

THE DEPARTMENT OF DEFENSE

TASK FORCE ON THE FUTURE OF MILITARY HEALTH CARE

A subcommittee of the Defense Health Board

May 3, 2007

National Transportation Safety Board Conference
Facility
Washington, D.C.

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P R O C E E D I N G S

DR. HALPERIN: This is the beginning of the Open Session. We're going to have Ms. Embrey call the meeting to order.

MS. EMBREY: Okay, thank you, Dr. Halperin. Can you hear me out there? Speak loudly.

As the designated federal official for the Defense Health Board, a Federal Advisory Committee to the Secretary of Defense, which serves as a continuing scientific advisory body to the Assistant Secretary of Defense for Health Affairs and the Surgeons General of the military departments, I hereby call this session of the Defense Health Board to order.

DR. HALPERIN: Thank you very much. Now, carrying on the tradition of boards, I'd like to ask you all to stand for a moment of silence because we are here to serve the men and women who serve our country.

(Silent observance)

Thank you very much. Colonel Gibson has

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some administrative remarks.

COL GIBSON: Good morning. I want to thank Mr. Chris Bassette and the staff of the National Transportation and Safety Board for helping with the arrangements for this meeting and my staff here at the Defense Health Board, and all the speakers who have worked hard to prepare their briefings for us today.

If you haven't signed the attendance roster out on the table in the entryway, please do so. One of the requirements of the Federal Advisory Committee is to track attendance. Bathrooms are located just outside this area, and if you need telephone facts or copies capability, see Karen Tripwood or Lisa Jared.

The next meeting of the Defense Health Board will be May 23rd at the Crystal City Holiday Inn here in Washington, D.C. This is the 4th Wednesday in May.

At this meeting we will deliberate the draft recommendations and findings of the Task Force on the future of military health care in

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preparation for their interim report to the Secretary of Defense. The Board will also hear briefings to include and update on the DoD's Global Emerging Infections Surveillance and Response System and Traumatic Brain Injury Prevention and Treatment Initiatives.

As a reminder, this meeting is being transcribed, so speak clearly into the microphones, state your name when you begin. Also turn off any pagers, blackberry, cell phones, et cetera. They interfere with the AV system in here. We're also under enough concrete that most of the time they don't work anyway.

DR. HALPERIN: Thank you, Colonel Gibson. We have numerous people who we should introduce today. I'd like to start with General Kelley. Next, if we could introduce members sitting at the front table, then we'll proceed to the audience.

Commander Carpenter, could you start?

CMDR CARPENTER: If I can get this to work. Yes, I am David Carpenter. I am the

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medical attache at the Canadian Embassy.

DR. LUEPKER: I'm Russell Luepker. I'm
the cardiologist and epidemiologist at the
University of Minnesota.

DR. KHAN: Ali Khan, Centers for Disease
Control and Prevention in Atlanta, Georgia.

LT. COL. SILVER: Lt. Col Aaron Silver,
Joint Staff of J4 Health Service Support Division.

DR. LAUDER: Tamara Lauder, Physical
Medicine and Rehabilitation, Minocqua, Wisconsin.

DR. GARDNER: Pierce Gardner, State
University of New York, Stoney Brook, Professor of
Medicine and Public Health.

DR. LEDNAR: Wayne Lednar, Corporate
Medical Director, Eastman Kodak Company,
Rochester, New York.

DR. MASON: I'm Tom Mason, Professor of
Epidemiology, University of South Florida, Tampa.

DR. KAPLAN: I'm Edward Kaplan,
Professor of Pediatrics, University of Minnesota,
Medical School, Minneapolis.

COL GIBSON: Roger Gibson, Executive

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Secretary of Defense Health Board.

DR. HALPERIN: Bill Halperin, Chair, Preventive Medicine at the New Jersey School in Newark, New Jersey, and Chair of the Department of Quantitative Methods of the School of Public Health of the University of Medicine and Dentistry of New Jersey in Newark, New Jersey.

MS. EMBREY: I'm Ellen Embrey, the Deputy for Force Health Protection and Readiness in the Department of Defense Health Affairs. I'm also the designated official for the Defense Health Board.

MAJ. GEN. KELLEY: Joe Kelley, the Joint Staff Surgeon.

DR. CLEMENTS: John Clements. I'm Chair of Biology and Immunology at Tulane University School of Medicine in New Orleans.

DR. SILVA: Joe Silva, Professor of Internal Medicine, Infectious Diseases and Immunology at the University of California, Davis.

DR. WALKER: David Walker, Chair of Pathology, University of Texas, Medical Branch at

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Galveston.

DR. PARKINSON: I'm Mike Parkinson,
Chief Medical Officer at Luminos, a
consumer-driven health plan part of Well Point.

DR. SHAMOO: Adil Shamoo, University of
Maryland, School of Medicine, Bioethicist.

DR. OXMAN: Mike Oxman, Professor of
Medicine and Pathology at the University of
California, San Diego, and Staff Physician in
Infectious Diseases at the VA Medical Center in
San Diego.

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

CMDR FEEKS: Commander Ed Feeks,
Preventive Medicine Officer at Headquarters,
Marine Corps.

LT. COL. HATCHEY: Wayne Hatchey,
Director of Preventive Medicine, OSD Health
Affairs, (off mike) Health Protection and
Readiness.

CAPT. JOHNSTON: Richard Johnston, I'm

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British Liaison Officer to the Department of
Defense in the Bay.

CAPT. NAITO: Neal Naito, Director of
Public Health, Navy Bureau of Medicine and
Surgery.

CMDR SCHWARTZ: Erica Schwartz,
Preventive Medicine Consultant, U.S. Coast Guard.

COL. STANEK: Scott Stanek, Preventive
Medicine, (off mike) Officer, Army, ODSG.

MR. MEYER: Bill Meyer, Air Force
Surgeon General's Office of Preventive Medicine.

DR. HALPERIN: Yes, could we start in
the audience? I think we need some technical
assistance. That microphone isn't working.

MS. JARRETT: Lisa Jarrett, Defense
Health Board.

COL. ROSS: Michelle Ross, Director of
CBRN Medical Defense Policy, Heath Affairs.

MR. DEFRAITES: Bob Defraites, Army
Medical Research, Materiel Command.

MR. KAMINSKY: Steve Kaminsky, Vice
President of Research, Uniform Services

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University.

LT. COL. SJOBERG: Paul Sjoberg, the
Air Force Institute for Operational Health at
Brook City Base, Texas.

MS. CANIS: Linda Kannis at the Division
of Epidemiological Surveillance at Brook City
Base.

MS. OWENS: Angela Owens, Air Force
Institute for Operational Health.

CAPT. KITCHEN (Ret.): Lynn Kitchen,
Deputy Director of Military Infectious Disease
Research Program.

COL. COX: Kenneth Cox, Force Health
Protection and Readiness Programs.

COL. GOODE: Don Goode, United States
Army Medical Materiel Development Activity.

LT. COL. YOSANDA: Lt. Col. Katie
Devlin Yosanda, Chief of Force Health Protection.

DR. ENGLER: Renata Engler, Director
of the Vaccine Health Care Centers Network, Walter
Reed.

MR. BURCH: John Burch, Preventive

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Medicine Residency, Uniform Services University.

MS. CARNEIRO: Charlotte Carneiro,
Infection Control and Epidemiology at Walter Reed
Army Medical Center.

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

MS. BRISSON: Joan Brisson with the
Competence in Health Services.

MS. DUVERNOY: Tracy Duvernoy,
Contractor, DoD, Guise.

MS. OTTO: Jean Otto, Senior
Epidemiologist Contractor, DoD, Guise.

MR. SANCHEZ: Jose Sanchez, Influenza
(off mike) Leader, DoD, Guise.

MR. NIEBUHR: Dave Niebuhr, Walter Reed
Army Center, Research.

MR. MYERS: Bryce Myers, Walter Reed
Army Center, Research Preventive Medicine.

MR. POTTER: Bob Potter with the
Mortality Surveillance Division of the Armed
Forces Medical Examiner's Office.

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MR. GADOS: Joel Gados, DoD, Guise.

MR. BRADSHAW: I'm Dana Bradshaw. I'm
Director of the General Preventive Medicine
Residency, at Uniform Services University.

DR. HALPERIN: Okay, before we start,
we're going to have a few comments by Ms. Embrey.

MS. EMBREY: I noted that we have
several folks from Walter Reed here in the
audience, and since this is a public session and
because of the great work that the folks there
have accomplished over the many years including
recent years, I just wanted to say, publicly and
for the record, that the work that the clinicians
and the folks that do and care for our service
members coming in from all places to Walter Reed
deserve the greatest credit and appreciation from
my office and from all that work with us. We very
much appreciate your work, and I wanted to say
that publicly.

(Applause)

DR. HALPERIN: Thank you. Now, Colonel
Anderson.

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COL. ANDERSON: Thank you very much. Appreciate the boys allowing us to come and get an update today on the military vaccinations programs. Next slide, please. We are going to cover the mission a little bit, a few of the changes, the different regulations that have come into place.

Yes, sir?

SPEAKER: I think we need some technical assistance with the computers up front.

COL. ANDERSON: Okay. We're going to cover the anthrax, smallpox, a little bit on the influenza program, and then cover a few of the other initiatives that are going on within the Department of Defense.

Next slide, please. I think it's always important to -- slide to a Tab 3 -- I think it's always important to put in context that vaccines are different. I think the board members acknowledge and are very aware of this, but when we talk to our people in the field, vaccines are very different. They're, typically, for the

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individual. You give them a medicine to make them feel better, but with vaccines you're injecting something foreign into a healthy person's body and saying, "You're probably going to be protected -- we hope you are -- against something you may never encounter."

For the person, the providers, that medic, that corpsman, vaccines are different, they sometimes forget. Vaccines are a preventive -- or they're a prescription medicine. When we have mandatory policies, they sometimes think, well, I've got a policy, that's my order to give a vaccine. And we have to remind them that they're prescription medicines that are prescribed, and for the leaders, the nonmedical leaders, vaccines are different 'cause they see it as a readiness indicator, just something -- I got to get my troops through there to get them green so they're ready to deploy. And you have to sometimes slow them down and explain just because safe and effective doesn't mean that people can't get hurt. We have to educate them about exemptions. They

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don't understand that.

So it's always important when you talk about these big programs, especially mandatory vaccines, that you put in context vaccines are different.

Next slide, please. Since the last time that the Military Vaccine Agency has briefed the Board, we have gotten a new DoD directive that gives the Army the Executive Agency for Military Immunization Programs. This is something that's been kind of working for awhile, but this formalized it. Up until now, starting in 1998, the AVIP, the Anthrax Vaccine Immunization Program, was started. And then smallpox got added on, and then it was kind of all vaccines. This is the first document that really codifies it and gives the Army the executive agency. It also directs the Surgeon General to have a military vaccine office. And you can see some of the language from it.

Next slide. We also, since the last time we briefed the Board, have come up with a

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joint regulation. This is probably even more important to our people in the field, and it's a product of a lot of the work taking the recommendations from this Board through the years and the work of the different services putting it into one document.

This is the -- now we're starting to have standards of care for immunization. We've got things in there about adverse event reporting; we've got even as simple as, you know, you should prioritize your vaccines. Instead of giving 15 shots, as the guys getting on the plane, take the first five and prioritize them. These are recommendations that have come from the Board and, like I said, though a lot of hard work have been put into a regulation.

All the members have this regulation after the briefing slides in your book there. This is a great effort upon a lot of very smart people.

Next slide. Taking the two different documents I just mentioned, it kind of boils down

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to these simple four bullets for our mission. We do not develop this service policy or execute the service policy. That's really up to the services, and each of them have a different flavor, but we try to help at least coordinate that to make sure that they're as close as possible, especially as we fight in a joint environment.

We also, like I said, are out there promoting quality immunization delivery, and that's a challenge when you look at the different cultures of the services and working through that.

And the last one, of course, enhancing the scientific understanding of vaccines is something we should never stop doing. Even though we use FDA approved and licensed vaccines, we owe it to our service members to continue that total understanding of the vaccines throughout the life cycle that we use them.

Next slide. To help us facilitate this mission, we've got regional analysts at 17 different locations around the world. These are one individual at each locations, a contractor.

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Many of them are retired military and not senior officers. These are the people that were immunizers and people working with health care that are back there in those environments.

And it's really reassuring when you go into these different commands and the general officer in charge of that poster division or whatever says, "You know, this is a key member of my staff, a key advisor." That lets us know that we're getting in there, that we're assessing the readiness, helping them make sure they understand the regulations.

Next slide. This slide shows the overseas locations looking at Hawaii, over in Germany, Korea, and Okinawa. And also we have an analyst that sits down in Tampa that focuses on the Central Command.

Next slide. Of course, the anthrax program is, like I said, where we started back in 1998. We have a anthrax website dedicated to specific knowledge on the anthrax program. We have one for the smallpox, and then I'll show you

a little bit later a vaccines in general one, which kind of encompasses both of these. But these are really specific to the different diseases.

Next slide. As this Board fully knows, that while our program started in '98, and through shortages of vaccines and changes in policy we have gone through a yo-yo effect. We had an injunction, we had an emergency use authorization, and for any large program like this that yo-yo effect is very disruptive. It's hard to execute. You lose confidence in programs, and so when the FDA issued the final rule and final order in December '05, the Department of Defense senior leadership went through a thorough review of the anthrax program and the smallpox program. And then on October 2006, the Deputy Secretary of Defense announced our new policy.

For the board members, the new policy that is in place -- Dr. Winkenwerder signed those service plans in February -- is that people in highest risk, primarily U.S. Central Command in

Korea. It is mandatory vaccinations, anthrax vaccinations for those populations plus some other forward deployed naval forces and other units that have a biodefense mission.

That's the mandatory groups. It's voluntary for family members that are over in those four deployed areas. Also for anybody who's ever received one shot or more since 1998, they can come back and continue the series voluntarily. And that is just to try to keep with that FDA a schedule that we're not forcing someone to start and not allowing them to continue their series.

The contractors and civilians, if they are emergency essential or the different criteria, they might be in that mandatory or voluntary population.

Any questions on the new policy or the policy that's in effect right now? I'd happily address them now, or also at the end.

Okay, next slide, please. To date with the anthrax program, the Department of Defense has given over six million doses to 1.5 million

people. One of the challenges in the past was that we ran into a shortage of the vaccine. That is not the case right now. Because of the slowdown, we've been stockpiling, and so we have an adequate surplus of that. Sometimes getting that vaccine over to the 10th that delivers it in Afghanistan is difficult, but, luckily, we have a backup supply to accomplish that.

The studies and research on this vaccine continue. Of course, we have got 26 published studies, and the different independent panels have reviewed it, plus there are still many ongoing studies, one that's been publicized by different news agencies lately at the Vaccine Health Care Center. There's also, I think there's about eight of them going on at USAM Road with Dr. Pittman up there. The last bullet there I want to highlight is that we have been -- something that's been recommended by this Board that's been ongoing is that CDC study for the dose reduction and the route change. As far as we understand it now, that all the data was completed. It went to the FDA one

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time and is back. It cleared it up between within the next three months -- three to four months -- that there will be an FDA approval for a change from a six-dose series down to a five-dose series, and also probably more important, at least from my standpoint, is that it'll change it from subcutaneous to IM. I think all the studies show that that reduces that 60 percent local, you know, adverse events for females and 30 percent for males to a very small number.

Next slide, please. I can mention smallpox started in 2002.

Next slide. And we have screened over 1.2 million folks and vaccinated just over 1.1 million people. I think those two numbers are important. Also, 'cause it shows that 100,000 people have been screen out of vaccination. If that number was very small, I'd be very concerned, though the board members know the profile of this vaccine. And so a large number there at least reassures me that they're doing a good job. There is screening going on, as I'll get to a little bit

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later. I think it's something we have to continuously try to improve.

Eighty percent of these people, this was their first smallpox vaccination. Eighty-nine percent have been male -- That we have had our first -- at least the Department of Defense knows about our first acknowledged and recorded case of eczema vicinetum. Of course, this was reported in the news, the two-year-old in Chicago. And I've got two other slides coming up on that I'd like to address at least some of our lessons learned from that in a time line.

You can also see six big treatments. Six people have received big treatments and are contract transfers that we're aware of. We know this is a much higher number, but 58, and primarily that's, I think a bandage coming off of, you know, in bed with a spouse or Marines playing basketball and stuff.

The probably more important one that concerns me the most is the myocarditis. We have got 137 cases, and continuing to look at that.

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Dr. Engler will be following me from the Vaccine Health Care Center, and this is something we jointly work on and are very concerned about. She's got some good research on that.

Next slide, please. That case of the eczema vicinetum was reported to the Vaccine Health Care Center on the same day that we got the CDC involved. I think the actual phone call came because of one of the educational brochures that DoD gave the service member.

You haven't probably seen that in the news, but also the mother had a less severe case of contact transfer.

You can see her cheek there. The child had a history of atopic dermatitis, and as I'll get to in a moment, the father also had reported that he had had dermatitis previously, although it had resolved. He had gone through a Army Soldier Readiness Center and prepared for, in part, preparation for deployment.

Then there was a delay in his deployment, so he was able to go home for four

days in February. You can see that time line. The 26th of January is when he received his vaccination, and 21 days later he was home with the family. He reported that he had received the briefing -- we have a standardized briefings -- he had received his trifolds. He had kept his scab covered, and it had fallen off.

The child developed lesions on the 24th of February, hospital admission, and then the continuation of that. The child is out of the hospital doing very well, you know, the different -- the dermatitis, or I mean looking at the skin but as far as the child doing very well.

Next slide. So of our lessons learned, the screening is important. They did use our standardized screening form, and the father did, you know, put on there -- you can see the top one, "Have You Ever Had Eczema" -- that he had. The physician at the site made the call that, well, it was resolved, it was in the history, we can go ahead with the vaccination, and signed off on that. That is not in accordance with all of our

guidance that we have put out.

So that continuing education of physicians is my first point.

Yes, Dr. Garder?

DR. GARDNER: There's a question there, did the contacts, the 16th to the 20th, those contacts between the 16th and the 20th and the child already has lesions on the 24th of February. That's a short incubation period, is it not, for eczema vicinetum, four to eight days? Is that okay?

MS. EMBREY: This child had, actually, active symptomatic eczema, and so, you know, in terms of besides the intrinsic skin deficit that we already know even in intact skin, the skin was open and I don't think it's at all unexpected that it could rapidly spread, because within three to four days you can see a take in terms of the range. And so again, giving the underlying severity of his eczema --

DR. GARDNER: Okay.

MS. EMBREY: It is not at all

surprising.

DR. GARDNER: Thank you.

COL. ANDERSON: I think they were reported as weeping lesions just. So that education of the providers is important.

What we have found is we had a great program up front. You know, there was a huge, after training all these people, all, you know, mandatory going through the different slides, and we got the education materials for them on line preparation. But as you get providers that come in and out of there -- they come in for 90 days and leave -- that that process sometimes diminishes. So we have to continue working that.

The other is that education of the service member is vital. We've got a -- I've given you our different trifolds that we put out, but we're now going back into a thorough review of exactly what we put in there. You know, in the past I think everybody had accepted that once your lesion fell off, that's kind of the standard time when you don't have to worry as much anymore. I

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think we're looking favorably at going back to something like 30 days. Try to keep your site covered 30 days even after the scab falls off. But it's an interactive between the Vaccine Health Care Center, ourselves, CDC's involved volunteering services as well.

The Vaccine Health Care Center is just -- you know, we cannot tell enough people about the great services they provide. If every physician and every service member that got a vaccination knew that they were there if they ever needed them, I think we would have a lot less problems, we could have a lot less issues in the press, we would have less court martials, everything else that goes with it. And so it's our effort to advertise them, to promote them. Every trifold that we give our service members has contact information on there as well as the DoD 24-hour Clinical Call Center which would put people in touch with them.

And the last one is that in interagency cooperation, sometimes you have to express

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operational concerns. Some of the people that we're trying to help said, well, why don't we just vaccinate, smallpox vaccinate everybody, just as they get on the plane and go in, you know, overseas so that we don't have any of these contact transfers? You know, then you have to explain to them that we are also concerned about myocarditis, and you would rather identify those issues and treat those in the States rather than a guy sitting in a tent or hauling, you know, heavy stuff around. Also, we would like to limit the number of big open wounds over in a sandy environment.

So those are just concerns and lessons learned that we found going through this case.

Next slide, please. Our seasonal influenza vaccine had a very successful year this year, I would say, about 83 percent across the board, different services at different rates. One thing that's really important here is that we have installations that are starting to practice mass vaccinations with their routine seasonal flue

drives in preparation for a pandemic. And so they have -- today's this big da, line everybody up, use the system that they would use for a pandemic vaccination and then take away the lessons learned and have people that are trained. I think that's very important, and that's something that we have emphasized.

The other one is, you know, just for the board members, I'd like to remind them that this vaccine is a little bit different because DoD does a central purchase. It's not just, you know, first, you know, whatever you buy from your prime vendor. It is a central purchase that comes in.

What then happens is we prioritize and say the people over fighting the war have our top priority.

The manufacturers give us the vaccine about the same rate as civilian communities, so our retirees then start getting vaccinated about Decemberish, November- Decemberish, and it causes this concern that there's a shortage, that, you know, our retirees have less priority. And

really, that's not the case; it's just the fact that DoD gets it about the same rate as the civilian community, because we are such a small piece of that.

The other thing that we have found is that with the two different vaccines, with flu mist, DoD gets top priority, so we have been receiving that as early as August. And then when you've got August to a December time frame, it creates a confusion about, you know, is there a shortage now because I can't get mine till December if I'm older than 49? It's just issues that we work out at the unit levels, and it takes some challenges.

The last one is the flu mist. Of course, this year is going to be a refrigerated version for storage, which will be operationally much easier for the Department of Defense to use overseas. In the past we did not ship it over there when you had to keep it frozen, so that will be of assistance to us as well.

Next slide. I had mentioned that our

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other website is of vaccines.dotmil. We track how many people come in here. About 1600 unique visitors per day. We can see where they come from, what type of -- if it's military or civilian. We get a lot of bleed- over from CDC. We can also watch where they go, you know, to target our information and make sure that if something's not being viewed that it's not taking up valuable space.

Our crossword puzzle does get viewed and used. That one's on anthrax. What you do is the tab's on the left, and almost every one of our policies is involved in this as well as the AFEB, you know, minutes from the past. It is a great -- and we get very few freedom of information requests just because there's so much open and available there.

Next slide, please. For every -- I think I have to really put my mouth up here, okay. There's, I think, about 32 different diseases. Every one of those has got policies, news, clinical information.

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DR. HALPERIN: They're adjusting for you up there, so just go ahead and hold them into--

COL ANDERSON: Random person, okay. So for every one of those, there's all the information. There's policies, there's information papers, the vaccine information statement, package inserts, all of the information tailored for each one of those. It's been a great site.

Next slide. Also for every one of those diseases, every one of the service policies across the board, those little red X's are hypolinks. So when the people in the field do not know, they can just -- we tell them go to the site, they can get it. Also, you know, 'cause some of these vaccines are regional. Some of these are by service. They're broken down by different tabs there.

Next slide. We also have the recommendations, you know, the guidance. That's pretty standard. You can see by the different co-coms at the top, some for Europe or Korea.

Next slide. And then the next thing I

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want to talk about is Immunization University. This is a collaboration, I believe, the last time that Dr. Gravenstein was here and briefed the Board that we were just starting to bring this together, and it really is the educational drive, taking a lot of great products that have been developed by the Vaccine Health Care Center, CDC, all the different universities trying to bring those under one umbrella so that our service members can go to a site and pickett. A lot of this is online training, a lot of this is things they can download or just even to request us to come in and train.

To highlight a couple is the clinic quality of improvement program. It's a self-assessment that a clinic can say, you know, do you have the vaccine information statements? They can assess themselves, and if they don't, here's where you download them, here's the requirement that says you have to have them.

And it's really kind of as we go up there, it helps them work through it. The biggest

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challenge has been getting the different services to understand we're not going to go up and report individually and badmouth people. It really is an improvement tool. We take away the lessons learned to go back and educate people.

The other one up there is -- that I wanted to highlight -- was the policies, the standard operating procedures. We find the best ones, we post them, say go in there. If you don't have an SOP, go in there, cut and past your name into it. We've got the Air Force ones, the other services, so that they're specific. It's been a very, very good service.

Next slide. Project immunity and readiness, something that was developed at the vaccine health care centers available through there. This is online training where they can get up to 50 hours of continuing education credits. We have recently -- we're going into the process of actually making these into paper copies, and now so the people deploy that don't have access can do almost like a correspondence course

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tailored at these individual trainings.

We will also do one on that new joint regulation to train them what's involved with that joint regulation, what the DoD standards are, no just about the different diseases.

And vaccine storage and handling, that's a big issue for the Department of Defense that we work on. We lose a lo of vaccine at different sites or through handling, and so we're out there training them with the best procedures. The folks at Fort Detrick are involved with that, and it's a continuous effort when you've got so many people around the world of course.

On that same issue, I wanted to -- one thing I blew over when I was talking about anthrax was one of the requirements of that new policy was to still maintain a registry. When we were under that emergency use authorization, each clinic that was going to give the vaccine had to register and have an agreement signed by us, and this was to control it. Only the vaccine would go to people that understand the policy.

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We have kept that alive, and currently we have 801 different clinics, or ships, or tents that, you know, the Italian aid stations around the world that are giving that vaccine.

And that's a huge challenge, it's a huge paper burden, but it really provides you that quality of reaching out and making sure that there's one standardization. If there was ever a change in the program, we could rapidly go out and touch those. We know that every month they do a monthly report to us, and if everybody that was voluntary -- you got to volunteer if everybody that was mandatory got it mandatory. So we know that the mail addresses are current. We update it when new officers and charge come in there, so at least we have a working list. But it's a huge burden getting 801 different clinics, you know, people in Iraq, Afghanistan, fighting the war to submit that.

Next slide, please. This is just a screen shot of that clinic quality improvement tool. Our analysts go into a site and work them,

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come back and later check to see how a site is doing.

Next slide, please. We do have live training. Two of the things that in the past I think our board members are familiar with our immunization leaders course. It started off in '98 as the spokesperson training when we were talking risk communication. We still incorporate risk communication in the three-day course, but we do have that cold chain storage. We've got, you know, adverse event reporting systems, all the different parts of getting as quality program and a real clinical focus on anthrax and smallpox.

To date, we've have over 2003 people go through that course. The next one is that immunization basic course. One thing we've found was -- at least I'll say for the Army -- our medics were trained very good injection technique, how to give a shot, but they really did not have the opportunity to learn the screening, who shouldn't be vaccinated or how to fill up the adverse event reporting systems. You know, but

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all the parts of a quality program were lacking in that training.

So Captain Chris, who's a reservist, was one of the key people in putting that together. Today we've given over 900 people training in this last year.

On that, it's just a huge program. It's a one-day course. We go into an insulation, it's free of charge to the commander. We train 60, 70 people at a time, they get a little technique, but it's just a real true benefit, and I thank Captain Chris for her efforts on that.

The last one is, like I said, that regional analyst provides on-site training. They go out to ships, they give briefings, they work with electronic tracking systems teaching people -- they're just priceless out there, worth their weight in gold.

Next slide. A couple of issues I want to talk about. One is a recommendation that was from the Board here back in 2004 that the services do immunity screening at our session sites. The

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Air Force program has been in place for awhile now. The Army has just started. We, in November '05 started that, and you can see our basic training sites where that's going in. We're estimating, at least from the Army standpoint, but by FY-011 there will be a \$40 million savings in that.

The Navy is looking at the business plan and working through the program as well, but that is just a great program once it's running. Once you convince the local people that they can make it work, that they change their business practices of getting the person on the first day and the labs get back electronically, working out all those key parts, the board members I'm sure realize, less shots, only people that need it get it, and you get a better, actually record of what people have received when you have that kind of a screening.

Next slide. The military vaccine monitoring system, this is something that I have recently briefed the Pandemic Preparation

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Subcommittee on. And this is something we've put in place. It was used for the smallpox, and then we've adapted it to influenza, but it's something we're putting in our pocket developing for a pandemic vaccine, and it's an online, self-reporting 14-day kind of a passive system. But through a phone system or through internet people can register, come in and report their adverse events.

But one of the key values of this is that at any time if they say I would like a health care provider to contact me, they just click a button, we get their information, and it's someone not coming into the clinic with a question, or, "I'm feeling sick."

We also can have our clinicians that are responsible for areas, set up different alerts based upon whatever parameters they set and so they get an email text message. So we continue to refine it and make it more, you know, tailored towards a pandemic, but we're also looking at redundant systems because the subcommittee did --

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was of concern that if we just had it on one web server and that web went down, then what?

Or if you don't have it on the phone, people without computers couldn't access it.

Next slide. In November of this last year, the Force Health Protection Committee proved the concept of realigning the Vaccine Health Care Center network with the Military Vaccine Agency. There is the GAO report or group investigating that right now, and they will give the back brief, or out-brief next Friday, the 11th of May. So we're interested to see what they say.

There are a lot of great advantages to this, and I think we've already expressed that through Dr. Engler's group and our group, and, you know, our education materials in the past have been very tied, but now we're just better. All the people know -- my regional analysts in the field can go out and advertise the VHCs. They can be feeders into this, and so there's -- we're experiencing the benefits of it.

My personal concern is that we have to

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make sure that people don't have the perception that the same people who make a policy or develop a policy to mandatory vaccinate you are also the people that are going to treat you or say that you're ill or not. You know, that's a perception issue that we will continue to, you know, be faced with but we have identified and will work through.

Next slide, please. And then this is a laundry list of some of the different efforts that I think are important to the DoD as we do our immunization programs, continuing to make sure that those, every vaccinator in the field is best prepared making sure every shot is well documented, is the best that they can give. Changing the leadership culture about exemptions. I highlighted that a little bit earlier, but we still have line leaders that think the only way I am a good leader is if every one of my people is vaccinated. They don't understand some people shouldn't be vaccinated, and giving an exemption is no a failure of leadership.

So that's a challenge. When I go out

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and talk to these commands, that's something I emphasize with them all the time that exemptions are important; it's not a failure of leadership on their part.

We've got, like I said, the Vaccine Health Care Center. We're still working to educate people about their presence and about their services that they provide. And then with the new smallpox vaccine coming on board, ACAM 2000, we will have a surveillance program that will be very tough, will be challenging because the people who were using that vaccine are the ones that are deploying, but looking at a large surveillance plan for that. And I think it's looking, if everything's on track, that vaccine could be licensed by this December.

And then the last one is improving our standardizing immunization tracking and reporting. Oh, one of the recommendations of this Board in the past has been that we need a joint tracking system, and that is somewhere where we are not. Each of the services still has their own tracking

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systems, and it's getting better. There's ALTA for the theater that, for those deployed, that could improve it, but we are constantly concerned about this and keep working with them and the different systems and how that we're finding they're getting better and better all the time. So we will continue to work on the Board's recommendation for that.

Next slide. You can read these yourselves. You know, the threat, however you interpret it, continues, and risk communication is important. We continue to be in the press. The anthrax vaccine continues, the same stories come up, and CBS News a couple weeks ago, it was brought up again, and up-to-date vaccinations are away for combat multipliers.

Next slide. I would happily take any of your questions. I would like to remind folks if you don't know, NOVACS is really four officers. And like I said, a network of contractors. So Colonel Ford and Colonel Boushene, and Captain Chris -- great people.

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(Applause)

DR. CLEMENTS: So I guess I would like to ask a question about the anthrax vaccine. And that is -- you talk about transition plans for the smallpox vaccine to ACAM, but what about transition plans from AVA to RPA? Is that in the pipeline?

COL. ANDERSON: Yes, sir.

DR. CLEMENTS: It's a two-part question, so --

COL. ANDERSON: For the first, it isn't in the plan. We, I guess from a surveillance standpoint, we think a longer transition would be better. That might not be up to us if the current manufacturer pulls their license. So, I mean, there are joint vaccine acquisition program people are trying to, you know, make sure that we have it as long as possible, that we have the capability. But we're in the planning phase of that. Colonel Ford's involved with that. Do you have a concern specific to it?

DR. CLEMENTS: Well, the second part,

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it has become, recently become, it's fairly common knowledge that there are natural isolates with bacillosin thoraces that you cannot protect against with RPA. And so in any sort of terror situation unless they just happen to pick AIMS, or something we conveniently work with, they're probably going to pick an environmental isolate. So that opens up the possibility of a window of susceptibility, because it will be a while before additional antigens like capsule or spore antigens come on by. And so I'm just curious about in your planning if you're thinking into that scenario so we don't create a cylindo of vulnerability as we transition from one vaccine to another.

COL ANDERSON: Right. I think you're touching on multiple different organizations, agencies.

But overall, I mean, of course, vaccines are just a piece of our protection that we provide people, and we will use the best one that comes along. And I think, based upon our history and everything, especially for a large program, we

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would want an FDA approval.

And so the short of that, there aren't a lot of other options to us. I mean, I don't know how else to address that. We would like something with a better cross protection or a different profile, but -- yes, sir?

Did I answer your question, or did I allude it or --

DR. CLEMENTS: We're in sort of a headlong rush to RPA as an alternative to AVA, and I understand the manufacturer is involved. I'm just not convinced that the science is going to tell us that we're going to get the same level of protection with RPA that we get with AVA. And from a vaccine point of view, I don't know what you're -- how the vaccinologists are thinking about that as we move forward. They're not the same product. They have different profiles.

COL. ANDERSON: Right.

DR. CLEMENTS: And are we committed to going to RPA? Is that something -- is that a fait accompli?

COL. ANDERSON: I would say that we're not committed. I don't -- Colonel Ross, do you want to --

COL ROSS: Yes, there's certainly been a slip on the development and ultimately procurement of the RPA vaccine, but it's still -- there is still a number of efforts both within DHHS and DOD to develop the vaccine. The intention is when that they -- to do a down select on a number of candidates when they are ready for development and on track for FDA licensure.

Part of the development and testing process, of course, involves a lot of testing, a lot of animal testing, a lot of data generation in humans for safety to determine the exact profile of the vaccine. But ultimately the best product will be selected, developed and licensed, and as Colonel Anderson pointed out, the overall treatment protocol is deoxidation in conjunction with the antibiotics.

In terms of the strains that you alluded to that are resistant to immunization -- and we

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haven't -- we really have not tested to date with the antibiotics resistance, so we haven't found any strains that have been resistant to our current overall treatment protocol. But, of course, there's always a potential for that, potential for that to develop. It has not been a clinical issue at this point in time.

DR. HALPERIN: There was a question down here.

COL ANDERSON: Yes?

DR. KAPLAN: Just to -- oh, Ed Kaplan -- just an editorial comment, and that is that I was, if I understood you correctly, that throughout your comments there still seems to be some significant differences among the services in how they approach some of these issues.

For example, you mentioned that Navy is still in consideration with the excession screening program and so forth. This seems to be a recurring theme for the Board that everybody does things a little bit different. Did I misunderstand?

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COL ANDERSON: I would say that I think we have our unique service culture still, but I think the projectory is more and more towards the joint, towards the standardized, everything that way. We're just not at the final gates yet.

Yes, ma'am?

MS. EMBREY: Could you elaborate a little bit on the status of the research and the progress towards moving to on the AVA reduce number of doses required for immunity?

COL ANDERSON: Right. So I highlighted. The first step was that, going from six doses down to five, and we believe that's in the process and, hopefully, will be approved within the next three months.

Dr. Pittman up at USAMRID I think would be a great person to bring in and get a deeper appreciation of his studies. But the ongoing studies of the reduction are still in place, still very important.

One of the things he published, last fall I believe, in vaccines, but that we've in the

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past known that the third dose brings you about, you know, one of the -- to the higher levels of protection. But there is a more rapid decay. He truly believes that the fourth dose is the one that locks you in into a longer sustainment. So it seems that there is that benefit up through that fourth dose. We've got his different research protocols, but I don't know exactly when there will be the science coming out. I know also the manufacturer of AVA is still involved and very energetic about reducing the number of doses.

And, of course, operationally, we would love that. That's a hard program to continue.

DR. LEDNAR: I have a question of clinical documentation. As vaccines are given or as exemptions are understood and clinically documented, since so much of the Force is in the Reserve and the Guard, and after an activated tour, they may return to the Guard and Reserve to have access to that information, and if there are any additional vaccinations given or exemptions applied, that that gets into a record that become

available should they get well downstream while their return to the Guard and Reserve have access to that information. And if there are any additional vaccinations given or exemptions applied that that gets into a record that becomes available should they get redeployed.

COL ANDERSON: All right. I think that we -- you know, first of all it goes into a standard no matter what COMPO -- you know, if they're Reservist or active duty -- it does go into a standard database and those exemptions are reported in those. That doesn't of course mean that a civilian provider would have access to it but it is in that record so the next time -- typically we see that these people when they are activated and take these vaccinations are at a site that does have access into one of the central repositories. That's far from a perfect system.

You know, some of the benefits of it is that we do have some standard exemptions across the services so at least there is that standardized coding so everybody understands so

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that if a medical decline or a temporary exemption -- exactly what that means. Keeping it into that more permanent record is exactly where we're going with that electronic record and that applies to all the different services. It's -- a lot of times it's what they have available when they go back to their site, you know, what they can access it with is the limiting factor. Did I answer it?

DR. LEDNAR: Well, yes. Just a thought in the last part of what you mentioned about the resource capability back in their home Reserve and Guard units. Has there been an assessment of the adequacy in that in terms of clinically documenting --

COL ANDERSON: I'm probably not the person to give you the full spectrum of where we are and where we're going but going to a more web based applications is definitely helped that. In the past where you had to have a certain type of terminal that was logged in that is -- that was a limiting factor. Now more and more we have got web based services that go into that and so as

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long as they -- for example a National Guard armory has got a computer with access to the internet a lot of times they can have an account that can pull those up. It -- yes ma'am?

MS. EMBREY: The Guard and Reserve have a responsibility to maintain the medical records for any kind of care delivered while they're on active duty including immunizations that are received. We have -- unfortunately the Guard and Reserve because they did not have access to ALTA, our systems, have developed their own applications in order to capture this electronically. With the increased use of the National Guard and Reserve in OIF and OEF it has become painfully obvious that we need a way in which to bring that data into the repository.

We have an initiative ongoing to evaluate how to port that information into the CDR so it's available whenever they show up at any one of our locations. And because the CDR is the source of sharing data with the VA it provides a seamless ability to provide that to the VA as

well. But we're not there yet, so right now it's based on the unit's ability to capture and document that in the record, which is a standing requirement, and right now that's limited to the care provided in the immunizations provided while the individuals are on active duty. It does not include unfortunately care provided when they're not on active duty, when they're in their civilian mode. And since some significant health incidents occur not on active duty we don't have a complete picture of our Reservists' health and any other kinds of vulnerabilities that they might have. So we have quite a challenge with the Reserve community and we're working through with the Reserve components to identify a more holistic view of their health and their health records.

DR. HALPERIN: Mike Oxman.

DR. OXMAN: Further question and a comment.

Mike Oxman, on the board. The question is, is that question now is that record now available -- the active duty record of

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immunizations available to the VA, do we know?

MS. EMBREY: To the extent that it is reported to the CDR yes, but otherwise, no.

DR. OXMAN: And then a comment on the fellow who was immunized -- vaccinated against smallpox and carried -- presumably carried it home. There was not an exemption because he gave a history of a rash that was called eczema in childhood. But that's a very common misdiagnosis -- very commonly rashes in childhood are called eczema. And so I must say that I would not hesitate or I would vaccinate someone who simply had a non-recurrent phenomenon, which doesn't fit the picture of eczema even if it was labeled eczema. So I think that setting those criteria for people who are not expert is a challenge.

COL ANDERSON: It is a challenge and we don't want to take away the authority of that licensed physician at that site. But to the one point that could have been a general perspective as we put this program together is you have to take into consideration what the threat is, and if

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we have a tracking system that we know who has been exempted you can always protect those people or go back and vaccinate them. I think with smallpox we would rather err on the side of safety especially considering the number of cases of myocarditis and contact transfer.

The other thing, just to highlight back to the immunization tracking, one of the board recommendations was to have the Department of Defense to have a system or a process to go back and kind of surveil to see how the shots are getting into the common repository. And we are currently in the process -- our analysts actually are out there, they go into to every different type of site, they see a vaccination going on and they get the information, see what it's centered into, record the date and we go back and track to see how long it takes to get into the big repository and see what percentage rate. So it is an active process but it's actually intensive -- labor intensive but otherwise there's not an automated process that could do that.

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DR. HALPERIN: Thank you, Dr. Henderson,
and Dr. Englar is speaking next.

DR. ENGLER: It's a real pleasure to be
here before the board. I'm Renata Engler and it's
been a few years since I've been here. I had the
privilege in 1998 to be a part of the subcommittee
that worked on the AFEB report of vaccines in the
military. And within that report is actually a
chapter that Greg Poland and I worked on about at
the time of deficiencies and the qualities of
immunization health care in the military system to
face the 21st century challenges of complex
immunizations. And I think Colonel Anderson's
excellent and eloquent presentation has laid out a
progress from that time that addressed how to
improve the standard and the quality of
immunization health care to provide resources to
our system to meet a challenge that -- when I was
last week at the CDC I reminded them at the CWSD
meeting that our population of 2.4 million active
duty service members and Reserve -- next slide
please -- basically receives as an adult

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population receives the most complex mixtures of vaccines of anyone. And this is from the museum at Walter Reed, needless to say World War II immunization delivery and the complexity and challenges of immunization health care in today's world and with dozens of vaccines potentially in the future is a very different world.

Next slide. I wanted to start with this because back at the start of our journey -- I'm an allergist, an immunologist and an internist so usually not a member of this kind of activity. I'm a clinician and with 32 years of active duty service the Walter Reed Center has a 30-year history of a school training medics. It's the designator school for the Air Force and the Army designator has just been brought back a few years ago for specialty training with medics. So I'm from the user end and I'm here to speak about what really happens to patients and the struggles that clinicians have to meet this mission and the work we've done to make that process better and that's what the vaccines health care center network

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represents.

But if you look at the numbers on this side as an expert in adverse drug reaction management, in general, any drug you give to a population you're going to have one to two percent of people who have side effects that are more severe, idiosyncratic reactions or problems where either the patient, vaccinee or the provider or the advocate of that particular individual is concerned about the safety of continuing the drug. And that's across the board the experience. And I think the 21st century and the recent IOM report about life cycled drug safety surveillance that it is that period where you start to learn and deal with the fact that human beings are not one size fits all and clinical care is dealing with patients who didn't read the book right and evolving medicine in response to the individual challenges that patients present.

And then in the context of the vaccine world we have the additional challenge of trying to address individual causality assessments in the

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World Health Organization and many others recognize that this is really a new set of skills. Bob Chen at the CDC several years ago felt vaccine safety, clinical immunology and the assessment of patients was really a new specialty in medicine. It crosses many traditional specialty lines. And so for the service members alone we have multiple vaccines, we have vaccines mixed with drugs and (off mike) prophylaxis, and I can tell you just in an inpatient mission, an ICU patient when you're dealing with somebody who has 10 drugs, you know how to sort out, what may be the cause of the problem, is it (off mike) or unrelated and what is the best strategy in the context of benefit risk for protection and these are not simple questions and the literature is remarkably deplete for evidence based support of clinical guidelines for that decision making and is largely still an art in medicine and in areas like allergies and immunology.

And for service members we have the additional challenge of disability clarification.

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If there is a question of a complex case with an adverse event that evolves into long term chronic clinical symptoms or illness and how to best address that. And in past years we became involved also for Reservists because if they had their medical problems as an adverse event it was after the weekend that they drilled and then access to care became a question so all of a sudden the pressure of causality assessment and is the person covered or not achieved a significant escalation and challenge.

Next slide. And so, you know, in the context of the anthrax program which came on board as a program of six doses in 18 months. For an immunologist that's a hyperimmunizing schedule and the rules changed. I can tell you, 10, 15 years ago if I exempted someone from their third hepatitis B because they were a high responder, didn't need that third dose no one cared; we wrote it in the chart and life went on. So the rules in our system dramatically changed with the Anthrax program and consequently those individuals who had

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issues and clinical symptoms that were more greater concern suddenly didn't have an outward place to go.

So I think people have asked me, well what changed; why were these new challenges and I think we understand very well and have learned a lot over the last five years. So we have a more -- a very complex immunization exposure in this mandatory setting and I can tell you at the beginning of that program exemptions although they were in the Joint Regs most people didn't know about them. At one point I was told that I was the only physician in the North Atlantic region who could issue a medical exemption. We quickly made forms to assist people to understand the definitions and to push that responsibility out.

And again, if you look in the literature for clinical guidelines for how to do exemptions, it's not there. So we actually made some of that up based on allergy experience with allergen immunotherapy with other drugs and again some of that still begs further validation in the context

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of good science and evidence based. And we made generic guidelines to assist so individuals were not coerced to get an next dose if they have a problem.

And it became very clear at the beginning of the program that there were thousands of people who had questions and how do you build a resource to support nationally and globally the questions that arise out of these programs because I'm sure you're all familiar, the devil is in the details and if we're going to leave no service member behind who may not have read the book, who is didn't fit the one size fits all. We had to have consultation services for folks who hadn't been training in the front lines about this or what the standards were in regards to benefit risk analysis and causality and alternative therapies.

And around this time I also had the privilege of being a part of the National Vaccine Advisory Committee as a DOD ex-officio representative and we took to heart those minimum standards for quality immunizations in

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non-traditional sites that were published in the MMWR in March of 2000 and everything that Colonel Anderson so eloquently presented you see is a building to do an infrastructure and to provide the resources to meet those minimum standards. But I would caution you that they were designed for flu and pneumonia only not for the degree of complexity of immunizations we currently deliver.

But it's a place to start and I think I speak for Colonel Anderson and all the folks in my shop that we are very proud of the progress that we've made to reaching those standards and supporting them.

Next slide. I wanted to just mention the issue of trust and vaccines because the complexity of clinical risk communication in our environment is really -- it is also a new area of expertise a learn incur. Someone like me with over 30 years of expertise and every week we are presented with questions and challenges surrounded with patient management that are not easy for me either and bringing people with a lot of expertise

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together to brainstorm how should this question be addressed, what do we know in the literature what don't we, this is tip of the spear front line medicine.

One of my good colleagues in rheumatology, George Sokus, who just retired and is going to Harvard and who we've used as an expert consultant to review cases said, You're where rheumatology was 50 years ago. You're just trying to figure out the case definitions that then can be used to potentially do research because rare adverse events do not lend themselves as readily to epidemiologic analysis because frequently the coding may not even fit.

So if we're going to build trust in what we represent and stand for and we're grateful that we have been preserved by the decision at the end of last year is an effort to tackle that problem, to manage service members case by case remotely worldwide, partnering with on the ground clinicians who may be struggling with questions and to capture the information we learn patient by

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patient in a registry process, and I'll mention some of the resources that we have built web based including retaining exemption evaluations so that somebody can contact us and get that wherever they go whenever they go.

So -- but again we also knew smallpox was coming and that if anthrax was a challenge smallpox was going to be a greater challenge so the Vaccine Health Care Center network as it evolved itself, you know, prepared for that, anticipated and we took a lot of the lessons learned from the anthrax vaccine program and applied it to smallpox by developing tools, training initiatives before the vaccine program was launched.

We anticipated for certain things like myopericarditis and I'm very proud of that fact. We put chest pain on the diary where the CDC did not because they felt it was just due to the Lister String. And again, in our population people have chest pain, they're young, healthy, they jump out of airplanes, the initial response

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of the primary care world's going to be take some Motrin, you've done too many pushups, march on.

So changing the culture and raising awareness so that we are able to detect the problems is really not a minor challenge and I think we've made major progress. And overall, what we've tried to build in the context of the VHC network is really a bookend to the military vaccine injury. The clinical bookend if you will, also an education component but very much integrated and not redundant to what existed in the Military Vaccine Agency. We do feel that the unification -- we can work very successfully and that we represent a strong response to the clinical concerns and to the unanswered questions in the diversity that exists in our population.

Next slide. This is at the present time our vision of how we've worked together and because I know time is short and I have perhaps less time than I thought I think you can look at this and see that we are continuing to work a plan to our working together while marinating some

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separateness because of the importance of our role as an advocate for the patient who has a problem and who needs assistance and needs a place they can come that is a place of trust and that is concerned take the time to fully understand the scenarios. And we are very proud also of working with anthrax refusals to work to solutions that do not result in the loss of a precious service member or a newspaper article but rather our win-wins. We are people who work towards win-wins and we are very proud of that.

Next slide. I think we have a huge challenge because the vaccines are a part of the employment requirement. And one of the things that we put in the Joint Regs Division is something that's not widely known. Since last summer I have lectured personally to over 600 health care workers. Less than one percent knew anything about the vaccine injury compensation program; less than one percent knew that our service members if they had Guillain-Barre after an influenza vaccine technically had their

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families could go to the vaccine injury compensation program.

Now the question is who does the evaluations and the documentation, which is time consuming, and our poor primary care folks at 15 minutes a hit for RBUs can't do that -- to really enable someone who might benefit from that program. And who has the competence to do the kind of work up that credibly addresses differential diagnosis and when it is potentially plausible or when it's not.

And again I would highlight the fact and I hope that at some point we can come back and share the many clinical questions that we have generated and that is that clinical immunology concerns about some of our vaccine mixtures because at the present time the pediatric experience -- I'm going to tell you as an immunologist -- children and their immune system -- adults are not big children and children are not little adults, they are different -- and the extrapolation of the mixtures of vaccines based on

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the pediatric experience has resulted in mixtures that have never been prospectively studied before. I'll give you the example of diphtheria tetanus, a cellular pertussis now at a two-year level.

Now imagine that in a hyperimmunized population with a subpopulation that we know may genetically be high responders and then you add smallpox vaccine which is a powerful TH1 antigen and what does that come out? And do -- are we potentially going to see certain issues that -- and how do we detect that?

So we have a long list in the last five years of clinical questions issues and concerns that we feel need to be addressed so that we can truly speak to the safety of the vaccine programs now and in the future. And again in those 700 plus providers that I have lectured since last summer in my effort to do outreach for culture change I have asked the question, How many of you have heard of thrombocytopenia after measles, mumps, rubella? Other than the people who had heard me talk before, 0.1% raised their hand and

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said they heard of it. That is a well-documented evidence based epidemiologically confirmed rare adverse event linked with MMR. Now it's only been studied in children so we don't even know whether it exists and at the medical school what really brought home to me the challenge we have in terms of culture education was the hematologist, oncologist, pediatric coming up to me and saying I'm embarrassed I couldn't raise my hand, I see people with thrombocytopenia all the time, I never take an immunization history.

So the truth is if you talk about other specialties and all their knowledge attitude beliefs survey done with CDC in 2004 again confirmed it, that our knowledge in the population both DOD and civilian in regards to theirs and recognition of adverse events is a mountain for quality improvement that deserves continued effort particularly in our system. And I think that that immunization adversity would work that Military Vaccine Agency has done and that we have done represents really something new and I think a

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national resource for the future.

Next slide. So you've already heard a lot about MIL VACs I'm going to just let you read this slide but I think one point I wanted to bring out is that we represent a VAERS quality improvement initiative. Everyone who's ever worked on reviewing VAERS can tell you that the quality of the information in VAERS makes it extremely difficult to make a causality assessment because rarely is there enough information.

And so I can tell you there are over 140 cases that have 300 pages of the information that's collected and it is painful and not easy, it's then distilled presented to a cardiology working group, matched to the epidemiologic case definition. We've done over 200 of those case evaluations, 141 meet either possible, probable or confirmed myopericarditis. I don't think in the history of rare adverse events has ever this kind of validated causality classified a large number of VAERS that then enabled the doing of the epidemiologic data to show that there's a clear

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causal relationship. This again represents something that we think benefits the entire country's vaccine safety surveillance process.

Next slide. I just want to mention in the context of the anthrax vaccine program something that people don't appreciate which is that the packages are changed from the one in the '90s to 2002 because of the clinical documentation on the ground that what was in the package about side effect rates and frequency was not what people were experiencing.

And so there is still a lot to learn about the anthrax vaccine and population diversity in terms of immune responses and adverse events and we have right now with the University of Oklahoma, John Harley, who is an molecular rheumatologist in the immunogenetic city to try to understand what we believe are new case definitions of rare but impacting in serious adverse events, and that work is in progress at the present time. And again, in terms of pregnancy we support the pregnancy registry

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process through our 24/7 call center with nurses that we've trained in a triage process to knowledgeable medical directors, we've built a HIPPA compliant Internet access email consultation service, which also is audited and reviewed. We're there if people know about us, really globally, for our service members, our health care workers and families as well.

Next slide. And I'm going to skip through this because you already have that information but at the vaccine safety surveillance meeting at NIH, which was an international meeting about what's the future, I think just like with drugs talking about life cycle vaccine safety surveillance and the need to have a process for evolving case definitions for more severe side effects. We work closely with the clinical organization safety assessment centers network, which was established by the Department of Defense -- or rather by the Center for Disease Control.

Next slide. And you've already heard about the smallpox vaccine, I just want to mention

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we're on version five of the clinical guidelines. We still get many calls from civilians who don't know about myopericarditis in smallpox who've labeled people with heart attacks, people we saved, people who would have been boarded with heart attacks inappropriately and again there's a lot of work going on in this regard, and I think highlights the fact that people thought they knew everything about a vaccine, an old vaccine, and here we are with far higher incidents than anyone expected.

Next slide. And I just want to mention that we are right now investigating a recurrence case spontaneously two years after recovery. We still do not know the natural history of his condition, although the majority of people appear to recover you have a number of abstracts that summarize some data that I provided to you and if you have questions please let me know.

Next slide. And I just want to mention that the tool kit that we provided although the web is wonderful the truth is that almost fifty

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percent don't like it and we had repeated requests that somebody needed something that they could spill coffee on put it in their pocket of their BTU uniform and if they didn't have time to go to the web. So again we have to listen to our customers; we don't just serve the patients we also serve those who serve the patients and they are a group that work extremely hard and really need support, and that the workload to do this mission correctly has not been recognized adequately either in the civilian world in terms of reimbursement and in terms of RBUs and I think there's some pressure to do that.

Next slide. And we've talked about quality improvement and some awareness issues and the partnership for education and, again, I would just say that web based information is not sufficient to evolve the culture to some of the new knowledge.

Next slide. Next slide. And the defense medical surveillance system you're all aware of but I just wanted to share that we are

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partnering with the vaccine safety data links and the CISA because there are some questions about perhaps different methodologies to try to study rare adverse events particularly where gender incidents are a factor, and there are just a number of issues that we feel deserve to be addressed in greater depth.

Next slide. These are just examples of the things through the call center, through ASVAC written inquiry reviews that we are struggling with and refining so that then a plan can be made for further study, and we don't have time to go into in today but just to kind of peak your interest and I'll be happy to do any additional sharing of information at a later date.

Next slide. These are just our current act of protocols. We do have a smallpox myopericarditis immunogenetics study with the molecular immunology department at the University of Washington. It's also a CISA collaboration and it is -- there's early data analysis that does identify some gene candidates that are risk

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factors. This does appear to be a Caucasian male disease predominantly, which is unusual in immunology and rheumatology. I think we're very proud of that study, it's been very difficult to do and we're just starting the anthrax immunogenetics study, and you see some of the others there and if we can answer questions there we'd be happy to.

Next slide. And we at the present time function as one network. We have one registry process for vaccine case management outcomes. We document all of our calls, our email consultation services in that system which is web based and allows our four sites at the present time Ft. Smith, Ft. Bragg, Wilford Hall, San Antonio, and Walter Reed. And with that platform of individuals we -- with medical directors and nurse practitioners we serve nationally and globally the demands as they arise.

Next slide. And just again for your reference, I meant to send this to you. Would call you attention if you search on WHO and

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adverse events following immunization causality assessment there are two-page sort of guidelines of what they see as needed to better understand rare adverse events. We have tried to follow this and utilize it in our case review process and I think we really represent an initiative exactly like the WHO has called for, and thank you for your time.

DR. HALPERIN: Thank you, Dr. Engler. A couple of questions. Yes.

DR. GARDNER: That was a great presentation.

DR. ENGLER: Thank you, sir.

DR. GARDNER: A couple of -- it seems to me the obvious we have a very uniform who gets immunized and we have a way to survey the adverse reactions. In a way it's better than VAERS, really, it validates it much more. And, really, I think the myocarditis story is certainly a classic in which the military can contribute to our understanding of a general problem.

A question for you -- the issue of

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Guillain-Barre following the conjugated meningococcal vaccine in adults was raised largely and I once inquired about that from what was happening and I believe it looked as though the military was not having the problem of Guillain-Barre that might have been anticipated and that would be again -- is that correct still, that we don't have an increased rate of Guillain-Barre --

DR. ENGLER: Right. In terms of -- and I know Colonel Anderson -- there are some people in the room who are monitoring in terms of doing the epidemiologic surveillance and as far as I understand that's true using the methodologies that have always been used but I would just say that at both the international meeting and the CDC meeting recently I think great question has been raised and the Canadian Guillain-Barre study with influenza vaccine used a self- controlled case study method as opposed to the methodologies that have been used which are confounded a great deal by a health warrior effect.

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So I -- we have some questions in terms of the approach based on our case reviews and are working right now as I've said with the VSDs and with some folks who are with this new methodology that may be better in rare adverse events when we know there are genetic risk factors potentially to look at is there slightly increased risk in a rare adverse event. Our feeling is there's some questions and we'd love to have a DOD civilian with a clinical brainstorming of case definitions. I think the experience of the VSDs where they look at the charts -- right now our case surveillance process uses ICD9 codes but there's not really any validation process in most of those. In less than forty percent, like if you take thrombocytopenia and the code of thrombocytopenia on the VSD sites was actually thrombocytopenia when they really did the review. So I don't know the answer at this point.

DR. GARDNER: Well, I guess I still believe that you need to shape up our system as best we can but it's still a better way -- it's

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the best way we can validate VAER reactions and this is a contribution that can benefit the world in general.

The other comment I wanted to make, I did just include my email the other day, but in our myopericarditis cases we need to follow those people for a very long period of time, I believe. I bring up the issue of post-polio syndrome where people look a year later like they're fully recovered but 20 years down the line their nervous system as it ages gives out. And it's not a far fetched scenario to worry it's still our folks who recovered could have some down the line consequences due to some scarring fibrosis or whatever that might influence their subsequent health.

So I'm going to make the plea -- and I know that funding has been difficult but this committee should be helping to foster and promote a longtime evaluation of people that have been identified. And I view this in the same way as our last meeting when we -- what do we owe our

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veterans who get injured in the line of duty and this is an injury -- an iatrogenic injury that we also need to make sure we provide long term care for.

DR. ENGLER: Well, I thank you for that. It is our passionate belief that it is necessary. Many of these service members leave because they appear well and they have no access to care afterwards. In fact we have a request in to health affairs to allow them to come back into our system so we can follow them and also enroll them in the protocol, which may be of help in the future. But what's particularly sobering is that the encompass data in terms of the incidents with three times the upper limits of normal lipotriponants is in the hundreds, one per hundreds. So if you remember what VAERS is supposed to be and anything we do here sort of passively ten percent at best. That means we have a larger population of service members who may have had this condition, it was dismissed, it wasn't evaluated, and what if -- it appears to be

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immune mediated, it's not the infection. Every piece of tissue we have, there's not vaccinia. There's eosinophils in the myocardium, which again is very atypical from other myocarditises.

So there's some clinical challenges that we would welcome and as we become part of MIL VACs in this next fiscal year I'm very grateful that we will have a subcommittee created under the DHB, we've got some clinical people we'd love to have potentially nominated to brainstorm about the really difficult questions we're wrestling with and what should be the long term plan. So thank you, and yes, we agree. We absolutely agree.

DR. HALPERIN: Thank you and the last question we will be able to take is from Dr. Shamoo.

DR. SHAMOO: I have a more rudimentary question. This maybe Colonel Anderson or yourself. I'm interested in the process -- if I'm a service man how do I hear about it, where do I go, how long is it going to take me and what do you do to me. Just that process, briefly.

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COL ANDERSON: I think it is a challenge to develop a process that gets out to every single individual and that is why especially with the anthrax and the smallpox vaccination we have put a lot of money, a lot of effort into having these standardized trifold cards that at least give you the numbers that talk about the different events, you know, the different services available. I really highly doubt those service members are cutting out that card and putting it in their wallet but they might take it home and put it somewhere, they might go back in the clinic and say, you know, I'm experiencing something can I get another one. But this is a big effort to do this, to make this get out into Iraq, you know, into the tents but that's one of our best outreaches.

The other is that, you know, that all of our different parts that we put out even policy letters, more and more we make sure that the vaccine health care centers services are put in there just as another reminder to our people in the field.

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DR. SHAMOO: So, my understanding is that there would be large numbers of servicemen who would get the vaccine -- they haven't really probably even read this.

COL ANDERSON: You know, we can't sit there and force them. We have standardized -- also briefings that are given to the individuals and to the leaders but what their retention is when they're also thinking about paying everything else is up to them. The key is making sure that we try to flood the environment with information so that it's close by to find it, it's not just one person in the DOD knows where it is.

DR. SHAMOO: If it is mandatory vaccination I can understand shortening the period but it is voluntary. I think there has to be some effort to inform the content of this brochure to servicemen -- what they are getting into.

DR. ENGLER: I think in a lot of sites now there's a standard for smallpox and anthrax -- a standardized slide set both for educating health care workers and a slideshow for service members.

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So in some of these processing sites, you know they'll go into an auditorium like this and they have an ongoing video of the material. So there've been a lot of attempts made -- and, again, remember that this is a huge pond and it is global and folks are I think, again, the progress is being made considering none of these things existed in 1998 is phenomenal.

DR. HALPERIN: Thank you, we have to move on at this point to Dr. Sjoberg is going to be talking about influenza surveillance.

MS. CANIS: Good morning, I'm Linda Canis. I'm actually working with Dr. Sjoberg. The DOD has had a very long history with influenza beginning with the vaccine -- first ones to have the vaccine in 1943 -- continuing to the Air Force surveillance in 1976 and now the (off mike) sponsored tri-service surveillance program that is becoming ever more robust.

Good to have slides. Next slide. I would point out that this is in two forms: The Air Force at AFIOH in San Antonio conducts

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sentinel based surveillance where we have sites around the world and the Navy in San Diego has population based with their eight recruit centers and eleven onboard ships. They contribute a great deal to this program. I'm not going to be going into that today; it's covered more fully in your notebooks.

Next slide. We do have considerable expansion efforts going on, we're always looking for those areas where we might be able to contribute in meeting with other people whether we they are continuing to be contacts that we could link up with if we need to.

One part besides the actual surveillance that we do there is the education aspect. We need people to know what is expected of them so educational materials have been developed that target the particular discipline that we need. So we're looking at giving them specific guidance for what is expected of them and information of where they can go to get their information so they are better able to fell this to their staff. The more

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buy-in we have from each group the more likely we are to get effective participation.

And this quick sheet that's provided gives them a very quick look at what is expected. And they can go down this list almost as a check list to see if they have done those individual steps that's needed and again guide them to where they can get more information.

And then the laboratory -- if they're going to know what to do we want to make sure they have all the supplies they need to carry this out. We're not expecting them to go out and get the cheapest biology transport media they can find; we're going to supply them with what we've already found to be the most effective. It's expensive to work up a viral sample so we want to make sure we are optimizing every opportunity to get what we need.

This includes shipping containers. This is probably the single hardest part of the program. We want to grow a virus so we need a viable sample and that requires very specific

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conditions. So those areas that do not have access to dry ice we have found containers that we're doing work with that will hold samples at a constant temperature for a number of days. And also then we're paying for that shipment, which of course always makes it a little easier for them. And this is in the context of our clinical laboratory where they're shipping samples in to us everyday.

Along with the supplies that we send out we make sure they have a questionnaire. This is available both online and with the supplies that we send to them. On one side we're asking for demographic information, travel histories, vaccination histories, those things that the epidemiologists need to put together what we get in the biology laboratory to be able to draw some conclusions. And then on the reverse side are instructions for collecting a nasal wash, which is the better sample in the laboratory than just a straight throat swab.

Besides this education then we are going

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to put all this together what we've provided, what we've isolated and then the epidemiologists are going to monitor what they receive.

LT COL SJOBERG: Lieutenant Colonel Sjoberg, for the reporter. And what we're looking at is two-pronged in this program. We have the laboratory portion and the epidemiological portion. And what we'd provide back to our sites -- military sites review some (off mike) surveillance through the essence program, however, what we've done is refined a look at the influenza-like illness and reported that back looking at trends over the past five years. We used it as a tool to be able to interact up closely with the sites to be able to let them know what is happening at their sites, increase that awareness and to also encourage the participation. We take a look at is what they're seeing out of the ordinary. Is it an outbreak looking at refined -- look at IOI and then provide a report to them to encourage them if this truly is an outbreak that they provide us samples and to be in

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that communication with them so that if they're seeing a large number we can provide them guidance on who to sample.

Our program looks at second surveillance with six to ten samples from each site weekly, however they're seeing a large number of IOI we ask them to focus in on those samples -- individuals that are more severely ill or hospitalized. We're trying to capture a virus -- to hunt for virus and to be able to have the best chance of isolating influenza from these samples to be able to identify if something out of the ordinary is occurring.

And also, too, to be able to interact with them weekly; to be able to see are they having any issues with shipping, are there any issues with information with the provider so that we can provide feedback to the whole gamut: The laboratory officer, the provider or the public health to be able to ensure success with the program.

Next, I'll turn it back over to Ms.

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Canis.

MS. CANIS: One of the things that I think truly helps this program and has made it successful is that it operates within the context of an existing clinical laboratory. We get samples from all over the world coming in to the Armed Forces Institute for Operational Health for clinical diagnosis. So it's very easy for them to throw in one throat swab that's been collected at Osan Air Force Base the day after collection that comes in with chlamydia samples and hepatitis and various others, so we get a more timely, cost effective way of getting these samples. And it is a high volume laboratory.

The other thing that helps us as far as growing a virus, and again, because it is a clinical laboratory existing under many different regulations, we -- for instance, the temperature of the box is taken as it comes in the door to make sure that it's within temperature limits for stability of that sample. So we're trying to limit the possibility of a false negative in our

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culture.

And we do various tests, where, you know, as more and more laboratories are going for rapid diagnosis, we're still looking for the virus. So we're trying to do many things to get a quick answer that there's something there, but then to go on and get that virus and be able to do more tests on it, send it to a molecular lab, and then share it with agencies like the CDC and the WHO that will continue to put this together in the context of what they see with other programs.

This is kind of a snapshot of this past season. The blue bars represent the samples that were received in the laboratory based on date of collection. Many of these are clinical samples that are coming in a day after a collection. But some of our more remote sites over in Thailand or South America, they may be a couple months old. So they're recorded by their date of collection, to get a snapshot of what was happening at that time. And then the lines give you a percent of the influenza. Overall, we've seen in our program

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this year about 27 percent of our samples were influenza, either A or B; that's probably a little higher than most. But we have a strict case definition that we stress, and we are looking for influenza, so we do fairly well on that.

We are, of course, operating with various other viruses that are -- we can isolate, but influenza is what we're looking for. Molecularly this year by sub-type, it was a very unusual year. It was one of the lighter years we've seen in some time, and it was later than most years.

It was quite, in the beginning, H-1, N-1 was almost exclusive, especially in the United States. One of the main benefits of our program is that, of course, it is global, and we do have access to that original sample. So about January we got a notice from CDC that any H-3's we had, to please send them to them as soon as we could, they needed them for analysis for the vaccine because there were so few in the United States.

Generally we send them an isolate that

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we have so they can look at it broadly and then they'll come back to us. If it's one of interest, then we can send the original sample that they can then look at as a possibility for a C virus for the vaccine. So it's another area that we have been working on developing is an archive, where we save an aliquot of that original sample that comes in, and then we also save any isolates that we have, and the RNA from the sample. That's a possibility for use down the road in examination of a particular influenza virus, maybe going back to look for other viruses, and also just being able to validate tests when you have samples that you can go back and use.

We know that this is a resource that we have. We're still working on how we're going to use it and who's going to have access to it.

MR. SJOBERG: Also, with our feedback to the sites, feeding back then also the result, clinical, of course, to be able to make determinations on care for the public health, it's a reportable event, so it's critical also to be

able to get that information back to the site so that the services can report that in their service specific reportable events systems.

Also, as Ms. CANIS had mentioned, we partner very closely with the Centers for Disease Control. Our information is included in the National Report, plus, the sharing of the isolates and the original samples to be able to make vaccine decisions is very critical, and our ability to have a global reach on receiving samples provides a very good picture and a very good partnership.

Also, molecular screening, we have been able to improve our screening, excuse me, our sequencing at the -- in the program due to funding. In the past, we were only sequencing viruses of interest, but now been able to approach nearly 100 percent of sequencing the virus, and sharing that, of course, too, with Los Alamos, GenBank, and CDC, to be able to allow that information to be viewed and shared with the rest of the nation.

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And just an example of the report, they say critical, we are a part of that, also working with local health departments and state health departments, being able to utilize our information to be able to integrate it, to be able to provide that in the U.S., a broader picture of what's occurring influenza-wise.

Also what we provide weekly is a five page report, and I'm not going to hit this again. But to our partners, to our sites, an overview of each week of what's occurring with influenza, to be able to look at what results we receive for the past week, and then also an accumulative view, and then be able to provide some spacial epidemiology on it, where are the samples coming in from, and what are we seeing, A, B, and where it's occurring in the world, and also providing information from CDC and WHO, to be able to give that situation awareness to our partners, to commanders, to our sites of what's occurring with influenza.

Also being able to use this information to do studies, to look at ILI and what's

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occurring, like I showed earlier with the reports that we use. Also vaccine effectiveness yearly, along with NHRC, our Navy counterparts who do the population base surveillance, their vaccine effectiveness, plus what we're seeing on the Sentinel site surveillance. And then also utilizing that information, along with our past two speakers have talked about the immunization tracking systems that are out there, but again, situational awareness for commanders at the military sites, of what's their coverage for, influenza vaccine in their population, in their active duty population, and then being able to add on that piece of, and then what are we seeing flu-wise, are we seeing A, are we seeing B, H-3, N-1, and then also layering on that sequencing part of it to see are we potentially seeing a virus that may be genetically different than what's being covered by the vaccine, and then providing that information also to CDC to make those decisions.

And what I just wanted to end up with in

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our part of the brief is just take a look at our review of what we've seen this past year with immunizations and with influenza.

And what we did was what -- this is our precursor to being able to do our vaccine effectiveness study, but just to take a look at, with our coverage, since we're able to well identify who has been vaccinated in our beneficiary population, and then take a look at with the influenza isolates that we received, were those individuals vaccinated or not, and then is there any interesting sequencing genetic information on those viruses that may be of interest to vaccine decisions for next year. Just a little background, we identified those that were vaccinated, if they were -- and had influenza, they were fully vaccinated 14 days after their immunization date. And we looked saying that starting on 1 August, that you were immunized with this years vaccine. And then the information we have for vaccine completion, looked at the DEER system.

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The number there that we took a look at, we looked only at our DOD beneficiaries, for the ability to be able to better identify their immunization status, and the number that's included there also includes our partner in UCOM Longtail Regional Medical Center, and their information, and that's why there's a little difference on the percent that were positive.

Of the number that were positive for flu, 21 percent had a history of flu immunization, and the reason there is that we included both beneficiaries and active duty; our active duty is close to 83 percent, as we mentioned, beneficiaries is less.

Of those that were immunized, we saw that 64 percent did receive the vaccine 14 days before they were identified with influenza, and this is just a breakout. What was of interest later on in the season, as Ms. Canis had mentioned, we were seeing more H-3's, and we saw a number of them from overseas, both the European theater and the Pacific theater. And a number of

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those individuals did come down with influenza after they had been immunized. And this is just a graph of where those individuals were found, countries that had these potential vaccine breakthroughs. We took a look at these viruses genetically and sequenced them, and what had been coming up of interest in a number of them was this mutation that occurred at the R142G position on the RNA.

And so that was the question, is this a mutation that potentially has, or is it occurring that may not be protected by the vaccine. And also, too, there were some other changes in some other sites, a few of them, but the majority of what we saw in our H-3 isolates was this mutation at the R142G.

Also, looking at the H-1, most of what we sequenced out for H-1 were matched, appeared to match well to the current strain that's in the vaccine, the New Caledonia component. However, we did see some where there may have been some changes, the clade 2 like breakdown on the

phylogeny tree, excuse me, and the majority of those samples were obtained CONUS.

CDC, of these that we went ahead and sent, CDC was of great interest of seeing these sequences and these isolates, and a number of them did show some reduced protective titers for the vaccine.

And so with that partnership, for what we saw this year and identified one, being able to send all of the H-3's to the CDC per their request, and also to be able to identify potential changes that were of interest and may have shown that some of our individuals may have been infected with an influenza virus that may not have been protected by the vaccine was great interest and I think shows the strength of our program, to be able to partner with our world partners, the CDC, WHO, with making those important decisions that are necessary for determining the vaccine each year, plus a situational awareness, like I mentioned before, for commanders to know also what is circulating in my area of operations, and are

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my troops going to be protected.

Some of the things that we're looking at in the future, the molecular screening is growing leaps and bounds. There's systems out there that are close to being FDA approved that we want to bring in and be on the cutting edge.

One of them is a screening product that's on the luminex instrumentation. ID tag it can basically screen for a number of respiratory viruses, and we feel that would be an important part to our program, to be able to provide feedback to the sites quickly.

And then also we've been in the past only sequencing the neuraminidase portion of the gene, of those of interest. But we have pressed forward with sequencing nearly 100 percent of the H, and now our goal is to also provide 100 percent sequencing of the N. I'm planning on having that up and going by 1 June. And to be able to provide that other critical piece to the information there for, again, situational awareness, are we potentially seeing resistance genetically and

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being able to provide that feedback to our partners. And then just starting discussion on possibly what the hemagglutinin inhibition and looking at titers there, to be able to see also another part of that point of is the virus we're seeing protected by the vaccine.

A number of collaborators that work in this program, it's a global program, it is all three services, it's I think a premier program in DOD, and definitely without these other partners and the work that's done across the globe, this program won't be a success. But because of our support and leadership from GEIS and these partners, we have a very robust system. With that, I'd like to open up to questions.

DR. HALPERIN: Thank you. Questions, yes, Doctor Kaplan.

DR. KAPLAN: Ed Kaplan; you mentioned, if I heard you correctly, that of the samples that were sent to you, 27 percent grew influenza virus; the rest of them -- I guess what I'm getting at, is it that they were samples of non-influenza

patients or was there a problem in the transportation of the samples? You mentioned some took a long time to get there.

MS. CANIS: We routinely look for influenza. We also, because we can get it easily, look for para 123 adenovirus, RSV, although that's not big in our population, we're not targeting children, it doesn't transport well, and so we don't worry about that so much. We also have the respiratory enteral viruses that we can pick up. But that is the challenge. Those are fairly easy to get, and in order to really have confidence in that negative, you want to know that you've ruled out, and there are so many other less -- those that are harder to isolate or identify, both bacterial and viral, and that is a challenge we're looking at. There's a whole panel out there, I think particularly chlamydia pneumoniae, microplasma, legionela, several on the horizon, too, so that's --

DR. KAPLAN: I was thinking particularly about adenovirus since there is such a large trial

that's currently going on.

MS. CANIS: That's one of our targets. We have several tests that are for influenza and adenovirus, and we do the full classic virology of ten days, and we work closely with NHRC on the adenovirus.

DR. HALPERIN: Mike Oxman.

DR. OXMAN: A couple of questions. First of all, what proportion of your influenza isolates which are called identifications are by PCR and what proportion are by culture, roughly?

MS. CANIS: Well, right now it's 100 percent culture.

DR. OXMAN: So it's 100 percent culture; so all of the data you have in your slides is culture based?

MS. CANIS: Yes, right.

DR. OXMAN: Do you have any comparisons with the same aliquots or the same specimen?

MS. CANIS: We do not at this point. This is certainly one of the things we're hoping to do soon. Because we are a clinical lab,

because these reports are going back for diagnosis, we're working with FDA clearance.

DR. OXMAN: A couple other things. First of all, when you look at your isolates and you receive specimens and there are varying intervals between the shipment of the specimen and its arrival, and some of them are frozen and some of them are not, do you have any data on batting averages in terms of isolation of influenza from the specimens that have traveled by different routes, if you will, in terms of temperature?

MS. CANIS: Well, we send out lots of information that we don't want them frozen at minus 20. But I have no way of knowing if that is part of the way they have been sent to us. That is a weak point. Like I said, we do take a temperature when the box arrives, so we know if it has been cold, we know if they're on dry ice. We track what kind of sample receive.

That's one of the things we'll be working out at the end of this season is what kind of sample did we receive and what did we isolate

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from it. We have rejected samples that are out of temperature and those that have been too long not frozen.

DR. OXMAN: But you're sending out the shipping containers, so you could, in fact, incorporate one of the continuous cold chain markers inside the package, which would give you more information in terms of the history of the temperature of that package than just measuring the temperature when it arrives?

MS. CANIS: That could be done. There's been some work with that in other parts of the laboratory. Compliance of that is difficult. We have, I don't know if you've seen them, there's some boxes that we have tested, they can hold frozen temperature, which doesn't work for viruses, but we've worked with one that holds refrigerated temperature, we've shown it to hold three degrees for five days. We have not -- we've sent those out to customers. We have not put the validators in them, but that would be --

DR. OXMAN: My last question. Are you

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planning to include corona virus among the possible isolates that you can detect, not the common cold corona viruses which are almost impossible to grow, but new corona viruses, considering the SARS the potential that SARS demonstrated for corona viruses to be more variant?

MS. CANIS: They're supposed to grow in a vero cell line, so we keep that in -- we run it in the lab so the techs are used to looking at it. We have not isolated any corona virus to date. That is on the panel of molecular tests, and that would be the best way to detect those in the first place. We are an LRN laboratory also, that is part of our laboratory, and we do have the SL3 capability. So SARS, H-5, any of those at this point in time would go through that route.

DR. HALPERIN: Thank you both. We're going to move on to hear Doctor Hachey talk about the influenza pandemic -- thank you.

DR. HACHEY: Thank you for allowing me to give this update on AI and PI. Next slide. So

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the agenda for the next 30 minutes will be first a discussion of avian influenza, to include the current status as far as avian and human disease, the epidemiology, and some current research activities, and then moving on to specifically PI, to include vaccines, antivirals, community mitigation strategies, surveillance, and communication.

Next slide. So to start out with H-5 and 1, next slide. Now 291 cases, 172 deaths as of 27 April. There really hasn't been any substantial activity for almost a month now. In 2006, Indonesia remained the hudsba with 55 cases and 45 deaths out of a global total of 115 cases and 79 deaths.

The mortality this year is actually down to 50 percent, although we've only got two months worth, compared to closer to 70 percent of last year. Next slide. This chart depicts the number of cases by month and by country. And that kind of melon color you see is Indonesia. So you can see that there's a lot of melon there over the

past year. The other thing I'd like you to look at is the cases for January and February of this year compared to last year. So far, so good, as far as the burden of disease. Next slide.

Moving on to avian cases, 63 countries identified by OIE as of 12 April with high path H-5 disease. We've seen the reemergence of disease in a number of countries that had thought they had eradicated the disease in their area. And bird migration still plays a less prominent role in comparison with domestic poultry as far as the spread. Next slide.

What about the U.S. Next slide. Well, the big risk that folks feel is in that Alaskan/European migratory bird pathway, and it does represent an area with diverse avian post from Asia and America that all seem to meet in Alaska.

But despite seven years of surveillance and over 8,000 samples, only five isolates, in H-3, H-4, and H-6, with no evidence of a Euroasian origin for any of the viruses. So the risk and

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probably the frequency of intercontinental viral transfer is considered quite low in that region. It's probably because they're very small birds and a very large land mass.

However, close genetic association between an H-5 species that was isolated in ducks in Alaska and finding that same species in a poultry outbreak in California does demonstrate that it is a possibility. And it does reflect a real-time vector connection between migratory birds in Alaska and pathways down into California with that potential factor with the Russian far east. Next slide. So where have we actually seen disease in birds? And this slide is courtesy of our folks in the UK. Next slide.

This evil graph just depicts where the disease is as far as the number of animal outbreaks. And just those top bars representing over 2,000 cases and 1,000 cases represent avian outbreaks in Vietnam and Thailand, with the other countries you can see having a much lower density of outbreaks. Next slide.

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If you just want to know where avian disease has been, just look for the red. And Asia is pretty much well covered. We pretty soon won't have to pay attention to the lines as far as covering in Africa. Europe is well on its way to being all red. And of note, there's no red in our continent. Next slide.

This is just a place marker for clades. Next slide. So as far as clades, there's two discrete lineages resulting in human disease, both descending from A/Goose/Guangdong virus isolated in '96. Clade 1 saw its hey day in 2004 and '05, and it was responsible for human disease in Vietnam, Thailand, and Cambodia.

Only two cases of human disease involving clade 1 this past year and both of those occurred in Thailand. Clade 2 circulated in birds in China and Indonesia in 2003 and 2004, and then spread off to Europe, the Middle East, and Africa in '05 and '06. So out of six subclades, there's three with a distinct geographic distribution causing human infections, there's 2.1 found in

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Indonesia, and that's the major player as far as human disease over the past year; 2.2, that new clade that's gone off to Europe, the Middle East, and Africa, and we'll talk a little bit about more of those in a few slides; and 2.3 in China.

Also worrisome, there's two emerging clades, still just an avian species, but there's a lack of cross protection with avian vaccine between those two emerging clades. So there may be more to come with subsequent briefings as far as those. Next slide.

And this chart just kind of gives you a graph of where the clades have started and where they've gone. And if I can maybe use the arrow. So clade 1 started in China and then went down into Thailand and Vietnam. Clade 2, subclade 1, again, starting out in China and then heading down to Indonesia, where it stayed. Clade 2, subclade 2, that's the one that, again, the same general origin, off to Africa and Europe. And then clade 2, subclade 3 returning down to the Thailand, Cambodia, Vietnam area.

Next slide. So as far as that European/Middle Eastern clade, the complete gene has recently been sequenced, and it's responsible for several human infections, primarily Egypt, Iraq, and the cases in Djibouti. It's been introduced at least three times into that region, and it's split into three distinct, independently evolving sub-lineages. In fact, one of the isolates may represent two of the sub-lineages that have actually reassorted. Next slide. So these represent viruses isolated primarily in the European/Middle Eastern area. The countries are listed here. The shared lineage suggest a single genetic source with an introduction from either Russia or the Qinghai Province area.

In their broad dispersal over a fairly short period of time, combined with really poor security in that area, strongly implicates a human related movement of poultry or poultry products as a source of the introduction, although wild birds still can't be ruled out as being the primary cause with human traffic and just helping the

process. Next slide.

This evil lineage just shows you what that large clade is looking like, and the EMA clade one is the one that's responsible for human disease thus far. Next slide.

So much for clades, but what about clades and how they interact with vaccines and antivirals? Well, as far as vaccines, a non-adjuvanted clade 1 vaccine doesn't inhibit any clade 2 viruses. A non-adjuvanted clade 2.1 vaccine doesn't inhibit any clade 1 viruses, and doesn't do a real spiffy job with clade 2.2 and 2.3 strains, as well.

Moving on to antivirals, resistance to M-2 channel blockers like amantadines, all of the clade 1's are resistant, most of the clade 2.1's are resistant, and clade 2.2 and 2.3's remain sensitive. Moving on to the neuraminidase inhibitors, clades 1, 2.1, and 2.3 are all sensitive. And only some cases of moderate resistance have been seen in clade 2.2. Next slide. So what else is new? Next slide. Well, a

couple things that we've learned about H5N1, first, that there's a high viral load and a wider tissue tropism than seen in seasonal flu. And high path AI, the cleavage sites are not limited to the normal trypsin and specific like protease, but more of a ubiquitous pattern of wide spread proteases.

Also, there's a suppressive effect of interferon alpha and gamma and tumor necrosis factor that leads to that barren to immune response or that cytokine storm seen in many of the fatal cases. Next slide.

Looking at bio replication, H-5, N-1 has a one to three log greater viral load than that of seasonal flu. And if you just look at H-5 alone, you have increased viral loads in fatal versus non-fatal cases. And this just gives you a snapshot of the percentage of either detectable RNA or virus isolated from both blood and rectal samples with H5N1 which is quite a bit higher than what you would expect with seasonal flu. Next slide.

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As far as the H5N1 cleavability, the hemagglutinin and precursor -- to an HA1 and HA2, which is a prerequisite for infectivity. And with low path AI, this represents just a single arginine residue that's recognized by trypsin like protease. But with high path, it's just multiple basic amino acids recognized by ubiquitous protease, so a lot easier to get from point A to point B in establishing an infection with this particular virus. Next slide. As far as the aberrant immune response, cytokines are increased in fatal versus non-fatal cases of H-5, N-1, and cytokines are increased in H-5 infections when compared to either H-3 or H-1 infections. And the cytokines that are increased are, again, interferon, alpha, and gamma, as well as toomacrosis factor alpha. Next slide.

Shifting to mice and men, this is one study that looked at humeral immunity elicited by human neuraminidase, N-1, that may provide partial protection against an avian H-5, N-1. And they used both mice and human models. And their

findings may be yet another indication for a universal influenza immunization. Next slide.

So mice were immunized against neuraminidase of a human H-1, N-1 strain. They also took naive mice and injected them with the serum from the vaccinated mice, and then they had a third group, a control. All were challenged with an H-5, N-1 Vietnam 1204 strain. And in both treatment groups, the ones that got the vaccine and the ones that got the cera, they had 50 percent survival versus 100 percent mortality in the control groups. Next slide.

Shifting to men, this looked at human serum samples. Thirty-eight subjects; 31 out of 38 demonstrated reactivity with an H-1, N-1 New Caledonia seasonal flu strain. The neuraminidase inhibition titers ranged from a (off mike) 20 to greater than 320.

Eight out of 38 also had low inhibitory titers ranging from 20 to against neuraminidase of a Vietnam avian flu strain. So despite the small sample size, it does suggest that some individuals

may have functionally significant levels of an avian N-1 reactive antibody with just seasonal flu immunizations, which is reassuring for folks like myself who have seen numerous seasonal flu vaccines. So the older folks may be the last ones standing. Next slide.

Which brings us to, is gray hair a protector factor for H-5, N-1. Well, out of almost 230 confirmed cases of H-5 over 30 months, the age was clearly skewed towards children and young adults, with a mean age right around 20 years of age.

And you can see that 29 percent of the sample represented folks who are ten to 19, and only 5.9 of those greater than 40. And looking at the age specific case rates per million, clearly was a clear advantage to being older. Next slide.

So whether you look at age by gender, whether you survived or recovered, the year that you caught H5N1, or the country that you were in at the time, if you were over 40, clearly had a better chance of not getting disease of fair and

better. Next slide. The next question is, could ferrets possibly lie about Tamiflu? And there's some new data using a ferret model with Tamiflu. Next slide. First of all, ferrets are a decent Tamiflu model as far as influenza. They're a naturally susceptible host, they have receptors the same as we do, and they have clinical symptoms that closely resemble that of humans. Next slide. So the first arm of this one particular study looked at early post-exposure administration of Tamiflu using survival as an endpoint.

They had a control group, as well as two experimental groups, one receiving a viral dose representing 10 EID 50, the other ten-fold higher, 100 EID 50. And four hours after infection, they all got a dose of oseltamivir or Tamiflu; that represented about half of what we would extrapolate to being a human dose.

Those animals in the control group that received the lower infected dose, almost all of them died, none of the treatment group died, and those that received the higher infected dose,

universal death in the control group and universal survival in the treatment group. Next slide.

This next slide looks at the same group of animals, but now examining the viral titers or the viral load in their upper airway. And you can see in both the lower dose and the higher infected dose, the viral loads in the treatment groups were substantially less than that of the controls.

Next slide.

Well, that was with early treatment with Tamiflu, which probably is not clinically likely. So what about a late treatment? And here they waited 24 hours after infection and used the higher dose, the 100 EID 50, and used the dose that was consistent with a human dose, ten milligrams per kilo, corresponding to the 75 milligrams that is the current recommendation, or a dose that was about two and a half times the extrapolated human dose. And in this case with late treatment, all of the lower dose treated ferrets died, whereas, again, universal survival with just a higher dose of oseltamivir. Next

slide.

Well, what happens if you get avian flu, you're treated with Tamiflu, you survive, and now do you have natural immunity? Well, if you're a ferret, you do. Again, late treatment, the larger infective dose, treated with the higher dose of oseltamivir, and then at day 21, rechallenged with the same avian flu species, a 120304 strain, and all of these animals survived. So there is, at least if we extrapolate from the ferret data, some reassuring data as far as Tamiflu is concerned.

Next slide.

So what's the way ahead as antivirals? Well, there's actually a couple handfuls of possible antivirals that may offer some solutions. The two front runners right now are parenteral zanamivir. The problems are that it's given IV, Q 12 hours, and it has a relatively short half life, 1.8 to actually about 2.5 hours. And it does appear to be protective when administered four hours prior to an infection, at least if you're a mouse.

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Peramivir, now in phase II clinical trials, and that's administered either IV or IM, and that's somewhat reassuring, good, but not complete protection in ferret and mouse models with the Vietnam 1203 challenge. The good news, that it's a lot easier to make and easier to achieve higher blood levels when compared to Tamiflu of oseltamivir. Next slide. The last new thing as far as antivirals are some new WHO clinical recommendations. And part of their recommendations include treatment is warranted even with a late presentation. So that 48 hour window, at least as far as the WHO is concerned, and their recommendations no longer applies.

They also suggest that you should consider higher doses and combination therapy with amantadine, but only on a case by case basis. No cortico steroids unless you have suspected adrenal insufficiency. They're not recommending antibiotic prophylaxis. And good news to neonatologists who have been doing this for decades, lung protective mechanical ventilation

strategies using low volume ventilators. Next slide.

What about DOD antivirals? Well, we have our Antiviral Guidelines and Release Policy that is hopefully inches away from final signature. We have a stockpile of oseltamivir, numbering about three million treatment courses divided into three depots, as well as just shy as 500,000 treatment courses already positioned at MTF.

We also have a small supply of zanamivir, about 242,000 treatment courses that's also divided into those three large depots. And our use guidelines are based on variable pandemic severity and supply. Next slide. So the new DOD antiviral guidance, if its current draft format makes it to its endpoint, establishes local use and a release for the MTF stockpiles. The primary stockpile release remains with ASD Health Affairs. Treatment is the primary use, with limited targeted prophylaxis, but depending on the effectiveness of non-pharmacologic measures,

expanded prophylaxis becomes more of an option, to include post- exposure prophylaxis and outbreak or operational prophylaxis.

And within these guidelines, we use the CDC's Pandemic Severity Index, which I'll show you in a few slides, for disease severity metrix, and reinforces the Community Mitigation Guidelines developed by the CDC for case reduction and greater antiviral flexibility. Next slide.

Moving on to vaccines, next slide. Well, again, my favorite animal, ferrets and vaccine, unadjuvanted vaccine, hemagglutination inhibition data suggests poor cross protection between clades and subclades.

But ferrets given a clade 1 vaccine do have cross protection with clade 2 challenges, specifically in the Indonesian 505 strain, if survival in that disease is your endpoint. So, again, switching to the ferret model, our current vaccine may not be as bad as we think. Next slide.

Moving on to adjuvanted vaccine, clade 1

vaccine with a clade 1 challenge, if you don't have the adjuvant, still poor immunogenicity; but if you do have the adjuvant, dropping your dose from 90 micrograms down to 3.8 micrograms, HI titers exceeding 40 percent are easily achieved. And you get a 90 percent protective effect with a dose as low as 2.9 micrograms. What about using a clade 1 adjuvanted vaccine with a clade 2 challenge? Well, and again, at 3.8 micrograms, neutralization inhibition with the clade 2 challenge is 77 percent versus 83 percent with the homologous challenge, so not too bad.

And in this particular model, all of the controls died. Only one of the vaccinated ferrets died, and that was at a 1.7 microgram dose, and it had universal survival with 3.8, 7.5, and micrograms. And more reassuring is that the CD4 T cell response following the clade 1 vaccination with the clade 2 challenge showed a four-fold increase in response. Next slide.

Will our clade 1 vaccine that we have now in hand actually serve as a reasonable primer?

And there is some evidence, there is hope. And this is looking at a clade 3 vaccine primer for a clade 1 challenge. So a little shell game as far as our vaccines.

But this is a revaccination study, looking at 37 individuals who received two doses of a clade 3 H5 vaccine back in 1998/1999, and then they were given a single dose of the Vietnam 1203 clade 1 vaccine that we now have in our stockpile.

And the antibody responses in the prime subjects compared to H5 naive subjects exceeded all of those who are unprimed, exceeded those from the '89/'90 study, and even exceeded those who received two doses of the 90 microgram dose without priming. The response is maybe due to the generation of some long lived memory CD4 cells, from memory B cells. And it's reassuring that this represents the possibility that we may see the same effect with a clade 1 primer and a clade 2 boost. Next slide. So what about the pre-pandemic vaccine that we have in hand? Well,

the (off mike) recommended FDA approval of the clade 1 Vietnam 120304 vaccine back in March, and in April, the FDA approved the same.

We currently hold 1.6 million doses of this. There's current a draft pre-pandemic vaccine policy that includes storage, distribution requirements, adverse event tracking, and immunogenicity monitoring. Next slide.

That draft policy offers the vaccine to lab personnel who have direct contact with high path H5N1. MILVAX and the services will be tracking administration. MILVAX and vaccine health centers will be monitoring for adverse events, GEIS to coordinate immunogenicity studies, and with the impending pandemic joint staff and NORTHCOM, will be designating prioritization based on risk, critical role, and the ability to receive two doses. And again, this is still in draft and still in coordination, so the end result may have no resemblance whatsoever with these guidelines. Next slide.

Pre-pandemic vaccine production, HHS has

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awarded almost \$200 million for a clade 2 vaccine. The actual number of doses that we'll have are pending depending on the actual production yield. Distribution allocation recommendations are being developed by intra-agency work groups for both pandemic and pre- pandemic vaccine prioritization of which DOD has included, but DOD's for this year is pursuing acquisition of this specific pre-pandemic vaccine so that we will be able to vaccinate at a total of 1.3 million personnel as required by the National Pandemic Implementation Plan. Next slide.

Moving on to Community Mitigation Guidelines, oh next slide. And in the spirit of time, we'll just blast through this one, just keep on clicking until it goes away.

The concept as far as the Community Mitigation Guidelines is finding ways to decrease the burden of disease without using drugs, and that's through targeted layered containment interventions, and these include voluntary isolation and quarantine, infection control

measures, social distancing, specifically closing schools and keeping kids either at home or in small groups, reducing adult social contact, and all of these are included in the DOD Clinical Practice Guidelines under Community Mitigation Strategies.

We also use pandemic categories as severity, use the pandemic categories as triggers, and the TLC's are to be employed early by installations. Next slide.

This is just some data that proves that what we speak is the truth. As far as the community mitigation, this is an example of three different modeling efforts. The larger bars represent the attack rates without interventions, and then with varying levels of compliance as low as 30 percent, with and without the use of antiviral drugs. You can see that using this targeted layer of containment strategy, the attack rates dropped down rather precipitously. And this is three independent modeling efforts. Next slide.

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Again, for the second time, we'll skip this one, which is just explaining one of those studies a bit more. The modeling is fine, but does the modeling actually match what we see in history. And there's two recent studies that were just published in April of this year, the first by Ferguson's group in the UK, and they found that, unlike Europe, in 1918, the U.S. actually employed public health measures.

And they looked at city specific per capita fatality rates and found that it was correlated with how early interventions were introduced. They then looked at their modeling and their modeling matched the historical perspective quite well, with time limited interventions reducing fatality by ten to 30 percent. But those cities that were the most effective initiating these interventions early were able to reduce their rates by sometimes up to 50 percent.

Another group, next slide, here in the U.S., Hatchett's group, looked at the same data,

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used data from the timing of 19 classes of non-pharmacologic interventions in 17 cities during 1918, and they found that cities who implemented multiple interventions at an early phase were able to drop their death rates down by about 50 percent lower than those who did not. Also had a trend towards lower cumulative excess fatality, about 20 percent. And it's important to note that few cities sustained these measures for much longer than six weeks. Next slide.

The Pandemic Severity Index developed by the CDC gives trigger points as far as when to start these targeted layered containment measures based on hurricane categories, one to five, one being a pandemic that has a case fatality rate that approaches that of seasonal flu; category five, a mild category five is 1918, and the interventions then vary with pandemic severity. Next slide.

And this just gives you an idea of the case fatality rates with the different categories as far as Pandemic Severity Index. Next slide.

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So the strategies differ depending on the severity of the pandemic. So taking school closure, school closures are not recommended for mild pandemics, whereas they should be considered for about a month with a moderate pandemic, but are highly recommended for three months with a severe pandemic. Next slide.

The triggers also vary. An alert is just kind of getting all your ducks in order, make sure you do have Tamiflu on the shelves and that you have a plan; whereas standby is, essentially you're one phone call away from closing your schools, that everybody is ready, all you need is one point to activate. And as you can see with Pandemic Severity Index, as it gets worse, you have a transition from alert to more standby and activate. Next slide.

Moving on to surveillance; DOD surveillance has steadily increased. Compared over the last two years, in FY '07, will have almost twice as many countries in our surveillance network than we did in '05, and some additions are

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South America and Africa.

Sampling capacity has pretty much doubled, or will have doubled compared to '05. The number of BSL 3 labs will double compared to FY '06. And data integration is now present through a coordinated center with 24/7 operations. Next slide, which I believe is even the last slide.

As far as communication, Health Affairs Pandemic Flu Watch Board has now evolved into the DOD pandemic flu site. It has an easier URL, just www.DOD.mil/pandemicflu. And the content has expanded to include non-medical guidance, as well as all the medical stuff that we used to have on it. So the COCOM's are represented, the DOD Education Activity is represented there, just to mention a few, as well as the Civilian Personnel Management Service. Next slide. And that concludes the brief.

DR. HALPERIN: Thank you very much. Are there a few questions?

DR. WALKER: Just one quick one. Wayne,

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a beautiful presentation, as usual. I didn't understand the first cartoon, what kind of animals these are.

DR. HACHEY: The Chicken Little cartoon?

DR. WALKER: Is that Chicken Little?

Okay, thank you, now I know.

DR. HACHEY: I hope all the other questions are as easy.

DR. PARKINSON: The slide that showed the percentage of virus and blood in rectal, those were human samples?

DR. HACHEY: Yes, sir, which is, from what I understand, with seasonal flu, the level of iremia tends to be fairly low, and being able to isolate virus from rectal samples is even lower, so this represents something fairly unique as far as a systemic involvement with H5.

SPEAKER: -- trimester --

DR. HACHEY: Could be.

DR. HALPERIN: We have two questions down this way; Doctor Kaplan.

DR. KAPLAN: One short question. You

differentiated between a minor epidemic, intermediate epidemic, and a severe epidemic; how do you tell when a minor is going to -- how do you classify those, I suppose?

DR. HACHEY: They're classified by the case fatality rate. And the hope is that the pandemic is going to start somewhere other than Boise, where it will have a fair amount of time to gather some data, to get a decent idea of what the case fatality rate is. And based on --

DR. KAPLAN: So the epidemic is not based on the number of cases because that requires you to predict what's going to happen?

DR. HACHEY: Well, it'll be -- well, you'll be predicting what's going to happen here in the U.S. based on what's happening hopefully where the pandemic is starting.

DR. KAPLAN: Okay.

DR. HALPERIN: Okay. Yes, Wayne.

DR. LEDNAR: I have a question about slide ten, which is the graph of geographic distribution of H5N1 avian disease, and I guess

it's a question of, given what we've seen over time about the spread of this infection in Asia, into Europe, and now into Africa, what's our guess based on that experience about when the western hemisphere will really start getting established?

DR. HACHEY: Well, actually the guess about six months ago was about six months ago. So using the best guess when it's going to arrive here, we're kind of running on borrowed time.

But -- and again, we were really concerned about migratory birds in the past, and everybody kind of had their undies in a bunch over Alaska, and it turns out that Alaska migratory route is probably a much lower threat. What's more than likely a much higher threat is smuggling birds and bird products into the U.S., or the same kind of smuggling into Mexico, where folks might not be quite as efficient as far as keeping those products out, it being introduced into the wild bird population and then seeing some migratory. So it's, you know, as long as the Department of Agriculture is doing as good of a job as it has

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been as far as keeping contraband materials out of the country, then there's continued hope.

But I think it's, you know, pretty much a crap shoot as far as when some products are going to kind of sneak through. But, you know, they've had duck tongue seized in Connecticut, chickens in the midwest already, so it's making it here, but fortunately, the Department of Agriculture has seized that and Customs have seized it before it's gotten a chance to be released.

DR. HALPERIN: Pierce.

DR. GARDNER: Yeah, thank you. Your information showing that clade 3 immunization prime for -- subsequent to clade immunization is interesting and reactivates the thoughts of some that perhaps we should be doing some immunization with these in order to prime for some future avian catastrophe. I wonder where you come down personally on that and whether that's something we, our sub-committee, needs to revisit?

DR. HACHEY: That question was how to

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personally?

DR. GARDNER: And also, we learned that the vaccine doesn't have a terribly long half life right now, shelf life, and so should we throw it away or should we give it to people before --

DR. HACHEY: Some issues as far as the vaccine. The potency had dropped off rather precipitously at first --

DR. GARDNER: Yeah.

DR. HACHEY: -- and then stabilized, so that's the good news. The bad news is that the clade 1 vaccine that we now have in hand will expire in December of '07. And whether we're able to extend that expiration date or not, that we're still working on. But there is a possibility that it will expire in a relatively short period of time.

So what we're to do with it then; the problem is as far as if you want to go ahead and just give it to folks when you don't have all that much vaccine. So it's a rather precious commodity if priming is a viable option. So the question

is, who do you give it to based today where we don't know where the thread is, which personnel are going to be at higher risk, which personnel are even going to be in DOD by the time that you want to give that boosting. I mean it's a lot of --

DR. GARDNER: Fun.

DR. HACHEY: And then do you give the vaccine without, again, a clear risk with that vaccine side effect profile that you have to live with.

DR. OXMAN: Wayne, what adjuvant, the data you showed us in both ferrets and humans, what's the adjuvant that was used?

DR. HACHEY: That data was from GSK, so it's their proprietary adjuvant.

DR. OXMAN: Oil basically, like -- not (off mike) but oil?

DR. HACHEY: There's some similar data using other companies and other adjuvants that isn't quite as striking as far as the immunogenicity.

DR. OXMAN: The second thing is, my understanding is that the Japanese have produced or are producing and have produced a whole virus vaccine which is -- appears to be a better primary immunogen; are there any plans to obtain any and at least look at it in comparison to the ones that you're planning to look at now?

DR. HACHEY: Actually, I'd defer that one to our colleagues from HHS, but not that I'm aware of. But that wouldn't be -- DOD isn't going to be giving a vaccine that's not FDA approved regardless. And it's even a slippery slope using a vaccine that's not even entertained for use in the U.S. even in a preapproval form.

So the vaccine that's being produced in Japan, from what I understand, there's a number of claims as far as its immunogenicity, but they've been -- they haven't actually shared their actual data as of yet. So whether it's as good as the claims are, that's yet to be seen. But a number of pilot vaccines using the whole virus does seem to give you a much nicer boost, but still not

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comparable to the low dose adjuvanted vaccines.
And those are much closer to FDA approval.

DR. HALPERIN: And one more question
from Doctor Luepker.

DR. LUEPKER: Yeah; thank you for an
interesting presentation. Two surveillance
questions that may indicate my lack of knowledge
in the field; one is about surveillance, and it's
my understanding, because we have one of the
grants, that CDC is establishing a surveillance
system; does that overlap at all with things that
are being done here?

And the second one is to help me dispel
what has perhaps become an urban legend that I
heard the other day, that the Indonesian
government is restricting access to biological
materials?

DR. HACHEY: Well, the second one is
easier. Well, they're restricting access to
release of those biological materials outside of
their borders. Number two is still receiving
those samples, they're just not able to ship them

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out to the CDC as they've done in the past.

And there are I guess intensive negotiations with the government of Indonesia through both the State Department and the WHO. And the last I heard, those restrictions were either loosening or had been dropped. But that does seem to be a major sticking point that the government of Indonesia has had, holding their samples kind of in ransom pending access to vaccine. But just recently, from what I understand, that embargo has been lifted; how long it's going to be lifted -- as far as the surveillance, if I speak on truth, Colonel Cox is here to correct me.

From what I understand, our surveillance data is automatically shared with the CDC, and we have influence of surveillance, both syndromic surveillance, as well as laboratory based surveillance with really a global footprint, and that data is shared with the CDC as part of that kind of global snapshot.

DR. HALPERIN: Well, thank you very

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much. That is a full morning that we've had.
Thank you. And after we're dismissed, the plan
will be that we'll meet again approximately at
2:00.

(Adjourn for lunch.)

MS. EMBREY: Thank you, Doctor Halperin.
As the designated (off mike) of the Defense Health
Board (off mike) to the Secretary of Defense,
which serves as a continuing advisory body to the
Assistant Secretary of Defense for Health Affairs,
and the Surgeons General of the Military
Department, I hereby call this afternoon meeting
of the Defense Health Board to order.

DR. HALPERIN: Thank you, Ms. Embrey.
So before we do introductions of the people around
the table, we'd like to continue a tradition of
taking a moment of silence and thinking about
those who we serve as a board of the men and women
who serve our country. So if you'll join me in
standing for a moment of silence.

(Moment of silence.)

DR. HALPERIN: Thank you very much. You

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may all be seated. Colonel Gibson, do you have administrative --

COL GIBSON: Yes, sir, a couple of administrative remarks. We will not be taking a break during this two hour session. The restrooms are located outside in the meeting area, in the sign-in area. If you need to use a telephone or a fax or make copies, et cetera, see Ms. Gerard or Karen Triplet.

The next meeting of the Defense Health Board will be May 23, at the Crystal City Holiday Inn, in Arlington, Virginia. At this meeting, the board will deliberate the draft findings and recommendations for the future of Military Health Care Task Force, its interim report, which is due to the Secretary of Defense on the 30th of May.

The board will also hear briefings and update on the DOD's Global Emerging Infectious Surveillance and Response System, and will hear about the traumatic brain injury prevention and treatment initiatives that the Department has underway.

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As a reminder, this meeting is being transcribed, so speak clearly into the microphones and state your name before you begin. Also, turn off any pages, blackberries, or cell phones that you have, they interfere with the AV system. And just my personal thanks to the National Transportation Safety Board for helping us make the meeting arrangements here, and to the Defense Health Board staff, Ms. Jean Ward, Ms. Lisa Gerard, and Ms. Karen Triplet. Doctor Halperin.

DR. HALPERIN: Thank you very much. So let's begin by introducing the folks at the front table. So, Colonel Pereira, would you begin?

COL PEREIRA: You're going to make me go first, although a precedent hasn't been set yet about how much or how little to say?

DR. HALPERIN: I'll set a precedent and give the example. My name is Bill Halperin, I'm Chair of Preventive Medicine at the New Jersey Medical School, I'm filling in for Greg Poland, who's the President of the Defense Health Board, and I'm happy that you are all here today.

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COL PEREIRA: Thank you. I'm Angela Pereira, I'm the social work representative on the Task Force. I have a ph.d in social work and 23 years of active duty social work in the full variety of social work positions available to a person in the Army, including two combat tours, the most recent one a year at Abugrabe, Iraq.

DR. McCURDY: I'm Layton McCurdy, I am a psychiatrist and Dean Emeritus from the Medical University of South Carolina.

DR. McCORMICK: I'm Dick McCormick, a clinical psychologist for the civilian --

CPT KLAM: I'm Warren Klam, I am a child and adolescent psychiatrist, I'm the Director of Mental Health at the Naval Hospital of San Diego and also the Navy Psychiatry Specialty Leader.

DR. LAUDER: I'm Tamara Lauder, physical medicine rehabilitation, Minaqua, Wisconsin.

DR. LUEPKER: Yes, I'm Russell Luepker, and I'm a cardiologist and epidemiologist at the University of Minnesota.

DR. GARDNER: Pierce Gardner, Professor

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of Medicine, Public Health, at the State
University of New York, at Stonybrook University.

DR. MASON: I'm Tom Mason, Professor of
Epidemiology, College Public Health, University of
South Florida, Tampa.

DR. KAPLAN: Edward Kaplan, Professor of
Pediatrics, University of Minnesota Medical
School, Minneapolis.

COL CAMPISE: Good afternoon, I'm Rick
Campise, I'm a pediatric psychologist, I'm the
Chief of Behavioral Health for Deployment Issues
for the Air Force Surgeon General.

MS. EMBREY: I'm Ellen Embrey, I'm the
Deputy Assistant Secretary of Defense for Force,
Health, Protection, and Readiness, and the
designated official for the -- federal official
for the Defense Health Board, and many of the
sub-committees and counsels and tasks forces
underneath it.

DR. MACDERMID: I'm Shelley MacDermid,
I'm a Professor of Child Development and Family
Studies at Purdue University and co-Chair of the

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Task Force.

DR. ARTHUR: I'm Vice Admiral Don Arthur, the Surgeon General of the Navy, and a graduate of the New Jersey Medical School.

DR. SILVA: I'm Joe Silva, Professor of Medicine, Diseases, and Immunology at the University of California, Davis.

DR. WALKER: David Walker, Chair Pathology, University of Texas, Medical Branch at Galveston.

DR. PARKINSON: Mike Parkinson, I'm Chief Medical Officer for Luminous, a consumer driven health plan, part of Well Point.

DR. SHAMOO: I'm Adil Shamoo, Professor, University of Maryland School of Medicine --

DR. OXMAN: Mike Oxman, Professor of Medicine and Pathology, the University of California, San Diego.

DR. McNEILL: Mills McNeill, I'm a public health physician, I'm currently serving as Director of the Public Health Laboratory with the Mississippi Department of Health.

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DR. CLEMENTS: I'm John Clements, I'm the Chair of Microbiology and Immunology at Two Lane University School of Medicine in New Orleans.

MR. WERBEL: I'm Aaron Werbel, I'm a clinical psychologist, currently the Behavioral Health Affairs Officer at Headquarters Marine Corps.

DR. ZEISS: Tony Zeiss, clinical psychologist, I'm the Deputy Chief Consultant for the Office of Mental Health in Department of Veterans Affairs.

GEN KELLEY: Joe Kelley, the Joint Staff Surgeon.

LT COL DOUGLAS: Lieutenant Colonel John Douglas, Headquarters Marine Corps, Manpower Reserve Affairs.

MS. FRYAR: Deborah Fryar, the family member representative to the Task Force.

COL GIBSON: Roger Gibson, I'm the Executive Secretary for the Defense Health Board.

DR. HALPERIN: Thank you all, and welcome. Before we begin our deliberations, I'd

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like to thank the co-chairs, members of the Mental Health Task Force. Since their appointment by Secretary of Defense on May 15, 2006, the Task Force has been fully engaged in gathering information on the status of mental health care within the Department of Defense and methods to improve the efficacy of mental health services.

I'd like to personally commend the efforts of the Task Force and their staff for all their hard work. I speak for the entire board when I say that we consider the prevention of mental health problems and delivery of top quality treatment to our service members absolutely essential. The predecessor of the board, that is, the Armed Forces Epidemiology Board, also weighed in with mental health related policy and program recommendations for DOD, including the February, 2005 report, Mental Health Activities and Programs for Military Service Members. One of our members, Doctor Dan Blazer, who also serves on the Task Force, led the board in developing that early report.

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Dan could not be with us today in person, but will be joining us by teleconference later on. As the board's representative and leading mental health expert, I asked him to prepare the board's opening remarks for today's session, which I will read for him. My thanks to Doctor Blazer for all his work.

And what follows now are comments by Dan Blazer. "Dear Health Defense Board members, I regret that I have not met with you as frequently in recent months. A prime reason has been my work with the Task Force on Mental Health of which I am a member and liaison from the Defense Health Board.

This week I am celebrating with our family the graduation of our daughter with a masters in social work degree, and therefore, must miss the current meeting. Let me provide you with some brief background.

Section 723 of the FY 2006 National Defense Authorization Act directed the Secretary of Defense to 'establish within the Department of

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Defense a task force to examine matters related to mental health and armed forces.' The Task Force was constituted as a sub-committee of the Defense Health Board and consists of seven military and seven civilian professionals, all with experience in the various areas related to military and mental health. The current members were nominated from sources both within and out of the Department of Defense and approved for membership by the Secretary of Defense.

Lieutenant General Kevin C. Kiley, the Surgeon General of the Army, was identified as the military co-chair person and served from the inception of the Task Force to March, 2007. Vice Admiral Donald A. Arthur, the Surgeon General of the Navy, has served as the co-chair person from March, 2007 to the present. Doctor Shelley MacDermid, Associate Dean of the College of Consumer and Family Studies, Purdue University, has served as the civilian co-chair person from May, 2006 to the present.

The Task Force is required to deliver a

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report to the Secretary of Defense no later than one year after the appointment of its members. The report is to contain an assessment of and recommendations for improving the efficacy of mental health services provided to members of the armed forces by the Department of Defense.

The Secretary of Defense is given 90 days to review the report and transmit it to the Committee on Armed Services and Veterans Affairs of the Senate and the House of Representatives. The act requires that the Secretary of Defense develop a plan based on the recommendations of the Task Force and submit the plan to the congressional defense committees not later than six months after receipt of the Task Force report. The members were appointed on May 15, 2006, and the Task Force is meeting May 3, 2007, to finalize the report.

Our Task Force has been extremely busy and diligent in obtaining the data, both qualitative and quantitative, necessary to write this report and deliver recommendations that both

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recognize and challenge organizationally and financially at present, yet also recognizing a critical need to improve the delivery of mental health services for our military personnel and their families.

We have met numerous times as a Task Force and have conducted 38 site visits at Army, Navy, Air Force, and Marine installations in the Continental United States, Korea, Okinawa, and Germany.

Without revealing our specific recommendations prematurely, I would like to comment on some unique challenges we face in which I believe mirror systemic issues that the Department of Defense must address if we are to meet the needs of our fighting forces, supporting forces, and family members.

Mental health is a major, perhaps the major long term adverse health consequence of our current conflicts in Iraq and Afghanistan. Mental health services, despite islands of excellence and many dedicated practitioners, from psychiatrists

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to drug abuse counselors to volunteer support groups are not well organized and frequently inadequate to meet the current needs. These gaps in service span both active duty provision of services and services contracted out by Tricare. Specific characteristics of the current conflict, such as the unpredictability of dangerous environments, frequent deployments, and significant use of guard and reserve forces, as well as active duty service personnel, place our forces at special risk.

The need for optimal mental health services is not a war time need alone, yet the current conflicts have been documented to increase the frequency of mental illness. Mental illnesses that originate during military service are often long term, spanning years or decades, by the very nature of the illnesses themselves, yet early detection and treatment has been demonstrated to reduce long term adverse health outcomes.

Evidence based treatments are available for many, if not most of the illnesses we are

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seeing deriving from the current conflicts. Through the site visits and deliberations of the committee, with much input from outside consultants, providers, and service personnel who have been afflicted with mental illnesses, the Task Force has identified a number of specific problems and considered specific actions that could be taken by the Department of Defense to remedy these problems. I would close by noting that we have not discussed mental health and mental illnesses in great detail during my tenure with the Defense Health Board. Yet as we look to the future, if we, as a board, are to respond to the overall health needs of our military personnel, attention to the prevention and treatment of mental illnesses must become a key component of our explicit, as well as our implicit charge." Dan Blazer.

I'd like to thank Dan Blazer for all of his efforts on the special committee, and also give special thanks to the co- chairs, Shelley MacDermid and Vice Admiral Donald Arthur, and

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really turn to them now and ask for opening remarks.

DR. ARTHUR: Thank you very much, Doctor Halperin and Ms. Embrey. We would -- Doctor MacDermid and I would like to give you a presentation which outlines some of the work that we have done and take questions thereafter. So I don't really have some opening remarks except to say thank you for all of your support and this wonderful effort.

DR. HALPERIN: Thank you very much. And let's proceed with the presentation then.

DR. ARTHUR: All right. We have the first slide on the screen there. If we could have the second slide. These are our members. I want to personally recognize Lieutenant General Kevin Kiley and his contributions for ten and a half months on this Task Force. They helped to set the direction of the Task Force and really to set it up to do much of what it has done. This is much more his work than mine, and due credit should go to General Kiley. Next slide, please. Our focus

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really has been on the service members and their families. One anecdote I would like to tell is, when I took over Bethesda Hospital as the Commander, one of the best pieces of advises were given to me by Chairman Bill Young's wife, Beverly, when she said, if you take care of your patients, nothing else matters; if you don't take care of your patients, nothing else matters, and I think that tone pervades this report.

It is about the service members and their families, and where we had to change structure, change careers, change thinking, we did so with the eye on what's the best thing for the service member and the family.

We also took a broad look at mental health, and not just the treatment of psychiatric disorders, but the larger picture of mental health, psychiatric, psychological resilience, and not with an aim towards an psychiatry, but also psychology, social work, consultative services, and a broad spectrum of people who were involved in ensuring the psychological health and fitness

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and resilience of our service members and their families. Next slide, please.

These were our data sources. The Task Force -- many members of the Task Force went to 38 site visits throughout the world, gathered testimony from subject matter experts that we requested, reviewed a great mass of existing literature, took public testimony, took input on the web site, and then we asked for a number of items of specific data. Next slide, please.

Here's our vision, a busy slide. I would like to summarize. Goal one was that we wanted to establish a culture of support for psychological health in the broadest terms. Goal two is, we wanted our members to be fully prepared to carry out their missions by being as psychologically fit and resilient as they could be.

Goal three, we wanted to have sufficient resources, which were money and people, to be able to get these jobs done. And then fourth is, we wanted to ensure that the leadership of the military systems had the view of psychological

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health and psychological resilience as part of their leadership strategy. Next slide, please.

We built the organization around these four bullets. And what I would like to do now is go through each of the four bullets, and Doctor MacDermid will present some of our findings, and then I will present the recommendations for each of the four bullets. Next slide, please.

DR. MACDERMID: With regard to psychological health, we found that there is good evidence to conclude that stigma remains a major concern, a major issue in the minds of service members and presents a significant barrier to care. We find that mental health professionals are not sufficiently accessible to service members, that the ability of service members to receive treatment depends too much on the ability of someone to get past their stigma and walk through a door some place as opposed to being able to reach over to some place or out to someone. We find that the training for leaders, family members, and medical personnel is insufficient

regarding psychological health, either too narrowly focuses, too brief, not present at all, or not effective in terms of creating a culture of support for psychological health.

We find that some DOD policies, particularly those related to command notification or self-disclosure or contact with mental health are unnecessarily conservative. And we find that existing processes for screening are not overcoming the stigma inherent in seeking mental health services, and therefore, not effective in accomplishing their stated goals.

DR. ARTHUR: Next slide, please. First and foremost, we want to dispel stigma. We realize this will be a very, very difficult thing to do, because after all, we are an armed services organization that has people who have to understand that they are the best at what they do and they are the strongest, the best war fighters that can be possible so that they can get their jobs done.

We pay a lot of attention to the

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physical fitness of people, but very little attention to the psychological fitness and the resilience to undergo combat mentally and psychologically. We would like to dispel stigma by better preparing people for combat and making the mental health support services a part of their every day lives for everyone so that it's not just those who have difficulties who seek psychiatric help, psychological counseling, but everyone as a part of the normal way that we do business. We want to make mental health professionals easily accessible, not just in the medical centers, but out in the units and in the Tricare network so that the families can have accessible services.

We want to embed psychological health training throughout the military, not just in the health care workers, but in the line leadership, so that they understand that psychological fitness for military service is just as important as physical fitness.

We want to revise military policy so that we get up to date knowledge, that the

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knowledge is based on evidence based procedures. And we want to have screening procedures that we will develop that are a normal part of how we deal with military members so that we can better anticipate their needs.

We know that many service members come into the military having already been psychologically traumatized by some of the events of their childhood, and we want to be sensitive to that and help them to better normalize their coping skills through better training. Next slide, please.

DR. MACDERMID: In terms of providing care for service members and their families, we felt that it was very important to focus on an entire spectrum of care from the earliest possible prevention all the way through effective treatment. We found that there are significant strengths in the continuum of care, but that there also are significant gaps. The gaps appear in terms of which services are offered, where services are offered, and who receives services,

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and our report describes specifically these gaps. We find that continuity of care is often disrupted during transitions between providers, and when it does occur, relies very heavily on the individual initiative of a conscientious provider.

There do not appear to be sufficient mechanisms to assure the use of evidence based treatments or monitoring a treatment effectiveness. And we also find that family members have difficulty obtaining adequate mental health services in the existing system.

DR. ARTHUR: Next slide, please. To mirror those findings, we want to make sure that prevention, detection, and treatment is readily available for all servicemen and their families, and this is why we believe in embedding psychiatric mental health support to psychological support in line units, in primary care clinics, in all of our facilities, and ensuring that an adequate network exists where Tricare provides for civilian contracted care.

We have found, as Doctor MacDermid said,

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difficulty with continuity, when a patient may change providers, a patient may change duty stations, or a service member may be deployed, and we want to make sure that those transitions, those themes in our system are adequately covered, often with a face-to-face, one-on-one turnover if there are significant issues that require provider to provider content. As always, we want to ensure the high quality care we already have benchmarked against civilian best practices. And again, we want to provide family members with excellent access, no matter where they are.

We recognize that many of the family members of deployed service members go home when their service member deploys, and we want to make sure that the Tricare network is adequate in terms of number of people and their availability to ensure that they get care wherever they are. Next slide, please.

DR. MACDERMID: This next finding undergirds all others in our report. Sorry, we changed undergirds to underpins this morning. The

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military system does not have sufficient resources, funding, or personnel to adequately support the psychological health of service members and the families in peace and during conflict. The recommendations that we make cannot be implemented without additional resources.

Military treatment facilities currently lack the resources to provide a full continuum of psychological health care for active duty service members and their families. This was true prior to the current conflict, to the best that we can determine, and it certainly is true now. The number of active duty mental health professionals is insufficient and likely to decrease significantly without substantial intervention. And delivery of the Tricare benefit for psychological health is hindered by fragmented rules and policies, inadequate oversight, and insufficient reimbursement.

DR. ARTHUR: Next slide, please. We recognize that the military health system is one of the best health systems in the world. It has

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over the 30 years prior to this current conflict shaped itself to meet the needs of its beneficiary population in basically peace time.

Since September 11, 2001, we have engaged on the global war on terror and have had many service members who have been effected by the combat experience, and we realize the military health system and, in fact, the nation has a debt of honor to repay these service members for their contributions and the effects that combat has had on them.

This will take greater resourcing because we have been resourced at a level which basically had accounted for peace time needs, and now we are in a combat setting, a combat setting whose impact will have long term effects on our service members and their families.

We want to ensure that staff are allocated based on a model that accounts for the population and assumes some risk basing or risk adjustment so that you look at your population, you take an analysis of how many people are in the

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population, what their risks are, what kind of units, how many people are there, how many family members, and then base your staffing on that population model.

We also feel that it is important to have uniform providers for many of the areas where they interface with service members because uniform providers have the experience in military service. They understand the culture. They have immediate confidence of the service members because they also wear a uniform, and many of us who wear a uniform have been in combat and therefore fundamentally, I think, better than many of our civilian colleagues, understand the combat environment.

We also want to ensure that the Tricare networks, the contracted networks, are adequate to fulfill the needs of family members including those of retirees. This is not just in number of providers but to ensure the availability and the reimbursement for providers to really assure our beneficiary population that they will have the

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services available in a timely fashion.

Thank you. Next slide, please.

DR. MACDERMID: We recognize that provision of a full support for psychological health for military members and their families depends on many organizations in the military. Although we are called the Department of Defense Taskforce on Mental Health, as the Admiral pointed out, we did not limit our focus to those who currently reside under the mental health label in the military. When a military member or his or her family member is in distress, they don't care which stovepipe they are going to. They care that they get help.

We do not have a recommendation that suggests that all of these stovepipes be collapsed. We recognize that that may be more than would be feasible.

But we do feel that there has been insufficient collaboration at the installation level, the service level, and DoD level among these entities to focus on promoting the

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psychological health of service members and their families. Too many of the evaluation structures focus on processes as opposed to outcomes. Too many of the processes focus on a particular part of the constituency group, not enough on the status of the beneficiary population and the degree to which their needs are being satisfactorily met.

DR. ARTHUR: Next slide, please.

There's just one bullet here, and it is because we feel that this is really another one of our underpinnings of this report is that we must fundamentally change the culture of the military to accept not only physical fitness as a requirement for military service but also the psychological fitness and resilience of our service members to go into these adverse environments. We feel that we could do better in assessing the psychological needs of our service members early in their careers and providing them some resilience training that may, and we need research to back this up, that may improve their

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ability to deal with combat environments and not be as affected as the people who are coming back from this current conflict have been.

We feel also that some of this psychological advocacy ought to start in our service academies, the Naval Academy, West Point and the Air Force Academy and every leadership school so that when we talk about carrying out combat operations, we talk about the service member as an integral part of the resources that we have. We take better care of our M-16s and our tanks than we do our service members. We don't give them the same regular maintenance, the same look and the same preventive maintenance, and I think we ought to take a look at how we view the psychological needs and make them at least as high a priority as the maintenance of our weapons systems.

Next slide, please. Here is a tabulation of our Next Steps. I take full responsibility for the slight delay of getting our report out. Since I've only been on the Taskforce

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for a month, it has taken me a while to read everything, to get up to speed and to fully appreciate the perspectives that have been gained over a year by all of the members. I apologize to the Defense Health Board for the delay, but I ask your indulgence so that we can put out the very best report that we can.

I think from my review of the report over the last couple of days that we have worked on a near final version, it will have great fidelity. It will bring us to the future of where we need to be with a vision, an achievable vision for how mental health services can be provided in the military health system. Thank you.

DR. HALPERIN: Thank you very, very much.

Before we begin the deliberations, I'd like to say that the intent of this session is to provide an opportunity to deliberate on the draft findings and make practical and valuable recommendations in this forum for use in revisions. This forum is an open forum. The

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discussions will be, to begin with, between the members of the Defense Health Board and the Taskforce.

If time allows, we would be happy to take questions and statements from the public at the end of the session. We ask that people who would like to make public statements, register to speak at the desk outside this room. Everyone, however, has the opportunity to submit written statements to the Board. Statements may be submitted today at the registration desk or by email or may be mailed to the Defense Health Board office.

I'd like to start the discussions by giving you my own impression, and I'm sure that other comments by other members will follow.

My sense is that in hearing about this effort from Dan, in particular, over a year is that a prodigious amount of field work has gone into collecting information without preconceived biases. I wondered during that time how all this information was going to be compiled and how it

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was going to be made into a useful document, but I have to say that, in my opinion, it has distinctly done that. The information has been collected. It's been digested. It's been put into many practical suggestions. Some are in detail, but some are really quite broad. Many are quite broad. I think it portends a change, much for the better, in the way that the issues of mental health and social well-being will be handled in the military. So I would just like to add my congratulations.

I would not be doing my job, however, if I didn't set the tone of the Board in giving you some practical or at least asking you some practical questions. So, here goes.

As is evident from my job of Chair of the Department of Preventive Medicine, to me, the issue of clinical medicine starts where preventive medicine fails. No wise person would want just preventive medicine because it's not always successful, so we need both clinical medicine, if you will, and preventive medicine.

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When I read through the report, particularly because of some prior orientation that the Board had been given, I looked for the term, domestic. I looked for the issue of how soldiers, under stress because of circumstances, deal with their families in a circumstance where the family is not there with a second or third generation, that is, a spouse may be there but not the spouse's parent or a grandparent. They're really pretty much alone, anomic, if you will, in a situation that is extremely stressful, and this can lead to circumstances that are expressed in an adversarial condition in the family, domestic violence, which to me is an issue of mental health.

I wonder whether, from both of you, of preventive medicine, what is done before a health care professional is visited, what can be done and what recommendations the report might make in order to reduce the stress that leads to some of the adverse family kinds of circumstances to truly prevent it before it may ever come to a

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psychological professional.

DR. ARTHUR: I think we took a broad look at what are the responsibilities of our leadership, not only to prepare service members and their families for the military experience, and we didn't just center on combat. We took a concerted effort to say that military service, by its very nature, is stressful and it's different from anything like it in the civilian sector. To go on deployment, which is a normal thing for the Navy, or to go into combat, has its elements of preparation, of support for the service member's spouse and/or family while they're deployed.

We talked about the volunteers. In fact, one of our recommendations will be that some of the heretofore voluntary organizational support become mandatory and part of the planned organizational support and properly funded, such as the ombudsmen and key volunteers, that we actually make them a part of the organization structure, that family support during deployments, during combat operations are maintained and they

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are part of the requirement for service.

We also looked at what happens when service members come back, their counseling, their assessment, and tried to make as many entry points for service members and their families as we could. That's why I said initially and I think Dr. MacDermid expressed, that this isn't just about psychiatry, psychology. It's about all of the consultative services. It's about social work. It's about nurse practitioners, physician assistants. It's about embedding mental health staff into primary care clinics. Wherever we can have an indication that a service member or his or her family has a psychological issue or an organic issue that might have a psychological basis, we have tried to be sensitive to that and put those resources there, so that even though they might not come in and say, I have a psychological issue, we might be sensitive because we have better training of our health professionals to see the psychological issue behind the other complaints.

We went as far as to talk about school

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counselors, guidance counselors for the children of deployed service members. We tried to take a very broad-based look so that our access point was as great as it had to be to allow accession by whatever means the family needed to have.

DR. HALPERIN: Okay, thank you. I'd like to now open it to members of the Taskforce and of the Committee to address questions.

Dr. Shamoo?

DR. SHAMOO: Thank you very much. I think we are all very grateful and the country, I think, is grateful for your efforts. It's an incredible amount of energy and talent you put into it.

The issues you're addressing really in the 91-page report are, in large part, societal issues. They're really not purely military issues.

I will give you a little small narrative with my apology to some of the Defense Health Board for doing that because some of them know that. I have a son with mental illness, and for

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15 years solidly, I was a strong activist for reforms in mental health services at the national, state and local levels. So I have seen literally and worked with thousands of patients with serious mental illnesses.

Between 1990 and 1994, it's important to note that some of the issues, just to give you an example, pre-college students whom all the officers and the servicemen come from, -- elementary school, middle school and high school -- there is embedded in them, issues of discrimination and stigma. The health insurance we have in this country discriminates.

My son, we had \$1 million lifetime maximum. While he was hospitalized, we got a letter saying, except mental illness is no longer \$1 million; it's only \$50,000. I sued the State of Maryland because the University of Maryland is part of the State of Maryland, and I won that lawsuit for all citizens of Maryland, but more importantly we worked for four years.

This is important because you are a like

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a fish in water. The military is like fish and the water is the community you live in. For four years, we co-lead a coalition of 35 organizations and passed the first and remains the most advanced mental health disparity law in the nation in Maryland, and it's written like a civil rights law that health insurance cannot discriminate, et cetera, et cetera. So we are part of the society.

On page 7, Building Cultural Support for Psychological Health, all the issues you address in my way, you could address them only in the military, but they will not be as effective and they will not be accelerated as if you address them as part of the society.

You mentioned, the last comment you said, if you look at page 46, your recommendation 6.1.1.10: Develop educational material to assist teachers and school administrators in supporting children of deployed parents.

Do you know how I would change that? I would change it to: Develop educational materials to assist teachers and school administrators in

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the country because these are all where our servicemen and officers come from.

The Department of Defense is known to have national defense education acts, national defense, a lot of things, they help beyond the Department of Defense. We never had a history of that. So my thinking is really this is very ripe for recommending National Defense Mental Health Education Act, that is, to give money and it's going to be peanuts compared to the overall Department of Defense budget to give help for school districts all around the country to start about mental illness in the elementary school, middle school and high school.

I thank you for listening.

DR. ARTHUR: Thank you, Doctor. I'm fond of saying that in the military health system, we never have to ask our patients how sick they can afford to be. Give the right care every single time. One of the other great things is every one of our patients is a patriot.

We can do, I believe, in the military

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health system, some things that in the civilian sector would not be possible. We can provide the broadest spectrum. We currently have the best mental health coverage of any insurance system, if you want to put it that way, but we can do better, and I think this report lays out how we can do better.

Thank you very much for your comments?

DR. HALPERIN: Bill?

DR. SHAMOO: She wanted to answer the question.

DR. HALPERIN: Oh, sorry.

DR. MACDERMID: That's all right. I was just going to give an example of a circumstance in which the military has really led the nation in a very inspiring way, not related to medicine but in the area of child care.

In 1989, the military child care system was really in not very good shape. It was an embarrassment in many ways. Legislation was passed to transform that, and today the military child care system is exponentially better than the

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nation. Every military child development center is accredited. About 8 percent of the child care centers in the civilian population are accredited. But the military example is showing everyone else that it's actually possible to do which they didn't know before.

As a relatively new citizen of this country, I would be very, very proud if it turned out to be the case that the military could lead the nation in transforming mental health.

DR. MASON: I'm Tom Mason at the University of South Florida, Tampa, and I would like to pick up on what my colleague, Dr. Shamo, has just said.

If you look at two of your recommendations, one that deals with screening and the other that deals with risk adjusted population-based models, and how the military can indeed, all the uniforms. I'm a reservist, so it would have to be all uniformed. If we pay attention to universal testing, without baseline, you don't know change. If you look at what you

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can do in terms of standard operating procedures, standard evaluations, sequence of events and making recommendations, what I would like to hear from you and other members of your Taskforce is what do you actually believe might prove to be an effective screening tool and arguably which risks are well enough accepted within your respective communities.

I'm a cancer epidemiologist. This is not my specific area. I'm really interested in which risks for any one of these particular outcomes you would like to get information on. I'm wholeheartedly wedded to the concept of risk adjusted population-based evidence being population and the opportunity that you can actually then step it out because if you look at the junior ROTCs in high school, if you look at the ROTCs at universities and colleges, it's not just our academies. If we look realistically at what's going on right now in terms of Reserves and Guard, it really has to be societal. It really has to be across the board. It's not just present

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active duty.

So I would welcome some comments from any and all of you in terms of where do you think we should place our bets, which are the best risks that we should be paying attention to, with what regularity should we be gathering this information because you're talking about lifelong. You're talking about a continuity of care.

DR. ARTHUR: One of the things we considered very seriously is the very significant stress of actual participation in combat, and we also recognized that 5 to 8 percent of the people who come in the military are like everybody, already have had some significant traumatic events in their lives.

What we wanted to do is not to label anyone but to find a way that we could apprise ourselves of what the risks were, try to build resiliency based on the risks of the population that came to us and, in some cases perhaps, steer people away from military specialties that led them to direct combat action where their

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psychological makeup for whatever reason, no fault of their own, would make them prone to more significant adverse impact from the combat experience.

We don't know exactly which studies would be most apropos, and I think this is why we are an advocate of research into the methods and the outcomes. All of the things that we're doing here now are relatively new in a big system sense, so we want to make sure research is done to ensure that we've got the right practice guidelines, the right staffing, the right outcomes, the right measures. So there's a lot of work yet to be done.

DR. MASON: I wholeheartedly accept that. I had the good fortune to fly with Captain Rupert Murdoch. I happened to serve on the rack for NAS Pensacola. The Navy has done a wonderful job in trying to figure out who should fly and who shouldn't fly because aviators will do anything to stay in the air. I mean they will never admit that there is something that they have that will

keep them out of the air, out of flight status.

So the issue then is if indeed you could come up with some reproducible intervention and measurement of some physiologic parameter that could indeed be universally administered and use that in a predictive sense. I agree. It's going to take a lot of time, a lot of effort and the talent that all of you guys on the Taskforce have. I applaud you for moving in that direction.

Then you get the buy-in because you've got too many bloody skeptics who are sitting out there that say no, no, no, you don't really understand. This particular person cannot deal with this issue.

DR. ARTHUR: Yes, but without study, I think that's very, very important.

DR. MASON: Yes.

DR. ARTHUR: Shelley?

DR. MACDERMID: I just wanted to add a couple of things.

This Board recommended two years ago that the Millennium Cohort Study be continued, and

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I think that's an particularly important piece of research for providing the prospective data that's needed to determine what risk factors really have predictive value because we haven't had that. I think the data that are coming from the screenings that are now happening, particularly the post-deployment health reassessment data, are particularly provocative in terms of the course of the development of concerns post-return. And so, those are data that aren't fully available to us yet to be able to make the kinds of recommendations that you're wanting.

But I also point out that others of our recommendations deal with creating an infrastructure that would allow more regular coordination and recognition of the best practice that you just identified.

I would caution that I would be somewhat pessimistic that it would make sense to have an absolutely universal under every circumstance for every person set of items because, as you know, jobs and risks do vary, and so you want to be

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smart about where it makes sense to apply what.
But we have the data emerging now that should
allow exactly what you're hoping for.

DR. HALPERIN: Yes, if you'll just state
your name for the record.

DR. MCCORMICK: I'm Dick McCormick from
the Taskforce.

The other thing I think is important to
underscore is where we're going from. Right now,
staffing at a mental health clinic in the military
is based on a RVU system, so you're rewarding,
treating disease that comes through the door.

One of the primary reasons we recommend
going to a population-based model is that it will
allow factoring in how many resources you need for
prevention, and that opens the door to other risk
factors because it's arguable, for example, the
MOS, the nature of the particular unit might
require more educational interventions and more
prevention interventions. Again, as I think
Shelley underscores, one of the very clear pieces
of data is that frequent deployments, frequent

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combat, the MHAT studies, for example, do increase the burden of disorders or issues needing intervention, and that can be put into the model as well.

DR. ARTHUR: I will point out that RVU is Relative Value Unit. That is a measure of productivity in the clinical setting.

DR. HALPERIN: Okay, let's do a little numbering here. One, two -- who else wanted to speak -- three, four, five, six. So let's start with number one.

DR. LEDNAR: Wayne Lednar. I'd like to first applaud the Taskforce for really, in a very brief amount of time, amassing a great amount of experience that you have then tried to form into a very useful way to frame this issue, I think in a way that really could become a model for the nation. I think the Taskforce has an opportunity that my thought I'd offer to you is to not miss this opportunity. As important as it is to have a way to recognize needs and respond and support those needs, we wouldn't be helping this group as

much if we medicalized this issue.

You talked about the realities of military life including combat, and I think a very clear statement by the Taskforce that I would personally find very helpful is that the commander owns this issue. The commanders can make resources flow. They can help to set priorities. They can help target special groups in need. But, in the end, it's more than just a resource allocation. It's a basic responsibility, and the mission, in fact, cannot be accomplished without this aspect of the total solution.

So I offer to you again if you would consider the wording that this issue, the commander owns this issue. Thank you.

DR. ARTHUR: Thank you. We did discuss that very specifically, in fact, and we said that without the commanders, not just approval but being the spearhead of these issues, we will not have the impact that we would like. Thank you.

DR. HALPERIN: Who was going second?

DR. LUEPKER: Yes, Russell Luepker,

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University of Minnesota.

Let me add my congratulations. I can't even wrap my mind around the concept of doing 38 visits with multiple groups in a year's period and bringing it down to 91 pages. Some of us might have liked it to be shorter, but you probably have four million pages of notes to work from.

I also want to echo what Wayne said a moment ago. I think the approach of psychological health as opposed to mental illness is an important distinction. Even though they're part of a continuum, if one wants to think about prevention, one has to think about psychological health as much as dealing with severely ill people at the other end.

One of the things that strikes me, though, is you tapped into what is a chronic problem in the services and in society as well is inadequate mental health services, but in this situation made acute by the deployments in Southwest Asia and putting enormous stress not only on families of active duty people but Guard

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and Reserve folks as well.

What I would have liked to have seen is a little more aggressive selling of a timeline here. The things that need to be done, in some ways, needed to be done yesterday or a year ago when the Committee started. I mean there are service people and their families who are suffering today in a system that's understaffed and underfunded, and I'm not sure how you make things happen fast. The sky isn't always falling in, but this one seems to need to rise to that level that something has to be done now.

DR. ARTHUR: Yes, sir. We discussed that, in fact, this morning and discussed the timetable for response from the Secretary of Defense to Congress. My read of Congress, having just testified yesterday in front of Congressman John Murtha and Congressman Bill Young, is that they are anxious for these reports. They are anxious for things to happen now, not just for reports to come to their desk but for things to change.

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DR. HALPERIN: Whose comment was next?

DR. PEREIRA: It might be me.

DR. HALPERIN: Yes.

DR. PEREIRA: Dr. Pereira, Taskforce member.

I wanted to go back to Dr. Mason's comment about screening for a minute. This is an issue that we've had a lot of debate about among Taskforce members, and we've looked at the kinds of screenings that are available at this point in time. The only thing that we can agree on is that, yes, we do need to do that. We need to get some good screening tools. There are a lot out there, but none have suggested that that's the final tool to be used.

We are also very cautious about suggesting that a tool is going to be an answer because, one, we don't want to imply that service members are any more vulnerable to psychological distress and illness than the general population.

We also need to be careful that we don't use a tool like that en masse, that the decision

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about whether somebody should go into a job that could expose them to combat or return them to combat must be made on a one to one basis. It should involve the commander, the provider if there is one, if that person has already been in care, and the individual. Sometimes we have to look at the individual because for their mental health, they may need to go back to that combat situation to actually master some of the issues and process some of the issues that they've been under.

So, while we talk about a screening, we are not anywhere near there at this point in time, and I think we need to be careful not to think that that's the answer.

DR. MASON: I think you for the additional information because that's exactly what I was hoping you would say because it doesn't exist, and it is a very personal set of circumstances. Every one of us, regardless of whether we've been in active combat or not, every one of us have had life experiences that were

tough. Many times, I mean getting thrown by a horse, you get back on the horse, and so you learn very quickly as you're growing up that there are sometimes that you just have to stare down and do something.

But what I'm saying to you guys as the providers -- you're the professionals -- is we are looking to you for this type of candor, this type of guidance because you will effect -- you will effect national policy.

DR. SILVA: Silva. I truly enjoyed the report also. I thought it read well, and there are some very powerful statements in here that really give a zing. The one that particularly turned me on is on page 14 where you talk about a vision for the future, and the preceding sentences talks about the extensive development of weapons system. The sentence that nails it all says the human weapons system, however, has not received the same careful attention, and that's true.

A lot of my colleagues had comments about costs and Tricare. I agree with them

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wholeheartedly, having been a CEO of a health system. Unfortunately, we also have a shortage in the civilian world of psychiatrists and psychologists. But if you have a system developed and nourished well within the military, that would be a strong signal for the youth that are making their choices right now for the future, having been the dean of a medical school also.

The only other comment I have is that I notice you didn't get into timelines much, but I suspect we can't micromanage that. The top command in the respective services will have to say: Okay, what are we going to demand now from leadership? What kind of workshops? What kind of sentinels are going to be there to indicate when a unit is doing it well or not?

I know the military can do that well. I've seen them do it for other entities. But that would be very important for commanders, as Wayne has said, to be held accountable for change in their units.

Thank you, very good report.

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DR. MACDERMID: Thank you very much, sir. You might be interested in knowing that in this morning's deliberations, a recommendation was added to the report that the Defense Health Board, in two years, monitor implementation of all of our recommendations. Enjoy.

DR. SILVA: Now, I'm impressed.

DR. HALPERIN: Mike Parkinson?

DR. WALKER: David Walker. I have two things. One, I would like to really commend you on one thing in particular, and that is your emphasis on resilience. I think that that's key. What is going to be the primary assessment of resilience is the question, and you all have address that too in that you plan to do research to determine, mandated research to determine what the elements are that lead to resilience.

The question that bothers me the most, and I'm sure it does you too, is the workforce plan. You've got many specific suggestions. Clearly, you probed this, and you've got a list of things that you can do, but they're all going to

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contribute only modestly to the solution as far as my adding up where the people are going to come from. I don't really see where the short term or long term sources are going to come from.

My question is, quantitatively, what are the implications of integrating the mental health professionals into the primary care clinics? I mean this is a wonderful idea, but exactly what is it going to take?

How many people is it going to take and what level of person are they going to be and where are we going to find them?

DR. ARTHUR: Sir, we actually think that it will be a resource, a conservative approach to put them in the primary care clinics because often primary care clinicians, who prescribe most of the antidepressants, never talk with the mental health professional. If the mental health professionals are embedded in the primary care, you'll get an instant consultation and perhaps avert a more lengthy consultation at a later time. We actually feel that we'll save time, we'll save money, we'll

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save personnel by embedding them in primary care clinics.

We also believe because the Army and the Navy and Marine Corps have experience in embedding psychologists, psychiatrists, and psychiatric technicians into field operational units, that they also deal with problems before they become so large that they need to go up to the military treatment facility for care.

So I don't think that this will add to the number of people that we're going to require. However, the plan in total will require more staff and more resources because you just are not going to be able to deliver more services by just asking people to work harder.

DR. WALKER: Do you have any idea how many more?

DR. ARTHUR: We haven't done the accounting on that yet. The timeframe for us to do that, I know that's something that we really need to do because we need to be able to provide DoD with a layout of the economics of this. I

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think that what was asked of the Taskforce was monument. As an outsider just a month into this, I agree they have done a monumental job in bringing it all together. I think the next step will be for the Department to take a look at this and for the economists to take a look at it and to evaluate.

I do think, however, that doing things differently in some of the ways that we have suggested will actually save time and money and certainly decrease the amount of morbidity due to psychological illness.

DR. MACDERMID: I will just add a couple of thoughts to that.

One is you'll note in our report that there are some categories of mental health professionals who are currently underused. For example, on our visits, we heard and saw examples of places where psych techs are doing clerical work instead of doing psych teching. That's an obvious place to try to make changes to increase the capacity. We also know that in the Tricare

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system, there is at least one entire class of care that is not reimbursable, and were that to be reimbursable, that would substantially increase the capacity.

So there are new resources needed. There are also existing resources that are not well used, that capacity could be found from.

COL. CAMPISE: In the civilian world, the mental health being integrated into primary care has been for around over a decade with Kaiser Permanente, Inova. Back in 1997, the Air Force began doing it and half of our clinics currently have a mental health person integrated into the primary care clinic. The standard is basically four hours per thousand people in panel to that clinic. So it would be a full time equivalent for 10,000 people.

The research in the civilian world and the Air Force show a high satisfaction rate among patients and providers. In fact, just in regards to efficiency, if someone is referred by a primary care physician to the mental health clinic, only

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25 percent actually show up for the appointment whereas if they're referred in the primary clinic to the integrated mental health person, 90 percent actually show up for that appointment. So it's much more efficient, and it reaches a much larger percentage of those in psychological need.

DR. PARKINSON: Mike Parkinson. Also, kudos to the panel for their work. It actually follows nicely on the AFEB's high level review of this issue several years ago which is nice.

A couple of comments just to offer for the Committee's consideration: The Institute of Medicine, at the request of NASA, tackled many of these issues over about a two-year period, and there's a report called Integrating Employee Health that was produced by the IOM. I actually served on that. Not surprisingly, not only for NASA but for every national employer, being able to define what is a healthy and productive worker was key, and there were four elements that were defined as quantifiable, metricable around a healthy workforce. Those were: Healthy, with a

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minimal amount of risk factors that we know to lead to premature morbidity and mortality and death. Second is productive as defined by the business unit, so that's a business metric that lends itself very well to things we do in the military. Third is ready, how do I know I'm ready, and the fourth is resilient.

So it might be a construct that you want to build on. Again, you can see some of the folks on that taskforce. It fits very well to the high ops tempo of the military.

The second is this morning we heard about how DoD has taken a systemwide approach to immunizations. The first slide, not surprisingly, from colleagues as I look at Admiral Arthur, going back nine or ten years ago when we talked about what should be standardized and what should be individualized based on service mission.

That first slide was vaccines are different. I think we can say that military psychological health is different and it may lend itself extremely well to a similar DoD directive

around such things. What is the strategy? What are the tactics? What are the operating measures? They can play out differently on an Air Force base versus a Navy base, but primary, secondary, tertiary prevention, both individual and community.

That gets to my third point. Nearly a decade ago, Admiral Arthur and I were grappling with such things as what does a population-based risk adjustment manpower model look like, and I see here we are back around the table again. But the timing couldn't be better, and a lot of the ground work has been done. So I think this will put it, hopefully, over the goal line so that we can move it forward structurally to ensure that in two years when we come back, there's visible progress the way that there has been in the immunization area. So just for comments and feedback.

DR. ARTHUR: Thank you very much. Thank you very much.

We took specific care to develop a

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strategic plan, a strategy to develop a strategic plan to embed the people at the health affairs level, at the DoD level that involve the services so that we can have an overarching strategic plan. It centers very much around your philosophy of having a DoD directive or instruction to cover this that really makes it uniform throughout the services. We are, after all, the uniformed services.

DR. OXMAN: I, too, would like to commend the Taskforce. It's a monumental job. I also want to thank you for educating a poor infectious disease doctor in this area, who's pretty ignorant although I think this does mirror the whole society.

There are two issues I'd just like to point out. One is very straightforward, and that is for those people who have been wounded and their families, wounded mentally, that it's a long-term proposition and that involves the VA. I cannot. If I put a tuberculin test on somebody's wife, I'm risking getting shot. So I think that

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legislation needs to be put in place that permits the VA, at least in these circumstances, to address the needs of the families as well as the servicemen.

The second point I want to make is the issue of stigma, and I think it's an enormous problem which is aggravated in the military because commanders have to be able to be sure that people who return to service are functional and not damaged. The difficulty for me, at least from my ignorant point of view, is that if someone breaks an arm, you can measure reliably the return to normal function and you can almost guarantee at a certain point that someone is able to safely go back to do their job. When somebody has a mental fracture, I'm unaware of any ways that are comparable in assuring that that fracture is completely healed and there won't be a breakdown.

So I only raise the issue because I think it's one of the challenges in illuminating the stigma.

DR. ARTHUR: Thank you. Thank you. I'd

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like to let Dr. Tony Zeiss talk about the VA issues, but we did talk about the responsibility that the Department of Veterans Affairs might have for family members, and they do not currently have that responsibility. That's something that we'd talk with Dr. Zeiss about, and that would take a lot of conversation to address that.

I do think, however, that we have some ability, clinically, to see when people are made better, perhaps not whole exactly with their psychological needs, but I don't know that we'll ever be perfect in saying that an arm is perfectly healed or a mind is perfectly recovered from such things as the trauma of combat or rape, domestic violence, loss of a loved one. All of those things create scars that are easily opened in the fragile mind.

So I don't know that we'll ever be back to perfection, but I think we can develop, through screening tools and through research for outcomes, the tools will allow us to do a much better job than we currently do.

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Tony, I don't know if you want to say something about the Veterans Administration, Affairs.

DR. ZEISS: Department of Veterans Affairs.

I can say a bit. Of course, you're exactly right. The issue is what we have the Congressional mandate to be able to do, and currently our mandate is to serve the veteran. Within that, the Comprehensive Mental Health Strategic Plan that VA has and is in the process of implementing, has really tried to encompass the importance of working with the family when working with mental health problems and to find more and more ways to be able to do that. There are also some legislative proposals coming from VA to be able to expand the envelop to some extent to have families more and more involved in care for mental health problems.

The other thing that is going on currently is a very nice, again Congressionally mandated and funded, opportunity to do

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demonstration projects in serving caregivers, and we are very much hoping that there will be some proposals around mental health issues and caregivers for mental health that will end up being a part of that.

So, you know, there are things that we are doing within the mandate that we currently have.

DR. KAPLAN: Ed Kaplan; I also would like to offer my congratulations for the report. I'd just like to ask a short question. You suggested that you would come back to the Defense Health Board in two years, and I fully support the fact that you come back to the Defense Health Board. What do you expect as you discuss this, to be done in two years? It's asking the same question that has sort of been asked before. If we look at the time table, it takes six months before it goes to the Senate and the House, if I remember it correctly, and so forth.

DR. MACDERMID: 90 days.

DR. KAPLAN: 90 days; and then there

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were six months for something. Was it -- or did I

--

DR. MACDERMID: I don't believe so, sir.

DR. KAPLAN: Okay.

DR. HALPERIN: -- (off mike) on the time tables, yes.

DR. KAPLAN: Yeah, it was a time table somewhere of six months. So if that's six months, and then this is going to take legislation, and so forth, and so on, how did that work out when you discuss that? I mean I would like for the Defense Health Board, personally, to have the chance to say either it's getting done or it's not getting done, or so forth, and so on, but is that realistic?

DR. MACDERMID: Well, first of all, it won't be us coming back to the Defense Health Board. We won't exist anymore. So --

DR. KAPLAN: And that's what bothers me.

DR. MACDERMID: I'm not sure --

DR. KAPLAN: I mean you've done such a good job, why do we let you go?

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DR. MACDERMID: Well, that is not for me to decide, sir.

DR. KAPLAN: Well, we'll take a vote on that if you'd like.

DR. MASON: All those in favor?

DR. MACDERMID: We did talk a great deal about timelines, and you will not find one in the report, in part, because we decided that it was not our place to do so, nor perhaps did we have all the people in the room who could tell us all of the things that would need to be taken into account to determine a timeline. We did, however, try to send some very clear signals about items that we thought could be undertaken immediately without delay, and acknowledging items that might take more time.

So items that could occur with delay; we can immediately engage in planning about how to recruit and retain additional uniformed providers, mental health professionals. Even before money or resources are available, those discussions can be had and those plans can be put in place. Training

education --

DR. KAPLAN: By whom?

DR. MACDERMID: I'm sorry?

DR. KAPLAN: By whom? I'm sorry, I
didn't mean --

DR. MACDERMID: It would be up to the --
well, the Secretary of Defense is obligated to
include, along with the report when it goes to
Congress, he has, I believe he has six months to
put together a plan; that's the six month piece.
He has six months to put together a plan for
implementation, and in our report then, we signal
things that can happen immediately like making
plans for recruiting and retaining, like designing
new educational materials, like changing research
foresight or adapting research foresight to
include the kinds of topics that we suggest.

We acknowledge that there are things in
the report, we know that there are things in the
report that require additional resources, and that
Congress may be required to be involved. Those
things will take longer. But we defer, I guess,

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to the experts in DOD to figure out a timeline that's reasonable, and then we rely on you all to include in your future liberations a routine focus on psychological health issues and routine questions about how DOD is responding to the issues that you all are expressing such enthusiasm for today.

MS. EMBREY: Ellen Embrey; I'd like to thank the Task Force for shining a light on this particular issue at a time when the Department most needs it. I do think that -- I'm intrigued by the idea and the programmatic implications of applying a public health model, if you will, to psychological health and fitness. How do you define it? How do you measure it? How do you monitor its change over time, and what are the triggers that would cause an individual to intervene based on those changes?

It seems to me that, as the person responsible for Force Health Protection, I think we've hit an actual conflagration of events triggered by what's going on in DOD. But I think

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the recent tragedy at Virginia Tech focuses on short comings in the overall society about indicators of stress, and how an individual can be obviously recognized with problems, and referred to multiple stovepipes, and multiple credible locations where care and services are available, and yet, there's no patient focused way to bring a person's psychological and physical health issues into one place.

And I like the ideas, but how do you practically -- I mean, the Department -- I see us now engaging on a patient focused kind of vector. But I also see us doing it using a case management approach. But I will tell you that for our wounded warriors, many of them have as many as 13 case managers for the various kinds of issues and problems that they have.

So case management isn't going to work. It's got to be an institutional change in the way we do business so that we are taking care of the whole person, that there's a connection between the mental health and the physical health, and the

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person they see first, whether it's in a medical setting or not, understands that relationship, with the same case definition if you will.

And that's why I think defining fitness is very, very important, and what does that mean, and how do we use that and carry that throughout the whole spectrum of care that's available to us in and out of a medical setting.

So I appreciate what you've done, but I -- if you have any incite into how we can practically approach institutionalizing that kind of change, because case management by itself isn't going to work. We need a fundamental change in how we approach dealing with people and their health concerns.

DR. ARTHUR: Absolutely agree, and I think one of the hardest things to do is predict human behavior. Police Departments, Fire Departments, the FBI, and other organizations have tried to predict behavior because they are risky businesses filled with great responsibility, and I don't think there are greater responsibilities any

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where in the world than our sailors, marines, soldiers, and air men have.

That said, part of the underpinning of this report is the research to determine what are the good guidelines for assessment, for mitigation, for recognition, for treatment, and long term follow up. I think there's a lot we have yet to learn, but I think you're exactly right. We also tried to focus on the leadership aspects of this, that to imbue psychological fitness as one of the pillars of military service, just as much as physical fitness.

Now, we have measures of physical fitness, push ups, pull ups, how many of whatever exercise you can do. It's much more difficult to look at psychological fitness and much more difficult to look at the mind of people who are trying to hide things, like hide their fears, hide their insecurities, that come out in unpredictable ways. Yes, Virginia Tech was terrible. It is terrible, partly, because it's such an aberration in the 300 million people in America, one of them

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unpredictably has done this. Looking back, could you have found signs?

I think we need to learn from every one of those experiences and key on prevention, and that's why resilience, I think is such a basic part of our report because once we recognize that there are issues that people have, can we mitigate those issues in the individuals, make them stronger, make their families stronger, so that not only are they better service members in their military jobs, but they are also better mothers, and fathers, and parents.

DR. MACDERMID: I would also point out that there are existing models, particularly on the prevention side, that inspired our discussion, so we talked about how it's not unusual to train people in first aid, very junior people, very early in their careers. When we train people about basic physical, medical first aid, are we saying anything to them about psychological first aid? Are we saying anything to them about things to worry about, signs of trouble, things to do?

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That's a question to ask every time we train about medical things, are we also training about mental things?

When we talk about the importance of dental check ups, are we ever talking about the importance of mental check ups? This parity issue, this parallelism, for us is compelling, and perhaps there are existing models that can be built on to help us think about the issues, that does not solve the problem of case management, which I agree, is hugely complex, and I don't think we've offered an adequate solution, particularly, because we are not a medical board, and there's a much larger community that this work would have to be imbedded into.

But particularly, in terms of the prevention side and the public health approach, I think we already do that in some ways, now we can think about when we do that for medical, are we doing that for mental.

DR. HALPERIN: I'd like to inject an idea here, which is -- is it on?

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DR. MACDERMID: No.

DR. HALPERIN: I think it's on.

DR. MACDERMID: No.

DR. HALPERIN: It's on now, yes. You know, we need to draw a distinction between preventive medicine and public health. When we talk about detection of an individual who's in distress, and training health professionals to detect an individual who's in distress, we're talking about preventive medicine.

DR. MACDERMID: Right.

DR. HALPERIN: The N is one; it's how do we help that individual before the progress or progress to the point where they've gone overboard. When we talk about public health, we talk about the health of the population, and I'm trying to think now whether the report actually, adequately, distinguishes between the two.

So in public health, we might, for example, be using the behavioral risk factor surveillance system that CDC uses in the non-institutionalized population, meaning it excludes

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people in the military; to ask questions about the prevalence of binge drinking, the prevalence of ideations, domestic violence, et cetera, which characterizes either the wellbeing or the misery of a population. Responsibility for preventive medicine clearly has to -- I agree, be integrated into medical care, and to be ensured that it's there.

Public health is really a whole other issue, and so the question is does the report call for, for example, a surveillance program for community mental health, just the way we talked about influenza this morning.

DR. MACDERMID: Right.

DR. ARTHUR: Yes, it absolutely does.

DR. HALPERIN: Okay. And fair enough.

DR. ARTHUR: It doesn't just distinguish by the words preventive medicine versus public health --

DR. HALPERIN: Yes.

DR. ARTHUR: -- but certainly, a great focus of the report is early identification and

mitigation, and imbuing in the culture of the
military --

DR. HALPERIN: Yeah.

DR. ARTHUR: -- such as like a heard
immunity --

DR. HALPERIN: Right.

DR. ARTHUR: -- to develop the immunity
of the organization by making it much more aware
of psychological issues. So yes, I believe it
does.

DR. HALPERIN: So the goal is not just
define the one person who's way at the edge of the
distribution, that's a goal, but the other is to
find out where the mean of the population is, and
if the mean is starting to shift towards misery,
that's a whole other public health basis.

DR. ARTHUR: Yes, and we have talked
about -- I'm sorry, about overlapping curves and
how resilience might move the entire curve in one
direction that is more beneficial. In fact, we
don't want to see the people whom we help, and I
don't know if we could be able to identify them,

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but there'll be a certain cohort of people who will be assisted by the tenants of this report, who will never find out because they have become more resilient and we never see that they've had an outcome, an adverse outcome.

DR. HALPERIN: Yes.

DR. MACDERMID: I'll just note one specific recommendation which is that the regular reports of the Surgeon Generals to Congress are recommended now to include data on the psychological health of service members and their families.

MS. EMBREY: Based on this most recent discussion, I think that, Admiral Arthur, you mentioned earlier that Congress is most interested in this report because it wants to take action, it wants to direct and have results quickly.

I think it would be very, very important to you, to this Task Force, to isolate those specific recommendations that you believe could be taken now or in the near future, as opposed to those that we shouldn't rush into, because there's

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a political need for us to address these issues now, even though we don't have the science, or the tools, or the mechanisms to move forward, because it would be more dangerous, in my opinion, to implement a solution that is not credible.

DR. ARTHUR: Absolutely agree.

MS. EMBREY: And so I think it would be very helpful if you could be very clear on that subject because I think nobody wants to do the wrong thing here, and although there is decades of experience and pockets of excellence everywhere, we can't do it all at the same time and in the near term. So we need to prioritize what we can do now, or now, you know, within the next six to eight months, and what we should, you know, what's acutely required --

DR. ARTHUR: Yes.

MS. EMBREY: -- now that we can do, what is a near or midterm kind of thing we can accomplish with a concrete, you know, set of achievable goals, and then some things that are going to take a while because we need to do the

research.

DR. ARTHUR: Sure.

MS. EMBREY: And I think it's not telling us how to suck the egg, but it is telling us that we have to have an egg.

DR. ARTHUR: Well, this report's much like a mall. I think there's something in it for everyone at every level. There's something in it for the line, the MTF's, the services, the DOD Health Affairs, and for Congress to work on legislation. I think there's a lot that can be done simultaneously because it's being done at different levels in the organization.

DR. HALPERIN: Joe, I'm sorry, Mike.

DR. PARKINSON: Yeah, Ms. Embrey, your comments about the applicability of the public health model, I think, it's just a hypothesis, I think there's adequate information, and DOD specific information, in fact, to build a specific and credible 80 percent public health psychological readiness model, and I do that a little bit based on the experience of, you

probably were aware of the suicide effort that was lead by the Air Force Chief of Staff about eight or nine years ago and ended up in NMWR.

We used a generic prevention model, it was never intended to be used for suicide, and essentially, built it backwards using Air Force specific metrics and Air Force non-medical programs. Suicide is not a medical problem until it hits the mortuary. Generally, these people we found never touched the health care system for perhaps all of the reasons we talked about, but they were not psychotically ill, they were normal people with two groups of acute stressors that were out in the system we didn't see. One was a relationship problem, a spouse, a lover, something like that, acute, and the second is they got in trouble with the law or with the, you know, or they had some type of major financial set back, all knowable, all out there, all preventable, and again, I think we could do that as a construct for things like a DOD directive to just raise the level of practice across the Board. So I'm

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excited by that concept, I think it's very doable.

DR. ARTHUR: And in fact, we took pains to address some of those issues, such as administrative processes, including, and non-judicial punishment, for people who have been exposed to combat and that the services should take a look at the underlying aspects of those behaviors.

MAJ GEN KELLEY: I had a comment in two areas. Thanks again for the report. We've talked a lot about screening and said there isn't a screening tool to identify the person at risk, but didn't hear any discussion or see anything that talked about screening as a baseline to see if there is a change after being exposed to something like combat.

DR. ARTHUR: Oh, yeah, absolutely; that's part of it. I think -- we talked a lot about base lining, base line in traumatic brain injury, base line in PTSD, and I think you have to have measurable quantifiable indicators, in order to see if you have any progress or that you have

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the right measures, and that you have the right treatments for those effects, so actually, research quantitative analysis is one of the tenants of our report.

MAJ GEN KELLEY: And I think that the other impressive thing about the report was the lack of data, you know, we -- all of the services have resiliency programs, but do they really work, and is the mental health going up, our problems going up, but we've added more programs, and so we don't have the data on resiliency, we don't have the data on screening, we don't have the data on when you're done with treatment, and all of those kind of things, over a wide range of topics.

DR. MACDERMID: True; I just wanted to add one comment about the screening issue, and this is not an area where I am the best expert on the Task Force, but screening a population is different from screening a person, as of course, you know, and therefore, the instruments that are being used today for screening are not appropriate instruments for tracking an individual, and we do

talk a fair amount about electronic records and tracking of outcomes and monitoring a person's status, which is not done, an enormous amount today, but is very important. So I just wanted to make sure that we acknowledge that we understand the distinction between those two things.

COL GIBSON: I just wanted to echo what Doctor MacDermid said. One of the issues with screening, and this goes to the neurocog TBI issue well, and that is less concern about the validity of, external validity of the instrument, but the repeatability of that instrument in that individual. That's a key component if we're going to look at change over time.

DR. HALPERIN: Before we turn to Doctor Lauder, it's our impression that nobody has signed up for a public comment. If that's erroneous, come see Colonel Gibson.

COL GIBSON: There's no names on the list for public comments. I do want to reinforce that if you do want to submit written comments, we have a sheet of paper out there that has all of

the information on how to do that, the website, the fax number, the mailing address, telephone number, all of those things that you can use to submit written comments to this Task Force and to the Defense Health Board in this issue, and that information is outside.

MS. EMBREY: What's the last date you will accept their comments?

COL GIBSON: The last date we'll accept comments for this issue will be the end of May.

DR. HALPERIN: Doctor Lauder.

DR. LAUDER: I have a couple of comments. One is going along with Tom Mason's comments, and then also the comments that we just talked about with screening, and that is when we talk about "screening", and perhaps, you know, put that in quotations, paying more attention to screening for mentally capable individuals or resilient individuals at the entrant level. I think somehow we're going to have to address how we're going to balance that with perhaps a lower threshold for entry, given our current state of

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war, and I think that's going to be a challenge that perhaps -- and you did talk about that in here. But perhaps it should be emphasized a bit more; comment one.

Comment two, I just want to really commend you on just a really fantastic piece of work, and I especially wanted to comment on the way you stated -- your special topics area, in particular, the TBI on page 69.

I think you just really put a beautiful paragraph in there, and I had some talks with a couple of colleagues just this last couple of weeks who express some really, you know, deep concern about the challenge differentiating TBI and PTSD, and I think you really just stated it very nicely when you said well, you know, trying to -- the differential diagnosis between TBI and PTSD can be difficult, you said, well, this is true, differential diagnosis may be a less important than attention to co-occurring diagnoses. And I think that's a beautiful statement, and I hope that you keep that in your

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final report.

DR. MACDERMID: Let me just take this moment to acknowledge the author of that sentence, Tony Zeiss, but also to acknowledge all of the people that -- and I think I can safely speak for the Admiral here, all of the people that we've had the opportunity to be briefed by, to be hosted by, who have given us testimony, and all of the people on the Task Force who not only work very hard, but have tremendous expertise and tremendous passion for the issues.

It's really been an honor to work with all of them and to meet all of the people that we've met in our travels, and also, incredible work by the staff. You can imagine the travel logistics of getting various pieces of 14 people to 38 places, and it was nightmarish and they did it all with great grace, and good efficiencies.

DR. HALPERIN: As a parting comment, on behalf of the Defense Health Board, and I'm sure on behalf of Doctor Poland and all of the members, this is not a committee that, in my impression,

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plays softball. It's very open, critical, and takes its job very seriously, and you've really got a round of congratulations, and appreciation for all of the work on the serious issue, and I want to add my congratulations to the boards. I think that that concludes our deliberations here on this topic. We're going to have a general discussion of various other issues, which you're welcome to stay for for about the next half hour, or not, and if you would like to make the final statement, it's totally up to you.

DR. ARTHUR: Well, Doctor MacDermid has already thanked everyone who has participated in this, and I would certainly echo that, also, to support you and your board, Doctor Halperin, and Ms. Embrey. Without your support and with the empowerment that we had, the authority and the task to think big, I think this report would have been less than it currently is, and thank you for your leadership.

DR. HALPERIN: Thank you -- thank you; I'm sorry.

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DR. MACDERMID: I was just going to exercise my briefly remaining powers as Co- Chair, to ask that the members of the Task Force actually convene in our room back there so we can touch base before we all have to disperse, so if this is okay with you we'll --

DR. HALPERIN: Thank you very much, and the --

COL GIBSON: So (off mike) the Board members, we ask that you stay for a short administrative session.

DR. HALPERIN: Thank you. Ms. Embrey is going to call the meeting to a close.

MS. EMBREY: The public aspects of this meeting are officially closed.

(Whereupon, at 3:55 p.m., the PROCEEDINGS were adjourned.)

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