personal, behavioral

reaction to the anatomical insult. So we're calling this a disability system and yet it seems like we're kind of impairment focused. So I guess I'd just be a little careful about the confluence of these questions for different purposes and it's going to be a challenge to make this evidence based.

DR. POLAND: Mike, any comments you want to make in regards to that?

DR. PARKINSON: I agree. These were the cautions, why we didn't want to find ourselves with one leg in a La Brea tar pit that we could not get out of and that we'd look ridiculous because there's no evidence, but we need to inform the mission as opposed to doing it and that's kind of -- that type of consideration, Wayne is very helpful, because you're right; impairment versus disability and do we need to reframe the semantics at some point? I don't know. Just something to think about.

CAPT JOHNSTON: The other issue that I think that's -- I'm not sure if you specifically

addressed it, it was raised this morning is the difference between fitness for deployment and fitness for duty. To me, to some extent, they seem to be the same things as part of your duties is to deploy, but clearly they're looked at differently and I wonder if that ought to be reflected in the way the regulation is assessed and ought to be a separate issue, it ought to be part of the same issue.

Perhaps, finally, one further way of looking at it is whether or not (off mike) mission makes you more vulnerable to the sorts of environmental stresses in the military (off mike) personal.

DR. PARKINSON: If I may just comment just on that, because this is more historical observation and evidence based. But I do think -- and we heard from Mr. Carr today that all science always lives in the context of culture and history and things that have happened. I think that the pendulum in the culture of the military services has swung from, in order to be on active duty

service, everybody must be deployable. We initially had the desk jobs and then you had the people at the point of the spear, to use that acronym and then everybody was going to be a warrior. Now we use the warrior term, which is an interesting term to me having a little distance from it. But now whether its compassion or the fact that we really need these good people who are amputees or they have disabilities, they're going to be serving our country, but they may not at all be deployable. So I think we want some time when there was clear fitness for duty, fitness for deploy like this, then we move together, whether it was total 100 percent overlap. And I sense that we are going like this again as a result of need of compassion, functional need of services, which is the right thing to do, so the people who are compared are not disabled because they're back at the job. So this a dynamic that's going on here and the words deployment are constantly changing. They are not static definitions, they're dynamic. And the culture, to me now,

seems to be they're going like this again in terms of how a person actually spends a duty time. It's just a reflection.

MR. CARR: It would probably not be unreasonable for the Defense Health Board to observe that it is complicated to the point of being impossible to say you are fit, but you cannot be deployed. Now I would report, as one of your representatives, doing the stuff we do, that it's become increasingly tough. That we have to someone who is non-deployable, but fit and in some cases, in the case of the Air Force, there's quite a concern about number of deployable and quite a pressure about on those who are not deployable to separate. That leads us to an impossible position. It means you are fit, but I want you out for a medical condition. You can see what I'm getting at. So I think it's reasonable for the Board to say this doesn't pass the giggle test; that you can be fit, yet non-deployable and therefore separated. If you're not fit for the full range of your duties, including

deployability, then we question your ability to be called fit in the first place. Now that wouldn't alter our ability to waive that, to say, you're right, if you can't deploy, you're unfit, but we'll waive it when it suits us to do so. A sympathetic person with prosthesis, if we thought gaming was coming up in the system and wanted to truncate the gaming, but the rule, the standard would be if you're non-deployable, you are presumptively unfit and then the service would make a judge about the need for you to stay avoiding the expectation of your staying.

DR. POLAND: Dr. Oxman.

DR. OXMAN: As someone at great distance from this, it seems that the distinction between impaired, which is a measure of difference between the ideal or the perfect and where you are as a result of an injury is a useful term and it's quite different between being fit, because the next thing, when you hear "fit", it's fit for what? So a paratrooper, who has a minor knee injury, may have a minor impairment, but he's no

longer fit to jump. He certainly is fit to do other things.

DR. POLAND: Wayne, maybe one more comment and then we'll move on.

DR. LEDNAR: There may be some assistance in thinking through this, again, that the civilian community would use and that is understanding one's work and what are the essential job functions? For those who are familiar with the American's with Disabilities Act, it really gets you to figure out what aspects of the job are critical that one be able to do; they are essential job functions. And for each MOS in each of the services, that's an answerable question. So if you're a paratrooper, if you can't jump out of airplanes; that's an essential job function. Now, if there's a service member who has some inability, temporary or permanent, to an essential job function, the question then becomes, for the employer, is can we accommodate? Can we deal with the fact that they may be non-deployable, but still able to do a CONUS,

garrison-based important job? Then it's really up to the employer to decide business necessity. Do we have a business to run and we can't afford to have so many non-deployables. If that logic is applied consistently could be fair as you think through this. So there isn't necessarily an obligation to go one way or the other, but to think through this in kind of a step-wise way.

DR. SHAMOO: Can I make a comment on that?

DR. POLAND: Briefly.

DR. SHAMOO: With one caveat: And that's in the civilian world the courts already have decided "with reasonable accommodation" and I guess the military has not reached that.

DR. POLAND: All right. Thank you, Mike, very much for that body of work.

Our next speaker is Dr. Ed Kaplan, Department of Pediatrics, University of Minnesota School of Medicine. Dr. Kaplan will update the Board on Group A beta streptococcal infection in military recruits and the penicillin supplies. I

think you and Commander Russell are going to jointly do this. We just need to be finished by 2:30 so that we have the capability of boarding on the busses on time.

DR. KAPLAN: I was asked today to briefly -- I emphasize briefly brief you on the issue that we discussed once before the streptococcal issue. Can I have the next slide, please?

The problems that were brought before us were Group A strep infections have always been a medical and public health problem among military recruits especially. Going back as far as one would like to go. This will likely continue unless or until a cost-effective vaccine is available. The morbidity and mortality are not insignificant. Then as we discussed previously, there has been no uniform inter, and in some cases, intra service approach to the issue. And then the other issue that we'll refer to is the supply of benzathine penicillin. Next please.

The current mainstay of streptococcal

prophylaxis among recruits is benzathine penicillin G. Note that this is the new manufacturer, and we'll talk about that in just a moment. Next, please.

With the help of Colonel Gibson, reports were sought from the various services and what I'm going to show you is really a cut-and-paste job from those of you who were kind enough to respond. But please correct me if I've made errors. In some cases I've corrected the spelling. Next, please.

The Coast Guard recruiting center at Cape May, New Jersey. Cape May does not have a specific policy or practice regarding the prevention, treatment and control of strep in the recruit population. Recruits do not receive intramuscular benzathine or oral Erythromycin as prophylaxis. Historically, Cape May typically has had sporadic and limited occurrences and they treat it on a case-by-case basis. And as Commander Russell will tell you in a little bit, Cape May is involved with the program at the NHRC.

Next, please.

From the Marine Corps, let me give you a very brief Navy instruction on the matter. You know the Navy medical facilities at the Marine Corps recruit training sites take care of this. The short version is that every recruit gets prophylaxis on arrival and that's benzathine and thereafter it's guided by surveillance. I believe there is local variation and you may want to comment on that. So we have prophylaxis in the Marine Corps with local variation. Next, please.

The Army has always had a problem with this and we have a very detailed report for Fort Leavenworth, Fort Benning and Fort Sill give Bicillin. We have a very detailed report for -- Fort Leavenworth, Fort Benning and Fort Sill give Bicillin to all soldiers in basic training and have not had a shortage of Bicillin, which we commented on the last time, since early 2007. Fort Knox uses Bicillin on a limited basis to those who have exudative pharyngitis or peritonsillar abcesses and those with culture

positive. If a particular unit has a large number of positive strep cases, the entire battalion may be prophylaxed with Bicillin. This has happened five times in the past year. Fort Jackson does not give Bicillin its recruits. Only Fort Benning and Fort Jackson have dedicated location as hospital quarters or medical quarters for soldiers with fever or illness not severe enough for admission to the hospital. The policy document from the Army respiratory disease surveillance program was attached. Next, please.

This was effective June last year, and it points out that there is a policy there. Of interest to us, to me, and this is my note here, was that this was sent from General Cates to everywhere, as far as I can tell, the then AFEB did not receive a copy. Next, please.

The Army's protocol is here and I'll show you an example in a moment, but they do have a way to calculate the ARD cases and the strep recovery rates and have come up with what they call a SASI index, which is a percentage of

streptococcal disease over the denominator of acute respiratory disease. And if this is greater than 25 for two consecutive weeks, it triggers a response. These documents are available in case anybody would like to read them further. Next, please.

This is an example of July 2005 through July 2007 from Army recruiting centers and you can see the ARD and the SASI indexes are shown here and the 25 is shown by the lines. These are the various recruit training centers and you can see, for example, at Fort Leonard Wood, which historically has always had a problem. But you can see there consecutive weeks where they do meet the criteria. Fort Sill is also there and there are other places like Fort Knox, which in this period of time Fort Jackson, in which this did not trigger a response. So this is a well-oiled mechanism it seems to me at this point. Next, please.

The recent information from the Air Force shows that basic military trainees receive

prophylaxis during the first week of training. A provider explains the medication which they will receive. All trainees who are not allergic to penicillin receive 1.2 million units of Bicillin. Trainees who are allergic are given Azithromycin 1 gm weekly times four weeks instead of the penicillin. In the past, they were using Levaquin, but apparently for those who were allergic to penicillin or could not take the microlides were given Levaquin and I understand that policy is under review. It's almost a little bit like -- seems to me like swatting flies with cannonballs here. The numbers not receiving any prophylaxis are very small. It was felt that herd immunity would be there. Of interest, and I think something that I really never heard of before and I called to the attention of the Board is they have apparently had several cases of cellulitis with MRSA at the site of the penicillin injection. There were no serious side effects from the penicillin itself and I've not seen this super infection with staphylococci. Next, please.

The Navy policy, as I understand it is Bicillin or Erythromycin at the Great Lakes and then as part of the Navy's policy --

DR. POLAND: Could you use the microphone, Ed?

DR. KAPLAN: I'm sorry. Would you like to comment a little bit about the activities at your laboratory and then I'll finish up.

CDR RUSSELL: Thank you, very much, Dr. Kaplan. Dr. Kaplan asked me last week to update some of the data that we provided to you all in December of last year. So we put some updated slides together for you and then he later said, "It's your data, will you present it?" I said, "Great." So I updated the slides. This morning I said, "Ten minutes?" He goes, "No, five." So we'll be real quick here. Some good points here that we're just going to bring up real quickly.

So a reminder again that the Naval Health Research Center does surveillance at nine different military treatment facilities that are associated with recruit training camps. So we

actually get Group A strep isolates that come from the recruits themselves and we analyze those in our lab in San Antonio for antibiotics, susceptibility or resistance patterns as well as emm types specifically. We don't follow rates, like the SASI index. We really just get isolates in and look at trends over time. Next.

Again, nine different sites. Next. They are located throughout the United States, the recruit training camps. Next. So, quickly, we published in 2003 about some of the data up to that point. At that point we noticed emm 75 was significantly associated with Erythromycin resistance seen at that time. Next.

Some of the conclusions of what I presented to you in 2006 was that, again, emm type associated with Erythromycin resistance as well as this emm type 5 being associated with a lot of the outbreaks that we've seen in recent years.

Here's the 75 and the resistance seen to Erythromycin. Not much in other emm types. Next.

The important, interesting thing about

this is that 75, seen mostly at Lackland during the years of that publication is the reason that there was also an association between Erythromycin- resistant and a particular site, and that being Lackland at the time. The question is what's happened and are we continuing to see more Erythromycin resistance over time and the next few slides will illustrate this a little bit. Next.

Here's at Parris Island, MCRD. You see the Erythromycin resistance here in pink and you see that in recent years there's just been very little. This is a direct result, actually, of the emm 75 type diminishing, because that's largely associated with the emm 75. Next.

Here you see at Lackland a lot of the Erythromycin resistance and there was that geographic association at the time and that has disappeared in recent years. Next.

Again, at Fort Leonard Wood the same trend. Next.

This is a graph of all of the different recruit training centers. I showed this to you

before. It's very busing but there's an awful lot of information in it. What I'm just going to say here briefly is all the sites do do chemoprophylaxis differently. And you'll see here at the MCRDs, San Diego for example, they do get a second Bicillin injection unlike Parris Island, but all the information is in there and we can provide that to the Board. Do they give an injection if they don't -- do they base other prophylaxis on surveillance? Do they give any kind of antibiotic to those that are Pen allergic? All of that information is in here and what do they use. Next.

A lot of outbreaks, but none since I presented to you in December. Next.

This was briefly an outbreak that occurred in 2003, which really demonstrated the fact that the Bicillin injection was not providing 30 days of coverage. So that led to the question, and Dr. Kaplan has been working with us for quite a long time to try and get this study to happen, and it has been financially supported by GEIS; and

that is the question of whether or not the current Bicillin injection, what time frame that Bicillin injection is providing to Group A strep. So the concern is that maybe the current manufacturing process for penicillin G are different from historic when so many of the studies were done that showed the duration of protection. We do have outbreaks that continue to occur despite the chemoprophylaxis that we use. The objective was to, once again, determine the pharmacodynamics of that injection at the serum penicillin level following injection in the recruit population. The recruit population is different. They are a different population. That's important. So the method is 200 trainees. We're going to do three blood draws over four weeks. We're going to go into the barracks nightly to do kind of a rolling blood draw so that we're not impacting their training very much, and then that serum is going to be analyzed by Dr. Blumer, University Hospitals in Cleveland to determine serum penicillin levels. Status is we do have preliminary approval and we

plan on implementing this study around November. Next.

So in summary, again, we continue to follow surveillance for Group A strep. Now that we do have the Bicillin product back we seem to have a reduction in numbers. That sums it up. Thank you.

DR. KAPLAN: So that basically is that. Next, please.

This was, in part, the reason for doing the study that Commander Russell has just pointed out you and that was a study by Jim Bass in Hawaii. And I took a quote directly from that. In the studies that they did and published in CID about 11 years ago, penicillin was detectable and only 40 percent of 86 samples after seven days. Detectable, it didn't say anything about levels. And in only three samples after 14 days. Age, height, weight and body surface area were not significantly related to penicillin concentration at one or seven days. These were Army recruits and the mean weight was 75 kilos as I recall.

This, I think, has an important possible impact. Next, please.

Currently, and to follow up, according to the Food and Drug Administration -- well, first of all, as you may know, the drug company which was making Bicillin for many, many, many years was Wyeth. They sold it to Monarch Pharmaceuticals and there became a shortage as those of you who have been involved with this know. I found out, with a meeting with the FDA a month or two ago that the FDA is only bound to determine whether the manufacturing process has changed from that used by the former producer. There appears to me no way of finding out and made public whether changes were made in the manufacturing process before the process was sold or afterwards. And the FDA does not require any biological levels or testing at all. That's one of the reasons that I think this study is going to prove useful. Next, please.

So for discussion and consideration; should there be, and we asked this question in the

past, a more uniform policy across the services or as close to it as possible. Should there be a uniform policy within the individual services? Is monitoring and surveillance realistic or possible? The policy regarding the adequacy of available Bicillin is going to be addressed. And then the issue regarding microlides. There were problems as Commander Russell pointed out with microlides resistance particularly in emm type 75. We don't seem to see that at this point right now, but I think it's just a matter of time before it comes back. I think that's the last slide.

DR. POLAND: Thank you, Ed. Why don't you stay there for questions. Let me start first with any of the preventive medicine officers. I think Ed, you were wanting to make a comment and there might be other.

CDR FEEKS: Just by way of clarification, it's interesting; I did pursue some more details in this matter. At San Diego, the practice is Bicillin prophylaxis on arrival and then every four weeks and this is done year round.

At Parris Island, on the other hand, it's Bicillin prophylaxis on arrival and then any further prophylaxis is based upon surveillance, namely indications of an outbreak would prompt another round of prophylaxis with Bicillin. Obviously in the penicillin allergic we use Azithromycin regimen. Interestingly, the officer candidate school at Quantico does not use a prophylaxis program and strep has not been a problem there and I don't know why that should be so. Maybe we in the Coast Guard have the same luck in that regard. I don't know.

DR. KAPLAN: It's always been in recruits. Not only in the U.S., but if you look at the literature around the world, it's in recruits, and I think it's because it's an epidemiologic phenomenon. People are coming from different parts of the country with previous exposure to various types and they bring new types in and you mix them all together and you end up with outbreaks.

CDR FEEKS: It's interesting to me.

During the summer in particular, at the officer candidate school at Quantico, you have not only those normal classes of college graduates who are there as officer candidates, entering the Marine Corps, you also have what they call a "Bull Dog," which is the name of the program of Marine officer training given to the Marine Corps option, Navy ROTC University students who come to Quantico for, I forget how many weeks it is, for training. But strep does not appear to be a problem in this coming from all corners of the country group either. I wonder what the difference is.

DR. KAPLAN: I don't know. I don't know.

COL GIBSON: I've done some studies on Group A beta strep too. Direct contact transmission is the number one way that this thing is spread. A lot has to do with the barracks environment. The type of barracks they're in -- are your officers staying in two to a room? Three to a room? Four to a room? Or are they in a barrack with another 50 bunks?

CDR FEEKS: In officer candidate school, they're in an open bay barracks, just like the enlisted guys are. When they graduate from that and go onto the "basic" school or TBS, then they live more like gentlemen.

DR. KAPLAN: Both points well taken.

LCDR LUKE: Also the question of course are the academies. Now at the naval academy the men and women are much more civilized, they live two to three to a room. But at WestPoint, of course, they start with beast barracks, which is tents and appropriate housing for those type of folks. In any case the issue that I thought was interesting was at Parris Island we were talking -- I was talking to a preventative medicine officer out there, they had been using Azithromycin and one aspect that we had been discussing was the fact that we had been discussing was the fact that some of the evidence that we can presented at this Board a few years ago, it raised the issue of Chlamydia infections, anywhere from three to nine percent, if I remember

correctly; whether or not Azithromycin was in some way helpful for prophylaxis of that problem that continues on now that we've gone back to Bicillin. His question was Would it be worthwhile that we should entertain using Azithromycin in our females since it would prophylaxes against G, A, BHS as well as Chlamydia and that's a question that he had posed to me and I guess I'll pose that back to DHB to consider that maybe there is a room to use Azithromycin at least in our female recruits.

DR. KAPLAN: I don't know the answer to that question, but someone will have to help me with this. Is the treatment does for Chlamydia the same? I mean, the doses that were used and it was used at Lackland for a while was once a week for four weeks at that point. I don't know what the treatment dose --

BROSCH: If I can comment on that, because that's what we did at Lackland when we didn't have Bicillin. A gram, the one gram will cover Chlamydia. That's it. You just need one gram, one time. We screen for Chlamydia at

Lackland in our female population. What we did, because we still wanted to know how prevalent is Chlamydia, we made sure we did the Chlamydia test before we gave (off mike).

DR. POLAND: Other comments from the Board members?

DR. KAPLAN: If it is done I would certainly keep watch on the resistance rate of the Group A strep.

LCDR LUKE: Certainly, but the Bicillin is not going to touch the -- you know, we already know we've got five percent on average. Our females are coming with Chlamydia. So I guess the question is if we're going to hit them with an antibiotic, perhaps we should be treating presumptively for Chlamydia as well as prophylaxing against the streptococcal disease.

COREPETER: I just had a quick comment. Just want to make sure that as you're doing these studies or evaluating the different posts, there are three different preparations I'm aware of Bicillin, BLA and CRN. I can't remember the

third, but depending on the amount of Procaine penicillin mixed in, because when proceed is mixed, it makes it less painful. So just ensuring that you have a standardized (off mike) use.

DR. KAPLAN: I think everybody's using the LA. The third used to be AP. They don't make that anymore. That had crystalline as well. I don't think that's made anymore.

DR. POLAND: Thank you, Ed. So we are done with the first day's activities other than meeting to go over to CFI. We are planning on leaving the hotel at 3:00, so you'll have a bit of a break. We'll meet in the lobby. What time would you like us to assemble?

COL GIBSON: About ten 'til. For the bus. About ten 'til.

DR. POLAND: Okay. Then can we have the Board members just stay in place for a minute or two, but everybody else is dismissed. Thank you.

(Whereupon, the PROCEEDINGS were adjourned.)

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